

104TH CONGRESS
1ST SESSION

H. R. 1627

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

IN THE HOUSE OF REPRESENTATIVES

MAY 12, 1995

Mr. BLILEY (for himself, Mr. TOWNS, Mr. ROBERTS, Mr. DE LA GARZA, Mr. EMERSON, Mr. CONDIT, Mr. BILIRAKIS, Mr. GUNDERSON, Mr. STENHOLM, Mr. COMBEST, Mr. MONTGOMERY, Mr. ALLARD, Mr. YOUNG of Alaska, Mr. JOHNSON of South Dakota, Mr. WALKER, Mr. DOOLEY, Mr. FIELDS of Texas, Mr. HALL of Texas, Mr. BARRETT of Nebraska, Mrs. THURMAN, Mr. HASTERT, Mr. POMEROY, Mr. WOLF, Mr. BISHOP, Mr. STUMP, Mrs. LINCOLN, Mr. EVERETT, Mr. PAXON, Mr. GOODLATTE, Mr. DOOLITTLE, Mr. CANADY of Florida, Mr. POMBO, Mr. KINGSTON, Mr. WALSH, Mr. HOEKSTRA, Mr. BAKER of Louisiana, Mr. CALVERT, Mr. SMITH of Michigan, Mr. COX of California, Mr. CRAPO, Mr. LUCAS, Mr. LEWIS of Kentucky, Mr. SHADEGG, Mr. HOSTETTLER, Mrs. CHENOWETH, Mr. HUTCHINSON, Mr. CHAMBLISS, Mr. LATHAM, Mr. LAHOOD, Mr. TAYLOR of North Carolina, Mr. BEREUTER, Mr. WHITFIELD, Mr. NETHERCUTT, Mr. BOUCHER, Mr. OXLEY, Mr. SKEEN, Mr. BOEHNER, Mr. STUPAK, Mr. THORNBERRY, Mr. BRYANT of Tennessee, Mr. HASTINGS of Washington, Mr. POSHARD, Mr. BURR, Mr. SENSENBRENNER, Mr. TALENT, Ms. DANNER, Mr. HEFLEY, Mr. ORTON, Mr. UPTON, Mr. BILBRAY, Mr. FOLEY, Mr. MCCRERY, Mr. COOLEY, Mr. MCHUGH, Mr. GANSKE, Mr. EWING, Mr. HOLDEN, Mr. MANZULLO, Mr. HAYWORTH, Mr. CHRYSLER, Mr. GILLMOR, Mr. METCALF, Mrs. SEASTRAND, Mr. MINGE, Mr. DICKEY, Mr. NORWOOD, Mr. DUNCAN, Mr. BARTON of Texas, Mr. GORDON, Mr. SCHAEFER, Mr. CLINGER, Mr. MOORHEAD, Mr. RADANOVICH, Mr. HANCOCK, Mr. ROSE, Mr. BUYER, and Mr. QUILLEN) introduced the following bill; Titles I–III, referred to the Committee on Agriculture; Title IV, referred to the Committee on Commerce

A BILL

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Food Quality Protec-
5 tion Act of 1995”.

6 **TITLE I—CANCELLATION AND**
7 **SUSPENSION**

8 **SEC. 101. REFERENCE.**

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

14 **SEC. 102. CANCELLATION.**

15 Section 6(b) (7 U.S.C. 136d(b)) is amended to read
16 as follows:

17 “(b) CANCELLATION AND CHANGE IN CLASSIFICA-
18 TION OR OTHER TERMS OR CONDITIONS OF REGISTRA-
19 TION.—

20 “(1) AUTHORITY.—Notwithstanding any other
21 provision of this Act, the Administrator may, by use

1 of informal rulemaking under this subsection, pre-
2 scribe requirements regarding the composition, pack-
3 aging, and labeling of a pesticide (or a group of pes-
4 ticides containing a common active ingredient), or
5 may classify any such pesticide, or may prohibit the
6 registration or continued registration of any such
7 pesticide for some or all purposes, to the extent nec-
8 essary to assure that the pesticide, when used in ac-
9 cordance with widespread and commonly recognized
10 practice, does not generally cause unreasonable ad-
11 verse effects on the environment.

12 “(2) BASIS FOR RULE.—The Administrator
13 may not initiate a rulemaking under this subsection
14 unless the rulemaking is based on a validated test or
15 other significant evidence raising prudent concerns
16 of unreasonable adverse effects to man or to the en-
17 vironment.

18 “(3) PRENOTICE OF RULEMAKING PROCE-
19 DURES.—

20 “(A) The Administrator may not initiate a
21 rulemaking under paragraph (1) until the Ad-
22 ministrator has furnished to the registrant of
23 each affected pesticide a notice that includes a
24 summary of the validated test or other signifi-
25 cant evidence upon which the Administrator

1 proposes to base the rulemaking and the basis
2 for a determination that such test or evidence
3 raises prudent concerns that the pesticide
4 causes unreasonable adverse risks to man or to
5 the environment. A registrant shall have 30
6 days after receipt of a notice provided under
7 this subparagraph to respond to such notice.

8 “(B) At the same time that the Adminis-
9 trator furnishes notice to registrants of the pes-
10 ticide under subparagraph (A), the Adminis-
11 trator shall also furnish such notice to the Sec-
12 retary of Agriculture and the Secretary of
13 Health and Human Services. Upon receipt of
14 such notification, the Secretary of Agriculture,
15 when an agricultural commodity is affected,
16 shall prepare an analysis of the benefit and use
17 data of the pesticide and provide the analysis to
18 the Administrator within the time limits of this
19 paragraph.

20 “(C) Not more than 60 days after issuing
21 a notice under this paragraph, the Adminis-
22 trator shall either—

23 “(i) issue a notice of proposed rule-
24 making under paragraph (5); or

1 “(ii) issue a notice of a decision not to
2 initiate a rulemaking.

3 “(4) DOCKET.—For each rulemaking under
4 paragraph (1), the Administrator shall establish a
5 docket. The docket shall include a copy of the notice
6 under paragraph (3), of the notice of proposed rule-
7 making under paragraph (5), of each timely com-
8 ment filed with the Administrator, of the report of
9 the Scientific Advisory Panel under paragraph (7),
10 of a record of each hearing held by the Adminis-
11 trator in connection with the rulemaking of the deci-
12 sion of the hearing examiner under paragraph (6),
13 and of the final rule or decision to withdraw the
14 rule. Information in the docket shall be made avail-
15 able to the public consistent with the requirements
16 of section 10. No factual material that has not been
17 entered into the docket in a timely manner may be
18 relied upon by the Administrator in issuing a final
19 rule or in withdrawing a proposed rule or by any
20 person in a judicial review proceeding, except for—

21 “(A) information of which the Adminis-
22 trator may properly take official notice; or

23 “(B) information of which a court may
24 properly take judicial notice.

25 “(5) NOTICE OF PROPOSED RULEMAKING.—

1 “(A) The notice of proposed rulemaking
2 shall include a statement of its basis and pur-
3 pose, a request for any additional data needed,
4 and a bibliography of all significant scientific
5 data and studies on which the proposed rule is
6 based. The statement of basis and purpose shall
7 include a summary of—

8 “(i) the factual data on which the pro-
9 posed rule is based;

10 “(ii) the major scientific assumptions,
11 legal interpretations, and policy consider-
12 ations underlying the proposed rule;

13 “(iii) a summary of available risk-ben-
14 efit information, including benefits and use
15 information as provided by the Secretary
16 of Agriculture; and

17 “(iv) the Administrator’s analysis and
18 tentative conclusions regarding the bal-
19 ancing of such risks and benefits.

20 “(B) Registrants of the pesticide and any
21 person who submits comments on the proposed
22 rule shall make a report to the Administrator of
23 all scientific data and studies in such person’s
24 possession concerning the risks and benefits of
25 the pesticide that are the subject of the rule-

1 making and were not included in the bibliog-
2 raphy included in the notice required in sub-
3 paragraph (A). If such person receives addi-
4 tional scientific data or studies pertinent to the
5 rulemaking that were not included in such bibli-
6 ography, the person shall make a report of such
7 scientific data and studies to the Administrator
8 promptly after receipt. If the Administrator re-
9 ceives reports containing additional data con-
10 cerning risks or benefits, the Administrator
11 shall revise the bibliography to reflect such data
12 and make the revised bibliography available to
13 the public.

14 “(C) The Administrator shall provide a
15 comment period of not less than 90 days after
16 the publication of the notice of proposed rule-
17 making. During such period any person may
18 submit comments, data, or documentary infor-
19 mation on the proposed rule. Promptly upon re-
20 ceipt by the Administrator, all written com-
21 ments and documentary information on the pro-
22 posed rule received from any person for inclu-
23 sion in the docket during the comment period,
24 shall be place in the docket.

1 “(D) At the same time that the Adminis-
2 trator publishes notice under subparagraph (A),
3 the Administrator shall provide the Secretary of
4 Agriculture and the Secretary of Health and
5 Human Services with a copy of the proposed
6 rule. Not later than 90 days after the publica-
7 tion of the notice of proposed rulemaking, the
8 Secretary of Agriculture and the Secretary of
9 Health and Human Services may provide com-
10 ments on such proposed rule. When an agricul-
11 tural commodity is affected, the Secretary of
12 Agriculture shall provide to the Administrator
13 an analysis of the impact of the proposed action
14 on the domestic and global availability, prices of
15 agricultural commodities and retail food prices,
16 and any associated societal impacts (including
17 consumer nutrition and health and low-income
18 consumers).

19 “(6) HEARING.—

20 “(A) Any person who has submitted a
21 comment may, not later than 15 days after the
22 close of the comment period, request of the Ad-
23 ministrator a hearing on questions of fact,
24 based on information submitted under para-
25 graph (5), and pertaining to the proposed rule

1 or comments thereon. Upon such request, the
2 Administrator shall schedule a hearing not to
3 exceed 20 days duration, to commence not later
4 than 30 days and to conclude not later than 90
5 days after the close of the comment period. The
6 Administrator shall announce the time, place,
7 and purpose of the hearing in the Federal Reg-
8 ister. The hearing shall be limited to addressing
9 questions of fact raised by materials in the
10 docket. A transcript shall be made of any oral
11 presentation, discussion, or debate and included
12 in the docket.

13 “(B) The Administrator shall appoint a
14 hearing examiner who shall have the authority
15 to administer oaths, issue subpoenas, regulate
16 the course of the hearing, conduct prehearing
17 conferences, schedule presentations, and exclude
18 irrelevant, immaterial, or unduly repetitious evi-
19 dence, or evidence that should have been sub-
20 mitted under subparagraph (5)(B).

21 “(C) The hearing examiner shall conduct
22 the hearing in a manner that encourages dis-
23 cussion and debate on questions of fact regard-
24 ing the docket, and conforms with the deadlines
25 set in this paragraph. The Administrator shall

1 designate one or more employees of the Envi-
2 ronmental Protection Agency to participate in
3 the hearing. Any person who submitted a com-
4 ment on the proposed rule may participate in
5 the hearing and shall be entitled to present evi-
6 dence and argument to support the partici-
7 pant's position or rebut a contrary position and
8 may choose to present materials in oral or writ-
9 ten form. The presentation of evidence and ar-
10 gument shall not delay the conclusion of the
11 hearing beyond 20 days of its commencement.

12 “(D) Subject to subparagraph (B), an in-
13 terested person is entitled—

14 “(i) to present such person's position
15 orally or by documentary submissions (or
16 both); and

17 “(ii) if the Administrator determines
18 that there are disputed issues of material
19 fact necessary to resolve, to present such
20 rebuttal submissions and to conduct such
21 cross-examination of persons as the hear-
22 ing examiner determines (I) to be appro-
23 priate, and (II) to be required for a full
24 and true disclosure with respect to such is-
25 sues.

1 “(E) As soon as practicable after comple-
2 tion of the hearing but not later than 180 days
3 after the close of the public comment period,
4 the hearing examiner shall issue a decision.
5 Such decision shall be based only on substantial
6 evidence of record of such hearing (including
7 the report of the Scientific Advisory Panel) and
8 shall set forth detailed findings of fact upon
9 which the decision is based.

10 “(7) REVIEW BY SCIENTIFIC ADVISORY
11 PANEL.—At the time the Administrator issues a no-
12 tice of proposed rulemaking under paragraph (5),
13 the Administrator shall provide a copy of such notice
14 to the Scientific Advisory Panel established under
15 section 25(d). The hearing examiner (or Adminis-
16 trator if no hearing is requested) shall request the
17 comments, evaluations, and recommendations of the
18 Panel as to the impact on health and the environ-
19 ment of the proposed rule and on any disputed ma-
20 terial issues of fact or scientific policy that appear
21 to be of significance in the hearing. The Panel may
22 hold a public hearing to discuss the proposed rule.
23 The Panel shall provide a report to the hearing ex-
24 aminer (or Administrator if no hearing is requested)
25 not later than 120 days after the close of comment

1 period. The Administrator shall allow a reasonable
2 time for written public comment on the Panel's re-
3 port. A copy of the Panel's report and any com-
4 ments shall be included in the rulemaking docket.

5 “(8) FINAL ACTION.—Not later than 365 days
6 after issuing a notice of proposed rulemaking and
7 after considering all material in the docket, the Ad-
8 ministrator shall publish in the Federal Register ei-
9 ther a final rule or a withdrawal of the proposed
10 rule. The Administrator may not prohibit a use of
11 a pesticide if alternative requirements will assure
12 that the pesticide, when used in accordance with
13 widespread and commonly recognized practice, will
14 not generally cause unreasonable adverse effects on
15 the environment. In taking any final action, the Ad-
16 ministrator shall take into account the impact of the
17 action on production and prices of agricultural com-
18 modities, retail food prices, and otherwise on agricul-
19 tural economy, and shall use the least burdensome
20 requirements to achieve the purposes of this Act.
21 The final rule or withdrawal of the proposal shall be
22 accompanied by a statement that—

23 “(A) explains the reasons for the action;

24 “(B) responds to any comments made by
25 the Secretary of Agriculture or the Secretary of

1 Health and Human Services, and responds to
2 any report of the Scientific Advisory Panel;

3 “(C) responds to each significant comment
4 contained in the docket; and

5 “(D) in the case of a final rule—

6 “(i) explains the reasons for any
7 major difference between the final rule and
8 the proposed rule;

9 “(ii) describes the impact of the final
10 rule on production and prices of agricul-
11 tural commodities, retail food prices, and
12 otherwise on the agricultural economy; and

13 “(iii) explains any significant dis-
14 agreements the Administrator may have
15 with the comments, evaluations, or rec-
16 ommendations contained in the report
17 under paragraph (7) or the benefits and
18 use information described in paragraph
19 (5)(A)(iii) and analysis in paragraph
20 (5)(D) as it bears on the final rule.

21 A final rule issued under this subsection shall
22 be effective upon the date of its publication in
23 the Federal Register.

24 “(9) MODIFICATION OR CANCELLATION.—

1 “(A) A final rule shall state any require-
2 ments, classifications, or prohibitions imposed
3 by the rule, and shall state that each affected
4 registrant shall have a 30-day period from the
5 date of publication of the rule in the Federal
6 Register to apply for an amendment to the reg-
7 istration to comply with the rule or to request
8 voluntary cancellation of the registration. How-
9 ever, if the rule unconditionally prohibits all
10 uses of a pesticide, the rule may provide that
11 cancellation of the registration of the pesticide
12 is effective upon publication of the rule.

13 “(B) Notwithstanding any other provision
14 of this Act, if an application for an amendment
15 to the registration to make it comply with a
16 rule issued under subparagraph (A) is not sub-
17 mitted within such 30-day period, the Adminis-
18 trator may issue and publish in the Federal
19 Register an order canceling the registration, ef-
20 fective upon the date of publication of the order
21 in the Federal Register.

22 “(10) DENIAL OF APPLICATIONS.—Notwith-
23 standing any other provision of this Act, no applica-
24 tion for initial or amended registration of any pes-
25 ticide under section 3 or 24(c) may be approved if

1 the registration would be inconsistent with a rule in
2 effect under this subsection.

3 “(11) AMENDMENT OF RULE.—A registrant, or
4 other interested person with the concurrence of the
5 registrant, may petition for the amendment or rev-
6 ocation of a rule that has been issued under this
7 subsection. The petition shall state the factual mate-
8 rial and argument that form the basis for the peti-
9 tion. The Administrator shall publish a notice of the
10 petition in the Federal Register and allow a 60-day
11 comment period thereon. Not later than 180 days
12 after publication of the notice, the Administrator
13 shall determine whether to deny the petition or to
14 propose to amend or revoke the rule, and publish the
15 determination and its basis in the Federal Register.
16 In making such a determination, the Administrator
17 shall give due regard to the desirability of finality,
18 to the opportunity that the petitioner had to present
19 the factual material and argument in question in the
20 prior rulemaking proceeding, and to any new evi-
21 dence submitted by the petitioner. If the Adminis-
22 trator proposes to amend or revoke the rule, then
23 the procedures established by paragraph (1) and
24 paragraphs (5) through (8) apply. A denial of a peti-

1 tion shall be judicially reviewable as provided in
2 paragraph (12).

3 “(12) JUDICIAL REVIEW.—A decision not to
4 initiate a rulemaking published under paragraph (3),
5 a final rule or a withdrawal of a proposed rule pub-
6 lished under paragraph (8) or a denial of a petition
7 under paragraph (11) shall be judicially reviewable
8 in the manner specified by section 16(b)(2).”.

9 **SEC. 103. PESTICIDES IN REVIEW.**

10 If the Administrator, on or before January 1, 1995,
11 has published a document instituting a special review pro-
12 ceeding or public interim administrative review proceeding
13 with respect to a particular pesticide or active ingredient
14 thereof, the Administrator may, in lieu of proceeding
15 under section 6(b) of the Federal Insecticide, Fungicide,
16 and Rodenticide Act, as amended by the Food Quality
17 Protection Act of 1995, elect to continue such review pro-
18 ceeding and, upon its completion, take action as warranted
19 in accordance with sections 3(c)(6), 6(b), and 6(d) as
20 those sections were in effect on the day before the date
21 of enactment of the Food Quality Protection Act of 1995.

22 **SEC. 104. SUSPENSION.**

23 (a) SECTION 6(c)(1).—The second sentence of sec-
24 tion 6(c)(1) (7 U.S.C. 136d(c)(1)) is amended to read:
25 “Except as provided in paragraph (3), no order of suspen-

1 sion may be issued under this subsection unless the Ad-
2 ministrator has issued, or at the same time issues, a pro-
3 posed rule under subsection (b).”.

4 (b) SECTION 6(c)(3).—Section 6(c)(3) (7 U.S.C.
5 136d(c)(3)) is amended by inserting after the first sen-
6 tence the following new sentence: “The Administrator may
7 issue an emergency order under this paragraph before is-
8 suing a proposed rule under subsection (b), provided that
9 the Administrator shall proceed expeditiously to issue a
10 proposed rule.”.

11 **SEC. 105. TOLERANCE REEVALUATION AS PART OF REREG-**
12 **ISTRATION.**

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

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

23 “(i) reassess each associated tolerance
24 and exemption from the requirement for a
25 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. 106. SCIENTIFIC ADVISORY PANEL.**

16 The first sentence of section 25(d) (7 U.S.C.
17 136w(d)) is amended—

18 (1) by striking “The Administrator shall” and
19 inserting “(1) IN GENERAL.—The Administrator
20 shall”; 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. The Scientific Advisory Panel shall select the
2 scientists from 60 nominations submitted each by
3 the National Science Foundation and the National
4 Institutes of Health. Members of the Board shall be
5 compensated in the same manner as members of the
6 Panel.”.

7 **SEC. 107 CONFORMING AMENDMENTS.**

8 (a) SECTION 3(c)(6).—Section 3(c)(6) (7 U.S.C.
9 136a(c)(6)) is amended to read as follows:

10 “(6) DENIAL OF APPLICATION FOR REGISTRA-
11 TION.—

12 “(A) Except as provided in subparagraph
13 (B), if the Administrator proposes to deny an
14 application for registration because it does not
15 satisfy the requirements of paragraph (5), the
16 Administrator shall notify the applicant of the
17 proposal and the reasons (including the factual
18 basis thereof). Unless the applicant makes the
19 necessary corrections to the application and no-
20 tifies the Administrator thereof during the 30-
21 day period beginning with the day after the
22 date the applicant receives the notice, or unless
23 during that time the applicant submits a re-
24 quest for a hearing, the Administrator may
25 issue an order denying the application. If dur-

1 ing that time the Administrator does not receive
2 such corrections to the application or such a re-
3 quest for hearing, the Administrator may issue
4 an order denying the application. Such an order
5 shall be published in the Federal Register and
6 shall not be subject to judicial review. If during
7 that time the Administrator receives a request
8 for a hearing, a hearing shall be conducted
9 under section 6(d) of the Act. If such a hearing
10 is held, a decision after completion of such
11 hearing shall be final and shall be subject to ju-
12 dicial review under section 16(b)(1) of this Act.

13 “(B) The Administrator may deny an ap-
14 plication for registration because it does not
15 comply with the requirements of a rule issued
16 under section 6(b) of this Act. The Adminis-
17 trator shall notify the applicant of such denial.
18 Such notice shall explain why the application
19 does not comply with such requirements and
20 shall state that the applicant may petition to
21 amend or revoke such rule under section
22 6(b)(12) of this Act.”.

23 (b) SECTION 3(c)(8).—Section 3(c)(8) (7 U.S.C.
24 136a(c)(8)) is repealed.

1 (c) SECTION 3(d).—Section 3(d) (7 U.S.C. 136a(d))
2 is amended—

3 (1) in paragraph (1)(A), by striking “on the
4 initial classification and registered pesticides” and
5 inserting “under section 6(b) of this Act. Registered
6 pesticides”; and

7 (2) in paragraph (2), by striking “the Adminis-
8 trator shall notify the registrant” and all that fol-
9 lows through the end of the paragraph, and insert-
10 ing “the Administrator may initiate a proceeding
11 under section 6(b) of the Act.”.

12 (d) SECTION 4(e).—Section 4(e)(3)(B)(iii)(III) (7
13 U.S.C. 136a–1(e)(3)(B)(iii)(III)) is amended—

14 (1) by striking “section 6(d), except that the”
15 and inserting “section 6(d). The”; and

16 (2) by inserting after “guidelines.” the follow-
17 ing: “If a hearing is held, a decision after completion
18 of such hearing shall be final.”.

19 (e) SECTION 6(c).—Section 6(c) (7 U.S.C. 136d(c))
20 is amended in paragraph (4) by striking “section 16” and
21 inserting “section 16(b)(1)”.

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

24 (1) by amending the first sentence to read as
25 follows: “If a hearing is requested pursuant to sec-

1 tion 3(c)(2)(B)(iv), 3(c)(6), 4(e)(3)(B)(iii)(III), 6(b),
2 6(c)(2), or 6(e)(2), such hearing shall be held for the
3 purpose of receiving evidence relevant and material
4 to the issues raised by the request for hearing.”; and

5 (2) by striking the ninth sentence and all that
6 follows through the end of the subsection and insert-
7 ing the following: “A hearing under this subsection
8 shall be held in accordance with the provisions of
9 sections 554, 556, and 557 of title 5, United States
10 Code.”.

11 (g) SECTION 16(b).—Section 16(b) (17 U.S.C.
12 136n(b)) is amended—

13 (1) by striking “(b) REVIEW BY COURT OF AP-
14 PEALS.—In the case of” and inserting the following:
15 “(b) REVIEW BY COURT OF APPEALS.—

16 “(1) REVIEW OF CERTAIN ORDERS.—In the
17 case of”;

18 (2) by striking “under this section” in the sixth
19 sentence of paragraph (1) (as so designated) and in-
20 serting “under this paragraph”, and

21 (3) by adding at the end the following new
22 paragraph:

23 “(2) REVIEW OF CERTAIN RULES.—In the case
24 of actual controversy as to the validity of any rule
25 issued by the Administrator under section 6(b)(8),

1 any decision by the Administrator under section
2 6(b)(8) not to issue a proposed rule or to withdraw
3 a proposed rule, or any denial of a petition to revoke
4 or amend a final rule under section 6(b)(11), any
5 person who will be adversely affected by such rule or
6 decision who filed comments in the proceedings lead-
7 ing to the rule or decision may obtain judicial review
8 by filing a petition in the United States court of ap-
9 peals for the circuit wherein such person resides or
10 has a place of business, within 60 days after the is-
11 suance of such rule or decision. The court shall hold
12 unlawful and set aside such rule or decision if it
13 finds that a rule of, or ruling by, the hearing exam-
14 iner under section 6(b)(6), limiting such petitioner's
15 cross-examination or oral presentations, has pre-
16 cluded disclosure of disputed material facts which
17 was necessary to a full determination by the Admin-
18 istrator of the rulemaking proceeding taken as a
19 whole. A copy of the petition shall be forthwith
20 transmitted by the clerk of the court to the Adminis-
21 trator or any officer designated by the Administrator
22 for that purpose, and thereupon the Administrator
23 shall file in court the record of the proceedings on
24 which the Administrator based such rule or decision,
25 as provided in section 2112 of title 28, United

1 States Code. Upon the filing of such petition the
2 court shall have exclusive jurisdiction to affirm or
3 set aside such rule or decision in whole or in part.
4 The standard of review shall be that set forth in sec-
5 tion 706 of title 5, United States Code. The judg-
6 ment of the court under this paragraph shall be
7 final, subject to review by the Supreme Court upon
8 certiorari or certification as provided in section 1254
9 of title 28, United States Code. The commencement
10 of proceedings under this section shall not, unless
11 specifically ordered by the court to the contrary, op-
12 erate as a stay of an order.”.

13 (h) SECTION 25(a).—Section 25(a) (7 U.S.C.
14 136w(a)) is amended by adding at the end the following:

15 “(5) EXCEPTION.—The requirements of this
16 subsection shall not apply to any rule or rulemaking
17 proceeding under section 6(b).”.

18 (i) SECTION 25(d).—Section 25(d) (7 U.S.C.
19 136w(d)) is amended—

20 (1) in the first sentence by striking “in notices
21 of intent issued under subsection 6(b) and”; and

22 (2) in the second sentence by striking “notices
23 of intent and” and by striking “6(b) or”.

24 (j) SECTION 25(e).—Section 25(e) (7 U.S.C.
25 136w(e)) is amended—

1 (1) by striking the period at the end of the sec-
2 ond sentence; and

3 (2) by inserting at the end of the second sen-
4 tence “, except for any action that may be taken
5 under section 6(b).”.

6 **TITLE II—MINOR USE CROP PROTECTION**

7 **ACT OF 1995**

8 **SEC. 201. SHORT TITLE.**

9 (a) SHORT TITLE.—This title may be cited as the
10 “Minor Use Crop Protection Act of 1995”.

11 (b) REFERENCE.—Whenever in this title an amend-
12 ment or repeal is expressed in terms of an amendment
13 to, or repeal of, a section or other provision, the reference
14 shall be considered to be made to a section or other provi-
15 sion of the Federal Insecticide, Fungicide, and
16 Rodenticide Act.

17 **SEC. 202. MINOR CROP PROTECTION.**

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

20 “(hh) MINOR USE.—The term ‘minor use’ means the
21 use of a pesticide on an animal, on a commercial agricul-
22 tural crop or site, or for the protection of public health
23 where—

24 “(1) the total United States acreage for the
25 crop is less than 300,000 acres; or

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

8 “(A) there are insufficient efficacious alter-
9 native registered pesticides available for the
10 use; or

11 “(B) the alternatives to the pesticide pose
12 greater risks to the environment or human
13 health; or

14 “(C) the pesticide plays or will play, a sig-
15 nificant part in managing pest resistance; or

16 “(D) the pesticide plays or will play a sig-
17 nificant part in an integrated pest management
18 program.

19 The status as a minor use under this subsection
20 shall continue as long as the Administrator has not
21 determined that, based on existing data, such use
22 may cause an unreasonable adverse effect on the en-
23 vironment and the use otherwise qualifies for such
24 status.”.

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

6 “(ii) The period of exclusive data use
7 for data submitted to support the applica-
8 tion for the original registration of a pes-
9 ticide under clause (i) shall be extended
10 one additional year for each 3 minor uses
11 registered after the date of enactment of
12 this clause and, before the expiration of
13 the period of exclusive use under this
14 clause, up to a total of 3 additional years
15 for all minor uses registered by the Admin-
16 istrator if the Administrator in consulta-
17 tion with the Secretary of Agriculture de-
18 termines that, based on information pro-
19 vided by an applicant for registration or a
20 registrant, that—

21 “(I) there are insufficient effica-
22 cious alternative registered pesticides
23 available for the use; or

1 “(II) the alternatives to the pes-
2 ticide pose greater risks to the envi-
3 ronment or human health; or

4 “(III) the pesticide plays or will
5 play a significant part in managing
6 pest resistance; or

7 “(IV) the pesticide plays or will
8 play a significant part in an inte-
9 grated pest management program.

10 The registration of a pesticide for a minor
11 use on a crop grouping established by the
12 Administrator shall be considered for pur-
13 poses of this clause one minor use for each
14 representative crop for which data are pro-
15 vided in the crop grouping. Any additional
16 exclusive use period under this clause shall
17 be modified as appropriate or terminated if
18 the registrant voluntarily cancels the prod-
19 uct or deletes from the registration the
20 minor uses which formed the basis for the
21 extension of the additional exclusive use
22 period or if the Administrator determines
23 that the registrant is not actually market-
24 ing the product for such minor uses.”.

1 (c) TIME EXTENSIONS FOR DEVELOPMENT OF
2 MINOR USE DATA.—

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

6 “(vi) Upon the request of a registrant
7 the Administrator shall, in the case of a
8 minor use, extend the deadline for the pro-
9 duction of residue chemistry data under
10 this subparagraph for data required solely
11 to support that minor use until the final
12 deadline for submission of data under sec-
13 tion 4 for the other use of the pesticide es-
14 tablished as of the date of enactment of
15 the Minor Use Crop Protection Act of
16 1995, if—

17 “(I) the data to support other
18 uses of the pesticide on a food are
19 being provided;

20 “(II) the registrant, in submit-
21 ting a request for such an extension,
22 provides a schedule, including interim
23 dates to measure progress, to assure
24 that the data production will be com-

1 pleted before the expiration of the ex-
2 tension period;

3 “(III) the Administrator has de-
4 termined that such extension will not
5 significantly delay the Administrator’s
6 schedule for issuing a reregistration
7 eligibility determination required
8 under section 4; and

9 “(IV) the Administrator has de-
10 termined in writing that based on ex-
11 isting data, such extension would not
12 significantly increase the risk of any
13 unreasonable adverse effect on the en-
14 vironment. If the Administrator
15 grants an extension under this clause,
16 the Administrator shall monitor the
17 development of the data and shall en-
18 sure that the registrant is meeting the
19 schedule for the production of the
20 data. If the Administrator determines
21 that the registrant is not meeting or
22 has not met the schedule for the pro-
23 duction of such data, the Adminis-
24 trator may proceed in accordance with
25 clause (iv) regarding the continued

1 registration of the affected products
2 with the minor use and shall inform
3 the public of such action. Notwith-
4 standing the provisions of this clause,
5 the Administrator may take action to
6 modify or revoke the extension under
7 this clause if the Administrator deter-
8 mines that the extension for the minor
9 use may cause an unreasonable ad-
10 verse effect on the environment. In
11 such circumstance, the Administrator
12 shall provide, in writing to the reg-
13 istrant, a notice revoking the exten-
14 sion of time for submission of data.
15 Such data shall instead be due in ac-
16 cordance with the date established by
17 the Administrator for the submission
18 of the data.”.

19 (2) REREGISTRATION.—Sections 4(d)(4)(B),
20 4(e)(2)(B), and 4(f)(2)(B) (7 U.S.C. 136a-
21 1(d)(4)(B), (e)(2)(B), and (f)(2)(B)) are each
22 amended by adding at the end the following: “Upon
23 the request of a registrant, the Administrator shall,
24 in the case of a minor use, extend the deadline for
25 the production of residue chemistry data under this

1 subparagraph for data required solely to support
2 that minor use until the final deadline for submis-
3 sion of data under this section for the other uses of
4 the pesticide established as of the date of enactment
5 of the Minor Use Crop Protection Act of 1995 if—

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

8 “(ii) the registrant, in submitting a request
9 for such an extension provides a schedule, in-
10 cluding interim dates to measure progress, to
11 assure that the data production will be com-
12 pleted before the expiration of the extension
13 period;

14 “(iii) the Administrator has determined
15 that such extension will not significantly delay
16 the Administrator’s schedule for issuing a re-
17 registration eligibility determination required
18 under this section; and

19 “(iv) the Administrator has determined in
20 writing that based on existing data, such exten-
21 sion would not significantly increase the risk of
22 any unreasonable adverse effect on the environ-
23 ment. If the Administrator grants an extension
24 under this subparagraph, the Administrator
25 shall monitor the development of the data and

1 shall ensure that the registrant is meeting the
2 schedule for the production of the data. If the
3 Administrator determines that the registrant is
4 not meeting or has not met the schedule for the
5 production of such data, the Administrator may
6 proceed in accordance with clause (iv) of section
7 3(c)(2)(B) or other provisions of this section, as
8 appropriate, regarding the continued registra-
9 tion of the affected products with the minor use
10 and shall inform the public of such action. Not-
11 withstanding the provisions of this subpara-
12 graph, the Administrator may take action to
13 modify or revoke the extension under this sub-
14 paragraph if the Administrator determines that
15 the extension for the minor use may cause an
16 unreasonable adverse effect on the environment.
17 In such circumstance, the Administrator shall
18 provide, in writing to the registrant, a notice re-
19 voking the extension of time for submission of
20 data. Such data shall instead be due in accord-
21 ance with the date then established by the Ad-
22 ministrator for submission of the data.”.

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

25 (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 expediently as possible, review and act on any
2 complete application—
3

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

8 “(II) for a registration or a registration amendment that proposes significant minor uses.
9

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

11 “(I) the term ‘as expeditiously as possible’ means that the Administrator shall to the greatest extent
12 practicable complete a review and evaluation of all data, submitted with a complete application, within 12
13 months after the submission of the complete application, and the failure of the Administrator to complete such
14 a review and evaluation under clause
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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 non-minor 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
18 required by the Administrator, pursuant to
19 paragraph (2)(E), and if the Administrator de-
20 nies in whole or in part such data waiver re-
21 quest, the registrant shall have a full time pe-
22 riod for providing such data. For purposes of
23 this subparagraph, the term ‘full time period’
24 means the time period originally established by
25 the Administrator for submission of such data,

1 beginning with the data of receipt by the reg-
2 istrant 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 Minor Use Crop Protection Act of 1995,
24 for the submission of data under this section
25 for the supported uses identified pursuant to

1 this paragraph unless the Administrator deter-
2 mines 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 Minor
4 Use Crop Protection Act of 1995, for the sub-
5 mission of data under this section for the sup-
6 port uses identified pursuant to this subpara-
7 graph unless the Administrator determines that
8 the absence of the data is significant enough
9 to cause human health or environmental con-
10 cerns. On the basis of such determination the
11 Administrator may refuse the request for exten-
12 sion by the registrant. Upon receipt of the re-
13 quest from the registrant, the Administrator
14 shall publish in the Federal Register a notice
15 of the receipt of the request and the effective
16 date upon which the uses not being supported
17 will be voluntarily deleted from the registration
18 pursuant to section 6(f)(1). If the Adminis-
19 trator grants an extension under this subpara-
20 graph, the Administrator shall monitor the de-
21 velopment of the data for the uses being sup-
22 ported and shall ensure that the registrant is
23 meeting the schedule for the production of such
24 data. If the Administrator determines that the
25 registrant is not meeting or has not met the

1 schedule for the production of such data, the
2 Administrator may proceed in accordance with
3 section 3(c)(2)(B)(iv) regarding the continued
4 registration of the affected products with the
5 minor and other uses and shall inform the pub-
6 lic of such action in accordance with section
7 6(f)(2). Notwithstanding this subparagraph, the
8 Administrator may deny, modify, or revoke the
9 temporary extension under this subparagraph if
10 the Administrator determines that the continu-
11 ation of the minor use may cause an unreason-
12 able adverse effect on the environment. In the
13 event of modification or revocation, the Admin-
14 istrator shall provide, in writing, to the reg-
15 istrant, a notice revoking the temporary exten-
16 sion and establish a new effective date by which
17 the minor use shall be deleted from the reg-
18 istration.”.

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

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

1 pesticide on a food, or if all uses of the pes-
2 ticide are nonfood uses and the registrant does
3 not commit to support a specific minor use of
4 the pesticide but is supporting and providing
5 data in a timely and adequate fashion to sup-
6 port other nonfood uses of the pesticide, the
7 Administrator, at the written request of the
8 registrant, shall not take any action pursuant
9 to this clause in regard to such unsupported
10 minor use until the final deadline established as
11 of the date of enactment of the Minor Use Crop
12 Production Act of 1995, for the submission of
13 data under section 4 for the supported uses
14 identified pursuant to this clause unless the Ad-
15 ministrator determines that the absence of the
16 data is significant enough to cause human
17 health or environmental concerns. On the basis
18 of such determination, the Administrator may
19 refuse the request for extension by the reg-
20 istrant. Upon receipt of the request from the
21 registrant, the Administrator shall publish in
22 the Federal Register a notice of receipt of the
23 request and the effective date upon which the
24 uses not being supported will be voluntarily de-
25 leted from the registration pursuant to section

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

1 the minor use shall be deleted from the reg-
2 istration.”.

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

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

24 (h) ENVIRONMENTAL PROTECTION AGENCY MINOR
25 USE PROGRAM.—The Federal Insecticide, Fungicide, and

1 Rodenticide Act (7 U.S.C. 136 et seq.) is amended by re-
2 designating sections 30 and 31 as sections 32 and 33, re-
3 spectively, and adding after section 29 the following:

4 **“SEC. 30. ENVIRONMENTAL PROTECTION AGENCY MINOR**
5 **USE PROGRAM.**

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

14 (i) DEPARTMENT OF AGRICULTURE MINOR USE
15 PROGRAM.—The Federal Insecticide, Fungicide, and
16 Rodenticide Act (7 U.S.C. 136 et seq.), as amended by
17 subsection (h), is amended by adding after section 30 the
18 following:

19 **“SEC. 31. DEPARTMENT OF AGRICULTURE MINOR USE**
20 **PROGRAM.**

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

1 “(1) carrying out the Inter-Regional Project
2 Number 4 (IR-4) as described in section 2(e) of the
3 Act entitled ‘An Act to facilitate the work of the De-
4 partment of Agriculture, and for other purposes’ (7
5 U.S.C. 4501(e)) and the national pesticide resistance
6 monitoring program established under section 1651
7 of the Food, Agriculture, Conservation, and Trade
8 Act of 1990 (7 U.S.C. 5882);

9 “(2) supporting integrated pest management
10 research;

11 “(3) consulting with growers to develop data for
12 minor uses; and

13 “(4) providing assistance for minor use reg-
14 istrations, tolerances, and reregistrations with the
15 Environmental Protection Agency.

16 “(b) MATCHING FUND PROGRAM.—

17 “(1) ESTABLISHMENT.—The Secretary of Agri-
18 culture, in consultation with the Administrator, shall
19 establish and administer a minor use matching fund
20 program. The matching fund program shall be uti-
21 lized to ensure the continued availability of minor
22 use crop protection chemicals, including the develop-
23 ment of data to support minor use pesticide registra-
24 tions and reregistrations. Access to the matching
25 fund program shall be available to any entity which

1 desires to develop data to support minor use reg-
2 istrations. Priority for access to the fund shall be
3 given those entities that do not directly receive funds
4 from the sale of products registered on minor uses.
5 Any entity that seeks such funding under this para-
6 graph shall be required to match such funds with an
7 equal amount of its own funds. Any data developed
8 through the matching fund program shall be jointly
9 owned by the Department of Agriculture and by the
10 entity that receives such funding. Any data devel-
11 oped under this subsection shall be subject to the
12 provisions of section 3(c)(1)(F). All compensation
13 received by the Department of Agriculture in return
14 for the use of such data under the matching fund
15 program shall be returned to a revolving fund which
16 will support the matching fund program.

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

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

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

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

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

18 (c) RESIDUE SURVEILLANCE.—The Secretary of Ag-
19 riculture shall ensure that the residue surveillance activi-
20 ties conducted by the Department of Agriculture provide
21 for the improved surveillance of pesticide residues, includ-
22 ing guidelines for the use of comparable analytical and
23 standardized reporting methods, and the increased sam-
24 pling of foods most likely consumed by infants and chil-
25 dren.

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

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

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

10 (c) COORDINATION.—The Secretary shall, as appro-
11 priate, coordinate with the Administrator of the Environ-
12 mental Protection Agency in the design of the surveys and
13 make available to the Administrator the aggregate results
14 of the surveys to assist the Administrator in benefits de-
15 terminations with respect to pesticide regulatory decisions.

16 **SEC. 303. INTEGRATED PEST MANAGEMENT.**

17 The Secretary of Agriculture, in cooperation with the
18 Administrator, shall implement research, demonstration,
19 and education programs to support adoption of integrated
20 pest management. Integrated Pest Management is a sus-
21 tainable approach to managing pests by combining biologi-
22 cal, cultural, physical, and chemical tools in a way that
23 minimizes economic, health, and environmental risks. The
24 Secretary of Agriculture and the Administrator shall make
25 information on integrated pest management widely avail-
26 able to pesticide users, including Federal agencies. Federal

1 agencies shall use integrated pest management techniques
2 in carrying out pest management activities and shall pro-
3 mote integrated pest management through procurement
4 and regulatory policies, and other activities.

5 **TITLE IV—AMENDMENTS TO THE FED-**
6 **ERAL FOOD, DRUG, AND COSMETIC**
7 **ACT**

8 **SEC. 401. REFERENCE.**

9 Whenever in this title an amendment is expressed in
10 terms of an amendment to a section or other provision,
11 or refers to a section or other provision, the reference shall
12 be considered to be made to a section or other provision
13 of the Federal Food, Drug, and Cosmetic Act.

14 **SEC. 402. DEFINITIONS.**

15 (a) Section 201(q) (21 U.S.C. 321(q)) is amended to
16 read as follows:

17 “(q)(1) The term ‘pesticide chemical’ means—

18 “(A) any substance that is a pesticide within
19 the meaning of the Federal Insecticide, Fungicide,
20 and Rodenticide Act; or

21 “(B) any active ingredient of a pesticide within
22 the meaning of the Federal Insecticide, Fungicide,
23 and Rodenticide Act.

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

4 “(A) a pesticide chemical; or

5 “(B) any other added substance that is present
6 in the commodity or food primarily as a result of the
7 metabolism or other degradation of a pesticide
8 chemical.

9 “(3) Notwithstanding paragraphs (1) and (2), the
10 Administrator may by regulation except a substance from
11 the definition of ‘pesticide chemical’ or ‘pesticide chemical
12 residue’ if—

13 “(A) its occurrence as a residue on a raw agri-
14 cultural commodity or processed food is attributable
15 primarily to natural causes or to human activities
16 not involving the use of any substances for a pes-
17 ticial purpose in the production, storage, process-
18 ing, or transportation of any raw agricultural com-
19 modity or processed food; and

20 “(B) the Administrator, after consultation with
21 the Secretary, determines that the substance more
22 appropriately should be regulated under one or more
23 provisions of this Act other than sections
24 402(a)(2)(B) and 408.”.

1 (b) Paragraphs (1) and (2) of section 201(s) (21
2 U.S.C. 321(s)) are amended to read as follows:

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

5 “(2) a pesticide chemical; or”.

6 (c) Section 201 (21 U.S.C. 321) is amended by add-
7 ing at the end the following:

8 “(bb) The term ‘processed food’ means any food
9 other than a raw agricultural commodity and includes any
10 raw agricultural commodity that has been subject to proc-
11 essing, such as canning, cooking, freezing, dehydration, or
12 milling.

13 “(cc) The term ‘Administrator’ means the Adminis-
14 trator of the United States Environmental Protection
15 Agency.”.

16 **SEC. 403. PROHIBITED ACTS.**

17 Section 301(j) (21 U.S.C. 331(j)) is amended—

18 (1) by striking the period at the end; and

19 (2) by inserting at the end “, or the violation
20 of section 408(g)(2) or any regulation issued under
21 that section.”.

22 **SEC. 404. ADULTERATED FOOD.**

23 Section 402(a)(2) (21 U.S.C. 342(a)(2)) is amended
24 to read as follows:

1 “(2)(A) if it bears or contains any added poi-
2 sonous or added deleterious substance (other than a
3 substance that is a pesticide chemical residue in or
4 on a raw agricultural commodity or processed food,
5 a food additive, a color additive, or a new animal
6 drug) that is unsafe within the meaning of section
7 406;

8 “(B) if it bears or contains a pesticide chemical
9 residue that is unsafe within the meaning of section
10 408(a); or

11 “(C) if it is or if it bears or contains—

12 “(i) any food additive that is unsafe within
13 the meaning of section 409; or

14 “(ii) a new animal drug (or conversion
15 product thereof) that is unsafe within the
16 meaning of section 512; or”.

17 **SEC. 405. TOLERANCES AND EXEMPTIONS FOR PESTICIDE**
18 **CHEMICAL RESIDUES.**

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

21 **“TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMI-**
22 **CAL RESIDUES**

23 “SEC. 408. (a) REQUIREMENT FOR TOLERANCE OR
24 EXEMPTION.—

1 “(1) GENERAL RULE.—For the purposes of this
2 section, the term ‘food,’ when used as a noun with-
3 out modification, shall mean a raw agricultural com-
4 modity or processed food. Except as provided in
5 paragraph (2) or (3), any pesticide chemical residue
6 in or on a food shall be deemed unsafe for the pur-
7 pose of section 402(a)(2)(B) unless—

8 “(A) a tolerance for such pesticide chemi-
9 cal residue in or on such food is in effect under
10 this section and the concentration of the residue
11 is within the limits of the tolerance; or

12 “(B) an exemption from the requirement
13 of a tolerance is in effect under this section for
14 the pesticide chemical residue.

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

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

1 essed food if the concentration of the pesticide
2 chemical residue in the processed food when
3 ready for consumption or use is not greater
4 than the tolerance prescribed for the pesticide
5 chemical residue in the raw agricultural com-
6 modity.

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

15 “(3) RESIDUES OF DEGRADATION PRODUCTS.—
16 If a pesticide chemical residue is present in or on a
17 food because it is a metabolite or other degradation
18 product of a precursor substance that itself is a pes-
19 ticide chemical or pesticide chemical residue, such a
20 residue shall not be considered to be unsafe within
21 the meaning of section 402(a)(2)(B) despite the lack
22 of a tolerance or exemption from the need for a tol-
23 erance for such residue in or on such food if—

24 “(A) the Administrator has not determined
25 that the degradation product is likely to pose

1 any potential health risk from dietary exposure
2 that is of a different type than, or of a greater
3 significance than, any risk posed by dietary ex-
4 posure to the precursor substance; and

5 “(B) either—

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

16 “(ii) an exemption from the need for
17 a tolerance is in effect under this section
18 for residues of the precursor substance in
19 or on the food; and

20 “(C) the tolerance or exemption for resi-
21 dues of the precursor substance does not state
22 that it applies only to particular named sub-
23 stances or states that it does not apply to resi-
24 dues of the degradation product.

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

9 “(b) AUTHORITY AND STANDARD FOR TOLER-
10 ANCES.—

11 “(1) AUTHORITY.—The Administrator may
12 issue regulations establishing, modifying, or revoking
13 a tolerance for a pesticide chemical residue in or on
14 a food—

15 “(A) in response to a petition filed under
16 subsection (d); or

17 “(B) on the Administrator’s initiative
18 under subsection (e).

19 “(2) STANDARD.—(A) A tolerance may not be
20 established for a pesticide chemical residue in or on
21 a food at a level that is higher than a level that the
22 Administrator determines is adequate to protect the
23 public health.

24 “(B) The Administrator shall modify or revoke
25 a tolerance if it is at a level higher than the level

1 that the Administrator determines is adequate to
2 protect the public health.

3 “(C) In making a determination under this
4 paragraph the Administrator shall take into account,
5 among other relevant factors, the validity, complete-
6 ness, and reliability of the available data from stud-
7 ies of the pesticide chemical residue, the nature of
8 any toxic effects shown to be caused by the pesticide
9 chemical in such studies, available information and
10 reasonable assumptions concerning the relationship
11 of the results of such studies to human risk, avail-
12 able information and reasonable assumptions con-
13 cerning the dietary exposure levels of food consum-
14 ers (and major identifiable subgroups of food con-
15 sumers, including infants and children) to the pes-
16 ticide chemical residue, and available information
17 and reasonable assumptions concerning the varia-
18 bility of the sensitivities of major identifiable groups,
19 including infants and children, and shall consider
20 other factors to the extent required by subparagraph
21 (F).

22 “(D) For purposes of subparagraph (A), a tol-
23 erance level for a pesticide chemical residue in or on
24 a food shall be deemed to be adequate to protect the
25 public health if the dietary risk posed to food con-

1 consumers by such level of the pesticide chemical resi-
2 due is negligible. The Administrator shall by regula-
3 tion set forth the factors and methods, including
4 tests which are appropriate for the determination of
5 dietary risk and most likely dietary exposure, for the
6 determination of negligible dietary risk.

7 “(E) Procedures shall be developed and imple-
8 mented that ensure that pesticide tolerances ade-
9 quately safeguard the health of infants and children.

10 “(F) Where reliable data are available, the Ad-
11 ministrator shall calculate the dietary risk posed to
12 food consumers by a pesticide chemical on the basis
13 of the percent of food actually treated with the pes-
14 ticide chemical and the actual residue levels of the
15 pesticide chemical that occur in food. In particular,
16 the Administrator shall take into account aggregate
17 pesticide use and residue data collected by the De-
18 partment of Agriculture.

19 “(G) For purposes of subparagraph (A), a level
20 of a pesticide chemical residue in or on a food that
21 poses a greater than negligible dietary risk to con-
22 sumers of the food shall be deemed to be adequate
23 to protect the public health if the Administrator de-
24 termines that such risk is not unreasonable
25 because—

1 “(i) use of the pesticide that produces the
2 residue protects humans or the environment
3 from adverse effects on public health or welfare
4 that would, directly or indirectly, result in
5 greater risk to the public or the environment
6 than the dietary risk from the pesticide chemi-
7 cal residue; or

8 “(ii) use of the pesticide avoids risks to
9 workers, the public, or the environment that
10 would be expected to result from the use of an-
11 other pesticide or pest control method on the
12 same food that are considered to be greater
13 than the risks that result from dietary exposure
14 to the pesticide chemical residue; or

15 “(iii) the availability of the pesticide would
16 enable domestic growers to maintain the avail-
17 ability of an adequate, wholesome, and economi-
18 cal food supply for consumers, taking into ac-
19 count national and regional effects.

20 In making the determination under this subpara-
21 graph, the Administrator shall not consider the ef-
22 fects on any pesticide registrant, manufacturer, or
23 marketer of a pesticide.

24 “(3) LIMITATIONS.—(A) A tolerance may be is-
25 sued under the authority of paragraph (2)(E) only

1 if the Administrator has assessed the extent to
2 which efforts are being made to develop either an al-
3 ternative method of pest control or an alternative
4 pesticide chemical for use on such commodity or
5 food that would meet the requirements of paragraph
6 (2)(D).

7 “(B) A tolerance for a pesticide chemical resi-
8 due in or on a food shall not be established by the
9 Administrator unless the Administrator determines,
10 after consultation with the Secretary, that there is
11 a practical method for detecting and measuring the
12 levels of the pesticide chemical residue in or on the
13 food, or that a practical method is unavailable or not
14 feasible.

15 “(C) A tolerance for a pesticide chemical resi-
16 due in or on a food shall not be established at a level
17 lower than the limit of detection of the method for
18 detecting and measuring the pesticide chemical resi-
19 due specified by the Administrator under subpara-
20 graph (B).

21 “(4) INTERNATIONAL STANDARDS.—In estab-
22 lishing a tolerance for a pesticide chemical residue in
23 or on a food, the Administrator shall determine
24 whether a maximum residue level for the chemical
25 has been established by the Codex Alimentarius

1 Commission. If a Codex maximum residue level has
2 been established for the chemical and the Adminis-
3 trator does not propose to adopt the Codex level, the
4 Administrator shall publish for public comment a
5 notice explaining the reasons for departing from the
6 Codex level. If the Administrator determines not to
7 adopt a Codex level, the Administrator shall publish
8 as part of the final tolerance decision a determina-
9 tion with supporting data that the Codex level is not
10 supported by adequate and reliable scientific data,
11 or is inadequate to protect the health of the United
12 States' consumers and that the effect of the toler-
13 ance on the availability to consumers of an adequate,
14 wholesome and economical food supply, does not out-
15 weigh the risk posed by the pesticide residue.

16 “(c) AUTHORITY AND STANDARD FOR EXEMP-
17 TIONS.—

18 “(1) AUTHORITY.—The Administrator may
19 issue a regulation establishing, modifying, or revok-
20 ing an exemption from the requirement for a toler-
21 ance for a pesticide chemical residue in or on a
22 food—

23 “(A) in response to a petition filed under
24 subsection (d); or

1 “(B) on the Administrator’s initiative
2 under subsection (e).

3 “(2) STANDARD.—(A) An exemption from the
4 requirement for a tolerance for a pesticide chemical
5 residue in or on a food may be established only if
6 the Administrator determines that a tolerance is not
7 needed to protect the public health, in view of the
8 levels of dietary exposure to the pesticide chemical
9 residue that could reasonably be expected to occur.

10 “(B) An exemption from the requirement for a
11 tolerance for a pesticide chemical residue in or on a
12 food shall be revoked if the Administrator, in re-
13 sponse to a petition for the revocation of the exemp-
14 tion or at the Administrator’s own initiative deter-
15 mines that the exemption does not satisfy the cri-
16 terion of subparagraph (A).

17 “(C) In making a determination under this
18 paragraph, the Administrator shall take into ac-
19 count, among other relevant factors, the factors set
20 forth in subsection (b)(2)(C).

21 “(3) LIMITATION.—An exemption from the re-
22 quirement for a tolerance for a pesticide chemical
23 residue in or on a food shall not be established by
24 the Administrator unless the Administrator deter-
25 mines, after consultation with the Secretary—

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

4 “(B) that there is no need for such a
5 method, and states the reasons for such deter-
6 mination in the order issuing the regulation es-
7 tablishing or modifying the regulation.

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

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

12 “(A) establishing, modifying, or revoking a
13 tolerance for a pesticide chemical residue in or
14 on a food; or

15 “(B) establishing or revoking an exemption
16 from the requirement of a tolerance for such a
17 residue.

18 “(2) PETITION CONTENTS.—

19 “(A) ESTABLISHMENT.—A petition under
20 paragraph (1) to establish a tolerance or ex-
21 emption for a pesticide chemical residue shall
22 be supported by such data and information as
23 are specified in regulations issued by the Ad-
24 ministrator, including—

1 “(i)(I) an informative summary of the
2 petition and of the data, information, and
3 arguments submitted or cited in support of
4 the petition;

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

12 “(ii) the name, chemical identity, and
13 composition of the pesticide chemical resi-
14 due and of the pesticide chemical that pro-
15 duces the residue;

16 “(iii) data showing the recommended
17 amount, frequency, method, and time of
18 application of that pesticide chemical;

19 “(iv) full reports of tests and inves-
20 tigations made with respect to the safety of
21 the pesticide chemical, including full infor-
22 mation as to the methods and controls
23 used in conducting those tests and inves-
24 tigations;

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

7 “(vi) a practical method for detecting
8 and measuring the levels of the pesticide
9 chemical residue in or on the food, or a
10 statement why such a method is not need-
11 ed;

12 “(vii) practical methods for removing
13 any amount of the residue that would ex-
14 ceed any proposed tolerance;

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

18 “(ix) all relevant data bearing on the
19 physical or other technical effect that the
20 pesticide chemical is intended to have and
21 the quantity of the pesticide chemical that
22 is required to produce the effect;

23 “(x) if the petition relates to a toler-
24 ance for a processed food, reports of inves-

1 tigitations conducted using the processing
2 method(s) used to produce that food;

3 “(xi) such information as the Admin-
4 istrator may require to make the deter-
5 mination under subsection (b)(2)(E); and

6 “(xii) such other data and information
7 as the Administrator requires by regulation
8 to support the petition.

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

17 “(B) MODIFICATION OR REVOCATION.—
18 The Administrator may by regulation establish
19 the requirements for information and data to
20 support a petition to modify or revoke a toler-
21 ance or to revoke an exemption from the re-
22 quirement for a tolerance.

23 “(3) NOTICE.—A notice of the filing of a peti-
24 tion that the Administrator determines has met the
25 requirements of paragraph (2) shall be published by

1 the Administrator within 30 days after such deter-
2 mination. The notice shall announce the availability
3 of a description of the analytical methods available
4 to the Administrator for the detection and measure-
5 ment of the pesticide chemical residue with respect
6 to which the petition is filed or shall set forth the
7 petitioner's statement of why such a method is not
8 needed. The notice shall include the summary re-
9 quired by paragraph (2)(A)(i).

10 “(4) ACTIONS BY THE ADMINISTRATOR.—The
11 Administrator shall, after giving due consideration
12 to a petition filed under paragraph (1) and any
13 other information available to the Administrator—

14 “(A) issue a final regulation (which may
15 vary from that sought by the petition) estab-
16 lishing, modifying, or revoking a tolerance for
17 the pesticide chemical residue or an exemption
18 of the pesticide chemical residue from the re-
19 quirement of a tolerance;

20 “(B) issue a proposed regulation under
21 subsection (e), and thereafter either issue a
22 final regulation under subsection (e) or an
23 order denying the petition; or

24 “(C) issue an order denying the petition.

1 “(5) EFFECTIVE DATE.—A regulation issued
2 under paragraph (4) shall take effect upon publica-
3 tion.

4 “(6) FURTHER PROCEEDINGS.—

5 “(A) Within 60 days after a regulation or
6 order is issued under paragraph (4), subsection
7 (e)(1), or subsection (f)(1), any person may file
8 objections thereto with the Administrator, speci-
9 fying with particularity the provisions of the
10 regulation or order deemed objectionable and
11 stating reasonable grounds therefor. If the reg-
12 ulation or order was issued in response to a pe-
13 tition under paragraph (d)(1), a copy of each
14 objection filed by a person other than the peti-
15 tioner shall be served by the Administrator on
16 the petitioner.

17 “(B) An objection may include a request
18 for a public evidentiary hearing upon the objec-
19 tion. The Administrator shall, upon the initia-
20 tive of the Administrator or upon the request of
21 an interested person and after due notice, hold
22 a public evidentiary hearing if and to the extent
23 the Administrator determines that such a public
24 hearing is necessary to receive factual evidence
25 relevant to material issues of fact raised by the

1 objections. The presiding officer in such a hear-
2 ing may authorize a party to obtain discovery
3 from other persons and may upon a showing of
4 good cause made by a party issue a subpoena
5 to compel testimony or production of documents
6 from any person. The presiding officer shall be
7 governed by the Federal Rules of Civil Proce-
8 dure in making any order for the protection of
9 the witness or the content of documents pro-
10 duced and shall order the payment of a reason-
11 able fees and expenses as a condition to requir-
12 ing testimony of the witness. On contest, such
13 a subpoena may be enforced by a Federal dis-
14 trict court.

15 “(C) As soon as practicable after receiving
16 the arguments of the parties, the Administrator
17 shall issue an order stating the action taken
18 upon each such objection and setting forth any
19 revision to the regulation or prior order that the
20 Administrator has found to be warranted. If a
21 hearing was held under subparagraph (B), such
22 order and any revision to the regulation or prior
23 order shall, with respect to questions of fact at
24 issue in the hearing, be based only on substan-
25 tial evidence of record at such hearing, and

1 shall set forth in detail the findings of facts and
2 the conclusions of law or policy upon which the
3 order or regulation is based.

4 “(D) An order issued under this paragraph
5 ruling on an objection shall not take effect be-
6 fore the 90th day after its publication unless
7 the Administrator finds that emergency condi-
8 tions exist necessitating an earlier effective
9 date, in which event the Administrator shall
10 specify in the order the Administrator’s find-
11 ings as to such conditions.

12 “(7) JUDICIAL REVIEW.—(A) In a case of ac-
13 tual controversy as to the validity of any order is-
14 sued under paragraph (6) or any regulation that is
15 the subject of such an order, any person who will be
16 adversely affected by such order or regulation may
17 obtain judicial review by filing in the United States
18 Court of Appeals for the circuit wherein that person
19 resides or has its principal place of business, or in
20 the United States Court of Appeals for the District
21 of Columbia Circuit, within 60 days after publication
22 of such order, a petition praying that the order or
23 regulation be set aside in whole or in part.

24 “(B) A copy of the petition shall be forthwith
25 transmitted by the clerk of the court to the Adminis-

1 trator, or any officer designated by the Adminis-
2 trator for that purpose, and thereupon the Adminis-
3 trator shall file in the court the record of the pro-
4 ceedings on which the Administrator based the order
5 or regulation, as provided in section 2112 of title 28,
6 United States Code. Upon the filing of such a peti-
7 tion, the court shall have exclusive jurisdiction to af-
8 firm or set aside the order or regulation complained
9 of in whole or in part. The findings of the Adminis-
10 trator with respect to questions of fact shall be sus-
11 tained only if supported by substantial evidence
12 when considered on the record as a whole.

13 “(C) If a party applies to the court for leave to
14 adduce additional evidence, and shows to the satis-
15 faction of the court that the additional evidence is
16 material and that there were reasonable grounds for
17 the failure to adduce the evidence in the proceeding
18 before the Administrator, the court may order that
19 the additional evidence (and evidence in rebuttal
20 thereof) shall be taken before the Administrator in
21 the manner and upon the terms and conditions the
22 court deems proper. The Administrator may modify
23 prior findings as to the facts by reason of the addi-
24 tional evidence so taken and may modify the order
25 or regulation accordingly. The Administrator shall

1 file with the court any such modified finding, order,
2 or regulation.

3 “(D) The judgment of the court affirming or
4 setting aside, in whole or in part, any order under
5 paragraph (6) and any regulation which is the sub-
6 ject of such an order shall be final, subject to review
7 by the Supreme Court of the United States as pro-
8 vided in section 1254 of title 28 of the United States
9 Code. The commencement of proceedings under this
10 paragraph shall not, unless specifically ordered by
11 the court to the contrary, operate as a stay of a reg-
12 ulation or order.

13 “(E) Any issue as to which review is or was ob-
14 tainable under paragraph (6) and this paragraph
15 shall not be the subject of judicial review under any
16 other provision of law.

17 “(e) ACTION ON ADMINISTRATOR’S OWN INITIA-
18 TIVE.—

19 “(1) GENERAL RULE.—The Administrator may
20 issue a regulation—

21 “(A) establishing, modifying, or revoking a
22 tolerance for a pesticide chemical or a pesticide
23 chemical residue;

1 “(B) establishing or revoking an exemption
2 of a pesticide chemical residue from the require-
3 ment of a tolerance; or

4 “(C) establishing general procedures and
5 requirements to implement this section.

6 A regulation issued under this paragraph shall be-
7 come effective upon its publication.

8 “(2) NOTICE.—Before issuing a final regulation
9 under paragraph (1), the Administrator shall issue
10 a notice of proposed rulemaking and provide a pe-
11 riod of not less than 60 days for public comment on
12 the proposed regulation, except that a shorter period
13 for comment may be provided if the Administrator
14 for good cause finds that it would be contrary to the
15 public interest to do so and states the reasons for
16 the finding in the notice of proposed rulemaking.
17 The Administrator shall provide an opportunity for
18 a public hearing during the rulemaking under proce-
19 dures provided in subsection (d)(6)(B).

20 “(f) SPECIAL DATA REQUIREMENTS.—

21 “(1) REQUIRING SUBMISSION OF ADDITIONAL
22 DATA.—If the Administrator determines that addi-
23 tional data or information are reasonably required to
24 support the continuation of a tolerance or exemption
25 that is in effect under this section for a pesticide

1 chemical residue on a food, the Administrator
2 shall—

3 “(A) issue a notice requiring the persons
4 holding the pesticide registrations associated
5 with such tolerance or exemption to submit the
6 data or information under section 3(c)(2)(B) of
7 the Federal Insecticide, Fungicide, and
8 Rodenticide Act;

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

12 “(C) publish in the Federal Register, after
13 first providing notice and an opportunity for
14 comment of not less than 90 days’ duration, an
15 order—

16 “(i) requiring the submission to the
17 Administrator by one or more interested
18 persons of a notice identifying the person
19 or persons who will submit the required
20 data and information;

21 “(ii) describing the type of data and
22 information requiring to be submitted to
23 the Administrator and stating why the
24 data and information could not be obtained
25 under the authority of section 3(c)(2)(B)

1 of the Federal Insecticide, Fungicide, and
2 Rodenticide Act or section 4 of the Toxic
3 Substances Control Act;

4 “(iii) describing the reports of the Ad-
5 ministrator required to be prepared during
6 and after the collection of the data and in-
7 formation;

8 “(iv) requiring the submission to the
9 Administrator of the data, information,
10 and reports referred to in clauses (ii) and
11 (iii); and

12 “(v) establishing dates by which the
13 submissions described in clauses (i) and
14 (iv) must be made.

15 The Administrator may revise any such order
16 to correct an error.

17 “(2) NONCOMPLIANCE.—If a submission re-
18 quired by a notice issued in accordance with para-
19 graph (1)(A) or an order issued under paragraph
20 (1)(B) is not made by the time specified in such no-
21 tice or order, the Administrator may by order pub-
22 lished in the Federal Register modify or revoke the
23 tolerance or exemption in question.

24 “(3) REVIEW.—An order issued under this subsection
25 shall be effective upon publication and shall be subject to

1 review in accordance with paragraphs (6) and (7) of sub-
2 section (d).

3 “(g) CONFIDENTIALITY AND USE OF DATA.—

4 “(1) GENERAL RULE.—Data and information
5 that are submitted to the Administrator under this
6 section in support of a tolerance or an exemption
7 from a tolerance shall be entitled to confidential
8 treatment for reasons of business confidentiality and
9 to exclusive use and data compensation, to the same
10 extent provided by sections 3 and 10 of the Federal
11 Insecticide, Fungicide, and Rodenticide Act.

12 “(2) EXCEPTIONS.—Data that are entitled to
13 confidential treatment under paragraph (1) may
14 nonetheless be disclosed to the Congress of the
15 United States, and may be disclosed, under such se-
16 curity requirements as the Administrator may pro-
17 vide by regulation, to—

18 “(A) employees of the United States au-
19 thorized by the Administrator to examine such
20 data in the carrying out of their official duties
21 under this Act or other Federal statutes in-
22 tended to protect the public health; or

23 “(B) contractors with the United States
24 authorized by the Administrator to examine

1 such data in the carrying out of contracts under
2 such statutes.

3 “(3) SUMMARIES.—Notwithstanding any provi-
4 sion of this subsection or other law, the Adminis-
5 trator may publish the informative summary re-
6 quired by subsection (d)(2)(A)(i) and may, in issu-
7 ing a proposed or final regulation or order under
8 this section, publish an informative summary of the
9 data relating to the regulation or order.

10 “(h) STATUS OF PREVIOUSLY ISSUED REGULA-
11 TIONS.—

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

21 “(2) REGULATIONS UNDER SECTION 409.—Reg-
22 ulations that established tolerances for substances
23 that are pesticide chemical residues on or in proc-
24 essed food, or that otherwise stated the conditions
25 under which such pesticide chemicals could be safely

1 used, and that were issued under section 409 on or
2 before the date of the enactment of this paragraph,
3 shall be deemed to be regulations issued under this
4 section and shall be subject to modification or rev-
5 ocation under subsection (d) or (e).

6 “(3) REGULATIONS UNDER SECTION 408.—Reg-
7 ulations that established tolerances or exemptions
8 under this section that were issued on or before the
9 date of the enactment of this paragraph shall remain
10 in effect unless modified or revoked under subsection
11 (d) or (e).

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

17 “(1) regarded by the Administrator or the Sec-
18 retary as generally recognized as safe for use within
19 the meaning of the provisions of section 408(a) or
20 201(s) as then in effect; or

21 “(2) regarded by the Secretary as a substance
22 described by section 201(s)(4), such a pesticide
23 chemical residue shall be regarded as exempt from
24 the requirement for a tolerance, as of the date of en-
25 actment of this subsection. The Administrator shall

1 by regulation indicate which substances are de-
2 scribed by this subsection. All exemption under this
3 subsection may be revoked or modified as if it had
4 been issued under subsection (c).

5 “(j) HARMONIZATION WITH ACTION UNDER OTHER
6 LAWS.—

7 “(1) LIMITATION.—Notwithstanding any other
8 provision of this Act, a final rule under this section
9 that revokes, modifies, or suspends a tolerance or
10 exemption for a pesticide chemical residue in or on
11 a food may be issued only if the Administrator has
12 first taken any necessary action under the Federal
13 Insecticide, Fungicide, and Rodenticide Act with re-
14 spect to the registration of the pesticide(s) whose
15 use results in such residue to ensure that any au-
16 thorized use of the pesticide in producing, storing,
17 processing, or transporting food that occurs after
18 the issuance of such final rule under this section will
19 not result in pesticide chemical residues on such
20 food that are unsafe within the meaning of sub-
21 section (a).

22 “(2) REVOCATION OF TOLERANCE OR EXEMP-
23 TION FOLLOWING CANCELLATION OF ASSOCIATED
24 REGISTRATIONS.—If the Administrator, acting under
25 the Federal Insecticide, Fungicide, and Rodenticide

1 Act, cancels the registration of each pesticide that
2 contains a particular pesticide chemical and that is
3 labeled for use on a particular food, or requires that
4 the registration of each such pesticide be modified to
5 prohibit its use in connection with the production,
6 storage, or transportation of such food, due in whole
7 or in part to dietary risks to humans posed by resi-
8 dues of that pesticide chemical on that food, the Ad-
9 ministrator shall revoke any tolerance or exemption
10 that allows the presence of the pesticide chemical, or
11 any pesticide chemical residue that results from its
12 use, in or on that food. The Administrator shall use
13 the procedures set forth in subsection (e) in taking
14 action under this paragraph. A revocation under this
15 paragraph shall become effective not later than 180
16 days after—

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

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

22 “(3) SUSPENSION OF TOLERANCE OR EXEMP-
23 TION FOLLOWING SUSPENSION OF ASSOCIATED REG-
24 ISTRATIONS.—

1 “(A) SUSPENSION.—If the Administrator,
2 acting under the Federal Insecticide, Fungicide,
3 and Rodenticide Act, suspends the use of each
4 registered pesticide that contains a particular
5 pesticide chemical and that is labeled for use on
6 a particular food, due in whole or in part to die-
7 tary risks to humans posed by residues of that
8 pesticide chemical on that food, the Adminis-
9 trator shall suspend any tolerance or exemption
10 that allows the presence of the pesticide chemi-
11 cal, or any pesticide chemical residue that re-
12 sults from its use, in or on that food. The Ad-
13 ministrator shall use the procedures set forth
14 in subsection (e) in taking action under this
15 paragraph. A suspension under this paragraph
16 shall become effective not later than 60 days
17 after the date by which each such suspension
18 of use has become effective.

19 “(B) EFFECT OF SUSPENSION.—The sus-
20 pension of a tolerance or exemption under sub-
21 paragraph (A) shall be effective as long as the
22 use of each associated registration of a pesticide
23 is suspended under the Federal Insecticide,
24 Fungicide, and Rodenticide Act. While a sus-
25 pension of a tolerance or exemption is effective

1 the tolerance or exemption shall not be consid-
2 ered to be in effect. If the suspension of use of
3 the pesticide under that Act is terminated, leav-
4 ing the registration of the pesticide for such use
5 in effect under that Act, the Administrator
6 shall rescind any associated suspension of toler-
7 ance or exemption.

8 “(4) TOLERANCES FOR UNAVOIDABLE RESI-
9 DUES.—In connection with action taken under para-
10 graph (2) or (3), or with respect to pesticides whose
11 registrations were canceled prior to the effective date
12 of this paragraph, if the Administrator determines
13 that a residue of the canceled or suspended pesticide
14 chemical will unavoidably persist in the environment
15 and thereby be present in or on a food, the Adminis-
16 trator may establish a tolerance for the pesticide
17 chemical residue at a level that permits such un-
18 avoidable residue to remain in such food. In estab-
19 lishing such a tolerance, the Administrator shall
20 take into account the factors set forth in subsection
21 (b)(2)(A)(iii) and shall use the procedures set forth
22 in subsection (e). The Administrator shall review
23 any such tolerance periodically and modify it as nec-
24 essary so that it allows only that level of the pes-
25 ticide chemical residue that is unavoidable.

1 “(5) PESTICIDE RESIDUES RESULTING FROM
2 LAWFUL APPLICATION OF PESTICIDE.—Notwith-
3 standing any other provision of this Act, if a toler-
4 ance or exemption for a pesticide chemical residue in
5 or on a food has been revoked, suspended, or modi-
6 fied under this section, an article of that food shall
7 not be deemed unsafe solely because of the presence
8 of such pesticide chemical residue in or on such food
9 if it is shown to the satisfaction of the Secretary
10 that—

11 “(A) the residue is present as the result of
12 an application or use of a pesticide at a time
13 and in a manner that was lawful under the
14 Federal Insecticide, Fungicide, and Rodenticide
15 Act; and

16 “(B) the residue does not exceed a level
17 that was authorized at the time of that applica-
18 tion or use to be present on the food under a
19 tolerance, exemption, food additive regulation,
20 or other sanction then in effect under this Act;
21 unless, in the case of any tolerance or exemption re-
22 voked, suspended, or modified under this subsection
23 or subsection (d) or (e), the Administrator has is-
24 sued a determination that consumption of the legally
25 treated food during the period of its likely availabil-

1 ity in commerce will pose an unreasonable dietary
2 risk.

3 “(k) FEES.—The Administrator shall by regulation
4 require the payment of such fees as will in the aggregate,
5 in the judgment of the Administrator, be sufficient over
6 a reasonable term to provide, equip, and maintain an ade-
7 quate service for the performance of the Administrator’s
8 functions under this section. Under the regulations, the
9 performance of the Administrator’s services or other func-
10 tions under this section, including—

11 “(1) the acceptance for filing of a petition sub-
12 mitted under subsection (d);

13 “(2) the promulgation of a regulation establish-
14 ing, modifying, or revoking a tolerance or establish-
15 ing or revoking an exemption from the requirement
16 of a tolerance under this section;

17 “(3) the acceptance for filing of objections
18 under subsection (d)(6); or

19 “(4) the certification and filing in court of a
20 transcript of the proceedings and the record under
21 subsection (d)(7);

22 may be conditioned upon the payment of such fees. The
23 regulations may further provide for waiver or refund of
24 fees in whole or in part when in the judgment of the Ad-

1 administrator such a waiver or refund is equitable and not
2 contrary to the purposes of this subsection.

3 “(I) NATIONAL UNIFORMITY OF TOLERANCES.—

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

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

19 “(B) was approved for such use in a rereg-
20 istration eligibility determination issued under
21 section 4(g) of that Act on or after the date of
22 enactment of the Food Quality Protection Act
23 of 1995.

1 “(2) QUALIFYING FEDERAL DETERMINATION.—
2 For purposes of this subsection, the term ‘qualifying
3 Federal determination’ means—

4 “(A) a tolerance or exemption from the re-
5 quirement for a tolerance for a qualifying pes-
6 ticide chemical residue that was—

7 “(i) issued under this section after the
8 date of enactment of the Food Quality
9 Protection Act of 1995; (or)

10 “(ii) issued (or, pursuant to sub-
11 section (h) or (i), deemed to have been is-
12 sued) under this section, and determined
13 by the Administrator to meet the standard
14 under subsection (b)(2) (in the case of a
15 tolerance) or (c)(2) (in the case of an ex-
16 emption); and

17 “(B) any statement, issued by the Sec-
18 retary, of the residue level below which enforce-
19 ment action will not be taken under this Act
20 with respect to any qualifying pesticide chemi-
21 cal residue, if the Secretary finds that such pes-
22 ticide chemical residue level permitted by such
23 statement during the period to which such
24 statement applies protects human health.

1 “(3) LIMITATION.—The Administrator may
2 make the determination described in paragraph
3 (2)(A)(ii) only by issuing a rule in accordance with
4 the procedure set forth in subsection (d) or (e) and
5 only if the Administrator issues a proposed rule and
6 allows a period of not less than 30 days for comment
7 on the proposed rule. Any such rule shall be
8 reviewable in accordance with subsections (d)(6) and
9 (d)(7).

10 “(4) STATE AUTHORITY.—Except as provided
11 in paragraph (5), no State or political subdivision
12 may establish or enforce any regulatory limit on a
13 qualifying pesticide chemical residue in or on any
14 food if a qualifying Federal determination applies to
15 the presence of such pesticide chemical residue in or
16 on such food, unless such State regulatory limit is
17 identical to such qualifying Federal determination. A
18 State or political subdivision shall be deemed to es-
19 tablish or enforce a regulatory limit on a pesticide
20 chemical residue in or on food if it purports to pro-
21 hibit or penalize the production, processing, ship-
22 ping, or other handling of a food because it contains
23 a pesticide residue (in excess of a prescribed limit),
24 or if it purports to require that a food containing a
25 pesticide residue be the subject of a warning or

1 other statement relating to the presence of the pes-
2 ticide residue in the food.

3 “(5) PETITION PROCEDURE.—

4 “(A) Any State may petition the Adminis-
5 trator for authorization to establish in such
6 State a regulatory limit on a qualifying pes-
7 ticide chemical residue in or on any food that
8 is not identical to the qualifying Federal deter-
9 mination applicable to such qualifying pesticide
10 chemical residue.

11 “(B) Any petition under subparagraph (A)
12 shall—

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

15 “(ii) be supported by scientific data
16 about the pesticide chemical residue that is
17 the subject of the petition or about chemi-
18 cally related pesticide chemical residues,
19 data on the consumption within such State
20 of food bearing the pesticide chemical resi-
21 due, and data on exposure of humans with-
22 in such State to the pesticide chemical res-
23 idue.

24 “(C) Subject to paragraph (6), the Admin-
25 istrator may, by order, grant the authorization

1 described in subparagraph (A) if the Adminis-
2 trator determines that the proposed State regu-
3 latory limit—

4 “(i) is justified by compelling local
5 conditions;

6 “(ii) would not unduly burden inter-
7 state commerce; and

8 “(iii) would not cause any food to be
9 in violation of Federal law.

10 “(D) In lieu of any action authorized
11 under subparagraph (C), the Administrator
12 may treat a petition under this paragraph as a
13 petition under subsection (d) to revoke or mod-
14 ify a tolerance or to revoke an exemption. If the
15 Administrator determines to treat a petition
16 under this paragraph as a petition under sub-
17 section (d), the Administrator shall thereafter
18 act on the petition pursuant to subsection (d).

19 “(E) Any order of the Administrator
20 granting or denying the authorization described
21 in subparagraph (A) shall be subject to review
22 in the manner described in subsections (d)(6)
23 and (d)(7).

24 “(6) RESIDUES FROM LAWFUL APPLICATION.—

25 No State or political subdivision may enforce any

1 regulatory limit on the level of a pesticide chemical
 2 residue that may appear in or on any food if, at the
 3 time of the application of the pesticide that resulted
 4 in such residue, the sale of such food with such resi-
 5 due level was lawful under this Act and under the
 6 law of such State, unless the State demonstrates
 7 that consumption of the food containing such pes-
 8 ticide residue level during the period of the food's
 9 likely availability in the State will pose an unreason-
 10 able dietary risk to the health of persons within such
 11 State.”.

12 **SEC. 406. AUTHORIZATION FOR INCREASE MONITORING.**

13 There is authorized to be appropriated an additional
 14 \$12,000,000 for increased monitoring by the Secretary of
 15 Health and Human Services of pesticide residues in im-
 16 ported and domestic food.

○

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