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H. R. 1627

IN THE SENATE OF THE UNITED STATES

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Received

AN ACT

To amend the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, and for other purposes.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Food Quality Protec-
3 tion Act of 1996”.

4 **TITLE I—SUSPENSION-**
5 **APPLICATORS**

6 **SEC. 101. REFERENCE.**

7 Whenever in this title an amendment or repeal is ex-
8 pressed in terms of an amendment to, or repeal of, a sec-
9 tion or other provision, the reference shall be considered
10 to be made to a section or other provision of the Federal
11 Insecticide, Fungicide, and Rodenticide Act.

12 **Subtitle A—Suspension**

13 **SEC. 102. SUSPENSION.**

14 (a) SECTION 6(c)(1).—The second sentence of sec-
15 tion 6(c)(1) (7 U.S.C. 136d(c)(1)) is amended to read:
16 “Except as provided in paragraph (3), no order of suspen-
17 sion may be issued under this subsection unless the Ad-
18 ministrator has issued, or at the same time issues, a notice
19 of intention to cancel the registration or change the classi-
20 fication of the pesticide under subsection (b).”.

21 (b) SECTION 6(c)(3).—Section 6(c)(3) (7 U.S.C.
22 136d(c)(3)) is amended—

23 (1) by inserting after the first sentence the fol-
24 lowing new sentence: “The Administrator may issue
25 an emergency order under this paragraph before is-
26 suing a notice of intention to cancel the registration

1 or change the classification of the pesticide under
2 subsection (b) and the Administrator shall proceed
3 to issue the notice under subsection (b) within 90
4 days of issuing an emergency order. If the Adminis-
5 trator does not issue a notice under subsection (b)
6 within 90 days of issuing an emergency order, the
7 emergency order shall expire.”; and

8 (2) by striking “In that case” and inserting “In
9 the case of an emergency order”.

10 **SEC. 103. TOLERANCE REEVALUATION AS PART OF REREG-**
11 **ISTRATION.**

12 Section 4(g)(2) (7 U.S.C. 136a–1(g)(2)) is amended
13 by adding at the end the following:

14 “(E) As soon as the Administrator has
15 sufficient information with respect to the die-
16 tary risk of a particular active ingredient, but
17 in any event no later than the time the Admin-
18 istrator makes a determination under subpara-
19 graph (C) or (D) with respect to pesticides con-
20 taining a particular active ingredient, the Ad-
21 ministrator shall—

22 “(i) reassess each associated tolerance
23 and exemption from the requirement for a
24 tolerance issued under section 408 of the

1 Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 346a);

3 “(ii) determine whether such tolerance
4 or exemption meets the requirements of
5 that Act;

6 “(iii) determine whether additional
7 tolerances or exemptions should be issued;

8 “(iv) publish in the Federal Register a
9 notice setting forth the determinations
10 made under this subparagraph; and

11 “(v) commence promptly such pro-
12 ceedings under this Act and section 408 of
13 the Federal Food, Drug, and Cosmetic Act
14 as are warranted by such determinations.”.

15 **SEC. 104. SCIENTIFIC ADVISORY PANEL.**

16 Section 25(d) (7 U.S.C. 136w(d)) is amended—

17 (1) in the first sentence, by striking “The Ad-
18 ministrator shall” and inserting:

19 “(1) IN GENERAL.—The Administrator shall”;
20 and

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

22 “(2) SCIENCE REVIEW BOARD.—There is estab-
23 lished a Science Review Board to consist of 60 sci-
24 entists who shall be available to the Scientific Advi-
25 sory Panel to assist in reviews conducted by the

1 Panel. Members of the Board shall be selected in the
 2 same manner as members of temporary subpanels
 3 created under paragraph (1). Members of the Board
 4 shall be compensated in the same manner as mem-
 5 bers of the Panel.”.

6 **SEC. 105. NITROGEN STABILIZER.**

7 (a) SECTION 2.—Section 2 (7 U.S.C. 136) is amend-
 8 ed—

9 (1) in subsection (a)—

10 (A) in paragraph (1) by striking “or” after
 11 “defoliant,” and inserting “, or nitrogen sta-
 12 bilizer” after “desiccant”;

13 (B) at the end of paragraph (3) by striking
 14 “and”;

15 (C) at the end of paragraph (4) by striking
 16 the period and inserting “; and”; and

17 (D) at the end by adding the following:

18 “(5) in the case of a nitrogen stabilizer, an in-
 19 gredient which will prevent or hinder the process of
 20 nitrification, denitrification, ammonia volatilization,
 21 or urease production through action affecting soil
 22 bacteria.”;

23 (2) in subsection (u), by striking “and” before
 24 “(2)” and by inserting “and (3) any nitrogen sta-
 25 bilizer,” after “desiccant,”; and

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

2 “(hh) NITROGEN STABILIZER.—The term ‘nitrogen
3 stabilizer’ means any substance or mixture of substances
4 intended for preventing or hindering the process of nitrifi-
5 cation, denitrification, ammonia volatilization, or urease
6 production through action upon soil bacteria. Such term
7 shall not include—

8 “(1) dicyandiamide;

9 “(2) ammonium thiosulfate; or

10 “(3) any substance or mixture of substances.—

11 “(A) that was not registered pursuant to
12 section 3 prior to January 1, 1992; and

13 “(B) that was in commercial agronomic
14 use prior to January 1, 1992, with respect to
15 which after January 1, 1992, the distributor or
16 seller of the substance or mixture has made no
17 specific claim of prevention or hindering of the
18 process of nitrification, denitrification, ammonia
19 volatilization urease production regardless of
20 the actual use or purpose for, or future use or
21 purpose for, the substance or mixture.

22 Statements made in materials required to be submitted
23 to any State legislative or regulatory authority, or required
24 by such authority to be included in the labeling or other
25 literature accompanying any such substance or mixture

1 shall not be deemed a specific claim within the meaning
 2 of this subsection.”.

3 (b) SECTION 3(f).—Section 3(f) (7 U.S.C. 136a(f))
 4 is amended by adding at the end the following:

5 “(4) MIXTURES OF NITROGEN STABILIZERS
 6 AND FERTILIZER PRODUCTS.—Any mixture or other
 7 combination of—

8 “(A) 1 or more nitrogen stabilizers reg-
 9 istered under this Act; and

10 “(B) 1 or more fertilizer products,
 11 shall not be subject to the provisions of this section
 12 or sections 4, 5, 7, 15, and 17(a)(2) if the mixture
 13 or other combination is accompanied by the labeling
 14 required under this Act for the nitrogen stabilizer
 15 contained in the mixture or other combination, the
 16 mixture or combination is mixed or combined in ac-
 17 cordance with such labeling, and the mixture or
 18 combination does not contain any active ingredient
 19 other than the nitrogen stabilizer.”.

20 **SEC. 106. PERIODIC REGISTRATION REVIEW.**

21 (a) SECTION 6.—Section 6 (7 U.S.C. 136d) is
 22 amended—

23 (1) in subsection (a), by striking the heading
 24 and inserting the following:

25 “(a) EXISTING STOCKS AND INFORMATION.—”; and

1 (2) by amending paragraph (1) of subsection
2 (a) to read as follows:

3 “(1) EXISTING STOCKS.—The Administrator
4 may permit the continued sale and use of existing
5 stocks of a pesticide whose registration is suspended
6 or canceled under this section, or section 3 or 4, to
7 such extent, under such conditions, and for such
8 uses as the Administrator determines that such sale
9 or use is not inconsistent with the purposes of this
10 Act.”.

11 (b) SECTION 3.—Section 3 (7 U.S.C. 136a) is
12 amended by adding at the end the following:

13 “(g) REGISTRATION REVIEW.—

14 “(1)(A) GENERAL RULE.—The registrations of
15 pesticides are to be periodically reviewed. The Ad-
16 ministrator shall by regulation establish a procedure
17 for accomplishing the periodic review of registra-
18 tions. The goal of these regulations shall be a review
19 of a pesticide’s registration every 15 years. No reg-
20 istration shall be canceled as a result of the registra-
21 tion review process unless the Administrator follows
22 the procedures and substantive requirements of sec-
23 tion 6.

1 “(B) LIMITATION.—Nothing in this subsection
2 shall prohibit the Administrator from undertaking
3 any other review of a pesticide pursuant to this Act.

4 “(2)(A) DATA.—The Administrator shall use
5 the authority in subsection (c)(2)(B) to require the
6 submission of data when such data are necessary for
7 a registration review.

8 “(B) DATA SUBMISSION, COMPENSATION, AND
9 EXEMPTION.—For purposes of this subsection, the
10 provisions of subsections (c)(1), (c)(2)(B), and
11 (c)(2)(D) shall be utilized for and be applicable to
12 any data required for registration review.”.

13 **Subtitle B—Training for Maintenance Applicators and Service**
14 **Technicians**
15

16 **SEC. 120. MAINTENANCE APPLICATORS AND SERVICE**
17 **TECHNICIANS DEFINITIONS.**

18 Section 2 (7 U.S.C. 136), as amended by section 106,
19 is amended by adding at the end the following:

20 “(jj) MAINTENANCE APPLICATOR.—The term ‘main-
21 tenance applicator’ means any individual who, in the prin-
22 cipal course of such individual’s employment, uses, or su-
23 pervises the use of, a pesticide not classified for restricted
24 use (other than a ready to use consumer products pes-
25 ticides); for the purpose of providing structural pest con-

1 trol or lawn pest control including janitors, general main-
 2 tenance personnel, sanitation personnel, and grounds
 3 maintenance personnel. The term ‘maintenance applicator’
 4 does not include private applicators as defined in section
 5 2(e)(2); individuals who use antimicrobial pesticides, sani-
 6 tizers or disinfectants; individuals employed by Federal,
 7 State, and local governments or any political subdivisions
 8 thereof, or individuals who use pesticides not classified for
 9 restricted use in or around their homes, boats, sod farms,
 10 nurseries, greenhouses, or other noncommercial property.

11 “(kk) SERVICE TECHNICIAN.—The term ‘service
 12 technician’ means any individual who uses or supervises
 13 the use of pesticides (other than a ready to use consumer
 14 products pesticide) for the purpose of providing structural
 15 pest control or lawn pest control on the property of an-
 16 other for a fee. The term ‘service technician’ does not in-
 17 clude individuals who use antimicrobial pesticides, sani-
 18 tizers or disinfectants; or who otherwise apply ready to
 19 use consumer products pesticides.”.

20 **SEC. 121. MINIMUM REQUIREMENTS FOR TRAINING OF**
 21 **MAINTENANCE APPLICATORS AND SERVICE**
 22 **TECHNICIANS.**

23 The Federal Insecticide, Fungicide, and Rodenticide
 24 Act (7 U.S.C. 136 et seq.) is amended—

1 (1) by redesignating sections 30 and 31 as sec-
2 tions 33 and 34, respectively; and

3 (2) by adding after section 29 the following:

4 **“SEC. 30. MINIMUM REQUIREMENTS FOR TRAINING OF**
5 **MAINTENANCE APPLICATORS AND SERVICE**
6 **TECHNICIANS.**

7 “Each State may establish minimum requirements
8 for training of maintenance applicators and service techni-
9 cians. Such training may include instruction in the safe
10 and effective handling and use of pesticides in accordance
11 with the Environmental Protection Agency approved label-
12 ing, and instruction in integrated pest management tech-
13 niques. The authority of the Administrator with respect
14 to minimum requirements for training of maintenance ap-
15 plicators and service technicians shall be limited to ensur-
16 ing that each State understands the provisions of this sec-
17 tion.”.

18 **TITLE II—MINOR USE CROP PRO-**
19 **TECTION, ANTIMICROBIAL**
20 **PESTICIDE REGISTRATION**
21 **REFORM, AND PUBLIC**
22 **HEALTH PESTICIDES**

23 **SEC. 201. REFERENCE.**

24 Whenever in this title an amendment or repeal is ex-
25 pressed in terms of an amendment to, or repeal of, a sec-

tion or other provision, the reference shall be considered to be made to a section or other provision of the Federal Insecticide, Fungicide, and Rodenticide Act.

Subtitle A—Minor Use Crop Protection

SEC. 210. MINOR CROP PROTECTION.

(a) DEFINITION.—Section 2 (7 U.S.C. 136), as amended by section 120, is further amended by adding at the end the following:

“(1) MINOR USE.—The term ‘minor use’ means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—

“(1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or

“(2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and—

1 “(A) there are insufficient efficacious alter-
2 native registered pesticides available for the
3 use;

4 “(B) the alternatives to the pesticide use
5 pose greater risks to the environment or human
6 health;

7 “(C) the minor use pesticide plays or will
8 play a significant part in managing pest resist-
9 ance; or

10 “(D) the minor use pesticide plays or will
11 play a significant part in an integrated pest
12 management program.

13 The status as a minor use under this subsection shall con-
14 tinue as long as the Administrator has not determined
15 that, based on existing data, such use may cause an unrea-
16 sonable adverse effect on the environment and the use oth-
17 erwise qualifies for such status.”.

18 (b) EXCLUSIVE USE OF MINOR USE PESTICIDES.—
19 Section 3(c)(1)(F) (7 U.S.C. 136a(c)(1)(F)) is amended—

20 (1) by redesignating clauses (ii) and (iii) as
21 clauses (iii) and (iv), respectively; and

22 (2) by inserting after clause (i) the following:

23 “(ii) The period of exclusive data use
24 provided under clause (i) shall be extended
25 1 additional year for each 3 minor uses

1 registered after the date of enactment of
2 this clause and within 7 years of the com-
3 mencement of the exclusive use period, up
4 to a total of 3 additional years for all
5 minor uses registered by the Administrator
6 if the Administrator, in consultation with
7 the Secretary of Agriculture, determines
8 that, based on information provided by an
9 applicant for registration or a registrant,
10 that—

11 “(I) there are insufficient effica-
12 cious alternative registered pesticides
13 available for the use;

14 “(II) the alternatives to the
15 minor use pesticide pose greater risks
16 to the environment or human health;

17 “(III) the minor use pesticide
18 plays or will play a significant part in
19 managing pest resistance; or

20 “(IV) the minor use pesticide
21 plays or will play a significant part in
22 an integrated pest management pro-
23 gram.

24 The registration of a pesticide for a minor
25 use on a crop grouping established by the

1 Administrator shall be considered for pur-
2 poses of this clause 1 minor use for each
3 representative crop for which data are pro-
4 vided in the crop grouping. Any additional
5 exclusive use period under this clause shall
6 be modified as appropriate or terminated if
7 the registrant voluntarily cancels the prod-
8 uct or deletes from the registration the
9 minor uses which formed the basis for the
10 extension of the additional exclusive use
11 period or if the Administrator determines
12 that the registrant is not actually market-
13 ing the product for such minor uses.”;

14 (3) in clause (iv), as amended by paragraph (1),
15 by striking “and (ii)” and inserting “, (ii), and
16 (iii)”;

17 (4) at the end of the section, as amended by
18 paragraph (1), by adding the following:

19 “(v) The period of exclusive use pro-
20 vided under clause (ii) shall not take into
21 effect until 1 year after enactment of this
22 clause, except where an applicant or reg-
23 istrant is applying for the registration of a
24 pesticide containing an active ingredient
25 not previously registered.

1 “(vi) With respect to data submitted
2 after the date of enactment of this clause
3 by an applicant or registrant to support an
4 amendment adding a new use to an exist-
5 ing registration that does not retain any
6 period of exclusive use, if such data relates
7 solely to a minor use of a pesticide, such
8 data shall not, without the written permis-
9 sion of the original data submitter, be con-
10 sidered by the Administrator to support an
11 application for a minor use by another per-
12 son during the period of 10 years following
13 the date of submission of such data. The
14 applicant or registrant at the time the new
15 minor use is requested shall notify the Ad-
16 ministrator that to the best of their knowl-
17 edge the exclusive use period for the pes-
18 ticide has expired and that the data per-
19 taining solely to the minor use of a pes-
20 ticide is eligible for the provisions of this
21 paragraph. If the minor use registration
22 which is supported by data submitted pur-
23 suant to this subsection is voluntarily can-
24 celed or if such data are subsequently used
25 to support a nonminor use, the data shall

1 no longer be subject to the exclusive use
2 provisions of this clause but shall instead
3 be considered by the Administrator in ac-
4 cordance with the provisions of clause (i),
5 as appropriate.”.

6 (c) TIME EXTENSIONS FOR DEVELOPMENT OF
7 MINOR USE DATA.—

8 (1) DATA CALL-IN.—Section 3(c)(2)(B) (7
9 U.S.C. 136a(c)(2)(B)) is amended by adding at the
10 end the following:

11 “(vi) Upon the request of a registrant the
12 Administrator shall, in the case of a minor use,
13 extend the deadline for the production of resi-
14 due chemistry data under this subparagraph for
15 data required solely to support that minor use
16 until the final deadline for submission of data
17 under section 4 for the other uses of the pes-
18 ticide established as of the date of enactment of
19 the Food Quality Protection Act of 1996, if—

20 “(I) the data to support other uses of
21 the pesticide on a food are being provided;

22 “(II) the registrant, in submitting a
23 request for such an extension, provides a
24 schedule, including interim dates to meas-
25 ure progress, to assure that the data pro-

1 duction will be completed before the expi-
2 ration of the extension period;

3 “(III) the Administrator has deter-
4 mined that such extension will not signifi-
5 cantly delay the Administrator’s schedule
6 for issuing a reregistration eligibility deter-
7 mination required under section 4; and

8 “(IV) the Administrator has deter-
9 mined that based on existing data, such
10 extension would not significantly increase
11 the risk of any unreasonable adverse effect
12 on the environment. If the Administrator
13 grants an extension under this clause, the
14 Administrator shall monitor the develop-
15 ment of the data and shall ensure that the
16 registrant is meeting the schedule for the
17 production of the data. If the Adminis-
18 trator determines that the registrant is not
19 meeting or has not met the schedule for
20 the production of such data, the Adminis-
21 trator may proceed in accordance with
22 clause (iv) regarding the continued reg-
23 istration of the affected products with the
24 minor use and shall inform the public of
25 such action. Notwithstanding the provi-

1 sions of this clause, the Administrator may
2 take action to modify or revoke the exten-
3 sion under this clause if the Administrator
4 determines that the extension for the
5 minor use may cause an unreasonable ad-
6 verse effect on the environment. In such
7 circumstance, the Administrator shall pro-
8 vide, in writing to the registrant, a notice
9 revoking the extension of time for submis-
10 sion of data. Such data shall instead be
11 due in accordance with the date established
12 by the Administrator for the submission of
13 the data.”.

14 (2) REREGISTRATION.—Sections 4(d)(4)(B),
15 4(e)(2)(B), and 4(f)(2)(B) (7 U.S.C. 136a–
16 1(d)(4)(B), (e)(2)(B), and (f)(2)(B)) are each
17 amended by adding at the end the following: “Upon
18 application of a registrant, the Administrator shall,
19 in the case of a minor use, extend the deadline for
20 the production of residue chemistry data under this
21 subparagraph for data required solely to support
22 that minor use until the final deadline for submis-
23 sion of data under this section for the other uses of
24 the pesticide established as of the date of enactment
25 of the Food Quality Protection Act of 1996 if—

1 “(i) the data to support other uses of
2 the pesticide on a food are being provided;

3 “(ii) the registrant, in submitting a
4 request for such an extension provides a
5 schedule, including interim dates to meas-
6 ure progress, to assure that the data pro-
7 duction will be completed before the expi-
8 ration of the extension period;

9 “(iii) the Administrator has deter-
10 mined that such extension will not signifi-
11 cantly delay the Administrator’s schedule
12 for issuing a reregistration eligibility deter-
13 mination required under this section; and

14 “(iv) the Administrator has deter-
15 mined that based on existing data, such
16 extension would not significantly increase
17 the risk of any unreasonable adverse effect
18 on the environment. If the Administrator
19 grants an extension under this subpara-
20 graph, the Administrator shall monitor the
21 development of the data and shall ensure
22 that the registrant is meeting the schedule
23 for the production of the data. If the Ad-
24 ministrator determines that the registrant
25 is not meeting or has not met the schedule

1 for the production of such data, the Ad-
2 ministrator may proceed in accordance
3 with clause (iv) of section 3(c)(2)(B) or
4 other provisions of this section, as appro-
5 priate, regarding the continued registration
6 of the affected products with the minor use
7 and shall inform the public of such action.
8 Notwithstanding the provisions of this sub-
9 paragraph, the Administrator may take ac-
10 tion to modify or revoke the extension
11 under this subparagraph if the Adminis-
12 trator determines that the extension for
13 the minor use may cause an unreasonable
14 adverse affect on the environment. In such
15 circumstance, the Administrator shall pro-
16 vide written notice to the registrant revok-
17 ing the extension of time for submission of
18 data. Such data shall instead be due in ac-
19 cordance with the date then established by
20 the Administrator for submission of the
21 data.”.

22 (d) MINOR USE WAIVER.—Section 3(c)(2) (7 U.S.C.
23 136a(c)(2)) is amended—

24 (1) by inserting “IN GENERAL.—” after “(A)”;

1 (2) by inserting “ADDITIONAL DATA.—” after
2 “(B)”;

3 (3) by inserting “SIMPLIFIED PROCEDURES.—”
4 after “(C)”;

5 (4) 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 expe-
2 ditiously as possible, review and act on any
3 complete application—

4 “(I) that proposes the initial reg-
5 istration of a new pesticide active in-
6 gredient if the active ingredient is
7 proposed to be registered solely for
8 minor uses, or proposes a registration
9 amendment solely for minor uses to
10 an existing registration; or

11 “(II) for a registration or a reg-
12 istration amendment that proposes
13 significant minor uses.

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

15 “(I) the term ‘as expeditiously as
16 possible’ means that the Adminis-
17 trator shall, to the greatest extent
18 practicable, complete a review and
19 evaluation of all data, submitted with
20 a complete application, within 12
21 months after the submission of the
22 complete application, and the failure
23 of the Administrator to complete such
24 a review and evaluation under clause

1 (i) shall not be subject to judicial re-
2 view; and

3 “(II) the term ‘significant minor
4 uses’ means 3 or more minor uses
5 proposed for every nonminor use, a
6 minor use that would, in the judgment
7 of the Administrator, serve as a re-
8 placement for any use which has been
9 canceled in the 5 years preceding the
10 receipt of the application, or a minor
11 use that in the opinion of the Admin-
12 istrator would avoid the reissuance of
13 an emergency exemption under section
14 18 for that minor use.

15 “(D) ADEQUATE TIME FOR SUBMISSION OF
16 MINOR USE DATA.—If a registrant makes a re-
17 quest for a minor use waiver, regarding data re-
18 quired by the Administrator, pursuant to para-
19 graph (2)(E), and if the Administrator denies
20 in whole or in part such data waiver request,
21 the registrant shall have a full-time period for
22 providing such data. For purposes of this sub-
23 paragraph, the term ‘full-time period’ means
24 the time period originally established by the Ad-
25 ministrator for submission of such data, begin-

1 ning with the date of receipt by the registrant
2 of the Administrator’s notice of denial.”.

3 (f) TEMPORARY EXTENSION OF REGISTRATION FOR
4 UNSUPPORTED MINOR USES.—

5 (1) REREGISTRATION.—

6 (A) Sections 4(d)(6) and 4(f)(3) (7 U.S.C.
7 136a–1(d)(6) and (f)(3)) are each amended by
8 adding at the end the following: “If the reg-
9 istrant does not commit to support a specific
10 minor use of the pesticide, but is supporting
11 and providing data in a timely and adequate
12 fashion to support uses of the pesticide on a
13 food, or if all uses of the pesticide are nonfood
14 uses and the registrant does not commit to sup-
15 port a specific minor use of the pesticide but is
16 supporting and providing data in a timely and
17 adequate fashion to support other nonfood uses
18 of the pesticide, the Administrator, at the writ-
19 ten request of the registrant, shall not take any
20 action pursuant to this paragraph in regard to
21 such unsupported minor use until the final
22 deadline established as of the date of enactment
23 of the Food Quality Protection Act of 1996, for
24 the submission of data under this section for
25 the supported uses identified pursuant to this

1 paragraph unless the Administrator determines
2 that the absence of the data is significant
3 enough to cause human health or environmental
4 concerns. On such a determination the Admin-
5 istrator may refuse the request for extension by
6 the registrant. Upon receipt of the request from
7 the registrant, the Administrator shall publish
8 in the Federal Register a notice of the receipt
9 of the request and the effective date upon which
10 the uses not being supported will be voluntarily
11 deleted from the registration pursuant to sec-
12 tion 6(f)(1). If the Administrator grants an ex-
13 tension under this paragraph, the Adminis-
14 trator shall monitor the development of the
15 data for the uses being supported and shall en-
16 sure that the registrant is meeting the schedule
17 for the production of such data. If the Adminis-
18 trator determines that the registrant is not
19 meeting or has not met the schedule for the
20 production of such data, the Administrator may
21 proceed in accordance with section
22 3(c)(2)(B)(iv) regarding the continued registra-
23 tion of the affected products with the minor
24 and other uses and shall inform the public of
25 such action in accordance with section 6(f)(2).

1 Notwithstanding this subparagraph, the Admin-
2 istrator may deny, modify, or revoke the tem-
3 porary extension under this paragraph if the
4 Administrator determines that the continuation
5 of the minor use may cause an unreasonable
6 adverse effect on the environment. In the event
7 of modification or revocation, the Administrator
8 shall provide, in writing, to the registrant a no-
9 tice revoking the temporary extension and es-
10 tablish a new effective date by which the minor
11 use shall be deleted from the registration.”.

12 (B) Section 4(e)(3)(A) (7 U.S.C. 136a-
13 1(e)(3)(A)) is amended by adding at the end
14 the following: “If the registrant does not com-
15 mit to support a specific minor use of the pes-
16 ticide, but is supporting and providing data in
17 a timely and adequate fashion to support uses
18 of the pesticide on a food, or if all uses of the
19 pesticide are nonfood uses and the registrant
20 does not commit to support a specific minor use
21 of the pesticide but is supporting and providing
22 data in a timely and adequate fashion to sup-
23 port other nonfood uses of the pesticide, the
24 Administrator, at the written request of the
25 registrant, shall not take any action pursuant

1 to this subparagraph in regard to such unsup-
2 ported minor use until the final deadline estab-
3 lished as of the date of enactment of the Food
4 Quality Protection Act of 1996, for the submis-
5 sion of data under this section for the sup-
6 ported uses identified pursuant to this subpara-
7 graph unless the Administrator determines that
8 the absence of the data is significant enough to
9 cause human health or environmental concerns.
10 On the basis of such determination, the Admin-
11 istrator may refuse the request for extension by
12 the registrant. 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 pursuant to sec-
18 tion 6(f)(1). If the Administrator grants an ex-
19 tension under this subparagraph, the Adminis-
20 trator shall monitor the development of the
21 data for the uses being supported and shall en-
22 sure that the registrant is meeting the schedule
23 for the production of such data. If the Adminis-
24 trator determines that the registrant is not
25 meeting or has not met the schedule for the

1 production of such data, the Administrator may
2 proceed in accordance with section
3 3(c)(2)(B)(iv) regarding the continued registra-
4 tion of the affected products with the minor
5 and other uses and shall inform the public of
6 such action in accordance with section 6(f)(2).
7 Notwithstanding this subparagraph, the Admin-
8 istrator may deny, modify, or revoke the tem-
9 porary extension under this subparagraph if the
10 Administrator determines that the continuation
11 of the minor use may cause an unreasonable
12 adverse effect on the environment. In the event
13 of modification or revocation, the Administrator
14 shall provide, in writing, to the registrant a no-
15 tice revoking the temporary extension and es-
16 tablish a new effective date by which the minor
17 use shall be deleted from the registration.”.

18 (2) DATA.—Section 3(c)(2)(B) (7 U.S.C.
19 136a(c)(2)(B)), as amended by subsection (c)(1), is
20 further amended by adding at the end the following:

21 “(vii) If the registrant does not commit to
22 support a specific minor use of the pesticide,
23 but is supporting and providing data in a timely
24 and adequate fashion to support uses of the
25 pesticide on a food, or if all uses of the pes-

1 ticide are nonfood uses and the registrant does
2 not commit to support a specific minor use of
3 the pesticide but is supporting and providing
4 data in a timely and adequate fashion to sup-
5 port other nonfood uses of the pesticide, the
6 Administrator, at the written request of the
7 registrant, shall not take any action pursuant
8 to this clause in regard to such unsupported
9 minor use until the final deadline established as
10 of the date of enactment of the Food Quality
11 Protection Act of 1996, for the submission of
12 data under section 4 for the supported uses
13 identified pursuant to this clause unless the Ad-
14 ministrator determines that the absence of the
15 data is significant enough to cause human
16 health or environmental concerns. On the basis
17 of such determination, the Administrator may
18 refuse the request for extension by the reg-
19 istrant. Upon receipt of the request from the
20 registrant, the Administrator shall publish in
21 the Federal Register a notice of the receipt of
22 the request and the effective date upon which
23 the uses not being supported will be voluntarily
24 deleted from the registration pursuant to sec-
25 tion 6(f)(1). If the Administrator grants an ex-

1 tension under this clause, the Administrator
2 shall monitor the development of the data for
3 the uses being supported and shall ensure that
4 the registrant is meeting the schedule for the
5 production of such data. If the Administrator
6 determines that the registrant is not meeting or
7 has not met the schedule for the production of
8 such data, the Administrator may proceed in
9 accordance with clause (iv) of this subpara-
10 graph regarding the continued registration of
11 the affected products with the minor and other
12 uses and shall inform the public of such action
13 in accordance with section 6(f)(2). Notwith-
14 standing the provisions of this clause, the Ad-
15 ministrator may deny, modify, or revoke the
16 temporary extension under this subparagraph if
17 the Administrator determines that the continu-
18 ation of the minor use may cause an unreason-
19 able adverse effect on the environment. In the
20 event of modification or revocation, the Admin-
21 istrator shall provide, in writing, to the reg-
22 istrant a notice revoking the temporary exten-
23 sion and establish a new effective date by which
24 the minor use shall be deleted from the reg-
25 istration.”.

1 (g) Section 6(f) (7 U.S.C. 136d(f)) is amended—

2 (1) in paragraph (1)(C)(ii) by striking “90-
3 day” each place it appears and inserting “180-day”;
4 and

5 (2) in paragraph (3)(A) by striking “90-day”
6 and inserting “180-day”.

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

10 “(4) UTILIZATION OF DATA FOR VOLUNTARILY
11 CANCELED PESTICIDE.—When an application is filed
12 with the Administrator for the registration of a pes-
13 ticide for a minor use and another registrant subse-
14 quently voluntarily cancels its registration for an
15 identical or substantially similar pesticide for an
16 identical or substantially similar use, the Adminis-
17 trator shall process, review, and evaluate the pend-
18 ing application as if the voluntary cancellation had
19 not yet taken place except that the Administrator
20 shall not take such action if the Administrator deter-
21 mines that such minor use may cause an unreason-
22 able adverse effect on the environment. In order to
23 rely on this subsection, the applicant must certify
24 that it agrees to satisfy any outstanding data re-
25 quirements necessary to support the reregistration of

1 the pesticide in accordance with the data submission
2 schedule established by the Administrator.”.

3 (i) ENVIRONMENTAL PROTECTION AGENCY MINOR
4 USE PROGRAM.—The Federal Insecticide, Fungicide, and
5 Rodenticide Act (7 U.S.C. 136 et seq.), as amended by
6 section 121, is amended by adding after section 30 the
7 following:

8 **“SEC. 31. ENVIRONMENTAL PROTECTION AGENCY MINOR**
9 **USE PROGRAM.**

10 “(a) The Administrator shall assure coordination of
11 minor use issues through the establishment of a minor use
12 program within the Office of Pesticide Programs. Such of-
13 fice shall be responsible for coordinating the development
14 of minor use programs and policies and consulting with
15 growers regarding minor use issues and registrations and
16 amendments which are submitted to the Environmental
17 Protection Agency.

18 “(b) The Office of Pesticide Programs shall prepare
19 a public report concerning the progress made on the reg-
20 istration of minor uses, including implementation of the
21 exclusive use as an incentive for registering new minor
22 uses, within 3 years of the passage of the Food Quality
23 Protection Act of 1996.”.

24 (j) DEPARTMENT OF AGRICULTURE MINOR USE
25 PROGRAM.—The Federal Insecticide, Fungicide, and

1 Rodenticide Act (7 U.S.C. 136 et seq.), as amended by
2 subsection (i), is amended by adding after section 31 the
3 following:

4 **“SEC. 32. DEPARTMENT OF AGRICULTURE MINOR USE PRO-**
5 **GRAM.**

6 “(a) IN GENERAL.—The Secretary of Agriculture
7 (hereinafter in this section referred to as the ‘Secretary’)
8 shall assure the coordination of the responsibilities of the
9 Department of Agriculture related to minor uses of pes-
10 ticides, including—

11 “(1) carrying out the Inter-Regional Project
12 Number 4 (IR-4) as described in section 2 of Public
13 Law 89-106 (7 U.S.C. 450i(e)) and the national
14 pesticide resistance monitoring program established
15 under section 1651 of the Food, Agriculture, Con-
16 servation, and Trade Act of 1990 (7 U.S.C. 5882);

17 “(2) supporting integrated pest management
18 research;

19 “(3) consulting with growers to develop data for
20 minor uses; and

21 “(4) providing assistance for minor use reg-
22 istrations, tolerances, and reregistrations with the
23 Environmental Protection Agency.

24 “(b)(1) MINOR USE PESTICIDE DATA.—

1 “(A) GRANT AUTHORITY.—The Secretary, in
2 consultation with the Administrator, shall establish a
3 program to make grants for the development of data
4 to support minor use pesticide registrations and re-
5 registrations. The amount of any such grant shall
6 not exceed 1/2 of the cost of the project for which the
7 grant is made.

8 “(B) APPLICANTS.—Any person who wants to
9 develop data to support minor use pesticide registra-
10 tions and reregistrations may apply for a grant
11 under subparagraph (A). Priority shall be given to
12 an applicant for such a grant who does not directly
13 receive funds from the sale of pesticides registered
14 for minor uses.

15 “(C) DATA OWNERSHIP.—Any data that is de-
16 veloped under a grant under subparagraph (A) shall
17 be jointly owned by the Department of Agriculture
18 and the person who received the grant. Such a per-
19 son shall enter into an agreement with the Secretary
20 under which such person shall share any fee paid to
21 such person under section 3(c)(1)(F).

22 “(2) MINOR USE PESTICIDE DATA REVOLVING
23 FUND.—

24 “(A) ESTABLISHMENT.—There is established in
25 the Treasury of the United States a revolving fund

1 to be known as the Minor Use Pesticide Data Re-
 2 volving Fund. The Fund shall be available without
 3 fiscal year limitation to carry out the authorized
 4 purposes of this subsection.

5 “(B) CONTENTS OF THE FUND.—There shall
 6 be deposited in the Fund—

7 “(i) such amounts as may be appropriated
 8 to support the purposes of this subsection; and

9 “(ii) fees collected by the Secretary for any
 10 data developed under a grant under paragraph
 11 (1)(A).

12 “(C) AUTHORIZATIONS OF APPROPRIATIONS.—
 13 There are authorized to be appropriated for each fis-
 14 cal year to carry out the purposes of this subsection
 15 \$10,000,000 to remain available until expended.”.

16 **Subtitle B—Antimicrobial Pesticide** 17 **Registration Reform**

18 **SEC. 221. DEFINITIONS.**

19 Section 2 (7 U.S.C. 136), as amended by section
 20 210(a) is further amended—

21 (1) in subsection (u), by adding at the end the
 22 following: “The term ‘pesticide’ does not include liq-
 23 uid chemical sterilant products (including any
 24 sterilant or subordinate disinfectant claims on such
 25 products) for use on a critical or semi-critical device,

1 as defined in section 201 of the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 321). For purposes of
3 the preceding sentence, the term ‘critical device’ in-
4 cludes any device which is introduced directly into
5 the human body, either into or in contact with the
6 bloodstream or normally sterile areas of the body
7 and the term ‘semi-critical device’ includes any de-
8 vice which contacts intact mucous membranes but
9 which does not ordinarily penetrate the blood barrier
10 or otherwise enter normally sterile areas of the
11 body.”; and

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

13 “(mm) ANTIMICROBIAL PESTICIDE.—

14 “(1) IN GENERAL.—The term ‘antimicrobial
15 pesticide’ means a pesticide that—

16 “(A) is intended to—

17 “(i) disinfect, sanitize, reduce, or miti-
18 gate growth or development of micro-
19 biological organisms; or

20 “(ii) protect inanimate objects, indus-
21 trial processes or systems, surfaces, water,
22 or other chemical substances from con-
23 tamination, fouling, or deterioration caused
24 by bacteria, viruses, fungi, protozoa, algae,
25 or slime; and

1 “(B) in the intended use is exempt from,
 2 or otherwise not subject to, a tolerance under
 3 section 408 of the Federal Food, Drug, and
 4 Cosmetic Act (21 U.S.C. 346a and 348) or a
 5 food additive regulation under section 409 of
 6 such Act.

7 “(2) EXCLUDED PRODUCTS.—The term
 8 ‘antimicrobial pesticide’ does not include —

9 “(A) a wood preservative or antifouling
 10 paint product for which a claim of pesticidal ac-
 11 tivity other than or in addition to an activity
 12 described in paragraph (1) is made;

13 “(B) an agricultural fungicide product; or

14 “(C) an aquatic herbicide product.

15 “(3) INCLUDED PRODUCTS.—The term
 16 ‘antimicrobial pesticide’ does include any other
 17 chemical sterilant product (other than liquid chemi-
 18 cal sterilant products exempt under subsection (u)),
 19 any other disinfectant product, any other industrial
 20 microbiocide product, and any other preservative
 21 product that is not excluded by paragraph (2).”.

22 **SEC. 222. FEDERAL AND STATE DATA COORDINATION.**

23 Section 3(c)(2)(B) (7 U.S.C. 136a(c)(2)(B)), as
 24 amended by section 210(f)(2), is amended by adding at
 25 the end the following:

“(viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

“(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

“(III) Not later than 1 year after the date of enactment of this clause, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.”.

SEC. 223. LABEL AND LABELING.

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

“(9) LABELING.—

“(A) ADDITIONAL STATEMENTS.—Subject to subparagraphs (B) and (C), it shall not be a violation of this Act for a registrant to modify the labeling of an antimicrobial pesticide prod-

1 uct to include relevant information on product
2 efficacy, product composition, container com-
3 position or design, or other characteristics that
4 do not relate to any pesticidal claim or pes-
5 ticial activity.

6 “(B) REQUIREMENTS.—Proposed labeling
7 information under subparagraph (A) shall not
8 be false or misleading, shall not conflict with or
9 detract from any statement required by law or
10 the Administrator as a condition of registration,
11 and shall be substantiated on the request of the
12 Administrator.

13 “(C) NOTIFICATION AND DISAPPROVAL.—

14 “(i) NOTIFICATION.—A registration
15 may be modified under subparagraph (A)
16 if —

17 “(I) the registrant notifies the
18 Administrator in writing not later
19 than 60 days prior to distribution or
20 sale of a product bearing the modified
21 labeling; and

22 “(II) the Administrator does not
23 disapprove of the modification under
24 clause (ii).

1 “(ii) DISAPPROVAL.—Not later than
2 30 days after receipt of a notification
3 under clause (i), the Administrator may
4 disapprove the modification by sending the
5 registrant notification in writing stating
6 that the proposed language is not accept-
7 able and stating the reasons why the Ad-
8 ministrator finds the proposed modification
9 unacceptable.

10 “(iii) RESTRICTION ON SALE.—A reg-
11 istrant may not sell or distribute a product
12 bearing a disapproved modification.

13 “(iv) OBJECTION.—A registrant may
14 file an objection in writing to a disapproval
15 under clause (ii) not later than 30 days
16 after receipt of notification of the dis-
17 approval.

18 “(v) FINAL ACTION.—A decision by
19 the Administrator following receipt and
20 consideration of an objection filed under
21 clause (iv) shall be considered a final agen-
22 cy action.

23 “(D) USE DILUTION.—The label or label-
24 ing required under this Act for an antimicrobial
25 pesticide that is or may be diluted for use may

1 have a different statement of caution or protec-
 2 tive measures for use of the recommended di-
 3 luted solution of the pesticide than for use of a
 4 concentrate of the pesticide if the Administrator
 5 determines that —

6 “(i) adequate data have been submit-
 7 ted to support the statement proposed for
 8 the diluted solution uses; and

9 “(ii) the label or labeling provides
 10 adequate protection for exposure to the di-
 11 luted solution of the pesticide.”.

12 **SEC. 224. REGISTRATION REQUIREMENTS FOR**
 13 **ANTIMICROBIAL PESTICIDES.**

14 Section 3 (7 U.S.C. 136a), as amended by section
 15 106(b), is further amended by adding at the end the fol-
 16 lowing:

17 “(h) REGISTRATION REQUIREMENTS FOR
 18 ANTIMICROBIAL PESTICIDES.—

19 “(1) EVALUATION OF PROCESS.—To the maxi-
 20 mum extent practicable consistent with the degrees
 21 of risk presented by a antimicrobial pesticide and
 22 the type of review appropriate to evaluate the risks,
 23 the Administrator shall identify and evaluate re-
 24 forms to the antimicrobial registration process that
 25 would reduce review periods existing as of the date

1 of enactment of this subsection for antimicrobial
2 pesticide product registration applications and appli-
3 cations for amended registration of antimicrobial
4 pesticide products, including—

5 “(A) new antimicrobial active ingredients;

6 “(B) new antimicrobial end-use products;

7 “(C) substantially similar or identical
8 antimicrobial pesticides; and

9 “(D) amendments to antimicrobial pes-
10 ticide registrations.

11 “(2) REVIEW TIME PERIOD REDUCTION
12 GOAL.—Each reform identified under paragraph (1)
13 shall be designed to achieve the goal of reducing the
14 review period following submission of a complete ap-
15 plication, consistent with the degree of risk, to a pe-
16 riod of not more than —

17 “(A) 540 days for a new antimicrobial ac-
18 tive ingredient pesticide registration;

19 “(B) 270 days for a new antimicrobial use
20 of a registered active ingredient;

21 “(C) 120 days for any other new
22 antimicrobial product;

23 “(D) 90 days for a substantially similar or
24 identical antimicrobial product;

1 “(E) 90 days for an amendment to an
2 antimicrobial registration that does not require
3 scientific review of data; and

4 “(F) 90 to 180 days for an amendment to
5 an antimicrobial registration that requires sci-
6 entific review of data and that is not otherwise
7 described in this paragraph.

8 “(3) IMPLEMENTATION.—

9 “(A) PROPOSED RULEMAKING.—

10 “(i) ISSUANCE.—Not later than 270
11 days after the date of enactment of this
12 subsection, the Administrator shall publish
13 in the Federal Register proposed regula-
14 tions to accelerate and improve the review
15 of antimicrobial pesticide products de-
16 signed to implement, to the extent prac-
17 ticable, the goals set forth in paragraph
18 (2).

19 “(ii) REQUIREMENTS.—Proposed reg-
20 ulations issued under clause (i) shall —

21 “(I) define the various classes of
22 antimicrobial use patterns, including
23 household, industrial, and institutional
24 disinfectants and sanitizing pesticides,
25 preservatives, water treatment, and

1 pulp and paper mill additives, and
2 other such products intended to dis-
3 infect, sanitize, reduce, or mitigate
4 growth or development of micro-
5 biological organisms, or protect inani-
6 mate objects, industrial processes or
7 systems, surfaces, water, or other
8 chemical substances from contamina-
9 tion, fouling, or deterioration caused
10 by bacteria, viruses, fungi, protozoa,
11 algae, or slime;

12 “(II) differentiate the types of re-
13 view undertaken for antimicrobial pes-
14 ticides;

15 “(III) conform the degree and
16 type of review to the risks and bene-
17 fits presented by antimicrobial pes-
18 ticides and the function of review
19 under this Act, considering the use
20 patterns of the product, toxicity, ex-
21 pected exposure, and product type;

22 “(IV) ensure that the registration
23 process is sufficient to maintain
24 antimicrobial pesticide efficacy and
25 that antimicrobial pesticide products

1 continue to meet product performance
2 standards and effectiveness levels for
3 each type of label claim made; and

4 “(V) implement effective and reli-
5 able deadlines for process manage-
6 ment.

7 “(iii) COMMENTS.—In developing the
8 proposed regulations, the Administrator
9 shall solicit the views from registrants and
10 other affected parties to maximize the ef-
11 fectiveness of the rule development process.

12 “(B) FINAL REGULATIONS.—

13 “(i) ISSUANCE.—The Administrator
14 shall issue final regulations not later than
15 240 days after the close of the comment
16 period for the proposed regulations.

17 “(ii) FAILURE TO MEET GOAL.—If a
18 goal described in paragraph (2) is not met
19 by the final regulations, the Administrator
20 shall identify the goal, explain why the goal
21 was not attained, describe the element of
22 the regulations included instead, and iden-
23 tify future steps to attain the goal.

24 “(iii) REQUIREMENTS.—In issuing
25 final regulations, the Administrator shall—

1 “(I) consider the establishment of
2 a certification process for regulatory
3 actions involving risks that can be re-
4 sponsibly managed, consistent with
5 the degree of risk, in the most cost-ef-
6 ficient manner;

7 “(II) consider the establishment
8 of a certification process by approved
9 laboratories as an adjunct to the re-
10 view process;

11 “(III) use all appropriate and
12 cost-effective review mechanisms, in-
13 cluding—

14 “(aa) expanded use of notifi-
15 cation and non-notification proce-
16 dures;

17 “(bb) revised procedures for
18 application review; and

19 “(cc) allocation of appro-
20 priate resources to ensure
21 streamlined management of
22 antimicrobial pesticide registra-
23 tions; and

1 “(IV) clarify criteria for deter-
2 mination of the completeness of an
3 application.

4 “(C) EXPEDITED REVIEW.—This sub-
5 section does not affect the requirements or ex-
6 tend the deadlines or review periods contained
7 in subsection (c)(3).

8 “(D) ALTERNATIVE REVIEW PERIODS.—If
9 the final regulations to carry out this paragraph
10 are not effective 630 days after the date of en-
11 actment of this subsection, until the final regu-
12 lations become effective, the review period, be-
13 ginning on the date of receipt by the Agency of
14 a complete application, shall be —

15 “(i) 2 years for a new antimicrobial
16 active ingredient pesticide registration;

17 “(ii) 1 year for a new antimicrobial
18 use of a registered active ingredient;

19 “(iii) 180 days for any other new
20 antimicrobial product;

21 “(iv) 90 days for a substantially simi-
22 lar or identical antimicrobial product;

23 “(v) 90 days for an amendment to an
24 antimicrobial registration that does not re-
25 quire scientific review of data; and

1 “(vi) 240 days for an amendment to
2 an antimicrobial registration that requires
3 scientific review of data and that is not
4 otherwise described in this subparagraph.

5 “(E) WOOD PRESERVATIVES.—An applica-
6 tion for the registration, or for an amendment
7 to the registration, of a wood preservative prod-
8 uct for which a claim of pesticidal activity listed
9 in section 2(mm) is made (regardless of any
10 other pesticidal claim that is made with respect
11 to the product) shall be reviewed by the Admin-
12 istrator within the same period as that estab-
13 lished under this paragraph for an
14 antimicrobial pesticide product application, con-
15 sistent with the degree of risk posed by the use
16 of the wood preservative product, if the applica-
17 tion requires the applicant to satisfy the same
18 data requirements as are required to support an
19 application for a wood preservative product that
20 is an antimicrobial pesticide.

21 “(F) NOTIFICATION.—

22 “(i) IN GENERAL.—Subject to clause
23 (iii), the Administrator shall notify an ap-
24 plicant whether an application has been
25 granted or denied not later than the final

1 day of the appropriate review period under
2 this paragraph, unless the applicant and
3 the Administrator agree to a later date.

4 “(ii) FINAL DECISION.—If the Admin-
5 istrator fails to notify an applicant within
6 the period of time required under clause
7 (i), the failure shall be considered an agen-
8 cy action unlawfully withheld or unreason-
9 ably delayed for purposes of judicial review
10 under chapter 7 of title 5, United States
11 Code.

12 “(iii) EXEMPTION.—This subpara-
13 graph does not apply to an application for
14 an antimicrobial pesticide that is filed
15 under subsection (c)(3)(B) prior to 90
16 days after the date of enactment of this
17 subsection.

18 “(4) ANNUAL REPORT.—

19 “(A) SUBMISSION.—Beginning on the date
20 of enactment of this subsection and ending on
21 the date that the goals under paragraph (2) are
22 achieved, the Administrator shall, not later than
23 March 1 of each year, prepare and submit an
24 annual report to the Committee on Agriculture
25 of the House of Representatives and the Com-

mittee on Agriculture, Nutrition, and Forestry
of the Senate.

“(B) REQUIREMENTS.—A report submitted under subparagraph (A) shall include a description of—

“(i) measures taken to reduce the backlog of pending registration applications;

“(ii) progress toward achieving reforms under this subsection; and

“(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.”.

SEC. 225. DISPOSAL OF HOUSEHOLD, INDUSTRIAL, OR INSTITUTIONAL ANTIMICROBIAL PRODUCTS.

Section 19(h) (7 U.S.C. 136q(h)) is amended—

(1) by striking “Nothing in” and inserting the following:

“(1) IN GENERAL.—Nothing in”; and

(2) by adding at the end the following:

“(2) ANTIMICROBIAL PRODUCTS.—A household, industrial, or institutional antimicrobial product that is not subject to regulation under the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.) shall not be subject to the provisions of subsections (a), (e), and

1 (f), unless the Administrator determines that such
2 product must be subject to such provisions to pre-
3 vent an unreasonable adverse effect on the environ-
4 ment.”.

5 **Subtitle C—Public Health**
6 **Pesticides**

7 **SEC. 230. DEFINITIONS.**

8 (a) ADVERSE EFFECTS.—Section 2(bb) (7 U.S.C.
9 136(bb)) is amended by adding at the end the following:
10 “The Administrator shall consider the risks and benefits
11 of public health pesticides separate from the risks and
12 benefits of other pesticides. In weighing any regulatory ac-
13 tion concerning a public health pesticide under this Act,
14 the Administrator shall weigh any risks of the pesticide
15 against the health risks such as the diseases transmitted
16 by the vector to be controlled by the pesticide.”.

17 (b) NEW DEFINITIONS.—Section 2 (7 U.S.C. 136),
18 as amended by section 221, is amended by adding at the
19 end the following:

20 “(nn) PUBLIC HEALTH PESTICIDE.—The term ‘pub-
21 lic health pesticide’ means any minor use pesticide product
22 registered for use and used predominantly in public health
23 programs for vector control or for other recognized health
24 protection uses, including the prevention or mitigation of
25 viruses, bacteria, or other microorganisms (other than vi-

1 ruses, bacteria, or other microorganisms on or in living
 2 man or other living animal) that pose a threat to public
 3 health.

4 “(oo) VECTOR.—The term ‘vector’ means any orga-
 5 nism capable of transmitting the causative agent of human
 6 disease or capable of producing human discomfort or in-
 7 jury, including mosquitoes, flies, fleas, cockroaches, or
 8 other insects and ticks, mites, or rats.”.

9 **SEC. 231. REGISTRATION.**

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

12 (1) by inserting after “pattern of use,” the fol-
 13 lowing: “the public health and agricultural need for
 14 such minor use,”; and

15 (2) by striking “potential exposure of man and
 16 the environment to the pesticide” and inserting “po-
 17 tential beneficial or adverse effects on man and the
 18 environment”.

19 **SEC. 232. REREGISTRATION.**

20 Section 4 (7 U.S.C. 136a–1) is amended—

21 (1) in subsection (i)(4), by redesignating sub-
 22 paragraphs (B) and (C) as subparagraphs (C) and
 23 (D), respectively, and by adding after subparagraph
 24 (A) the following:

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

10 (2) in subsection (i)(5), by redesignating sub-
11 paragraphs (F) and (G) as subparagraphs (G) and
12 (H), respectively, and by adding after subparagraph
13 (E) the following:

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

23 (3) in subsection (i)(7)(B), by striking “or to
24 determine” and inserting “, to determine” and by
25 inserting before the period the following: “, or to de-

1 terminate the volume usage for public health pes-
2 ticides”; and

3 (4) in subsection (k)(3)(A), by striking “or” at
4 the end of clause (i), by striking the period at the
5 end of clause (ii) and inserting thereof “; or”, and
6 by adding after clause (ii) the following:

7 “(iii) proposes the initial or amended
8 registration of an end use pesticide that, if
9 registered as proposed, would be used for
10 a public health pesticide.”.

11 **SEC. 233. CANCELLATION.**

12 Section 6(b) (7 U.S.C. 136d(b)) is amended by add-
13 ing after the eighth sentence the following: “When a public
14 health use is affected, the Secretary of Health and Human
15 Services should provide available benefits and use informa-
16 tion, or an analysis thereof, in accordance with the proce-
17 dures followed and subject to the same conditions as the
18 Secretary of Agriculture in the case of agricultural pes-
19 ticides.”.

20 **SEC. 234. VIEWS OF THE SECRETARY OF HEALTH AND**
21 **HUMAN SERVICES.**

22 Section 21 (7 U.S.C. 136s) is amended by redesignat-
23 ing subsections (b) and (c) as subsections (c) and (d), re-
24 spectively, and by adding after subsection (a) the follow-
25 ing:

1 “(b) SECRETARY OF HEALTH AND HUMAN SERV-
 2 ICES.—The Administrator, before publishing regulations
 3 under this Act for any public health pesticide, shall solicit
 4 the views of the Secretary of Health and Human Services
 5 in the same manner as the views of the Secretary of Agri-
 6 culture are solicited under section 25(a)(2).”.

7 **SEC. 235. AUTHORITY OF ADMINISTRATOR.**

8 Section 25(a)(1) (7 U.S.C. 136w(a)(1)) is amend-
 9 ed—

10 (1) by inserting after “various classes of pes-
 11 ticides” the following: “, including public health pes-
 12 ticides,”; and

13 (2) by striking “and nonagricultural pesticides”
 14 and inserting “, nonagricultural, and public health
 15 pesticides”.

16 **SEC. 236. IDENTIFICATION OF PESTS.**

17 Section 28 (7 U.S.C. 136w–3) is amended by adding
 18 at the end the following:

19 “(d) PUBLIC HEALTH PESTS.—The Administrator,
 20 in coordination with the Secretary of Agriculture and the
 21 Secretary of Health and Human Services, shall identify
 22 pests of significant public health importance and, in co-
 23 ordination with the Public Health Service, develop and im-
 24 plement programs to improve and facilitate the safe and
 25 necessary use of chemical, biological, and other methods

1 to combat and control such pests of public health impor-
2 tance.”.

3 **SEC. 237. PUBLIC HEALTH DATA.**

4 Section 4 (7 U.S.C. 136a–1) is amended by adding
5 at the end the following:

6 “(m) AUTHORIZATION OF FUNDS TO DEVELOP PUB-
7 LIC HEALTH DATA.—

8 “(1) DEFINITION.—For the purposes of this
9 section, ‘Secretary’ means the Secretary of Health
10 and Human Services, acting through the Public
11 Health Service.

12 “(2) CONSULTATION.—In the case of a pes-
13 ticide registered for use in public health programs
14 for vector control or for other uses the Adminis-
15 trator determines to be human health protection
16 uses, the Administrator shall, upon timely request by
17 the registrant or any other interested person, or on
18 the Administrator’s own initiative may, consult with
19 the Secretary prior to taking final action to suspend
20 registration under section 3(c)(2)(B)(iv), or cancel a
21 registration under section 4, 6(e), or 6(f). In con-
22 sultation with the Secretary, the Administrator shall
23 prescribe the form and content of requests under
24 this section.

1 “(3) BENEFITS TO SUPPORT FAMILY.—The Ad-
2 ministrator, after consulting with the Secretary,
3 shall make a determination whether the potential
4 benefits of continued use of the pesticide for public
5 health or health protection purposes are of such sig-
6 nificance as to warrant a commitment by the Sec-
7 retary to conduct or to arrange for the conduct of
8 the studies required by the Administrator to support
9 continued registration under section 3 or reregistra-
10 tion under section 4.

11 “(4) ADDITIONAL TIME.—If the Administrator
12 determines that such a commitment is warranted
13 and in the public interest, the Administrator shall
14 notify the Secretary and shall, to the extent nec-
15 essary, amend a notice issued under section
16 3(c)(2)(B) to specify additional reasonable time peri-
17 ods for submission of the data.

18 “(5) ARRANGEMENTS.—The Secretary shall
19 make such arrangements for the conduct of required
20 studies as the Secretary finds necessary and appro-
21 priate to permit submission of data in accordance
22 with the time periods prescribed by the Adminis-
23 trator. Such arrangements may include Public
24 Health Service intramural research activities, grants,
25 contracts, or cooperative agreements with academic,

public health, or other organizations qualified by experience and training to conduct such studies.

“(6) SUPPORT.—The Secretary may provide for support of the required studies using funds authorized to be appropriated under this section, the Public Health Service Act, or other appropriate authorities. After a determination is made under subsection (d), the Secretary shall notify the Committees on Appropriations of the House Representatives and the Senate of the sums required to conduct the necessary studies.

“(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out the purposes of this section \$12,000,000 for fiscal year 1997, and such sums as may be necessary for succeeding fiscal years.”.

Subtitle D—Expedited Registration of Reduced Risk Pesticides

SEC. 250. EXPEDITED REGISTRATION OF PESTICIDES .

Section 3(c) (7 U.S.C. 136a(c)), as amended by section 223, is amended—

(1) by adding at the end of paragraph (1) the following:

“(G) If the applicant is requesting that the registration or amendment to the registration of

1 a pesticide be expedited, an explanation of the
2 basis for the request must be submitted, in ac-
3 cordance with paragraph (10) of this sub-
4 section.”; and

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

6 “(10) EXPEDITED REGISTRATION OF PES-
7 TICIDES.—

8 “(A) Not later than 1 year after the date
9 of enactment of this paragraph, the Adminis-
10 trator shall, utilizing public comment, develop
11 procedures and guidelines, and expedite the re-
12 view of an application for registration of a pes-
13 ticide or an amendment to a registration that
14 satisfies such guidelines.

15 “(B) Any application for registration or an
16 amendment, including biological and conven-
17 tional pesticides, will be considered for expe-
18 dited review under this paragraph. An applica-
19 tion for registration or an amendment shall
20 qualify for expedited review if use of the pes-
21 ticide proposed by the application may reason-
22 ably be expected to accomplish 1 or more of the
23 following:

24 “(i) Reduce the risks of pesticides to
25 human health.

1 “(ii) Reduce the risks of pesticides to
2 nontarget organisms.

3 “(iii) Reduce the potential for con-
4 tamination of groundwater, surface water,
5 or other valued environmental resources.

6 “(iv) Broaden the adoption of inte-
7 grated pest management strategies, or
8 make such strategies more available or
9 more effective.

10 “(C) The Administrator, not later than 30
11 days after receipt of an application for expe-
12 dited review, shall notify the applicant whether
13 the application is complete. If it is found to be
14 incomplete, the Administrator may either reject
15 the request for expedited review or ask the ap-
16 plicant for additional information to satisfy the
17 guidelines developed under subparagraph (A).”.

1 **TITLE III—DATA COLLECTION**
2 **ACTIVITIES TO ASSURE THE**
3 **HEALTH OF INFANTS AND**
4 **CHILDREN AND OTHER MEAS-**
5 **URES**

6 **SEC. 301. DATA COLLECTION ACTIVITIES TO ASSURE THE**
7 **HEALTH OF INFANTS AND CHILDREN.**

8 (a) IN GENERAL.—The Secretary of Agriculture, in
9 consultation with the Administrator of the Environmental
10 Protection Agency and the Secretary of Health and
11 Human Services, shall coordinate the development and im-
12 plementation of survey procedures to ensure that adequate
13 data on food consumption patterns of infants and children
14 are collected.

15 (b) PROCEDURES.—To the extent practicable, the
16 procedures referred to in subsection (a) shall include the
17 collection of data on food consumption patterns of a statis-
18 tically valid sample of infants and children.

19 (c) RESIDUE DATA COLLECTION.—The Secretary of
20 Agriculture shall ensure that the residue data collection
21 activities conducted by the Department of Agriculture in
22 cooperation with the Environmental Protection Agency
23 and the Department of Health and Human Services, pro-
24 vide for the improved data collection of pesticide residues,
25 including guidelines for the use of comparable analytical

1 and standardized reporting methods, and the increased
2 sampling of foods most likely consumed by infants and
3 children.

4 **SEC. 302. COLLECTION OF PESTICIDE USE INFORMATION.**

5 (a) IN GENERAL.—The Secretary of Agriculture shall
6 collect data of statewide or regional significance on the
7 use of pesticides to control pests and diseases of major
8 crops and crops of dietary significance, including fruits
9 and vegetables.

10 (b) COLLECTION.—The data shall be collected by sur-
11 veys of farmers or from other sources offering statistically
12 reliable data.

13 (c) COORDINATION.—The Secretary of Agriculture
14 shall, as appropriate, coordinate with the Administrator
15 of the Environmental Protection Agency in the design of
16 the surveys and make available to the Administrator the
17 aggregate results of the surveys to assist the Adminis-
18 trator.

19 **SEC. 303. INTEGRATED PEST MANAGEMENT.**

20 The Secretary of Agriculture, in cooperation with the
21 Administrator, shall implement research, demonstration,
22 and education programs to support adoption of Integrated
23 Pest Management. Integrated Pest Management is a sus-
24 tainable approach to managing pests by combining biologi-
25 cal, cultural, physical, and chemical tools in a way that

1 minimizes economic, health, and environmental risks. The
2 Secretary of Agriculture and the Administrator shall make
3 information on Integrated Pest Management widely avail-
4 able to pesticide users, including Federal agencies. Federal
5 agencies shall use Integrated Pest Management techniques
6 in carrying out pest management activities and shall pro-
7 mote Integrated Pest Management through procurement
8 and regulatory policies, and other activities.

9 **SEC. 304. COORDINATION OF CANCELLATION.**

10 Section 2(bb) (7 U.S.C. 136(bb)) is amended—

11 (1) by inserting “(1)” after “means”; and

12 (2) by striking the period at the end of the first
13 sentence and inserting “, or (2) a human dietary
14 risk from residues that result from a use of a pes-
15 ticide in or on any food inconsistent with the stand-
16 ard under section 408 of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 346a).”.

18 **SEC. 305. PESTICIDE USE INFORMATION STUDY.**

19 (a) The Secretary of Agriculture shall, in consultation
20 with the Administrator of the Environmental Protection
21 Agency, prepare a report to Congress evaluating the cur-
22 rent status and potential improvements in Federal pes-
23 ticide use information gathering activities. This report
24 shall at least include—

1 (1) an analysis of the quality and reliability of
2 the information collected by the Department of Agri-
3 culture, the Environmental Protection Agency, and
4 other Federal agencies regarding the agricultural
5 use of pesticides; and

6 (2) an analysis of options to increase the effec-
7 tiveness of national pesticide use information collec-
8 tion, including an analysis of costs, burdens placed
9 on agricultural producers and other pesticide users,
10 and effectiveness in tracking risk reduction by those
11 options.

12 (b) The Secretary shall submit this report to Con-
13 gress not later than 1 year following the date of enactment
14 of this section.

15 **TITLE IV—AMENDMENTS TO THE**
16 **FEDERAL FOOD, DRUG, AND**
17 **COSMETIC ACT**

18 **SEC 401. SHORT TITLE AND REFERENCE.**

19 (a) SHORT TITLE.—This title may be cited as the
20 “Food Quality Protection Act of 1996 ”.

21 (b) REFERENCE.—Whenever in this title an amend-
22 ment or repeal is expressed in terms of an amendment
23 to, or repeal of, a section or other provision, the reference
24 shall be considered to be made to a section or other provi-
25 sion of the Federal Food, Drug, and Cosmetic Act.

1 **SEC. 402. DEFINITIONS.**

2 (a) SECTION 201(q).—Section 201(q) (21 U.S.C.
3 321(q)) is amended to read as follows:

4 “(q)(1) The term ‘pesticide chemical’ means any sub-
5 stance that is a pesticide within the meaning of the Fed-
6 eral Insecticide, Fungicide, and Rodenticide Act, including
7 all active and inert ingredients of such pesticide.

8 “(2) The term ‘pesticide chemical residue’ means a
9 residue in or on raw agricultural commodity or processed
10 food of—

11 “(A) a pesticide chemical; or

12 “(B) any other added substance that is present
13 on or in the commodity or food primarily as a result
14 of the metabolism or other degradation of a pesticide
15 chemical.

16 “(3) Notwithstanding paragraphs (1) and (2), the
17 Administrator may by regulation except a substance from
18 the definition of ‘pesticide chemical’ or ‘pesticide chemical
19 residue’ if—

20 “(A) its occurrence as a residue on or in a raw
21 agricultural commodity or processed food is attrib-
22 utable primarily to natural causes or to human ac-
23 tivities not involving the use of any substances for
24 a pesticidal purpose in the production, storage, proc-
25 essing, or transportation of any raw agricultural
26 commodity or processed food; and

1 “(B) the Administrator, after consultation with
2 the Secretary, determines that the substance more
3 appropriately should be regulated under one or more
4 provisions of this Act other than sections
5 402(a)(2)(B) and 408.”.

6 (b) SECTION 201(s).—Paragraphs (1) and (2) of sec-
7 tion 201(s) (21 U.S.C. 321(s)) are amended to read as
8 follows:

9 “(1) a pesticide chemical residue in or on a raw
10 agricultural commodity or processed food; or

11 “(2) a pesticide chemical; or”.

12 (c) SECTION 201.—Section 201 (21 U.S.C. 321) is
13 amended by adding at the end the following:

14 “(gg) The term ‘processed food’ means any food
15 other than a raw agricultural commodity and includes any
16 raw agricultural commodity that has been subject to proc-
17 essing, such as canning, cooking, freezing, dehydration, or
18 milling.

19 “(hh) The term ‘Administrator’ means the Adminis-
20 trator of the United States Environmental Protection
21 Agency.”.

22 **SEC. 403. PROHIBITED ACTS.**

23 Section 301(j) (21 U.S.C. 331(j)) is amended in the
24 first sentence by inserting before the period the following:

1 “; or the violating of section 408(i)(2) or any regulation
2 issued under that section.”.

3 **SEC. 404. ADULTERATED FOOD.**

4 Section 402(a) (21 U.S.C. 342(a)) is amended by
5 striking “(2)(A) if it bears” and all that follows through
6 “(3) if it consists” and inserting the following: “(2)(A)
7 if it bears or contains any added poisonous or added dele-
8 terious substance (other than a substance that is a pes-
9 ticide chemical residue in or on a raw agricultural com-
10 modity or processed food, a food additive, a color additive,
11 or a new animal drug) that is unsafe within the meaning
12 of section 406; or (B) if it bears or contains a pesticide
13 chemical residue that is unsafe within the meaning of sec-
14 tion 408(a); or (C) if it is or if it bears or contains (i)
15 any food additive that is unsafe within the meaning of sec-
16 tion 409; or (ii) a new animal drug (or conversion product
17 thereof) that is unsafe within the meaning of section 512;
18 or (3) if it consists”.

19 **SEC. 405. TOLERANCES AND EXEMPTIONS FOR PESTICIDE**
20 **CHEMICAL RESIDUES.**

21 Section 408 (21 U.S.C. 346a) is amended to read as
22 follows:

23 “TOLERANCES AND EXEMPTIONS FOR PESTICIDE
24 CHEMICAL RESIDUES

25 “SEC. 408. (a) REQUIREMENT FOR TOLERANCE OR
26 EXEMPTION.—

1 “(1) GENERAL RULE.—Except as provided in
2 paragraph (2) or (3), any pesticide chemical residue
3 in or on a food shall be deemed unsafe for the pur-
4 pose of section 402(a)(2)(B) unless—

5 “(A) a tolerance for such pesticide chemi-
6 cal residue in or on such food is in effect under
7 this section and the quantity of the residue is
8 within the limits of the tolerance; or

9 “(B) an exemption from the requirement
10 of a tolerance is in effect under this section for
11 the pesticide chemical residue.

12 For the purposes of this section, the term ‘food’,
13 when used as a noun without modification, shall
14 mean a raw agricultural commodity or processed
15 food.

16 “(2) PROCESSED FOOD.—Notwithstanding
17 paragraph (1)—

18 “(A) if a tolerance is in effect under this
19 section for a pesticide chemical residue in or on
20 a raw agricultural commodity, a pesticide chem-
21 ical residue that is present in or on a processed
22 food because the food is made from that raw
23 agricultural commodity shall not be considered
24 unsafe within the meaning of section
25 402(a)(2)(B) despite the lack of a tolerance for

1 the pesticide chemical residue in or on the proc-
2 essed food if the pesticide chemical has been
3 used in or on the raw agricultural commodity in
4 conformity with a tolerance under this section,
5 such residue in or on the raw agricultural com-
6 modity has been removed to the extent possible
7 in good manufacturing practice, and the con-
8 centration of the pesticide chemical residue in
9 the processed food is not greater than the toler-
10 ance prescribed for the pesticide chemical resi-
11 due in the raw agricultural commodity; or

12 “(B) if an exemption for the requirement
13 for a tolerance is in effect under this section for
14 a pesticide chemical residue in or on a raw agri-
15 cultural commodity, a pesticide chemical residue
16 that is present in or on a processed food be-
17 cause the food is made from that raw agricul-
18 tural commodity shall not be considered unsafe
19 within the meaning of section 402(a)(2)(B).

20 “(3) RESIDUES OF DEGRADATION PRODUCTS.—

21 If a pesticide chemical residue is present in or on a
22 food because it is a metabolite or other degradation
23 product of a precursor substance that itself is a pes-
24 ticide chemical or pesticide chemical residue, such a
25 residue shall not be considered to be unsafe within

1 the meaning of section 402(a)(2)(B) despite the lack
2 of a tolerance or exemption from the need for a tol-
3 erance for such residue in or on such food if—

4 “(A) the Administrator has not determined
5 that the degradation product is likely to pose
6 any potential health risk from dietary exposure
7 that is of a different type than, or of a greater
8 significance than, any risk posed by dietary ex-
9 posure to the precursor substance;

10 “(B) either—

11 “(i) a tolerance is in effect under this
12 section for residues of the precursor sub-
13 stance in or on the food, and the combined
14 level of residues of the degradation product
15 and the precursor substance in or on the
16 food is at or below the stoichiometrically
17 equivalent level that would be permitted by
18 the tolerance if the residue consisted only
19 of the precursor substance rather than the
20 degradation product; or

21 “(ii) an exemption from the need for
22 a tolerance is in effect under this section
23 for residues of the precursor substance in
24 or on the food; and

1 “(C) the tolerance or exemption for resi-
2 dues of the precursor substance does not state
3 that it applies only to particular named sub-
4 stances and does not state that it does not
5 apply to residues of the degradation product.

6 “(4) EFFECT OF TOLERANCE OR EXEMP-
7 TION.—While a tolerance or exemption from the re-
8 quirement for a tolerance is in effect under this sec-
9 tion for a pesticide chemical residue with respect to
10 any food, the food shall not by reason of bearing or
11 containing any amount of such a residue be consid-
12 ered to be adulterated within the meaning of section
13 402(a)(1).

14 “(b) AUTHORITY AND STANDARD FOR TOLER-
15 ANCE.—

16 “(1) AUTHORITY.—The Administrator may
17 issue regulations establishing, modifying, or revoking
18 a tolerance for a pesticide chemical residue in or on
19 a food—

20 “(A) in response to a petition filed under
21 subsection (d); or

22 “(B) on the Administrator’s own initiative
23 under subsection (e).

1 As used in this section, the term ‘modify’ shall not
2 mean expanding the tolerance to cover additional
3 foods.

4 “(2) STANDARD.—

5 “(A) GENERAL RULE.—

6 “(i) STANDARD.—The Administrator
7 may establish or leave in effect a tolerance
8 for a pesticide chemical residue in or on a
9 food only if the Administrator determines
10 that the tolerance is safe. The Adminis-
11 trator shall modify or revoke a tolerance if
12 the Administrator determines it is not safe.

13 “(ii) DETERMINATION OF SAFETY.—

14 As used in this section, the term ‘safe’,
15 with respect to a tolerance for a pesticide
16 chemical residue’, means that the Adminis-
17 trator has determined that there is a rea-
18 sonable certainty that no harm will result
19 from aggregate exposure to the pesticide
20 chemical residue, including all anticipated
21 dietary exposures and all other exposures
22 for which there is reliable information.

23 “(iii) RULE OF CONSTRUCTION.—

24 With respect to a tolerance, a pesticide
25 chemical residue meeting the standard

1 under clause (i) is not an eligible pesticide
2 chemical residue for purposes of subpara-
3 graph (B).

4 “(B) TOLERANCES FOR ELIGIBLE PES-
5 TICIDE CHEMICAL RESIDUES.—

6 “(i) DEFINITION.—As used in this
7 subparagraph, the term ‘eligible pesticide
8 chemical residue’ means a pesticide chemi-
9 cal residue as to which—

10 “(I) the Administrator is not able
11 to identify a level of exposure to the
12 residue at which the residue will not
13 cause or contribute to a known or an-
14 ticipated harm to human health (re-
15 ferred to in this section as a ‘non-
16 threshold effect’);

17 “(II) the lifetime risk of experi-
18 encing the nonthreshold effect is ap-
19 propriately assessed by quantitative
20 risk assessment; and

21 “(III) with regard to any known
22 or anticipated harm to human health
23 for which the Administrator is able to
24 identify a level at which the residue
25 will not cause such harm (referred to

1 in this section as a ‘threshold effect’),
2 the Administrator determines that the
3 level of aggregate exposure is safe.

4 “(ii) DETERMINATION OF TOLER-
5 ANCE.—Notwithstanding subparagraph
6 (A)(i), a tolerance for an eligible pesticide
7 chemical residue may be left in effect or
8 modified under this subparagraph if—

9 “(I) at least one of the conditions
10 described in clause (iii) is met; and

11 “(II) both of the conditions de-
12 scribed in clause (iv) are met.

13 “(iii) CONDITIONS REGARDING USE.—
14 For purposes of clause (ii), the conditions
15 described in this clause with respect to a
16 tolerance for an eligible pesticide chemical
17 residue are the following:

18 “(I) Use of the pesticide chemical
19 that produces the residue protects
20 consumers from adverse effects on
21 health that would pose a greater risk
22 than the dietary risk from the residue.

23 “(II) Use of the pesticide chemi-
24 cal that produces the residue is nec-
25 essary to avoid a significant disrupt-

tion in domestic production of an adequate, wholesome, and economical food supply.

“(iv) CONDITIONS REGARDING RISK.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

“(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

“(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

“(v) REVIEW.—Five years after the date on which the Administrator makes a determination to leave in effect or modify

1 a tolerance under this subparagraph, and
2 thereafter as the Administrator deems ap-
3 propriate, the Administrator shall deter-
4 mine, after notice and opportunity for com-
5 ment, whether it has been demonstrated to
6 the Administrator that a condition de-
7 scribed in clause (iii)(I) or clause (iii)(II)
8 continues to exist with respect to the toler-
9 ance and that the yearly and lifetime risks
10 from aggregate exposure to such residue
11 continue to comply with the limits specified
12 in clause (iv). If the Administrator deter-
13 mines by such date that such demonstra-
14 tion has not been made, the Administrator
15 shall, not later than 180 days after the
16 date of such determination, issue a regula-
17 tion under subsection (e)(1) to modify or
18 revoke the tolerance.

19 “(vi) INFANTS AND CHILDREN.—Any
20 tolerance under this subparagraph shall
21 meet the requirements of subparagraph
22 (C).

23 “(C) EXPOSURE OF INFANTS AND CHIL-
24 DREN.—In establishing, modifying, leaving in
25 effect, or revoking a tolerance or exemption for

1 a pesticide chemical residue, the Adminis-
2 trator—

3 “(i) shall assess the risk of the pes-
4 ticide chemical residue based on—

5 “(I) available information about
6 consumption patterns among infants
7 and children that are likely to result
8 in disproportionately high consump-
9 tion of foods containing or bearing
10 such residue among infants and chil-
11 dren in comparison to the general
12 population;

13 “(II) available information con-
14 cerning the special susceptibility of in-
15 fants and children to the pesticide
16 chemical residues, including neuro-
17 logical differences between infants and
18 children and adults, and effects of in
19 utero exposure to pesticide chemicals;
20 and

21 “(III) available information con-
22 cerning the cumulative effects on in-
23 fants and children of such residues
24 and other substances that have a com-
25 mon mechanism of toxicity; and

1 “(ii) shall—

2 “(I) ensure that there is a rea-
3 sonable certainty that no harm will re-
4 sult to infants and children from ag-
5 gregate exposure to the pesticide
6 chemical residue; and

7 “(II) publish a specific deter-
8 mination regarding the safety of the
9 pesticide chemical residue for infants
10 and children.

11 The Secretary of Health and Human Services
12 and the Secretary of Agriculture, in consulta-
13 tion with the Administrator, shall conduct sur-
14 veys to document dietary exposure to pesticides
15 among infants and children. In the case of
16 threshold effects, for purposes of clause (ii)(I)
17 an additional tenfold margin of safety for the
18 pesticide chemical residue and other sources of
19 exposure shall be applied for infants and chil-
20 dren to take into account potential pre- and
21 post-natal toxicity and completeness of the data
22 with respect to exposure and toxicity to infants
23 and children. Notwithstanding such require-
24 ment for an additional margin of safety, the
25 Administrator may use a different margin of

1 safety for the pesticide chemical residue only if,
2 on the basis of reliable data, such margin will
3 be safe for infants and children.

4 “(D) FACTORS.—In establishing, modify-
5 ing, leaving in effect, or revoking a tolerance or
6 exemption for a pesticide chemical residue, the
7 Administrator shall consider, among other rel-
8 evant factors—

9 “(i) the validity, completeness, and re-
10 liability of the available data from studies
11 of the pesticide chemical and pesticide
12 chemical residue;

13 “(ii) the nature of any toxic effect
14 shown to be caused by the pesticide chemi-
15 cal or pesticide chemical residue in such
16 studies;

17 “(iii) available information concerning
18 the relationship of the results of such stud-
19 ies to human risk;

20 “(iv) available information concerning
21 the dietary consumption patterns of con-
22 sumers (and major identifiable subgroups
23 of consumers);

24 “(v) available information concerning
25 the cumulative effects of such residues and

1 other substances that have a common
2 mechanism of toxicity;

3 “(vi) available information concerning
4 the aggregate exposure levels of consumers
5 (and major identifiable subgroups of con-
6 sumers) to the pesticide chemical residue
7 and to other related substances, including
8 dietary exposure under the tolerance and
9 all other tolerances in effect for the pes-
10 ticide chemical residue, and exposure from
11 other non-occupational sources;

12 “(vii) available information concerning
13 the variability of the sensitivities of major
14 identifiable subgroups of consumers;

15 “(viii) such information as the Admin-
16 istrator may require on whether the pes-
17 ticide chemical may have an effect in hu-
18 mans that is similar to an effect produced
19 by a naturally occurring estrogen or other
20 endocrine effects; and

21 “(ix) safety factors which in the opin-
22 ion of experts qualified by scientific train-
23 ing and experience to evaluate the safety of
24 food additives are generally recognized as

1 appropriate for the use of animal experi-
2 mentation data.

3 “(E) DATA AND INFORMATION REGARDING
4 ANTICIPATED AND ACTUAL RESIDUE LEVELS.—

5 “(i) AUTHORITY.—In establishing, modify-
6 ing, leaving in effect, or revoking a tolerance for
7 a pesticide chemical residue, the Administrator
8 may consider available data and information on
9 the anticipated residue levels of the pesticide
10 chemical in or on food and the actual residue
11 levels of the pesticide chemical that have been
12 measured in food, including residue data col-
13 lected by the Food and Drug Administration.

14 “(ii) REQUIREMENT.—If the Administrator
15 relies on anticipated or actual residue levels in
16 establishing, modifying, or leaving in effect a
17 tolerance, the Administrator shall pursuant to
18 subsection (f)(1) require that data be provided
19 five years after the date on which the tolerance
20 is established, modified, or left in effect, and
21 thereafter as the Administrator deems appro-
22 priate, demonstrating that such residue levels
23 are not above the levels so relied on. If such
24 data are not so provided, or if the data do not
25 demonstrate that the residue levels are not

1 above the levels so relied on, the Administrator
2 shall, not later than 180 days after the date on
3 which the data were required to be provided,
4 issue a regulation under subsection (e)(1), or
5 an order under subsection (f)(2), as appro-
6 priate, to modify or revoke the tolerance.

7 “(F) PERCENT OF FOOD ACTUALLY
8 TREATED.—In establishing, modifying, leaving
9 in effect, or revoking a tolerance for a pesticide
10 chemical residue, the Administrator may, when
11 assessing chronic dietary risk, consider available
12 data and information on the percent of food ac-
13 tually treated with the pesticide chemical (in-
14 cluding aggregate pesticide use data collected
15 by the Department of Agriculture) only if the
16 Administrator—

17 “(i) finds that the data are reliable
18 and provide a valid basis to show what per-
19 centage of the food derived from such crop
20 is likely to contain such pesticide chemical
21 residue;

22 “(ii) finds that the exposure estimate
23 does not understate exposure for any sig-
24 nificant subpopulation group;

1 “(iii) finds that, if data are available
2 on pesticide use and consumption of food
3 in a particular area, the population in such
4 area is not dietarily exposed to residues
5 above those estimated by the Adminis-
6 trator; and

7 “(iv) provides for the periodic reevalua-
8 tion of the estimate of anticipated dietary
9 exposure.

10 “(3) DETECTION METHODS.—

11 “(A) GENERAL RULE.—A tolerance for a
12 pesticide chemical residue in or on a food shall
13 not be established or modified by the Adminis-
14 trator unless the Administrator determines,
15 after consultation with the Secretary, that there
16 is a practical method for detecting and measur-
17 ing the levels of the pesticide chemical residue
18 in or on the food.

19 “(B) DETECTION LIMIT.—A tolerance for
20 a pesticide chemical residue in or on a food
21 shall not be established at or modified to a level
22 lower than the limit of detection of the method
23 for detecting and measuring the pesticide chem-
24 ical residue specified by the Administrator
25 under subparagraph (A).

1 “(4) INTERNATIONAL STANDARDS.—In estab-
2 lishing a tolerance for a pesticide chemical residue in
3 or on a food, the Administrator shall determine
4 whether a maximum residue level for the pesticide
5 chemical has been established by the Codex
6 Alimentarius Commission. If a Codex maximum resi-
7 due level has been established for the pesticide
8 chemical and the Administrator does not propose to
9 adopt the Codex level, the Administrator shall pub-
10 lish for public comment a notice explaining the rea-
11 sons for departing from the Codex level.

12 “(c) AUTHORITY AND STANDARD FOR EXEMP-
13 TIONS.—

14 “(1) AUTHORITY.—The Administrator may
15 issue a regulation establishing, modifying, or revok-
16 ing an exemption from the requirement for a toler-
17 ance for a pesticide chemical residue in or on food—

18 “(A) in response to a petition filed under
19 subsection (d); or

20 “(B) on the Administrator’s initiative
21 under subsection (e).

22 “(2) STANDARD.—

23 “(A) GENERAL RULE.—

24 “(i) STANDARD.—The Administrator
25 may establish or leave in effect an exemp-

1 tion from the requirement for a tolerance
2 for a pesticide chemical residue in or on
3 food only if the Administrator determines
4 that the exemption is safe. The Adminis-
5 trator shall modify or revoke an exemption
6 if the Administrator determines it is not
7 safe.

8 “(ii) DETERMINATION OF SAFETY.—
9 The term ‘safe’, with respect to an exemp-
10 tion for a pesticide chemical residue,
11 means that the Administrator has deter-
12 mined that there is a reasonable certainty
13 that no harm will result from aggregate ex-
14 posure to the pesticide chemical residue,
15 including all anticipated dietary exposures
16 and all other exposures for which there is
17 reliable information.

18 “(B) FACTORS.—In making a determina-
19 tion under this paragraph, the Administrator
20 shall take into account, among other relevant
21 considerations, the considerations set forth in
22 subparagraphs (C) and (D) of subsection
23 (b)(2).

24 “(3) LIMITATION.—An exemption from the re-
25 quirement for a tolerance for a pesticide chemical

1 residue in or on food shall not be established or
2 modified by the Administrator unless the Adminis-
3 trator determines, after consultation with the Sec-
4 retary—

5 “(A) that there is a practical method for
6 detecting and measuring the levels of such pes-
7 ticide chemical residue in or on food; or

8 “(B) that there is no need for such a
9 method, and states the reasons for such deter-
10 mination in issuing the regulation establishing
11 or modifying the exemption.

12 “(d) PETITION FOR TOLERANCE OR EXEMPTION.—

13 “(1) PETITIONS AND PETITIONERS.—Any per-
14 son may file with the Administrator a petition pro-
15 posing the issuance of a regulation—

16 “(A) establishing, modifying, or revoking a
17 tolerance for a pesticide chemical residue in or
18 on a food; or

19 “(B) establishing, modifying, or revoking
20 an exemption from the requirement of a toler-
21 ance for such a residue.

22 “(2) PETITION CONTENTS.—

23 “(A) ESTABLISHMENT.—A petition under
24 paragraph (1) to establish a tolerance or ex-
25 emption for a pesticide chemical residue shall

1 be supported by such data and information as
2 are specified in regulations issued by the Ad-
3 ministrator, including—

4 “(i)(I) an informative summary of the
5 petition and of the data, information, and
6 arguments submitted or cited in support of
7 the petition; and

8 “(II) a statement that the petitioner
9 agrees that such summary or any informa-
10 tion it contains may be published as a part
11 of the notice of filing of the petition to be
12 published under this subsection and as
13 part of a proposed or final regulation is-
14 sued under this section;

15 “(ii) the name, chemical identity, and
16 composition of the pesticide chemical resi-
17 due and of the pesticide chemical that pro-
18 duces the residue;

19 “(iii) data showing the recommended
20 amount, frequency, method, and time of
21 application of that pesticide chemical;

22 “(iv) full reports of tests and inves-
23 tigations made with respect to the safety of
24 the pesticide chemical, including full infor-
25 mation as to the methods and controls

1 used in conducting those tests and inves-
2 tigations;

3 “(v) full reports of tests and inves-
4 tigations made with respect to the nature
5 and amount of the pesticide chemical resi-
6 due that is likely to remain in or on the
7 food, including a description of the analyt-
8 ical methods used;

9 “(vi) a practical method for detecting
10 and measuring the levels of the pesticide
11 chemical residue in or on the food, or for
12 exemptions, a statement why such a meth-
13 od is not needed;

14 “(vii) a proposed tolerance for the
15 pesticide chemical residue, if a tolerance is
16 proposed;

17 “(viii) if the petition relates to a toler-
18 ance for a processed food, reports of inves-
19 tigations conducted using the processing
20 method(s) used to produce that food;

21 “(ix) such information as the Admin-
22 istrator may require to make the deter-
23 mination under subsection (b)(2)(C);

24 “(x) such information as the Adminis-
25 trator may require on whether the pes-

1 pesticide chemical may have an effect in hu-
2 mans that is similar to an effect produced
3 by a naturally occurring estrogen or other
4 endocrine effects;

5 “(xi) information regarding exposure
6 to the pesticide chemical residue due to
7 any tolerance or exemption already granted
8 for such residue;

9 “(xii) practical methods for removing
10 any amount of the residue that would ex-
11 ceed any proposed tolerance; and

12 “(xiii) such other data and informa-
13 tion as the Administrator requires by regu-
14 lation to support the petition.

15 If information or data required by this subpara-
16 graph is available to the Administrator, the per-
17 son submitting the petition may cite the avail-
18 ability of the information or data in lieu of sub-
19 mitting it. The Administrator may require a pe-
20 tition to be accompanied by samples of the pes-
21 ticide chemical with respect to which the peti-
22 tion is filed.

23 “(B) MODIFICATION OR REVOCATION.—

24 The Administrator may by regulation establish
25 the requirements for information and data to

1 support a petition to modify or revoke a toler-
2 ance or to modify or revoke an exemption from
3 the requirement for a tolerance.

4 “(3) NOTICE.—A notice of the filing of a peti-
5 tion that the Administrator determines has met the
6 requirements of paragraph (2) shall be published by
7 the Administrator within 30 days after such deter-
8 mination. The notice shall announce the availability
9 of a description of the analytical methods available
10 to the Administrator for the detection and measure-
11 ment of the pesticide chemical residue with respect
12 to which the petition is filed or shall set forth the
13 petitioner’s statement of why such a method is not
14 needed. The notice shall include the summary re-
15 quired by paragraph (2)(A)(i)(I).

16 “(4) ACTIONS BY THE ADMINISTRATOR.—

17 “(A) IN GENERAL.—The Administrator
18 shall, after giving due consideration to a peti-
19 tion filed under paragraph (1) and any other
20 information available to the Administrator—

21 “(i) issue a final regulation (which
22 may vary from that sought by the petition)
23 establishing, modifying, or revoking a tol-
24 erance for the pesticide chemical residue or
25 an exemption of the pesticide chemical res-

1 idue from the requirement of a tolerance
2 (which final regulation shall be issued
3 without further notice and without further
4 period for public comment);

5 “(ii) issue a proposed regulation
6 under subsection (e), and thereafter issue
7 a final regulation under such subsection; or

8 “(iii) issue an order denying the peti-
9 tion.

10 “(B) PRIORITIES.—The Administrator
11 shall give priority to petitions for the establish-
12 ment or modification of a tolerance or exemp-
13 tion for a pesticide chemical residue that ap-
14 pears to pose a significantly lower risk to
15 human health from dietary exposure than pes-
16 ticide chemical residues that have tolerances in
17 effect for the same or similar uses.

18 “(C) EXPEDITED REVIEW OF CERTAIN PE-
19 TITIONS.—

20 “(i) DATE CERTAIN FOR REVIEW.—If
21 a person files a complete petition with the
22 Administrator proposing the issuance of a
23 regulation establishing a tolerance or ex-
24 emption for a pesticide chemical residue
25 that presents a lower risk to human health

1 than a pesticide chemical residue for which
2 a tolerance has been left in effect or modi-
3 fied under subsection (b)(2)(B), the Ad-
4 ministrator shall complete action on such
5 petition under this paragraph within 1
6 year.

7 “(ii) REQUIRED DETERMINATIONS.—
8 If the Administrator issues a final regula-
9 tion establishing a tolerance or exemption
10 for a safer pesticide chemical residue under
11 clause (i), the Administrator shall, not
12 later than 180 days after the date on
13 which the regulation is issued, determine
14 whether a condition described in subclause
15 (I) or (II) of subsection (b)(2)(B)(iii) con-
16 tinues to exist with respect to a tolerance
17 that has been left in effect or modified
18 under subsection (b)(2)(B). If such condi-
19 tion does not continue to exist, the Admin-
20 istrator shall, not later than 180 days after
21 the date on which the determination under
22 the preceding sentence is made, issue a
23 regulation under subsection (e)(1) to mod-
24 ify or revoke the tolerance.

1 “(e) ACTION ON ADMINISTRATOR’S OWN INITIA-
2 TIVE.—

3 “(1) GENERAL RULE.—The Administrator may
4 issue a regulation—

5 “(A) establishing, modifying, suspending
6 under subsection (l)(3), or revoking a tolerance
7 for a pesticide chemical or a pesticide chemical
8 residue;

9 “(B) establishing, modifying, suspending
10 under subsection (l)(3), or revoking an exemp-
11 tion of a pesticide chemical residue from the re-
12 quirement of a tolerance; or

13 “(C) establishing general procedures and
14 requirements to implement this section.

15 “(2) NOTICE.—Before issuing a final regulation
16 under paragraph (1), the Administrator shall issue
17 a notice of proposed rulemaking and provide a pe-
18 riod of not less than 60 days for public comment on
19 the proposed regulation, except that a shorter period
20 for comment may be provided if the Administrator
21 for good cause finds that it would be in the public
22 interest to do so and states the reasons for the find-
23 ing in the notice of proposed rulemaking.

24 “(f) SPECIAL DATA REQUIREMENTS.—

1 “(1) REQUIRING SUBMISSION OF ADDITIONAL
2 DATA.—If the Administrator determines that addi-
3 tional data or information are reasonably required to
4 support the continuation of a tolerance or exemption
5 that is in effect under this section for a pesticide
6 chemical residue on a food, the Administrator
7 shall—

8 “(A) issue a notice requiring the person
9 holding the pesticide registrations associated
10 with such tolerance or exemption to submit the
11 data or information under section 3(c)(2)(B) of
12 the Federal Insecticide, Fungicide, and
13 Rodenticide Act;

14 “(B) issue a rule requiring that testing be
15 conducted on a substance or mixture under sec-
16 tion 4 of the Toxic Substances Control Act; or

17 “(C) publish in the Federal Register, after
18 first providing notice and an opportunity for
19 comment of not less than 60 days’ duration, an
20 order—

21 “(i) requiring the submission to the
22 Administrator by one or more interested
23 persons of a notice identifying the person
24 or persons who will submit the required
25 data and information;

1 “(ii) describing the type of data and
2 information required to be submitted to
3 the Administrator and stating why the
4 data and information could not be obtained
5 under the authority of section 3(c)(2)(B)
6 of the Federal Insecticide, Fungicide, and
7 Rodenticide Act or section 4 of the Toxic
8 Substances Control Act;

9 “(iii) describing the reports of the Ad-
10 ministrator required to be prepared during
11 and after the collection of the data and in-
12 formation;

13 “(iv) requiring the submission to the
14 Administrator of the data, information,
15 and reports referred to in clauses (ii) and
16 (iii); and

17 “(v) establishing dates by which the
18 submissions described in clauses (i) and
19 (iv) must be made.

20 The Administrator may under subparagraph
21 (C) revise any such order to correct an error.
22 The Administrator may under this paragraph
23 require data or information pertaining to
24 whether the pesticide chemical may have an ef-
25 fect in humans that is similar to an effect pro-

1 duced by a naturally occurring estrogen or
2 other endocrine effects.

3 “(2) NONCOMPLIANCE.—If a submission re-
4 quired by a notice issued in accordance with para-
5 graph (1)(A), a rule issued under paragraph (1)(B),
6 or an order issued under paragraph (1)(C) is not
7 made by the time specified in such notice, rule, or
8 order, the Administrator may by order published in
9 the Federal Register modify or revoke the tolerance
10 or exemption in question. In any review of such an
11 order under subsection (g)(2), the only material
12 issue shall be whether a submission required under
13 paragraph (1) was not made by the time specified.

14 “(g) EFFECTIVE DATE, OBJECTIONS, HEARINGS,
15 AND ADMINISTRATIVE REVIEW.—

16 “(1) EFFECTIVE DATE.—A regulation or order
17 issued under subsection (d)(4), (e)(1), or (f)(2) shall
18 take effect upon publication unless the regulation or
19 order specifies otherwise. The Administrator may
20 stay the effectiveness of the regulation or order if,
21 after issuance of such regulation or order, objections
22 are filed with respect to such regulation or order
23 pursuant to paragraph (2).

24 “(2) FURTHER PROCEEDINGS.—

1 “(A) OBJECTIONS.—Within 60 days after
2 a regulation or order is issued under subsection
3 (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or
4 (n)(5)(C), any person may file objections there-
5 to with the Administrator, specifying with par-
6 ticularity the provisions of the regulation or
7 order deemed objectionable and stating reason-
8 able grounds therefor. If the regulation or order
9 was issued in response to a petition under sub-
10 section (d)(1), a copy of each objection filed by
11 a person other than the petitioner shall be
12 served by the Administrator on the petitioner.

13 “(B) HEARING.—An objection may include
14 a request for a public evidentiary hearing upon
15 the objection. The Administrator shall, upon
16 the initiative of the Administrator or upon the
17 request of an interested person and after due
18 notice, hold a public evidentiary hearing if and
19 to the extent the Administrator determines that
20 such a public hearing is necessary to receive
21 factual evidence relevant to material issues of
22 fact raised by the objections. The presiding offi-
23 cer in such a hearing may authorize a party to
24 obtain discovery from other persons and may
25 upon a showing of good cause made by a party

1 issue a subpoena to compel testimony or pro-
2 duction of documents from any person. The
3 presiding officer shall be governed by the Fed-
4 eral Rules of Civil Procedure in making any
5 order for the protection of the witness or the
6 content of documents produced and shall order
7 the payment of a reasonable fees and expenses
8 as a condition to requiring testimony of the wit-
9 ness. On contest, such a subpoena may be en-
10 forced by a Federal district court.

11 “(C) FINAL DECISION.—As soon as prac-
12 ticable after receiving the arguments of the par-
13 ties, the Administrator shall issue an order
14 stating the action taken upon each such objec-
15 tion and setting forth any revision to the regu-
16 lation or prior order that the Administrator has
17 found to be warranted. If a hearing was held
18 under subparagraph (B), such order and any
19 revision to the regulation or prior order shall,
20 with respect to questions of fact at issue in the
21 hearing, be based only on substantial evidence
22 of record at such hearing, and shall set forth in
23 detail the findings of facts and the conclusions
24 of law or policy upon which the order or regula-
25 tion is based.

1 “(h) JUDICIAL REVIEW.—

2 “(1) PETITION.—In a case of actual con-
3 troversy as to the validity of any regulation issued
4 under subsection (e)(1)(C), or any order issued
5 under subsection (f)(1)(C) or (g)(2)(C), or any regu-
6 lation that is the subject of such an order, any per-
7 son who will be adversely affected by such order or
8 regulation may obtain judicial review by filing in the
9 United States Court of Appeals for the circuit
10 wherein that person resides or has its principal place
11 of business, or in the United States Court of Ap-
12 peals for the District of Columbia Circuit, within 60
13 days after publication of such order or regulation, a
14 petition praying that the order or regulation be set
15 aside in whole or in part.

16 “(2) RECORD AND JURISDICTION.—A copy of
17 the petition under paragraph (1) shall be forthwith
18 transmitted by the clerk of the court to the Adminis-
19 trator, or any officer designated by the Adminis-
20 trator for that purpose, and thereupon the Adminis-
21 trator shall file in the court the record of the pro-
22 ceedings on which the Administrator based the order
23 or regulation, as provided in section 2112 of title 28,
24 United States Code. Upon the filing of such a peti-
25 tion, the court shall have exclusive jurisdiction to af-

1 firm or set aside the order or regulation complained
2 of in whole or in part. As to orders issued following
3 a public evidentiary hearing, the findings of the Ad-
4 ministrator with respect to questions of fact shall be
5 sustained only if supported by substantial evidence
6 when considered on the record as a whole.

7 “(3) ADDITIONAL EVIDENCE.—If a party ap-
8 plies to the court for leave to adduce additional evi-
9 dence and shows to the satisfaction of the court that
10 the additional evidence is material and that there
11 were reasonable grounds for the failure to adduce
12 the evidence in the proceeding before the Adminis-
13 trator, the court may order that the additional evi-
14 dence (and evidence in rebuttal thereof) shall be
15 taken before the Administrator in the manner and
16 upon the terms and conditions the court deems
17 proper. The Administrator may modify prior find-
18 ings as to the facts by reason of the additional evi-
19 dence so taken and may modify the order or regula-
20 tion accordingly. The Administrator shall file with
21 the court any such modified finding, order, or regu-
22 lation.

23 “(4) FINAL JUDGMENT; SUPREME COURT RE-
24 VIEW.—The judgment of the court affirming or set-
25 ting aside, in whole or in part, any regulation or any

1 order and any regulation which is the subject of
2 such an order shall be final, subject to review by the
3 Supreme Court of the United States as provided in
4 section 1254 of title 28 of the United States Code.
5 The commencement of proceedings under this sub-
6 section shall not, unless specifically ordered by the
7 court to the contrary, operate as a stay of a regula-
8 tion or order.

9 “(5) APPLICATION.—Any issue as to which re-
10 view is or was obtainable under this subsection shall
11 not be the subject of judicial review under any other
12 provision of law.

13 “(i) CONFIDENTIALITY AND USE OF DATA.—

14 “(1) GENERAL RULE.—Data and information
15 that are or have been submitted to the Adminis-
16 trator under this section or section 409 in support
17 of a tolerance or an exemption from a tolerance shall
18 be entitled to confidential treatment for reasons of
19 business confidentiality and to exclusive use and
20 data compensation to the same extent provided by
21 sections 3 and 10 of the Federal Insecticide, Fun-
22 gicide, and Rodenticide Act.

23 “(2) EXCEPTIONS.—

24 “(A) IN GENERAL.—Data and information
25 that are entitled to confidential treatment

1 under paragraph (1) may be disclosed, under
2 such security requirements as the Adminis-
3 trator may provide by regulation, to—

4 “(i) employees of the United States
5 authorized by the Administrator to exam-
6 ine such data and information in the carry-
7 ing out of their official duties under this
8 Act or other Federal statutes intended to
9 protect the public health; or

10 “(ii) contractors with the United
11 States authorized by the Administrator to
12 examine such data and information in the
13 carrying out of contracts under this Act or
14 such statutes.

15 “(B) CONGRESS.—This subsection does
16 not authorize the withholding of data or infor-
17 mation from either House of Congress or from,
18 to the extent of matter within its jurisdiction,
19 any committee or subcommittee of such com-
20 mittee or any joint committee of Congress or
21 any subcommittee of such joint committee.

22 “(3) SUMMARIES.—Notwithstanding any provi-
23 sion of this subsection or other law, the Adminis-
24 trator may publish the informative summary re-
25 quired by subsection (d)(2)(A)(i) and may, in issu-

1 ing a proposed or final regulation or order under
2 this section, publish an informative summary of the
3 data relating to the regulation or order.

4 “(j) STATUS OF PREVIOUSLY ISSUED REGULA-
5 TIONS.—

6 “(1) REGULATIONS UNDER SECTION 406.—Reg-
7 ulations affecting pesticide chemical residues in or
8 on raw agricultural commodities promulgated, in ac-
9 cordance with section 701(e), under the authority of
10 section 406(a) upon the basis of public hearings in-
11 stituted before January 1, 1953, shall be deemed to
12 be regulations issued under this section and shall be
13 subject to modification or revocation under sub-
14 sections (d) and (e), and shall be subject to review
15 under subsection (q).

16 “(2) REGULATIONS UNDER SECTION 409.—Reg-
17 ulations that established tolerances for substances
18 that are pesticide chemical residues in or on proc-
19 essed food, or that otherwise stated the conditions
20 under which such pesticide chemicals could be safely
21 used, and that were issued under section 409 on or
22 before the date of the enactment of this paragraph,
23 shall be deemed to be regulations issued under this
24 section and shall be subject to modification or rev-

1 ocation under subsection (d) or (e), and shall be
2 subject to review under subsection (q).

3 “(3) REGULATIONS UNDER SECTION 408.—Reg-
4 ulations that established tolerances or exemptions
5 under this section that were issued on or before the
6 date of the enactment of this paragraph shall remain
7 in effect unless modified or revoked under subsection
8 (d) or (e), and shall be subject to review under sub-
9 section (q).

10 “(k) TRANSITIONAL PROVISION.—If, on the day be-
11 fore the date of the enactment of this subsection, a sub-
12 stance that is a pesticide chemical was, with respect to
13 a particular pesticidal use of the substance and any result-
14 ing pesticide chemical residue in or on a particular food—

15 “(1) regarded by the Administrator or the Sec-
16 retary as generally recognized as safe for use within
17 the meaning of the provisions of subsection (a) or
18 section 201(s) as then in effect; or

19 “(2) regarded by the Secretary as a substance
20 described by section 201(s)(4);

21 such a pesticide chemical residue shall be regarded as ex-
22 empt from the requirement for a tolerance, as of the date
23 of enactment of this subsection. The Administrator shall
24 by regulation indicate which substances are described by
25 this subsection. Any exemption under this subsection may

1 be modified or revoked as if it had been issued under sub-
2 section (c).

3 “(l) HARMONIZATION WITH ACTION UNDER OTHER
4 LAWS.—

5 “(1) COORDINATION WITH FIFRA.—To the ex-
6 tent practicable and consistent with the review dead-
7 lines in subsection (q), in issuing a final rule under
8 this subsection that suspends or revokes a tolerance
9 or exemption for a pesticide chemical residue in or
10 on food, the Administrator shall coordinate such ac-
11 tion with any related necessary action under the
12 Federal Insecticide, Fungicide, and Rodenticide Act.

13 “(2) REVOCATION OF TOLERANCE OR EXEMP-
14 TION FOLLOWING CANCELLATION OF ASSOCIATED
15 REGISTRATIONS.—If the Administrator, acting under
16 the Federal Insecticide, Fungicide, and Rodenticide
17 Act, cancels the registration of each pesticide that
18 contains a particular pesticide chemical and that is
19 labeled for use on a particular food, or requires that
20 the registration of each such pesticide be modified to
21 prohibit its use in connection with the production,
22 storage, or transportation of such food, due in whole
23 or in part to dietary risks to humans posed by resi-
24 dues of that pesticide chemical on that food, the Ad-
25 ministrator shall revoke any tolerance or exemption

1 that allows the presence of the pesticide chemical, or
2 any pesticide chemical residue that results from its
3 use, in or on that food. Subsection (e) shall apply to
4 actions taken under this paragraph. A revocation
5 under this paragraph shall become effective not later
6 than 180 days after—

7 “(A) the date by which each such cancella-
8 tion of a registration has become effective; or

9 “(B) the date on which the use of the can-
10 celed pesticide becomes unlawful under the
11 terms of the cancellation, whichever is later.

12 “(3) SUSPENSION OF TOLERANCE OR EXEMP-
13 TION FOLLOWING SUSPENSION OF ASSOCIATED REG-
14 ISTRATIONS.—

15 “(A) SUSPENSION.—If the Administrator,
16 acting under the Federal Insecticide, Fungicide,
17 and Rodenticide Act, suspends the use of each
18 registered pesticide that contains a particular
19 pesticide chemical and that is labeled for use on
20 a particular food, due in whole or in part to die-
21 tary risks to humans posed by residues of that
22 pesticide chemical on that food, the Adminis-
23 trator shall suspend any tolerance or exemption
24 that allows the presence of the pesticide chemi-
25 cal, or any pesticide chemical residue that re-

1 sults from its use, in or on that food. Sub-
2 section (e) shall apply to actions taken under
3 this paragraph. A suspension under this para-
4 graph shall become effective not later than 60
5 days after the date by which each such suspen-
6 sion of use has become effective.

7 “(B) EFFECT OF SUSPENSION.—The sus-
8 pension of a tolerance or exemption under sub-
9 paragraph (A) shall be effective as long as the
10 use of each associated registration of a pesticide
11 is suspended under the Federal Insecticide,
12 Fungicide, and Rodenticide Act. While a sus-
13 pension of a tolerance or exemption is effective
14 the tolerance or exemption shall not be consid-
15 ered to be in effect. If the suspension of use of
16 the pesticide under that Act is terminated, leav-
17 ing the registration of the pesticide for such use
18 in effect under that Act, the Administrator
19 shall rescind any associated suspension of toler-
20 ance or exemption.

21 “(4) TOLERANCES FOR UNAVOIDABLE RESI-
22 DUES.—In connection with action taken under para-
23 graph (2) or (3), or with respect to pesticides whose
24 registrations were suspended or canceled prior to the
25 date of the enactment of this paragraph under the

1 Federal Insecticide, Fungicide, and Rodenticide Act,
2 if the Administrator determines that a residue of the
3 canceled or suspended pesticide chemical will un-
4 avoidably persist in the environment and thereby be
5 present in or on a food, the Administrator may es-
6 tablish a tolerance for the pesticide chemical residue.
7 In establishing such a tolerance, the Administrator
8 shall take into account both the factors set forth in
9 subsection (b)(2) and the unavailability of the resi-
10 due. Subsection (e) shall apply to the establishment
11 of such tolerance. The Administrator shall review
12 any such tolerance periodically and modify it as nec-
13 essary so that it allows no greater level of the pes-
14 ticide chemical residue than is unavoidable.

15 “(5) PESTICIDE RESIDUES RESULTING FROM
16 LAWFUL APPLICATION OF PESTICIDE.—Notwith-
17 standing any other provision of this Act, if a toler-
18 ance or exemption for a pesticide chemical residue in
19 or on a food has been revoked, suspended, or modi-
20 fied under this section, an article of that food shall
21 not be deemed unsafe solely because of the presence
22 of such pesticide chemical residue in or on such food
23 if it is shown to the satisfaction of the Secretary
24 that—

1 “(A) the residue is present as the result of
2 an application or use of a pesticide at a time
3 and in a manner that was lawful under the
4 Federal Insecticide, Fungicide, and Rodenticide
5 Act; and

6 “(B) the residue does not exceed a level
7 that was authorized at the time of that applica-
8 tion or use to be present on the food under a
9 tolerance, exemption, food additive regulation,
10 or other sanction then in effect under this Act;
11 unless, in the case of any tolerance or exemption re-
12 voked, suspended, or modified under this subsection
13 or subsection (d) or (e), the Administrator has is-
14 sued a determination that consumption of the legally
15 treated food during the period of its likely availabil-
16 ity in commerce will pose an unreasonable dietary
17 risk.

18 “(6) TOLERANCE FOR USE OF PESTICIDES
19 UNDER AN EMERGENCY EXEMPTION.—If the Admin-
20 istrator grants an exemption under section 18 of the
21 Federal Insecticide, Fungicide, and Rodenticide Act
22 (7 U.S.C. 136p) for a pesticide chemical, the Admin-
23 istrator shall establish a tolerance or exemption from
24 the requirement for a tolerance for the pesticide
25 chemical residue. Such a tolerance or exemption

1 from a tolerance shall have an expiration date. The
2 Administrator may establish such a tolerance or ex-
3 emption without providing notice or a period for
4 comment on the tolerance or exemption. The Admin-
5 istrator shall promulgate regulations within 365
6 days after the date of the enactment of this para-
7 graph governing the establishment of tolerances and
8 exemptions under this paragraph. Such regulations
9 shall be consistent with the safety standard under
10 subsections (b)(2) and (c)(2) and with section 18 of
11 the Federal Insecticide, Fungicide, and Rodenticide
12 Act.

13 “(m) FEES.—

14 “(1) AMOUNT.—The Administrator shall by
15 regulation require the payment of such fees as will
16 in the aggregate, in the judgment of the Adminis-
17 trator, be sufficient over a reasonable term to pro-
18 vide, equip, and maintain an adequate service for the
19 performance of the Administrator’s functions under
20 this section. Under the regulations, the performance
21 of the Administrator’s services or other functions
22 under this section, including—

23 “(A) the acceptance for filing of a petition
24 submitted under subsection (d);

1 “(B) establishing, modifying, leaving in ef-
2 fect, or revoking a tolerance or establishing,
3 modifying, leaving in effect, or revoking an ex-
4 emption from the requirement for a tolerance
5 under this section;

6 “(C) the acceptance for filing of objections
7 under subsection (g); or

8 “(D) the certification and filing in court of
9 a transcript of the proceedings and the record
10 under subsection (h);

11 may be conditioned upon the payment of such fees.
12 The regulations may further provide for waiver or
13 refund of fees in whole or in part when in the judg-
14 ment of the Administrator such a waiver or refund
15 is equitable and not contrary to the purposes of this
16 subsection.

17 “(2) DEPOSIT.—All fees collected under para-
18 graph (1) shall be deposited in the Reregistration
19 and Expedited Processing Fund created by section
20 4(k) of the Federal Insecticide, Fungicide, and
21 Rodenticide Act. Such fees shall be available to the
22 Administrator, without fiscal year limitation, for the
23 performance of the Administrator’s services or func-
24 tions as specified in paragraph (1).

25 “(n) NATIONAL UNIFORMITY OF TOLERANCES.—

1 “(1) QUALIFYING PESTICIDE CHEMICAL RESI-
2 DUE.—For purposes of this subsection, the term
3 ‘qualifying pesticide chemical residue’ means a pes-
4 ticide chemical residue resulting from the use, in
5 production, processing, or storage of a food, of a
6 pesticide chemical that is an active ingredient and
7 that—

8 “(A) was first approved for such use in a
9 registration of a pesticide issued under section
10 3(c)(5) of the Federal Insecticide, Fungicide,
11 Rodenticide Act on or after April 25, 1985, on
12 the basis of data determined by the Adminis-
13 trator to meet all applicable requirements for
14 data prescribed by regulations in effect under
15 that Act on April 25, 1985; or

16 “(B) was approved for such use in a rereg-
17 istration eligibility determination issued under
18 section 4(g) of that Act on or after the date of
19 enactment of this subsection.

20 “(2) QUALIFYING FEDERAL DETERMINATION.—
21 For purposes of this subsection, the term ‘qualifying
22 Federal determination’ means a tolerance or exemp-
23 tion from the requirement for a tolerance for a
24 qualifying pesticide chemical residue that—

1 “(A) is issued under this section after the
2 date of the enactment of this subsection and de-
3 termined by the Administrator to meet the
4 standard under subsection (b)(2)(A) (in the
5 case of a tolerance) or (c)(2) (in the case of an
6 exemption); or

7 “(B)(i) pursuant to subsection (j) is re-
8 maining in effect or is deemed to have been is-
9 sued under this section, or is regarded under
10 subsection (k) as exempt from the requirement
11 for a tolerance; and

12 “(ii) is determined by the Administrator to
13 meet the standard under subsection (b)(2)(A)
14 (in the case of a tolerance) or (c)(2) (in the
15 case of an exemption).

16 “(3) LIMITATION.—The Administrator may
17 make the determination described in paragraph
18 (2)(B)(ii) only by issuing a rule in accordance with
19 the procedure set forth in subsection (d) or (e) and
20 only if the Administrator issues a proposed rule and
21 allows a period of not less than 30 days for comment
22 on the proposed rule. Any such rule shall be
23 reviewable in accordance with subsections (g) and
24 (h).

1 “(4) STATE AUTHORITY.—Except as provided
2 in paragraphs (5), (6), and (8) no State or political
3 subdivision may establish or enforce any regulatory
4 limit on a qualifying pesticide chemical residue in or
5 on any food if a qualifying Federal determination
6 applies to the presence of such pesticide chemical
7 residue in or on such food, unless such State regu-
8 latory limit is identical to such qualifying Federal
9 determination. A State or political subdivision shall
10 be deemed to establish or enforce a regulatory limit
11 on a pesticide chemical residue in or on a food if it
12 purports to prohibit or penalize the production, proc-
13 essing, shipping, or other handling of a food because
14 it contains a pesticide residue (in excess of a pre-
15 scribed limit).

16 “(5) PETITION PROCEDURE.—

17 “(A) IN GENERAL.—Any State may peti-
18 tion the Administrator for authorization to es-
19 tablish in such State a regulatory limit on a
20 qualifying pesticide chemical residue in or on
21 any food that is not identical to the qualifying
22 Federal determination applicable to such quali-
23 fying pesticide chemical residue.

24 “(B) PETITION REQUIREMENTS.—Any pe-
25 tition under subparagraph (A) shall—

1 “(i) satisfy any requirements pre-
2 scribed, by rule, by the Administrator; and

3 “(ii) be supported by scientific data
4 about the pesticide chemical residue that is
5 the subject of the petition or about chemi-
6 cally related pesticide chemical residues,
7 data on the consumption within such State
8 of food bearing the pesticide chemical resi-
9 due, and data on exposure of humans with-
10 in such State to the pesticide chemical res-
11 idue.

12 “(C) AUTHORIZATION.—The Adminis-
13 trator may, by order, grant the authorization
14 described in subparagraph (A) if the Adminis-
15 trator determines that the proposed State regu-
16 latory limit—

17 “(i) is justified by compelling local
18 conditions; and

19 “(ii) would not cause any food to be
20 a violation of Federal law.

21 “(D) TREATMENT.—In lieu of any action
22 authorized under subparagraph (C), the Admin-
23 istrator may treat a petition under this para-
24 graph as a petition under subsection (d) to
25 modify or revoke a tolerance or an exemption.

1 If the Administrator determines to treat a peti-
2 tion under this paragraph as a petition under
3 subsection (d), the Administrator shall there-
4 after act on the petition pursuant to subsection
5 (d).

6 “(E) REVIEW.—Any order of the Adminis-
7 trator granting or denying the authorization de-
8 scribed in subparagraph (A) shall be subject to
9 review in the manner described in subsections
10 (g) and (h).

11 “(6) URGENT PETITION PROCEDURE.—Any
12 State petition to the Administrator pursuant to
13 paragraph (5) that demonstrates that consumption
14 of a food containing such pesticide residue level dur-
15 ing the period of the food’s likely availability in the
16 State will pose a significant public health threat
17 from acute exposure shall be considered an urgent
18 petition. If an order by the Administrator to grant
19 or deny the requested authorization in an urgent pe-
20 tition is not made within 30 days of receipt of the
21 petition, the petitioning State may establish and en-
22 force a temporary regulatory limit on a qualifying
23 pesticide chemical residue in or on the food. The
24 temporary regulatory limit shall be validated or ter-

1 minated by the Administrator’s final order on the
2 petition.

3 “(7) RESIDUES FROM LAWFUL APPLICATION.—

4 No State or political subdivision may enforce any
5 regulatory limit on the level of a pesticide chemical
6 residue that may appear in or on any food if, at the
7 time of the application of the pesticide that resulted
8 in such residue, the sale of such food with such resi-
9 due level was lawful under this section and under
10 the law of such State, unless the State demonstrates
11 that consumption of the food containing such pes-
12 ticide residue level during the period of the food’s
13 likely availability in the State will pose an unreason-
14 able dietary risk to the health of persons within such
15 State.

16 “(8) SAVINGS.—Nothing in this Act preempts
17 the authority of any State or political subdivision to
18 require that a food containing a pesticide chemical
19 residue bear or be the subject of a warning or other
20 statement relating to the presence of the pesticide
21 chemical residue in or on such food.

22 “(o) CONSUMER RIGHT TO KNOW.—Not later than
23 2 years after the date of the enactment of the Food Qual-
24 ity Protection Act of 1996, and annually thereafter, the
25 Administrator shall, in consultation with the Secretary of

1 Agriculture and the Secretary of Health and Human Serv-
2 ices, publish in a format understandable to a lay person,
3 and distribute to large retail grocers for public display (in
4 a manner determined by the grocer), the following infor-
5 mation, at a minimum:

6 “(1) A discussion of the risks and benefits of
7 pesticide chemical residues in or on food purchased
8 by consumers.

9 “(2) A listing of actions taken under subpara-
10 graph (B) of subsection (b)(2) that may result in
11 pesticide chemical residues in or on food that
12 present a yearly or lifetime risk above the risk al-
13 lowed under subparagraph (A) of such subsection,
14 and the food on which the pesticide chemicals pro-
15 ducing the residues are used.

16 “(3) Recommendations to consumers for reduc-
17 ing dietary exposure to pesticide chemical residues in
18 a manner consistent with maintaining a healthy diet,
19 including a list of food that may reasonably sub-
20 stitute for food listed under paragraph (2).

21 Nothing in this subsection shall prevent retail grocers
22 from providing additional information.

23 “(p) ESTROGENIC SUBSTANCES SCREENING PRO-
24 GRAM.—

1 “(1) DEVELOPMENT.—Not later than 2 years
2 after the date of enactment of this section, the Ad-
3 ministrator shall in consultation with the Secretary
4 of Health and Human Services develop a screening
5 program, using appropriate validated test systems
6 and other scientifically relevant information, to de-
7 termine whether certain substances may have an ef-
8 fect in humans that is similar to an effect produced
9 by a naturally occurring estrogen, or such other en-
10 docrine effect as the Administrator may designate.

11 “(2) IMPLEMENTATION.—Not later than 3
12 years after the date of enactment of this section,
13 after obtaining public comment and review of the
14 screening program described in paragraph (1) by the
15 scientific advisory panel established under section
16 25(d) of the Federal Insecticide, Fungicide, and
17 Rodenticide Act or the science advisory board estab-
18 lished by section 8 of the Environmental Research,
19 Development, and Demonstration Act of 1978 (42
20 U.S.C. 4365), the Administrator shall implement the
21 program.

22 “(3) SUBSTANCES.—In carrying out the screen-
23 ing program described in paragraph (1), the Admin-
24 istrator—

1 “(A) shall provide for the testing of all
2 pesticide chemicals; and

3 “(B) may provide for the testing of any
4 other substance that may have an effect that is
5 cumulative to an effect of a pesticide chemical
6 if the Administrator determines that a substan-
7 tial population may be exposed to such sub-
8 stance.

9 “(4) EXEMPTION.—Notwithstanding paragraph
10 (3), the Administrator may, by order, exempt from
11 the requirements of this section a biologic substance
12 or other substance if the Administrator determines
13 that the substance is anticipated not to produce any
14 effect in humans similar to an effect produced by a
15 naturally occurring estrogen.

16 “(5) COLLECTION OF INFORMATION.—

17 “(A) IN GENERAL.—The Administrator
18 shall issue an order to a registrant of a sub-
19 stance for which testing is required under this
20 subsection, or to a person who manufactures or
21 imports a substance for which testing is re-
22 quired under this subsection, to conduct testing
23 in accordance with the screening program de-
24 scribed in paragraph (1), and submit informa-
25 tion obtained from the testing to the Adminis-

1 trator, within a reasonable time period that the
2 Administrator determines is sufficient for the
3 generation of the information.

4 “(B) PROCEDURES.—To the extent prac-
5 ticable the Administrator shall minimize dupli-
6 cative testing of the same substance for the
7 same endocrine effect, develop, as appropriate,
8 procedures for fair and equitable sharing of test
9 costs, and develop, as necessary, procedures for
10 handling of confidential business information.

11 “(C) FAILURE OF REGISTRANTS TO SUB-
12 MIT INFORMATION.—

13 “(i) SUSPENSION.—If a registrant of
14 a substance referred to in paragraph
15 (3)(A) fails to comply with an order under
16 subparagraph (A) of this paragraph, the
17 Administrator shall issue a notice of intent
18 to suspend the sale or distribution of the
19 substance by the registrant. Any suspen-
20 sion proposed under this paragraph shall
21 become final at the end of the 30-day pe-
22 riod beginning on the date that the reg-
23 istrant receives the notice of intent to sus-
24 pend, unless during that period a person
25 adversely affected by the notice requests a

1 hearing or the Administrator determines
2 that the registrant has complied fully with
3 this paragraph.

4 “(ii) HEARING.—If a person requests
5 a hearing under clause (i), the hearing
6 shall be conducted in accordance with sec-
7 tion 554 of title 5, United States Code.
8 The only matter for resolution at the hear-
9 ing shall be whether the registrant has
10 failed to comply with an order under sub-
11 paragraph (A) of this paragraph. A deci-
12 sion by the Administrator after completion
13 of a hearing shall be considered to be a
14 final agency action.

15 “(iii) TERMINATION OF SUSPEN-
16 SIONS.—The Administrator shall terminate
17 a suspension under this subparagraph is-
18 sued with respect to a registrant if the Ad-
19 ministrator determines that the registrant
20 has complied fully with this paragraph.

21 “(D) NONCOMPLIANCE BY OTHER PER-
22 SONS.—Any person (other than a registrant)
23 who fails to comply with an order under sub-
24 paragraph (A) shall be liable for the same pen-
25 alties and sanctions as are provided under sec-

1 tion 16 of the Toxic Substances Control Act
2 (15 U.S.C. 2601 and following) in the case of
3 a violation referred to in that section. Such pen-
4 alties and sanctions shall be assessed and im-
5 posed in the same manner as provided in such
6 section 16.

7 “(6) AGENCY ACTION.—In the case of any sub-
8 stance that is found, as a result of testing and eval-
9 uation under this section, to have an endocrine ef-
10 fect on humans, the Administrator shall, as appro-
11 priate, take action under such statutory authority as
12 is available to the Administrator, including consider-
13 ation under other sections of this Act, as is nec-
14 essary to ensure the protection of public health.

15 “(7) REPORT TO CONGRESS.—Not later than 4
16 years after the date of enactment of this section, the
17 Administrator shall prepare and submit to Congress
18 a report containing—

19 “(A) the findings of the Administrator re-
20 sulting from the screening program described in
21 paragraph (1);

22 “(B) recommendations for further testing
23 needed to evaluate the impact on human health
24 of the substances tested under the screening
25 program; and

1 “(C) recommendations for any further ac-
2 tions (including any action described in para-
3 graph (6)) that the Administrator determines
4 are appropriate based on the findings.

5 “(q) SCHEDULE FOR REVIEW.—

6 “(1) IN GENERAL.—The Administrator shall re-
7 view tolerances and exemptions for pesticide chemi-
8 cal residues in effect on the day before the date of
9 the enactment of the Food Quality Protection Act of
10 1996, as expeditiously as practicable, assuring
11 that—

12 “(A) 33 percent of such tolerances and ex-
13 emptions are reviewed within 3 years of the
14 date of enactment of such Act;

15 “(B) 66 percent of such tolerances and ex-
16 emptions are reviewed within 6 years of the
17 date of enactment of such Act; and

18 “(C) 100 percent of such tolerances and
19 exemptions are reviewed within 10 years of the
20 date of enactment of such Act.

21 In conducting a review of a tolerance or exemption,
22 the Administrator shall determine whether the toler-
23 ance or exemption meets the requirements of sub-
24 sections (b)(2) or (c)(2) and shall, by the deadline
25 for the review of the tolerance or exemption, issue

1 a regulation under subsection (d)(4) or (e)(1) to
2 modify or revoke the tolerance or exemption if the
3 tolerance or exemption does not meet such require-
4 ments.

5 “(2) PRIORITIES.—In determining priorities for
6 reviewing tolerances and exemptions under para-
7 graph (1), the Administrator shall give priority to
8 the review of the tolerances or exemptions that ap-
9 pear to pose the greatest risk to public health.

10 “(3) PUBLICATION OF SCHEDULE.—Not later
11 than 12 months after the date of the enactment of
12 the Food Quality Protection Act of 1996, the Ad-
13 ministrator shall publish a schedule for review of tol-
14 erances and exemptions established prior to the date
15 of the enactment of the Food Quality Protection Act
16 of 1996. The determination of priorities for the re-
17 view of tolerances and exemptions pursuant to this
18 subsection is not a rulemaking and shall not be sub-
19 ject to judicial review, except that failure to take
20 final action pursuant to the schedule established by
21 this paragraph shall be subject to judicial review.

22 “(r) TEMPORARY TOLERANCE OR EXEMPTION.—The
23 Administrator may, upon the request of any person who
24 has obtained an experimental permit for a pesticide chemi-
25 cal under the Federal Insecticide, Fungicide, and

1 Rodenticide Act or upon the Administrator's own initia-
2 tive, establish a temporary tolerance or exemption for the
3 pesticide chemical residue for the uses covered by the per-
4 mit. Subsections (b)(2), (c)(2), (d), and (e) shall apply to
5 actions taken under this subsection.

6 “(s) SAVINGS CLAUSE.—Nothing in this section shall
7 be construed to amend or modify the provisions of the
8 Toxic Substances Control Act or the Federal Insecticide,
9 Fungicide, and Rodenticide Act.”.

10 **SEC. 406. AUTHORIZATION FOR INCREASED MONITORING.**

11 For the fiscal years 1997 through 1999, there is au-
12 thorized to be appropriated in the aggregate an additional
13 \$12,000,000 for increased monitoring by the Secretary of
14 Health and Human Services of pesticide residues in im-
15 ported and domestic food.

16 **SEC. 407. ALTERNATIVE ENFORCEMENT.**

17 Section 303(g) (21 U.S.C. 333(f)) is amended—

18 (1) by redesignating paragraphs (2), (3), and
19 (4) as paragraphs (3), (4), and (5), respectively,
20 (2) by inserting after paragraph (1) the follow-
21 ing:

22 “(2)(A) Any person who introduces into interstate
23 commerce or delivers for introduction into interstate com-
24 merce an article of food that is adulterated within the
25 meaning of section 402(a)(2)(B) shall be subject to a civil

1 money penalty of not more than \$50,000 in the case of
2 an individual and \$250,000 in the case of any other person
3 for such introduction or delivery, not to exceed \$500,000
4 for all such violations adjudicated in a single proceeding.

5 “(B) This paragraph shall not apply to any person
6 who grew the article of food that is adulterated. If the
7 Secretary assesses a civil penalty against any person under
8 this paragraph, the Secretary may not use the criminal
9 authorities under this section to sanction such person for
10 the introduction or delivery for introduction into interstate
11 commerce of the article of food that is adulterated. If the
12 Secretary assesses a civil penalty against any person under
13 this paragraph, the Secretary may not use the seizure au-
14 thorities of section 304 or the injunction authorities of sec-
15 tion 302 with respect to the article of food that is adulter-
16 ated.

17 “(C) In a hearing to assess a civil penalty under this
18 paragraph, the presiding officer shall have the same au-
19 thority with regard to compelling testimony or production
20 of documents as a presiding officer has under section
21 408(g)(2)(B). The third sentence of paragraph (3)(A)
22 shall not apply to any investigation under this para-
23 graph.”;

1 (3) in paragraph (3), as so redesignated, by
 2 striking “paragraph (1)” each place it occurs and
 3 inserting “paragraph (1) or (2)”;

4 (4) in paragraph (4), as so redesignated, by
 5 striking “(2)(A)” and inserting “(3)(A)”;

6 (5) in paragraph (5), as so redesignated, by
 7 striking “(3)” each place it occurs and inserting
 8 “(4)”.

9 **TITLE V—FEES**

10 **SEC. 501. REREGISTRATION FEES.**

11 (a) SECTION 4(i).—Section 4(i) (7 U.S.C. 136a–
 12 1(i)), as amended by section 232(2), is amended—

13 (1) in paragraphs (5)(H) and (6), by striking
 14 “1997” and inserting “2001”; and

15 (2) in paragraph (5)(C), by inserting “(i)” after
 16 “(C)” and by adding at the end the following:

17 “(ii) in each of the fiscal years 1998,
 18 1999, and 2000, the Administrator is author-
 19 ized to collect up to an additional \$2,000,000 in
 20 a manner consistent with subsection (k)(5) and
 21 the recommendations of the Inspector General
 22 of the Environmental Protection Agency. The
 23 total fees that may be collected under this
 24 clause shall not exceed \$6,000,000.”.

1 (b) SECTION 4(k)(1).—Section 4(k)(1) (7 U.S.C.
2 136a–1(k)(1) is amended by inserting before the period
3 the following: “which shall be known as the Reregistration
4 and Expedited Processing Fund”.

5 (c) SECTION 4(k)(2).—Section 4(k)(2) (7 136a–
6 1(k)(2)) is amended to read as follows:

7 “(2) SOURCE AND USE.—

8 “(A) All moneys derived from fees collected
9 by the Administrator under subsection (i) shall
10 be deposited in the fund and shall be available
11 to the Administrator, without fiscal year limita-
12 tion, specifically to offset the costs of rereg-
13 istration and expedited processing of the appli-
14 cations specified in paragraph (3). Such moneys
15 derived from fees may not be expended in any
16 fiscal year to the extent such moneys derived
17 from fees would exceed money appropriated for
18 use by the Administrator and expended in such
19 year for such costs of reregistration and expe-
20 dited processing of such applications. The Ad-
21 ministrator shall, prior to expending any such
22 moneys derived from fees—

23 “(i) effective October 1, 1997, adopt
24 specific and cost accounting rules and pro-
25 cedures as approved by the General Ac-

1 counting Office and the Inspector General
2 of the Environmental Protection Agency to
3 ensure that moneys derived from fees are
4 allocated solely to the costs of reregistra-
5 tion and expedited processing of the appli-
6 cations specified in paragraph (3) in the
7 same portion as appropriated funds;

8 “(ii) prohibit the use of such moneys
9 derived from fees to pay for any costs
10 other than those necessary to achieve re-
11 registration and expedited processing of
12 the applications specified in paragraph (3);
13 and

14 “(iii) ensure that personnel and facil-
15 ity costs associated with the functions to
16 be carried out under this paragraph do not
17 exceed agency averages for comparable
18 personnel and facility costs.

19 “(B) The Administrator shall also—

20 “(i) complete the review of unreviewed
21 reregistration studies required to support
22 the reregistration eligibility decisions
23 scheduled for completion in accordance
24 with subsection (l)(2); and

1 “(ii) contract for such outside assist-
2 ance as may be necessary for review of re-
3 quired studies, using a generally accepted
4 competitive process for the selection of
5 vendors of such assistance.”.

6 (d) SECTION 4(k)(3).—Section 4(k)(3) (7 U.S.C.
7 136a–1(k)(3)) is amended—

8 (1) in subparagraph (A), by striking out “for
9 each of the fiscal years 1992, 1993, and 1994, $\frac{1}{7}$ th
10 of the maintenance fees collected, up to 2 million
11 each year” and inserting in lieu thereof “for each of
12 the fiscal years 1997 through 2001, not more than
13 $\frac{1}{7}$ of the maintenance fees collected in such fiscal
14 year”; and

15 (2) by adding a new subparagraph (C) to read
16 as follows:

17 “(C) So long as the Administrator has not
18 met the time frames specified in clause (ii) of
19 section 3(c)(3)(B) with respect to any applica-
20 tion subject to section 3(c)(3)(B) that was re-
21 ceived prior to the date of enactment of the
22 Food Quality Protection Act of 1996, the Ad-
23 ministrator shall use the full amount of the fees
24 specified in subparagraph (A) for the purposes
25 specified therein. Once all applications subject

1 to section 3(c)(3)(B) that were received prior to
 2 such date of enactment have been acted upon,
 3 no limitation shall be imposed by the preceding
 4 sentence of this subparagraph so long as the
 5 Administrator meets the time frames specified
 6 in clause (ii) of section 3(c)(3)(B) on 90 per-
 7 cent of affected applications in a fiscal year.
 8 Should the Administrator not meet such time
 9 frames in a fiscal year, the limitations imposed
 10 by the first sentence of this subparagraph shall
 11 apply until all overdue applications subject to
 12 section 3(c)(3)(B) have been acted upon.”.

13 (e) SECTION 4(k)(5).—Section 4(k)(5) (7 U.S.C.
 14 136a–1(k)(5)) is amended to read as follows:

15 “(5) ACCOUNTING AND PERFORMANCE.—The
 16 Administrator shall take all steps necessary to en-
 17 sure that expenditures from fees authorized by sub-
 18 section (i)(5)(C)(ii) are used only to carry out the
 19 goals established under subsection (l). The Rereg-
 20 istration and Expedited Processing Fund shall be
 21 designated as an Environmental Protection Agency
 22 component for purposes of section 3515(c) of title
 23 31, United States Code. The annual audit required
 24 under section 3521 of such title of the financial
 25 statements of activities under this Act under section

1 3515(b) of such title shall include an audit of the
 2 fees collected under subsection (i)(5)(C) and dis-
 3 bursed, of the amount appropriated to match such
 4 fees, and of the Administrator’s attainment of per-
 5 formance measure and goals established under sub-
 6 section (l). Such an audit shall also include a review
 7 of the reasonableness of the overhead allocation and
 8 adequacy of disclosures of direct and indirect costs
 9 associated with carrying out the reregistration and
 10 expedited processing of the applications specified in
 11 paragraph (3), and the basis for and accuracy of all
 12 costs paid with moneys derived from such fees. The
 13 Inspector General shall conduct the annual audit
 14 and report the findings and recommendations of
 15 such audit to the Administrator and to the Commit-
 16 tees on Agriculture of the House of Representatives
 17 and the Senate. The cost of such audit shall be paid
 18 for out of the fees collected under subsection
 19 (i)(5)(C).”.

20 (f) GOALS.—Subsections (l) and (m) of section 4 (7
 21 U.S.C. 136a–1), as amended by section 237, are redesign-
 22 nated as subsections (m) and (n) respectively and the fol-
 23 lowing is inserted after subsection (k):

24 “(l) PERFORMANCE MEASURES AND GOAL.—The
 25 Administrator shall establish and publish annually in the

1 Federal Register performance measures and goals. Such
2 measures and goals shall include—

3 “(1) the number of products reregistered, can-
4 celed, or amended, the status of reregistration, the
5 number and type of data requests under section
6 3(c)(2)(B) issued to support product reregistration
7 by active ingredient, the progress in reducing the
8 number of unreviewed, required reregistration stud-
9 ies, the aggregate status of tolerances reassessed,
10 and the number of applications for registration sub-
11 mitted under subsection (k)(3) that were approved
12 or disapproved;

13 “(2) the future schedule for reregistrations, in-
14 cluding the projection for such schedules that will be
15 issued under subsection (g)(2)(A) and (B) in the
16 current fiscal year and the succeeding fiscal year;
17 and

18 “(3) the projected year of completion of the re-
19 registrations under this section.”.

Passed the House of Representatives July 23, 1996.

Attest:

ROBIN H. CARLE,

Clerk.

By LINDA NAVE,

Deputy Clerk.