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H. R. 967

IN THE SENATE OF THE UNITED STATES

OCTOBER 5 (legislative day, SEPTEMBER 12), 1994

Received; read twice and referred to the Committee on Agriculture, Nutrition,
and Forestry

AN ACT

To amend the Federal Insecticide, Fungicide, and
Rodenticide Act with respect to minor use pesticides.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CON-**
4 **TENTS.**

5 (a) SHORT TITLE.—This Act may be cited as the
6 “Minor Crop Protection Act of 1994”.

1 (b) REFERENCE.—Whenever in this Act an amend-
2 ment or repeal is expressed in terms of an amendment
3 to, or repeal of, a section or other provision, the reference
4 shall be considered to be made to a section or other provi-
5 sion of the Federal Insecticide, Fungicide, and
6 Rodenticide Act.

7 (c) TABLE OF CONTENTS.—The table of contents for
8 this Act is as follows:

Sec. 1. Short title; reference; table of contents.

TITLE I—MINOR CROP PROTECTION

Sec. 101. Minor crop protection.

TITLE II—PUBLIC HEALTH PESTICIDES

- Sec. 201. Definitions.
- Sec. 202. Registration.
- Sec. 203. Reregistration.
- Sec. 204. Cancellation.
- Sec. 205. Views of the Secretary of Health and Human Services.
- Sec. 206. Authority of Administrator.
- Sec. 207. Identification of pests.
- Sec. 208. Authorization of appropriations.

TITLE III—ANTIMICROBIAL PESTICIDES

- Sec. 301. Antimicrobial pesticides.
- Sec. 302. Pesticide labeling.

TITLE IV—EXPEDITED REVIEW OF CERTAIN PESTICIDE REGISTRATIONS

- Sec. 401. Office of accelerated review.
- Sec. 402. Expedited review of certain pesticide registrations.
- Sec. 403. Conditional registration for certain pesticides.
- Sec. 404. Integrated pest management.
- Sec. 405. Resistance management.

1 **TITLE I—MINOR CROP**
2 **PROTECTION**

3 **SEC. 101. MINOR CROP PROTECTION.**

4 (a) **DEFINITION.**—Section 2 (7 U.S.C. 136) is
5 amended by adding at the end the following:

6 “(hh) **MINOR USE.**—The term ‘minor use’ means the
7 use of a pesticide on an animal, on a commercial agricul-
8 tural crop or site, or for the protection of public health
9 where—

10 “(1) the Administrator, in consultation with the
11 Secretary of Agriculture, determines that, based on
12 information provided by an applicant, the use does
13 not provide sufficient economic incentive to support
14 the initial registration or continuing registration of
15 a pesticide for such use; and

16 “(2) the Administrator has not determined
17 that, based on existing data, such use presents a
18 risk of an unreasonable adverse effect on the envi-
19 ronment.”.

20 (b) **EXCLUSIVE USE OF MINOR USE PESTICIDES.**—
21 Section 3(c)(1)(F) (7 U.S.C. 136a(c)(1)(F)) is amended
22 by redesignating clauses (ii) and (iii) as clauses (iii) and
23 (iv), respectively, and by inserting after clause (i) the fol-
24 lowing:

1 “(ii) The period of exclusive data use
2 for data submitted to support the applica-
3 tion for the original registration of a pes-
4 ticide under clause (i) shall be granted an
5 additional 3 years if, after the date of en-
6 actment of this clause, the Administrator
7 approves at least 3 minor uses of the pes-
8 ticide before the expiration of the period of
9 exclusive use under this clause. Any addi-
10 tional exclusive use period under this
11 clause shall terminate if the original data
12 submitter voluntarily cancels all registra-
13 tions of the pesticide containing such
14 minor uses.”.

15 (c) TIME EXTENSIONS FOR DEVELOPMENT OF
16 MINOR USE DATA.—

17 (1) DATA CALL-IN.—Subparagraph (B) of sec-
18 tion 3(c)(2) (7 U.S.C. 136a(c)(2)(B)) is amended by
19 adding at the end the following:

20 “(vi) Upon the request of a registrant,
21 the Administrator shall, in the case of a
22 minor use, extend the deadline for the pro-
23 duction of residue chemistry data under
24 this subsection for data required solely to
25 support that minor use until the final

1 deadline for submission of data under sec-
2 tion 4 for the other uses of the pesticide
3 if—

4 “(I) the data to support other
5 uses of the pesticide are being pro-
6 vided;

7 “(II) the registrant, in submit-
8 ting a request for such an extension,
9 provides a schedule, including dates to
10 measure progress, to assure that the
11 data production will be completed be-
12 fore the expiration of the extension
13 period;

14 “(III) the Administrator has de-
15 termined that such extension will not
16 significantly delay the Administrator’s
17 schedule for issuing a reregistration
18 eligibility determination required
19 under section 4; and

20 “(IV) the Administrator has de-
21 termined in writing that based on ex-
22 isting data, such extension would not
23 significantly increase the risk of any
24 unreasonable adverse effect on the en-
25 vironment.

1 If the Administrator grants an extension
2 under this clause, the Administrator shall
3 monitor the development of the data and
4 shall ensure that the registrant is meeting
5 the schedule for the production of the
6 data. If the Administrator determines that
7 the registrant is not meeting the schedule
8 for the production of such data, the Ad-
9 ministrato r may proceed in accordance
10 with clause (iv) regarding the continued
11 registration of the minor use and shall in-
12 form the public of such action. If, during
13 the extension period, the Administrator is
14 furnished data which are sufficient to de-
15 termine that an unreasonable adverse ef-
16 fect exists involving the minor use of the
17 pesticide, the Administrator shall provide,
18 in writing, to the registrant, a notice re-
19 voking the extension of time for submission
20 of data. Such data shall instead be due
21 within 30 days of receipt of such notice by
22 the registrant. Nothing in this clause shall
23 preclude the Administrator from proceed-
24 ing in accordance with the provisions of
25 section 6.”.

1 (2) REREGISTRATION.—Sections 4(d)(4)(B),
2 4(e)(2)(B), and 4(f)(2)(B) (7 U.S.C. 136a-
3 1(d)(4)(B), (e)(2)(B), and (f)(2)(B)) are each
4 amended by adding at the end the following: “Upon
5 the request of a registrant, the Administrator shall,
6 in the case of a minor use, extend the deadline for
7 the production of residue chemistry data under this
8 subsection for data required solely to support that
9 minor use until the final deadline for submission of
10 data under section 4 for the other uses of the pes-
11 ticide if—

12 “(i) the data to support other uses of
13 the pesticide are being provided;

14 “(ii) the registrant, in submitting a
15 request for such an extension provides a
16 schedule, including interim dates to meas-
17 ure progress, to assure that the data pro-
18 duction will be completed before the expi-
19 ration of the extension period;

20 “(iii) the Administrator has deter-
21 mined that such extension will not signifi-
22 cantly delay the Administrator’s schedule
23 for issuing a reregistration eligibility deter-
24 mination required under this section; and

1 “(iv) the Administrator has deter-
2 mined in writing that based on existing
3 data, such extension would not signifi-
4 cantly increase the risk of any unreason-
5 able adverse effect on the environment.

6 If the Administrator determines that the reg-
7 istrant is not meeting the schedule for the pro-
8 duction of such data, the Administrator may
9 proceed in accordance with section
10 3(c)(2)(B)(iv) regarding the continued registra-
11 tion of the minor use and shall inform the pub-
12 lic of such action. If, during the extension pe-
13 riod, the Administrator is furnished data which
14 are sufficient to determine that an unreasonable
15 adverse effect exists involving the minor use of
16 the pesticide, the Administrator shall provide in
17 writing, to the registrant, a notice revoking the
18 extension of time for submission of data. Such
19 data shall instead be due within 30 days of re-
20 ceipt of such notice by the registrant. Nothing
21 in this subparagraph shall preclude the Admin-
22 istrator from proceeding in accordance with the
23 provisions of section 6.”.

24 (d) MINOR USE WAIVER.—Section 3(c)(2) (7 U.S.C.
25 136a(c)(2)) is amended—

1 (1) by inserting “IN GENERAL” after “(A)”, by
2 inserting “ADDITIONAL DATA” after “(B)”, and by
3 inserting “SIMPLIFIED PROCEDURES” after “(C)”,
4 and

5 (2) by adding at the end the following:

6 “(E) MINOR USE WAIVER.—In handling
7 the registration of a pesticide for a minor use,
8 the Administrator may waive otherwise applica-
9 ble data requirements if the Administrator de-
10 termines that the absence of such data will not
11 prevent the Administrator from determining—

12 “(i) the incremental risk presented by
13 the minor use of the pesticide, and

14 “(ii) that such risk, if any, would not
15 be an unreasonable adverse effect on the
16 environment.”.

17 (e) EXPEDITING MINOR USE REGISTRATIONS.—Sec-
18 tion 3(c)(3) (7 U.S.C. 136a(c)(3)) is amended—

19 (1) by inserting after “(A)” the following: “IN
20 GENERAL.—,

21 (2) by inserting after “(B)” the following:
22 “IDENTICAL OR SUBSTANTIALLY SIMILAR”.—, and

23 (3) by adding at the end the following:

24 “(C) MINOR USE REGISTRATION.—

1 “(i) The Administrator shall, as expeditiously as possible, review and act on any
2 application (I) that proposes the initial
3 registration of a new pesticide active ingredient if the active ingredient is proposed to
4 be registered solely for minor uses or for
5 non-minor uses and significant minor uses,
6 or (II) for a registration or a registration
7 amendment that proposes a new minor
8 use.
9

10 “(ii) For the purposes of clause (i)—

11 “(I) the term ‘as expeditiously as possible’ means that the Administrator shall complete a review and
12 evaluation of all data submitted with
13 the application, to the greatest extent
14 practicable, no later than 6 months
15 after the submission of the applica-
16 tion, and
17

18 “(II) the term ‘significant minor
19 uses’ means 3 or more minor uses
20 proposed for every non-minor use, a
21 minor use that would, in the judgment
22 of the Administrator, serve as a re-
23 placement for any use which has been
24
25

1 canceled in the 5 years preceding the
2 receipt of the application, or a minor
3 use that in the opinion of the Admin-
4 istrator would avoid the reissuance of
5 an emergency exemption under section
6 18 for that minor use.

7 “(D) ADEQUATE TIME FOR SUBMISSION
8 OF MINOR USE DATA.—If a registrant makes
9 a good faith request for a minor use waiver re-
10 garding data required by the Administrator
11 pursuant to paragraph (2)(B), and if the Ad-
12 ministrator denies in whole or in part such data
13 waiver request, the registrant shall have a full
14 time period for providing such data. Such full
15 time period extension shall not be available if
16 the Administrator determines that the data
17 waiver request was not made in good faith. Any
18 determination by the Administrator that a data
19 waiver request was not submitted in good faith
20 shall be made in writing to the registrant and
21 shall be subject to judicial review under the pro-
22 cedures prescribed by section 16(b).”.

23 (f) TEMPORARY EXTENSION OF REGISTRATION FOR
24 UNSUPPORTED MINOR USES.—

25 (1) REREGISTRATION.—

1 (A) Sections 4(d)(6) and 4(f)(3) (7 U.S.C.
2 136a-1(d)(6) and (f)(3)) are each amended by
3 adding at the end the following: “If the reg-
4 istrant is not supporting a specific minor use of
5 the pesticide, but is supporting and providing
6 data in a timely fashion to support other food
7 uses the Administrator, at the written request
8 of the registrant, shall not take any action pur-
9 suant to this paragraph in regard to such un-
10 supported minor use until the final deadline for
11 the submission of data under section 4 for the
12 supported uses under this paragraph. Upon re-
13 ceipt of the request from the registrant, the Ad-
14 ministrator shall publish in the Federal Reg-
15 ister a notice of the receipt of the request and
16 the effective date upon which the uses not being
17 supported will be voluntarily deleted from the
18 registration. Notwithstanding the provisions of
19 this paragraph, the Administrator may take ac-
20 tion to cancel or suspend such minor use, pur-
21 suant to section 6, if the Administrator deter-
22 mines that the continuation of the minor use
23 may cause an unreasonable adverse effect on
24 the environment.”.

1 (B) Section 4(e)(3)(A) (7 U.S.C. 136a-
2 1(e)(3)(A)) is amended by adding at the end
3 the following: “If the registrant is not support-
4 ing a specific minor use of the pesticide, but is
5 supporting and providing data in a timely fash-
6 ion to support other food uses, the Adminis-
7 trator, at the written request of the registrant,
8 shall not take any action pursuant to this sub-
9 paragraph in regard to such unsupported minor
10 use until the final deadline for the submission
11 of data for the supported uses under this sub-
12 paragraph. Upon receipt of the request from
13 the registrant, the Administrator shall publish
14 in the Federal Register a notice of the receipt
15 of the request and the effective date upon which
16 the uses not being supported will be voluntarily
17 deleted from the registration. Notwithstanding
18 the provisions of this subparagraph, the Admin-
19 istrator may take action to cancel or suspend
20 such minor use, pursuant to section 6, if the
21 Administrator determines that the continuation
22 of the minor use may cause an unreasonable
23 adverse effect on the environment .”.

1 (2) DATA.—Section 3(c)(2)(B) (7 U.S.C.
2 136a(c)(2)(B)), as amended by subsection (c), is
3 further amended by adding at the end the following:

4 “(vii) If the registrant is not supporting a
5 specific minor use of the pesticide, but is sup-
6 porting and providing data in a timely fashion
7 to support other food uses, the Administrator,
8 at the written request of the registrant, shall
9 not take any action pursuant to this subpara-
10 graph in regard to such unsupported minor use
11 until the final deadline for the submission of
12 data under section 4 for the supported uses
13 under this paragraph. Upon receipt of the re-
14 quest from the registrant, the Administrator
15 shall publish in the Federal Register a notice of
16 the receipt of the request and the effective date
17 upon which the uses not being supported will be
18 voluntarily deleted from the registration. Not-
19 withstanding the provisions of this subpara-
20 graph, the Administrator may take action to
21 cancel or suspend such minor use, pursuant to
22 section 6, if the Administrator determines that
23 the continuation of the minor use would violate
24 the criteria contained in section 6.”.

1 (g) UTILIZATION OF DATA FOR VOLUNTARILY CAN-
2 CELED CHEMICALS.—Section 6(f) (7 U.S.C. 136d) is
3 amended by adding at the end the following:

4 “(4) UTILIZATION OF DATA FOR VOLUNTARILY
5 CANCELED CHEMICALS.—When an application is
6 filed with the Administrator for the registration of
7 a pesticide for a minor use not later than 2 years
8 after another registrant voluntarily cancels its reg-
9 istration for an identical or substantially similar pes-
10 ticide for an identical or substantially similar use,
11 the Administrator shall process, review, and evaluate
12 the pending application as if the voluntary cancella-
13 tion had not yet taken place for purposes of the use
14 of data from such registration, except that the Ad-
15 ministrator may not take such action if the Adminis-
16 trator has evidence that such minor use presents a
17 risk of an unreasonable adverse effect on the envi-
18 ronment.”.

19 (h) ENVIRONMENTAL PROTECTION AGENCY MINOR
20 USE PROGRAM.—The Federal Insecticide, Fungicide, and
21 Rodenticide Act (7 U.S.C. 121 et seq.) is amended by re-
22 designating sections 30 and 31 as sections 32 and 33, re-
23 spectively and adding after section 29 the following:

1 **“SEC. 30. ENVIRONMENTAL PROTECTION AGENCY MINOR**
2 **USE PROGRAM.**

3 “The Environmental Protection Agency shall assure
4 coordination of minor use issues through the establish-
5 ment of a minor use program within the Office of Pes-
6 ticide Programs. Such office shall be responsible for co-
7 ordinating the development of minor use programs and
8 policies, consulting with growers regarding minor use is-
9 sues and registrations, and tracking and expediting minor
10 use registrations and amendments which are submitted to
11 the Environmental Protection Agency.”.

12 (i) DEPARTMENT OF AGRICULTURE MINOR USE
13 PROGRAM.—The Federal Insecticide, Fungicide, and
14 Rodenticide Act (7 U.S.C. 121 et seq.), as amended by
15 subsection (h), is amended by adding at the end the follow-
16 ing:

17 **“SEC. 31. DEPARTMENT OF AGRICULTURE MINOR USE PRO-**
18 **GRAM.**

19 “(a) IN GENERAL.—The Secretary of Agriculture
20 (hereinafter in this section referred to as the ‘Secretary’)
21 shall ensure the coordination of the responsibilities of the
22 Department of Agriculture related to minor uses of pes-
23 ticides, including—

24 “(1) carrying out the Inter-Regional Research
25 Project Number 4 (IR-4) as described in section
26 2(e) of the Act entitled ‘An Act to facilitate the

1 work of the Department of Agriculture, and for
2 other purposes' (7 U.S.C. 4501(e)) and the national
3 pesticide resistance monitoring program established
4 under section 1651 of the Food, Agriculture, Con-
5 servation, and Trade Act of 1990 (7 U.S.C. 5882);

6 “(2) supporting integrated pest management
7 research;

8 “(3) consulting with growers to develop data for
9 minor uses; and

10 “(4) providing assistance for minor use reg-
11 istrations, tolerances, and reregistrations with the
12 Environmental Protection Agency.

13 “(b) MATCHING FUND PROGRAM.—

14 “(1) ESTABLISHMENT.—The Secretary of Agri-
15 culture shall establish a minor use matching fund
16 program. The matching fund program shall be uti-
17 lized to ensure the continued availability of minor
18 use crop protection chemicals, including the develop-
19 ment of data to support minor use pesticide registra-
20 tions and reregistrations. Access to the matching
21 fund program shall be available to any entity which
22 desires to develop data to support minor use reg-
23 istrations. Access to the fund shall be given only
24 those entities that do not directly receive funds from
25 the sale of products registered on minor uses. Any

1 entity that seeks such funding under this paragraph
2 shall be required to match such funds with an equal
3 amount of its own funds. Any data developed
4 through the matching fund program shall be jointly
5 owned by the Department of Agriculture and by the
6 entity that receives such funding. All fees received
7 by the Department of Agriculture in return for the
8 use of such data under the matching fund program
9 shall be returned to a revolving fund which will sup-
10 port the matching fund program.

11 “(2) AUTHORIZATION.— There is authorized to
12 be appropriated for the revolving fund for the
13 matching fund program an annual sum not to ex-
14 ceed \$10,000,000.”.

15 **TITLE II—PUBLIC HEALTH** 16 **PESTICIDES**

17 **SEC. 201. DEFINITIONS.**

18 (a) ADVERSE EFFECTS.—Section 2(bb) (7 U.S.C.
19 136(bb)) is amended by adding at the end the following:
20 “The Administrator shall consider the risks and benefits
21 of public health pesticides separate from the risks and
22 benefits of other pesticides. In weighing any regulatory ac-
23 tion concerning a public health pesticide under this Act,
24 the Administrator shall weigh any risks of the pesticide

1 against the health risks such as the diseases transmitted
2 by the vector to be controlled by the pesticide.”.

3 (b) NEW DEFINITIONS.—Section 2 (7 U.S.C. 136),
4 as amended by section 101, is amended by adding at the
5 end the following:

6 “(ii) PUBLIC HEALTH PESTICIDE.—The term ‘public
7 health pesticide’ means any minor use pesticide product
8 registered for use and used predominantly in public health
9 programs for vector control or for other recognized health
10 protection uses, including the prevention or mitigation of
11 viruses, bacteria, or other microorganisms (other than vi-
12 ruses, bacteria, or other microorganisms on or in living
13 man or other living animal) that pose a threat to public
14 health.

15 “(jj) VECTOR.—The term ‘vector’ means any orga-
16 nism capable of transmitting the causative agent of human
17 disease or capable of producing human discomfort or in-
18 jury, including mosquitoes, flies, fleas, cockroaches, or
19 other insects and ticks, mites, or rats.”.

20 **SEC. 202. REGISTRATION.**

21 Section 3(c)(2)(A) (7 U.S.C 136a(c)(2)(A)) is
22 amended—

23 (1) by inserting after “pattern of use,” the fol-
24 lowing: “the public health and agricultural need for
25 such minor use,”, and

1 (2) by striking out “potential exposure of man
2 and the environment to the pesticide” and inserting
3 in lieu thereof “potential beneficial or adverse effects
4 on man and the environment”.

5 **SEC. 203. REREGISTRATION.**

6 Section 4 (7 U.S.C. 136a-1) is amended—

7 (1) in subsection (i)(4), by redesignating sub-
8 paragraphs (B) and (C) as subparagraphs (C) and
9 (D), respectively and by adding after subparagraph
10 (A) the following:

11 “(B) The Administrator shall exempt any
12 public health pesticide from the payment of the
13 fee prescribed under paragraph (3) if, in con-
14 sultation with the Secretary of Health and
15 Human Services, the Administrator determines,
16 based on information supplied by the registrant,
17 that the economic return to the registrant from
18 sales of the pesticide does not support the reg-
19 istration or reregistration of the pesticide.”;

20 (2) in subsection (i)(5), by redesignating sub-
21 paragraphs (F) and (G) as subparagraphs (G) and
22 (H), respectively, and by adding after subparagraph
23 (E) the following:

24 “(F) The Administrator shall exempt any
25 public health pesticide from the payment of the

1 fee prescribed under paragraph (3) if, in con-
2 sultation with the Secretary of Health and
3 Human Services, the Administrator determines,
4 based on information supplied by the registrant,
5 that the economic return to the registrant from
6 sales of the pesticide does not support the reg-
7 istration or reregistration of the pesticide.”;

8 (3) in subsection (i)(7)(B), by striking out “or
9 to determine” and inserting in lieu thereof “, to de-
10 termine” and by inserting before the period the fol-
11 lowing: “, or to determine the volume usage for pub-
12 lic health pesticides”; and

13 (4) in subsection (k)(3)(A), by striking out “or”
14 at the end of clause (i), by striking the period at the
15 end of clause (ii) and inserting in lieu thereof “; or”,
16 and by inserting after clause (ii) the following:

17 “(iii) proposes the initial or amended
18 registration of an end use pesticide that, if
19 registered as proposed, would be used for
20 a public health pesticide.”.

21 **SEC. 204. CANCELLATION.**

22 Section 6(b) is amended by striking out “or” at the
23 end of paragraph (1), by striking out the period at the
24 end of paragraph (2) and inserting in lieu thereof “; or”,
25 and by adding after paragraph (2) the following:

1 “(3) if a pesticide is registered or proposed for
2 registration for public health uses, to send the notice
3 specified in this subsection to the Secretary of
4 Health and Human Services for review.

5 The Secretary of Health and Human Services shall com-
6 ment under this subsection in accordance with the proce-
7 dures followed and subject to the same conditions as com-
8 ments by the Secretary of Agriculture in the case of agri-
9 cultural pesticides.”.

10 **SEC. 205. VIEWS OF THE SECRETARY OF HEALTH AND**
11 **HUMAN SERVICES.**

12 Section 21 (7 U.S.C. 136s) is amended by redesi-
13 gnating subsections (b) and (c) as subsections (c) and (d),
14 respectively, and by adding after subsection (a) the follow-
15 ing:

16 “(b) SECRETARY OF HEALTH AND HUMAN SERV-
17 ICES.—The Administrator, before publishing regulations
18 under this Act for any public health pesticide, shall solicit
19 the views of the Secretary of Health and Human Services
20 in the same manner as the views of the Secretary of Agri-
21 culture are solicited under section 25(a).”.

22 **SEC. 206. AUTHORITY OF ADMINISTRATOR.**

23 Section 25(a)(1) (7 U.S.C 136w(a)(1)) is amended—

1 (1) by inserting after “various classes of pes-
2 ticides” the following: “, including public health pes-
3 ticides,” and

4 (2) by striking out “and nonagricultural pes-
5 ticides” and inserting in lieu thereof “, non-
6 agricultural, and public health pesticides”.

7 **SEC. 207. IDENTIFICATION OF PESTS.**

8 Section 28 (7 U.S.C. 136w-3) is amended by adding
9 at the end the following:

10 “(d) PUBLIC HEALTH PESTS.—The Administrator,
11 in coordination with the Secretary of Health and Human
12 Services, shall identify pests of significant public health
13 importance and, in coordination with the Public Health
14 Service, develop and implement programs to improve and
15 facilitate the safe and necessary use of chemical, biologi-
16 cal, and other methods to combat and control such pests
17 of public health importance.”.

18 **SEC. 208. AUTHORIZATION OF APPROPRIATIONS.**

19 There is authorized to be appropriated to carry out
20 the purposes of this title \$12,000,000 for fiscal year 1995
21 and such sums as may be necessary for succeeding fiscal
22 years.

1 **TITLE III—ANTIMICROBIAL**
2 **PESTICIDES**

3 **SEC. 301. ANTIMICROBIAL PESTICIDES.**

4 (a) DEFINITIONS.—Section 2 (7 U.S.C. 136), as
5 amended by sections 101 and 201, is amended by adding
6 at the end the following:

7 “(kk) ANTIMICROBIAL PESTICIDE.—The term
8 ‘antimicrobial pesticide’ means a pesticide which—

9 “(1) is intended to sterilize, disinfect, sanitize,
10 mitigate growth and development, or protect inani-
11 mate objects, industrial processes or systems, sur-
12 faces, or chemical substances from contamination,
13 degradation, fouling, inefficiency, or deterioration
14 caused by microbiological organisms (including bac-
15 teria, viruses, fungi, algae, or composite slime); and

16 “(2) in the intended use is exempt from, or oth-
17 erwise not subject to, a tolerance under sections 408
18 or 409 of the Federal Food, Drug, and Cosmetic
19 Act.”.

20 (b) REQUIREMENTS FOR REGISTRATION.—Section 3
21 (7 U.S.C. 136a) is amended by adding at the end the fol-
22 lowing:

23 “(g) REGISTRATION REQUIREMENTS FOR
24 ANTIMICROBIAL PESTICIDES.—Within 1 year of the date
25 of the enactment of the Minor Crop Protection Act of

1 1994, the Administrator shall propose regulations estab-
2 lishing requirements for the registration of antimicrobial
3 pesticides, including guidelines specifying the information
4 and data required for registration. Such guidelines shall
5 provide applicants for registration with information suffi-
6 cient to determine each scientific study that must be sub-
7 mitted as part of a registration application, specify re-
8 quired methods for data developed or submitted in support
9 of a registration, and describe registration application for-
10 mat requirements and any objective criteria for evaluating
11 the completeness of the application.

12 “(h) STUDY OF ANTIMICROBIAL REGISTRATION PRO-
13 CEDURES.—Not later than 2 years after the date of the
14 enactment of this subsection, the Administrator shall pre-
15 pare a report for Congress that evaluates the process for
16 registering antimicrobial pesticides. The Administrator
17 shall submit the report to the Committee on Agriculture
18 of the House of Representatives and the Committee on
19 Agriculture, Nutrition, and Forestry of the Senate. The
20 report shall include the following:

21 “(1) An evaluation of different ways to acceler-
22 ate the review of pesticides which meet the criteria
23 of paragraph (3)(B)(i) and an estimate of the re-
24 sources the Administrator would need to implement
25 such changes.

1 “(2) An estimate of the resources needed to
2 make a decision—

3 “(A) within 90 days of receipt of an appli-
4 cation to register a pesticide that meets the cri-
5 teria of paragraph (3)(B)(i), whether to ap-
6 prove the application;

7 “(B) within 300 days of receipt of an ap-
8 plication to register an antimicrobial pesticide
9 that contains a new active ingredient, whether
10 to approve the application; or

11 “(C) within 200 days of receipt of an ap-
12 plication to add a new use to the registration of
13 an antimicrobial pesticide, whether to approve
14 the application.

15 “(3) A calculation of the amount of fees paid
16 under section 4(i)(5) that are paid for antimicrobial
17 pesticides.

18 “(4) A calculation of the amount of appro-
19 priated funds involving the registration and rereg-
20 istration of antimicrobial pesticides.”.

21 **SEC. 302. PESTICIDE LABELING.**

22 For pesticides that are or may be diluted for use, the
23 label or labeling required under the Federal Insecticide,
24 Fungicide, and Rodenticide Act may have a different
25 statement of caution or protective measures for use of rec-

1 ommended diluted solutions of the pesticide than for use
2 of concentrates of the pesticide. Such a precautionary
3 statement shall provide adequate protection for exposure
4 to the dilute solution of the pesticide.

5 **TITLE IV—EXPEDITED REVIEW**
6 **OF CERTAIN PESTICIDE REG-**
7 **ISTRATIONS**

8 **SEC. 401. OFFICE OF ACCELERATED REVIEW.**

9 The Administrator shall establish within the Office
10 of Pesticide Programs an office to oversee and expedite
11 the evaluation of applications for the registration of pes-
12 ticides that meet the criteria of paragraph (9) of section
13 3(c) of the Federal Insecticide, Fungicide, and
14 Rodenticide Act.

15 **SEC. 402. EXPEDITED REVIEW OF CERTAIN PESTICIDE REG-**
16 **ISTRATIONS.**

17 Section 3(c) (7 U.S.C. 136a(c)) is amended—

18 (1) in paragraph (1) by adding at the end the
19 following:

20 “(G) If the applicant is requesting the ex-
21 pedited registration, or amendment to the reg-
22 istration, of a pesticide, an explanation of the
23 basis for the request, in accordance with para-
24 graph (9) of this subsection.”; and

25 (2) by adding at the end the following:

1 “(9) EXPEDITED REGISTRATION OF CERTAIN
2 PESTICIDES.—

3 “(A)(i) Not later than 1 year after the
4 date of the enactment of this paragraph and
5 after opportunity for public comment, the Ad-
6 ministrator shall develop regulations and guide-
7 lines for the expedited review of applications for
8 the registration of pesticides that meet the cri-
9 teria of this subparagraph.

10 “(ii) The Administrator shall expedite the
11 review of an application for registration of a
12 pesticide or an amendment to a registration
13 that satisfies the guidelines developed under
14 this subparagraph. Biological pesticides will be
15 presumed to qualify for expedited review under
16 this paragraph. In developing guidelines for the
17 expedited review of a pesticide under this para-
18 graph, the Administrator shall consider the ex-
19 tent to which a pesticide may reasonably be ex-
20 pected to—

21 “(I) reduce the risks of pesticides to
22 human health;

23 “(II) exhibit a high degree of specific-
24 ity for the target pest and pose a low risk
25 for nontarget organisms;

1 “(III) facilitate the management of
2 pests while conserving existing natural con-
3 trols; or

4 “(IV) minimize the potential for
5 ground water or surface water contamina-
6 tion, or other valued environmental re-
7 sources.

8 “(B)(i) The Administrator, not later than
9 30 days after receipt of an application for expe-
10 dited review, shall notify the applicant whether
11 the application is complete. If it is found to be
12 incomplete, the Administrator shall reject the
13 request for an expedited review.

14 “(ii) If the application is complete, the Ad-
15 ministrator shall notify the applicant whether
16 the application qualifies for expedited review
17 within 60 days.

18 “(iii) If an application for registration or
19 an amendment qualifies for expedited review
20 under this paragraph, the Administrator shall,
21 not later than 6 months after accepting such
22 application, notify the registrant if the applica-
23 tion has been granted or denied. If the applica-
24 tion is denied, the Administrator shall comply
25 with the procedure under section 3(c)(6).

1 “(C) If at any time after the expedited
2 registration of a pesticide, the registrant has
3 additional information bearing on the pes-
4 ticide’s ability to meet the guidelines established
5 under subparagraph (A), the registrant shall
6 immediately submit a report containing such in-
7 formation to the Administrator.”.

8 **SEC. 403. CONDITIONAL REGISTRATION FOR CERTAIN PES-**
9 **TICIDES.**

10 Section 3(c)(7) (7 U.S.C. 136a(c)(7)) is amended by
11 adding at the end the following:

12 “(D)(i) The Administrator may condi-
13 tionally register or amend the registration of a
14 pesticide that meets the criteria of paragraph
15 (9) if—

16 “(I) the applicant agrees to generate
17 any additional data that the Administrator
18 deems appropriate to evaluate the pes-
19 ticide; and

20 “(II) the applicant agrees to submit
21 periodic reports as the Administrator may
22 require.

23 A conditional registration under this subpara-
24 graph shall be granted only if the Administrator
25 determines, based on available information, that

1 use of the pesticide during such period will not
2 cause any unreasonable adverse effect on the
3 environment and that use of the pesticide is in
4 the public interest.

5 “(ii) If at any time after a conditional reg-
6 istration is approved under this subparagraph,
7 and before a complete set of data has been sub-
8 mitted in support of the registration, the Ad-
9 ministrator determines that a pesticide does not
10 meet the criteria specified in clause (i), the Ad-
11 ministrator may by order suspend the registra-
12 tion until such time as the registrant dem-
13 onstrates that the criteria for conditional reg-
14 istration are met. Such order shall be sent to
15 the registrant and published in the Federal
16 Register. The order shall include the bases for
17 suspension together with a description of the
18 types of information the Administrator believes
19 must be submitted to determine whether the
20 pesticide meets the criteria for conditional reg-
21 istration.

22 “(iii) A registrant, or any other interested
23 person with the concurrence of the registrant,
24 may, within 30 days of publication of the sus-
25 pension order in the Federal Register, petition

1 the Administrator to reconsider the issuance of
2 the suspension order. A petitioner must include
3 in the petition specific bases supporting the pe-
4 tition. The Administrator shall, within 90 days
5 of receipt of the last of such petitions, issue an
6 order granting or denying petitions timely re-
7 ceived. Such order shall be sent to the peti-
8 tioner and published in the Federal Register,
9 and shall include the factual and legal bases for
10 the Administrator's determination of the peti-
11 tion.

12 “(iv) If the Administrator receives infor-
13 mation or a petition with respect to any adverse
14 effects of a pesticide for which a conditional
15 registration has been granted under this sub-
16 paragraph, the Administrator may refer the
17 matter to a Scientific Advisory Panel for re-
18 view.”.

19 **SEC. 404. INTEGRATED PEST MANAGEMENT.**

20 (a) INTEGRATED PEST MANAGEMENT PROJECTS.—
21 The Secretary of Agriculture, in consultation with the Ad-
22 ministrator of the Environmental Protection Agency, shall
23 encourage integrated pest management projects to be or-
24 ganized around specific pests and specific environmental
25 problems faced by growers and others in partnership with

1 scientists from local research organizations, including
2 land-grant or other universities and the Department, or
3 growers, and funded by a competitive, peer review grants
4 program.

5 (b) GOALS AND OBJECTIVES.—The goals and objec-
6 tives of integrated pest management projects shall be
7 area-specific and commodity or crop-specific in manner
8 that allows the projects to be qualitatively and quan-
9 titatively evaluated. The Environmental Protection Agency
10 and the Department of Agriculture shall evaluate the im-
11 plementation and effectiveness of integrated pest manage-
12 ment projects based on the following criteria:

13 (1) Risks to growers from crop losses and dras-
14 tic yield variations.

15 (2) Effectiveness of the utilization of alternative
16 pesticides, including resistant hosts, biological con-
17 trol agents, and cultural controls.

18 (3) Use of practices that avoid or minimize the
19 development of genetic resistance in pests to chemi-
20 cals or other tactics used to control them.

21 **SEC. 405. RESISTANCE MANAGEMENT.**

22 Section 3(c) (7 U.S.C. 136a(c)), as amended by sec-
23 tion 402, is amended by adding at the end the following:

24 “(10) EVIDENCE OF PEST RESISTANCE.—If the
25 Secretary of Agriculture, in consultation with the

1 Administrator, determines that pest resistance to a
2 pesticide is detected and is likely to diminish the ef-
3 ficacy of the product or threatens to accelerate the
4 evolution of resistance to other registrations of the
5 same or similar products, the Administrator shall
6 provide technical assistance to the applicant or reg-
7 istrant to—

8 “(A) develop a plan to minimize the poten-
9 tial for development of resistance that includes
10 amended labeling directions for resistance strat-
11 egies; and

12 “(B) conduct monitoring and submit re-
13 ports as the Administrator may deem necessary
14 to evaluate the effectiveness of the resistance
15 plan.

16 The plan developed under subparagraph (A) should
17 also address the potential for resistance development
18 in other geographical areas of the United States.”.

HR 967 RFS—2

HR 967 RFS—3

HR 967 RFS—4