

103D 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

APRIL 1, 1993

Mr. LEHMAN (for himself, Mr. BLILEY, Mr. ROWLAND, Mr. SMITH of Oregon, Mr. ROBERTS, Mr. PENNY, Mr. ENGLISH of Oklahoma, Mr. HOLDEN, Mr. EMERSON, Mr. KINGSTON, Mr. SARPALIUS, Mr. EWING, Mr. DOOLEY, Mr. JOHNSON of South Dakota, Mr. BARRETT of Nebraska, Mr. BOEHNER, Mr. COMBEST, Mr. DOOLITTLE, Mr. CONDIT, Mr. BISHOP, Mr. GUNDERSON, Mr. POMEROY, Mr. ALLARD, Mr. TOWNS, Mr. COOPER, Mr. HALL of Texas, Mr. McMILLAN, Mr. HASTERT, Mr. UPTON, Mr. PAXON, Mr. KLUG, Mr. FRANKS of Connecticut, Mr. MANTON, Mr. BOUCHER, Mr. CRAPO, Mr. BARTON of Texas, Mr. GILLMOR, Mr. OXLEY, Mr. TAUZIN, and Mr. MOOREHEAD) introduced the following bill; which was referred jointly to the Committees on Agriculture and Energy and Commerce

AUGUST 18, 1993

Additional sponsors: Mr. JOHNSON of Georgia, Mr. PARKER, Mr. DARDEN, Mr. LIPINSKI, Mr. STUMP, Mr. HANCOCK, Mr. BEREUTER, Mr. WALSH, Mr. DORNAN, Mr. BATEMAN, Mr. HUGHES, Mr. SMITH of Michigan, Mr. HERGER, Mr. BAKER of Louisiana, Mr. PAYNE of Virginia, Mr. INHOFE, Mr. COBLE, Mr. SUNDQUIST, Mr. RAVENEL, Mr. POMBO, Mr. SISISKY, Mr. WISE, Mr. LAROCO, Mr. CAMP, Mr. CANADY, Mr. WALKER, Mr. ROTH, Mr. HOUGHTON, Mr. COLEMAN, Mr. STEARNS, Mr. THOMAS of Wyoming, Mr. HEFNER, Mr. MCCRERY, Ms. DANNER, Mr. GOODLING, Mr. MCDADE, Mr. VALENTINE, Mr. BURTON of Indiana, Mr. DREIER, Mr. LEWIS of Florida, Mr. CLYBURN, Mr. GEKAS, Mr. DEAL, Mr. KANJORSKI, Mr. GINGRICH, Mr. SHUSTER, Mr. GRAMS, Mr. TAYLOR of North Carolina, Mr. TRAFICANT, Mr. SCHAEFER, Mr. GALLEGLY, Mr. HUTCHINSON, Mr. ANDREWS of New Jersey, Mr. PETERSON of Minnesota, Ms. DUNN, Mr. GALLO, Mr. BALLENGER, Mr. ZELIFF, Mr. GOODLATTE, Mr. BAKER of California, Mr. ARMEY, Mr. BREWSTER, Mr. PETERSON of Florida, Mr. HANSEN, Mrs. LLOYD, Mr. SOLOMON, Mr. NEAL of North Carolina, Mr. BONILLA, Mr. GONZALEZ, Mr. GUTIERREZ, Mr. COLLINS

of Georgia, Mr. DUNCAN, Mr. COX, Mr. LIGHTFOOT, Ms. KAPTUR, Mr. YOUNG of Alaska, Mr. GILCHREST, and Mr. FAZIO

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 1993”.

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:

1 “(b) CANCELLATION AND CHANGE IN CLASSIFICA-
2 TION OR OTHER TERMS OR CONDITIONS OF REGISTRA-
3 TION.—

4 “(1) AUTHORITY.—Notwithstanding any other
5 provision of this Act, the Administrator may, by use
6 of informal rulemaking under this subsection, pre-
7 scribe requirements regarding the composition, pack-
8 aging, and labeling of a pesticide (or a group of pes-
9 ticides containing a common active or inert ingredi-
10 ent), or may classify any such pesticide, or may pro-
11 hibit the registration or continued registration of
12 any such pesticide for some or all purposes, to the
13 extent necessary to assure that the pesticide, when
14 used in accordance with widespread and commonly
15 recognized practice, does not generally cause unrea-
16 sonable adverse effects on the environment.

17 “(2) BASIS FOR RULE.—

18 “(A) The Administrator may not initiate a
19 rulemaking under this subsection unless the
20 rulemaking is based on a validated test or other
21 significant evidence raising prudent concerns of
22 unreasonable adverse effects to man or to the
23 environment.

24 “(B)(i) The Administrator shall submit to
25 a scientific peer review committee established

1 by the Administrator the validated test or other
2 significant evidence upon which the Adminis-
3 trator proposes to base a rulemaking under
4 paragraph (1).

5 “(ii) The scientific peer review committee
6 shall provide written recommendations to the
7 Administrator as to whether the test or evi-
8 dence reviewed satisfies the criteria under para-
9 graph (1) for initiating a rulemaking under
10 paragraph (1).

11 “(iii) The scientific peer review committee
12 shall consist of employees of or consultants to
13 the Environmental Protection Agency who have
14 not been involved in any previous analysis of
15 the validated test or significant evidence pre-
16 sented to the committee and who are expert in
17 the physical or biological disciplines involved in
18 the proposed rulemaking.

19 “(3) PRENOTICE PROCEDURES.—

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.

19 “(4) ADVANCE NOTICE TO PUBLIC.—

20 “(A) The Administrator after receiving the
21 recommendation of the peer review committee
22 established under paragraph (2)(B) together
23 with any comments submitted by the Secretary
24 of Agriculture, the Secretary of Health and

1 Human Services, and any registrant shall ei-
2 ther—

3 “(i) issue an advance notice of pro-
4 posed rulemaking, or

5 “(ii) issue a notice of a proposed deci-
6 sion not to initiate a rulemaking under
7 paragraph (1).

8 “(B) The Administrator shall publish such
9 notice in the Federal Register and provide a pe-
10 riod of not less than 60 days for comment
11 thereon. The notice shall contain a statement of
12 its basis and purpose, which shall include a
13 summary of—

14 “(i) the factual data on which the no-
15 tice is based,

16 “(ii) the major scientific assumptions
17 underlying the notice, and

18 “(iii) a summary of the notice under
19 paragraph (3) and any significant com-
20 ments received from any registrant, the
21 Secretary of Agriculture, and the Secretary
22 of Health and Human Services.

23 “(C) If the Administrator, after consider-
24 ing any comments received, decides not to issue
25 a notice of proposed rulemaking, the Adminis-

1 trator shall publish in the Federal Register a
2 notice setting forth the decision and its basis.

3 “(5) 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 any notice issued under
7 paragraph (4), of the notice of proposed rulemaking
8 under paragraph (6), of each timely comment filed
9 with the Administrator, of the report of the Sci-
10 entific Advisory Panel under paragraph (8), of a
11 record of each hearing held by the Administrator in
12 connection with the rulemaking, and of the final rule
13 or decision to withdraw the rule. Information in the
14 docket shall be made available to the public consist-
15 ent with the requirements of section 10. No factual
16 material that has not been entered into the docket
17 in a timely manner may be relied upon by the Ad-
18 ministrator in issuing a final rule or in withdrawing
19 a proposed rule or by any person in a judicial review
20 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 “(6) NOTICE OF PROPOSED RULEMAKING.—

1 “(A) Not less than 60 days after an ad-
2 vance notice of proposed rulemaking, except as
3 provided in paragraph (14), the Administrator
4 may issue a notice of proposed rulemaking. The
5 notice of proposed rulemaking shall include a
6 statement of its basis and purpose, a request
7 for any additional data needed, and a bibliog-
8 raphy of all significant scientific data and stud-
9 ies on which the proposed rule is based. The
10 statement of basis and purpose shall include a
11 summary of—

12 “(i) the factual data on which the pro-
13 posed rule is based,

14 “(ii) the major scientific assumptions,
15 legal interpretations, and policy consider-
16 ations underlying the proposed rule,

17 “(iii) a summary of available risk-ben-
18 efit information, including benefits and use
19 information as provided by the Secretary
20 of Agriculture, and

21 “(iv) the Administrator’s analysis and
22 tentative conclusions regarding the bal-
23 ancing of such risks and benefits.

24 “(B) Registrants of the pesticide and any
25 person who submits comments on the proposed

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

18 “(C) The Administrator shall provide a
19 comment period of not less than 90 days after
20 the publication of the notice of proposed rule-
21 making. During such period any person may
22 submit comments, data, or documentary infor-
23 mation on the proposed rule. Promptly upon re-
24 ceipt by the Administrator, all written com-
25 ments and documentary information on the pro-

1 posed rule received from any person for inclu-
2 sion in the docket during the comment period,
3 shall be placed in the docket.

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

22 “(7) INFORMAL HEARING.—

23 “(A) Any person who has submitted a
24 comment may, not later than 15 days after the
25 close of the comment period, request of the Ad-

1 administrator an informal hearing on questions of
2 fact pertaining to the proposed rule or com-
3 ments thereon. Upon such request, the Admin-
4 istrator shall schedule an informal hearing not
5 to exceed 20 days duration, and to conduct not
6 later than 60 days after the close of the com-
7 ment period. The Administrator shall announce
8 the time, place, and purpose of the hearing in
9 the Federal Register. The informal hearing
10 shall be limited to addressing questions of fact
11 raised by materials in the docket. A transcript
12 shall be made of any oral presentation, discus-
13 sion, or debate and included in the docket.

14 “(B) The Administrator shall appoint a
15 presiding officer who shall have the authority to
16 administer oaths, regulate the course of the
17 hearing, conduct prehearing conferences, sched-
18 ule presentations, and exclude irrelevant, immat-
19 erial, or unduly repetitious evidence.

20 “(C) The presiding officer shall conduct
21 the informal hearing in a manner that encour-
22 ages discussion and debate on questions of fact
23 regarding the docket. The Administrator shall
24 designate one or more employees of the Envi-
25 ronmental Protection Agency to participate in

1 the hearing. Any person who submitted a com-
2 ment on the proposed rule may participate in
3 the hearing and shall be entitled to present evi-
4 dence and argument to support the partici-
5 pant’s position or rebut a contrary position and
6 may choose to present materials in oral or writ-
7 ten form.

8 “(8) REVIEW BY SCIENTIFIC ADVISORY
9 PANEL.—At the time the Administrator issues a no-
10 tice of proposed rulemaking under paragraph (6),
11 the Administrator shall provide a copy of such notice
12 to the Scientific Advisory Panel established under
13 section 25(d). If any person submits comments
14 under paragraph (6) in opposition to the proposed
15 rule, the Administrator shall request the comments,
16 evaluations, and recommendations of the Panel as to
17 the impact on health and the environment of the
18 proposed rule and on any disputed issues of fact or
19 scientific policy that appear to be of significance in
20 the rulemaking. The Panel may hold a public hear-
21 ing to discuss the proposed rule. The Panel shall
22 provide a report to the Administrator not later than
23 30 days after the close of comment period (or, if a
24 hearing has been requested under paragraph (7), not
25 later than 30 days after the end of such hearing).

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

5 “(9) FINAL ACTION.—After considering all ma-
6 terial in the docket, the Administrator shall publish
7 in the Federal Register either a final rule or a with-
8 drawal of the proposed rule. The Administrator may
9 not prohibit a use of a pesticide if alternative re-
10 quirements will assure that the pesticide, when used
11 in accordance with widespread and commonly recog-
12 nized practice, will not generally cause unreasonable
13 adverse effects on the environment. In taking any
14 final action, the Administrator shall take into ac-
15 count the impact of the action on production and
16 prices of agricultural commodities, retail food prices,
17 and otherwise on agricultural economy. The final
18 rule or withdrawal of the proposal shall be accom-
19 panied by a statement that—

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

21 “(B) responds to any comments made by
22 the Secretary of Agriculture or the Secretary of
23 Health and Human Services, and responds to
24 any report of the Scientific Advisory Panel;

1 “(C) responds to each significant comment
2 contained in the docket; and

3 “(D) in the case of a final rule—

4 “(i) explains the reasons for any
5 major differences between the final rule
6 and the proposed rule;

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

11 “(iii) explains any significant dis-
12 agreements the Administrator may have
13 with the comments, evaluations, or rec-
14 ommendations contained in the report
15 under paragraph (8) or the benefits and
16 use information described in paragraph
17 (6)(A)(iii) and analysis in paragraph
18 (6)(D) as it bears on the final rule.

19 A final rule issued under this subsection shall be ef-
20 fective upon the date of its publication in the Fed-
21 eral Register.

22 “(10) MODIFICATION OR CANCELLATION.—

23 “(A) A final rule shall state any require-
24 ments, classifications, or prohibitions imposed
25 by the rule, and shall state that each affected

1 registrant shall have a 30-day period from the
2 date of publication of the rule in the Federal
3 Register to apply for an amendment to the reg-
4 istration to comply with the rule or to request
5 voluntary cancellation of the registration. How-
6 ever, if the rule unconditionally prohibits all
7 uses of a pesticide, the rule may provide that
8 cancellation of the registration of the pesticide
9 is effective upon publication of the rule. The
10 final rule may prohibit or limit distribution or
11 sale by the registrant of the affected pesticide
12 to any other person in any State during such
13 30-day period.

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

23 “(11) DENIAL OF APPLICATIONS.—Notwith-
24 standing any other provision of this Act, no applica-
25 tion for initial or amended registration of any pes-

1 ticide under section 3 or 24(c) may be approved if
2 the registration would be inconsistent with a rule in
3 effect under this subsection.

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

1 tion shall be judicially reviewable as provided in
2 paragraph (13).

3 “(13) JUDICIAL REVIEW.—A decision not to
4 initiate a rulemaking published under paragraph (4),
5 a final rule or a withdrawal of a proposed rule pub-
6 lished under paragraph (9) or a denial of a petition
7 under paragraph (12) shall be judicially reviewable
8 in the manner specified by section 16(b)(2).

9 “(14) EXCEPTION TO REQUIREMENTS.—If the
10 Administrator finds it necessary to issue a suspen-
11 sion order under subsection (c), the Administrator
12 may waive the requirements of paragraphs (3) and
13 (4) of this subsection.”.

14 **SEC. 103. PESTICIDES IN REVIEW.**

15 If the Administrator, on or before January 1, 1993,
16 has published a document instituting a special review pro-
17 ceeding or public interim administrative review proceeding
18 with respect to a particular pesticide or active ingredient
19 thereof, the Administrator may, in lieu of proceeding
20 under section 6(b) of the Federal Insecticide, Fungicide,
21 and Rodenticide Act as amended by the Food Quality Pro-
22 tection Act of 1993, elect to continue such review proceed-
23 ing and, upon its completion, take action as warranted in
24 accordance with sections 3(c)(6), 6(b), and 6(d) as those

1 sections were in effect on the day before the date of enact-
2 ment of the Food Quality Protection Act of 1993.

3 **SEC. 104. SUSPENSION.**

4 (a) SECTION 6(c)(1).—The second sentence of sec-
5 tion 6(c)(1) (7 U.S.C. 136d(c)(1)) is revised to read: “Ex-
6 cept as provided in paragraph (3), no order of suspension
7 may be issued under this subsection unless the Adminis-
8 trator has issued, or at the same time issues, a proposed
9 rule under subsection (b).”.

10 (b) SECTION 6(c)(3).—Section 6(c)(3) (7 U.S.C.
11 136d(c)(1)) is amended by inserting after the first sen-
12 tence the following new sentence: “The Administrator may
13 issue an emergency order under this paragraph before is-
14 suing a proposed rule under subsection (b), provided that
15 the Administrator shall proceed expeditiously to issue a
16 proposed rule.”.

17 **SEC. 105. TOLERANCE REEVALUATION AS PART OF**
18 **REREGISTRATION.**

19 Section 4(g) (7 U.S.C. 136b(g)) is amended in para-
20 graph (2) by adding at the end the following:

21 “(E) As soon as the Administrator has
22 sufficient information with respect to the die-
23 tary risk of a particular active ingredient, but
24 in any event no later than the time the Admin-
25 istrator makes a determination under subpara-

1 graph (C) or (D) with respect to pesticides con-
2 taining a particular active ingredient, the Ad-
3 ministrator shall—

4 “(i) reassess each associated tolerance
5 and exemption from the requirement for a
6 tolerance issued under section 408 of the
7 Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 346a),

9 “(ii) determine whether such tolerance
10 or exemption meets the requirements of
11 that Act,

12 “(iii) determine whether additional
13 tolerances or exemptions should be issued,

14 “(iv) publish in the Federal Register a
15 notice setting forth the determinations
16 made under this subparagraph, and

17 “(v) commence promptly such pro-
18 ceedings under this Act and section 408 of
19 the Federal Food, Drug, and Cosmetic Act
20 as are warranted by such determinations.”.

21 **SEC. 106. SCIENTIFIC ADVISORY PANEL.**

22 The first sentence of section 25(d) (7 U.S.C.
23 136w(d)) is amended by striking out “The Administrator
24 shall” and inserting in lieu thereof “(1) IN GENERAL.—

1 The Administrator shall” and such section is amended by
2 adding at the end the following:

3 “(2) SCIENCE REVIEW BOARD.—There is estab-
4 lished a Science Review Board to consist of 60 sci-
5 entists who shall be available to the Scientific Advi-
6 sory Panel to assist in reviews conducted by the
7 Panel. The Scientific Advisory Panel shall select the
8 scientists from 60 nominations submitted each by
9 the National Science Foundation and the National
10 Institutes of Health. Members of the Board shall be
11 compensated in the same manner as members of the
12 Panel.”.

13 **SEC. 107. CONFORMING AMENDMENTS.**

14 (a) SECTION 3(c)(6).—Section 3(c)(6) (7 U.S.C.
15 136a(c)(6)) is amended to read as follows:

16 “(6) DENIAL OF APPLICATION FOR REGISTRA-
17 TION.—

18 “(A) Except as provided in subparagraph
19 (B), if the Administrator proposes to deny an
20 application for registration because it does not
21 satisfy the requirements of paragraph (5), the
22 Administrator shall notify the applicant of the
23 proposal and the reasons (including the factual
24 basis thereof). Unless the applicant makes the
25 necessary corrections to the application and no-

1 tifies the Administrator thereof during the 30-
2 day period beginning with the day after the
3 date the applicant receives the notice, or during
4 that time the applicant submits a request for a
5 hearing, the Administrator may issue an order
6 denying the application. If during that time the
7 Administrator does not receive such corrections
8 to the application or such a request for hearing,
9 the Administrator may issue an order denying
10 the application. Such an order shall be pub-
11 lished in the Federal Register and shall not be
12 subject to judicial review. If during that time
13 the Administrator receives a request for a hear-
14 ing, a hearing shall be conducted under section
15 6(d) of the Act. If such a hearing is held, a de-
16 cision after completion of such hearing shall be
17 final and shall be subject to judicial review
18 under section 16(b)(1) of this Act.

19 “(B) The Administrator may deny an ap-
20 plication for registration because it does not
21 comply with the requirements of a rule issued
22 under section 6(b) of this Act. The Adminis-
23 trator shall notify the applicant of such denial.
24 Such notice shall explain why the application
25 does not comply with such requirements and

1 shall state that the applicant may petition to
2 amend or revoke such rule under section
3 6(b)(12) of this Act.”.

4 (b) SECTION 3(c)(8).—Section 3(c)(8) (7 U.S.C.
5 136a(c)(8)) is repealed.

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

8 (1) in paragraph (1)(A), by striking out “on the
9 initial classification and registered pesticides” and
10 inserting in lieu thereof “under section 6(b) of this
11 Act. Registered pesticides”; and

12 (2) in paragraph (2), by striking out all that
13 follows “on the environment,” and inserting in lieu
14 thereof “the Administrator may initiate a proceeding
15 under section 6(b) of the Act.”.

16 (d) SECTION 4(e).—Section 4(e)(3)(B)(iii)(III) (7
17 U.S.C. 136b(e)(3)(B)(iii)(III)) is amended—

18 (1) by striking out “section 6(d), except that
19 the” and inserting in lieu thereof “section 6(d).
20 The”; and

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

1 (e) SECTION 6(c).—Section 6(c) (7 U.S.C. 136d(c))
2 is amended in paragraph (4) by striking out “section 16”
3 and inserting in lieu thereof “section 16(b)(1)”.

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

6 (1) by revising the first sentence to read as fol-
7 lows: “If a hearing is requested pursuant to section
8 3(c)(2)(B)(iv), 3(c)(6), 4(e)(3)(B)(iii)(III), 6(c)(2),
9 or 6(e)(2), such hearing shall be held for the pur-
10 pose of receiving evidence relevant and material to
11 the issues raised by the request for hearing.”; and

12 (2) by striking all that follows the eighth sen-
13 tence and inserting the following: “A hearing under
14 this subsection shall be held in accordance with the
15 provisions of sections 554, 556, and 557 of title 5,
16 United States Code. As soon as practicable after the
17 completion of the hearing, the Administration shall
18 issue a final order setting forth the Administrator’s
19 decision. Such order and decision shall be based only
20 on substantial evidence of record of such hearing,
21 shall set forth detailed findings of fact upon which
22 the order is based, and shall be subject to judicial
23 review under section 16(b)(1).”.

1 (g) SECTION 16(a).—Section 16(a) (7 U.S.C.
2 136n(a)) is amended by inserting “or a proceeding under
3 section 6(b)” after “a hearing”.

4 (h) SECTION 16(b).—Section 16(b) (17 U.S.C.
5 136n(b)) is amended—

6 (1) by striking out “(b) REVIEW BY COURT OF
7 APPEALS.—In the case of” and inserting in lieu
8 thereof the following:

9 “(b) REVIEW BY COURT OF APPEALS.—

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

12 (2) by striking “under this section” in the sixth
13 sentence of paragraph (1) (as so designated) and in-
14 serting “under this paragraph”; and

15 (3) by adding at the end the following new
16 paragraph:

17 “(2) REVIEW OF CERTAIN RULES.—In the case
18 of actual controversy as to the validity of any rule
19 issued by the Administrator under section 6(b)(9),
20 any decision by the Administrator under section
21 6(b)(4) or 6(b)(9) not to issue a proposed rule or to
22 withdraw a proposed rule, or any denial of a petition
23 to revoke or amend a final rule under section
24 6(b)(12), any person who will be adversely affected
25 by such rule or decision and who has filed comments

1 in the proceeding leading to the rule or decision may
2 obtain judicial review by filing a petition in the Unit-
3 ed States court of appeals for the circuit wherein
4 such person resides or has a place of business, with-
5 in 60 days after the entry of such order. A copy of
6 the petition shall be forthwith transmitted to the Ad-
7 ministrator or any officer designated by the Admin-
8 istrator for that purpose, and thereupon the Admin-
9 istrator shall file in court the record of the proceed-
10 ings on which the Administrator based such rule or
11 decision, as provided in section 2112 of title 28,
12 United States Code. Upon the filing of such petition
13 the court shall have exclusive jurisdiction to affirm
14 or set aside such rule or decision in whole or in part.
15 The standard review shall be that set forth in sec-
16 tion 706 of title 5, United States Code. The judg-
17 ment of the court under this paragraph shall be
18 final, subject to review by the Supreme Court upon
19 certiorari or certification as provided in section 1254
20 of title 28 of the United States Code. The com-
21 mencement of proceedings under this section shall
22 not, unless specifically ordered by the court to the
23 contrary, operate as a stay of an order.”.

1 (i) SECTION 25(a).—Section 25(a) (7 U.S.C.
2 136w(a)) is amended by adding a new paragraph (5) at
3 the end, to read as follows:

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

7 (j) SECTION 25(d).—Section 25(d) (7 U.S.C.
8 136w(d)) is amended—

9 (1) in the first sentence by striking out “in no-
10 tices of intent issued under subsection 6(b) and”;
11 and

12 (2) in the second sentence by striking out “no-
13 tices of intent and” and by striking out “section
14 6(b) or”.

15 (k) SECTION 25(e).—Section 25(e) (7 U.S.C.
16 136w(e)) is amended by striking out the period at the end
17 of the second sentence and substituting “, except for any
18 action that may be taken under section 6(b).”.

19 **TITLE II—DATA COLLECTION**

20 **SEC. 201. COLLECTION OF PESTICIDE USE INFORMATION.**

21 The Secretary of Agriculture shall collect data of
22 Statewide or regional significance on the use of pesticides
23 to control pests and diseases of major crops and crops of
24 dietary significance, including fruits and vegetables. Such
25 data shall be collected by surveys of farmers or from other

1 sources offering statistically reliable data. The Secretary
2 shall, as appropriate, coordinate with the Administrator
3 of the Environmental Protection Agency in the design of
4 such surveys and make available to the Administrator the
5 aggregate results of such surveys to assist the Adminis-
6 trator in developing exposure calculations and benefits de-
7 terminations with respect to pesticide regulatory decisions.

8 **SEC. 202. INTEGRATED PEST MANAGEMENT.**

9 Section 28(c) of the Federal Insecticide, Fungicide,
10 and Rodenticide Act (7 U.S.C. 136w-3(c)) is amended—

11 (1) by designating the text of such section as
12 paragraph (1) with the margin indented one em, and

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

14 “(2) The Administrator and the Secretary of Agri-
15 culture shall research, develop, and disseminate integrated
16 pest management techniques and other pest control meth-
17 ods that enable producers to reduce or eliminate applica-
18 tions of pesticides which pose a greater than negligible die-
19 tary risk to humans, with a special focus on crops critical
20 to a balanced, healthy diet and which are considered as
21 minor crops in terms of acreage produced.”.

1 **TITLE III—AMENDMENTS TO THE FED-**
2 **ERAL FOOD, DRUG, AND COSMETIC**
3 **ACT**

4 **SEC. 301. REFERENCE.**

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

10 **SEC. 302. DEFINITIONS.**

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

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

14 “(A) any substance that is a pesticide within
15 the meaning of the Federal Insecticide, Fungicide,
16 and Rodenticide Act, or

17 “(B) any active or inert ingredient of a pes-
18 ticide within the meaning of the Federal Insecticide,
19 Fungicide, and Rodenticide Act.

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

23 “(A) a pesticide chemical, or

24 “(B) any other added substance that is present
25 in the commodity or food primarily as a result of the

1 metabolism or other degradation of a pesticide
2 chemical.

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

7 “(A) its occurrence as a residue on a raw agri-
8 cultural commodity or processed food is attributable
9 primarily to natural causes or to human activities
10 not involving the use of any substances for a pes-
11 ticial purpose in the production, storage, process-
12 ing, or transportation of any raw agricultural com-
13 modity or processed food, and

14 “(B) the Administrator, after consultation with
15 the Secretary, determines that the substance more
16 appropriately should be regulated under one or more
17 provisions of this Act other than sections
18 402(a)(2)(B) and 408.”.

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

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

23 “(2) a pesticide chemical; or”.

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

1 “(bb) The term ‘processed food’ means any food
2 other than a raw agricultural commodity and includes any
3 raw agricultural commodity that has been subject to proc-
4 essing, such as canning, cooking, freezing, dehydration, or
5 milling.

6 “(cc) The term ‘Administrator’ means the Adminis-
7 trator of the United States Environmental Protection
8 Agency.”.

9 **SEC. 303. PROHIBITED ACTS.**

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

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

12 (2) by adding at the end “, or the violation of
13 section 408(g)(2) or any regulation issued under
14 that section.”.

15 **SEC. 304. ADULTERATED FOOD.**

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

18 “(2)(A) if it bears or contains any added poi-
19 sonous or added deleterious substance (other than a
20 substance that is a pesticide chemical residue in or
21 on a raw agricultural commodity or processed food,
22 a food additive, a color additive, or a new animal
23 drug) that is unsafe within the meaning of section
24 406;

1 this section and the concentration of the residue
2 is within the limits of the tolerance, or

3 “(B) an exemption from the requirement
4 of a tolerance is in effect under this section for
5 the pesticide chemical residue.

6 “(2) PROCESSED FOOD.—Notwithstanding
7 paragraph (1)—

8 “(A) if a tolerance is in effect under this
9 section for a pesticide chemical residue in or on
10 a raw agricultural commodity, a pesticide chem-
11 ical residue that is present in or on a processed
12 food because the food is made from that raw
13 agricultural commodity shall not be considered
14 unsafe within the meaning of section
15 402(a)(2)(B) despite the lack of a tolerance for
16 the pesticide chemical residue in or on the proc-
17 essed food if the concentration of the pesticide
18 chemical residue in the processed food when
19 ready for consumption or use is not greater
20 than the tolerance prescribed for the pesticide
21 chemical residue in the raw agricultural com-
22 modity.

23 “(B) If an exemption from the requirement
24 for a tolerance is in effect under this section for
25 a pesticide chemical residue in or on a raw agri-

1 cultural commodity, a pesticide chemical residue
2 that is present in or on a processed food be-
3 cause the food is made from that raw agricul-
4 tural commodity shall not be considered unsafe
5 within the meaning of section 402(a)(2)(B).

6 “(3) RESIDUES OF DEGRADATION PRODUCTS.—
7 If a pesticide chemical residue is present in or on a
8 food because it is a metabolite or other degradation
9 product of a precursor substance that itself is a pes-
10 ticide chemical or pesticide chemical residue, such a
11 residue shall not be considered to be unsafe within
12 the meaning of section 402(a)(2)(B) despite the lack
13 of a tolerance or exemption from the need for a tol-
14 erance for such residue in or on such food if—

15 “(A) the Administrator has not determined
16 that the degradation product is likely to pose
17 any potential health risk from dietary exposure
18 that is of a different type than, or of a greater
19 significance than, any risk posed by dietary ex-
20 posure to the precursor substance, and

21 “(B) either—

22 “(i) a tolerance is in effect under this
23 section for residues of the precursor sub-
24 stance in or on the food, and the combined
25 level of residues of the degradation product

1 and the precursor substance in or on the
2 food is at or below the stoichiometrically
3 equivalent level that would be permitted by
4 the tolerance if the residue consisted only
5 of the precursor substance rather than the
6 degradation product, or

7 “(ii) an exemption from the need for
8 a tolerance is in effect under this section
9 for residues of the precursor substance in
10 or on the food, and

11 “(C) the tolerance or exemption for resi-
12 dues of the precursor substance does not state
13 that it applies only to particular named sub-
14 stances or states that it does not apply to resi-
15 dues of the degradation product.

16 “(4) EFFECT OF TOLERANCE OR EXEMP-
17 TION.—While a tolerance or exemption from the re-
18 quirement for a tolerance is in effect under this sec-
19 tion for a pesticide chemical residue with respect to
20 any food, the food shall not by reason of bearing or
21 containing any amount of such a residue be consid-
22 ered to be adulterated within the meaning of section
23 402(a)(1).

24 “(b) AUTHORITY AND STANDARD FOR TOLER-
25 ANCES.—

1 “(1) AUTHORITY.—The Administrator may
2 issue regulations establishing, modifying, or revoking
3 a tolerance for a pesticide chemical residue in or on
4 a food—

5 “(A) in response to a petition filed under
6 subsection (d), or

7 “(B) on the Administrator’s initiative
8 under subsection (e).

9 “(2) STANDARD.—(A) A tolerance may not be
10 established for a pesticide chemical residue in or on
11 a food at a level that is higher than a level that the
12 Administrator determines is adequate to protect the
13 public health.

14 “(B) The Administrator shall modify or revoke
15 a tolerance if it is at a level higher than the level
16 that the Administrator determines is adequate to
17 protect the public health.

18 “(C) In making a determination under this
19 paragraph the Administrator shall take into account,
20 among other relevant factors, the validity, complete-
21 ness, and reliability of the available data from stud-
22 ies of the pesticide chemical residue, the nature of
23 any toxic effects shown to be caused by the pesticide
24 chemical in such studies, available information and
25 reasonable assumptions concerning the relationship

1 of the results of such studies to human risk, avail-
2 able information and reasonable assumptions con-
3 cerning the dietary exposure levels of food consum-
4 ers (and major identifiable subgroups of food con-
5 sumers) to the pesticide chemical residue, and avail-
6 able information and reasonable assumptions con-
7 cerning the variability of the sensitivities of major
8 identifiable groups and shall consider other factors
9 to the extent required by subparagraph (F).

10 “(D) For purposes of subparagraph (A), a tol-
11 erance level for a pesticide chemical residue in or on
12 a food shall be deemed to be adequate to protect the
13 public health if the dietary risk posed to food con-
14 sumers by such level of the pesticide chemical resi-
15 due is negligible. The Administrator shall by regula-
16 tion set forth the factors and methods for determin-
17 ing whether such a risk is negligible.

18 “(E) Where reliable data are available, the Ad-
19 ministrator shall calculate the dietary risk posed to
20 food consumers by a pesticide chemical on the basis
21 of the percent of food actually treated with the pes-
22 ticide chemical and the actual residue levels of the
23 pesticide chemical that occur in food. In particular,
24 the Administrator shall take into account aggregate

1 pesticide use and residue data collected by the De-
2 partment of Agriculture.

3 “(F) For purposes of subparagraph (A), a level
4 of a pesticide chemical residue in or on a food that
5 poses a greater than negligible dietary risk to con-
6 sumers of the food shall be deemed to be adequate
7 to protect the public health if the Administrator de-
8 termines that such risk is not unreasonable be-
9 cause—

10 “(i) use of the pesticide that produces the
11 residue protects humans or the environment
12 from adverse effects on public health or welfare
13 that would, directly or indirectly, result in
14 greater risk to the public or the environment
15 than the dietary risk from the pesticide chemi-
16 cal residue; or

17 “(ii) use of the pesticide avoids risks to
18 workers, the public, or the environment that
19 would be expected to result from the use of an-
20 other pesticide or pest control method on the
21 same food and that are greater than the risks
22 that result from dietary exposure to the pes-
23 ticide chemical residue; or

24 “(iii) the unavailability of the pesticide
25 would limit the availability to consumers of an

1 adequate, wholesome, and economical food sup-
2 ply, taking into account regional and domestic
3 effects, and such adverse effects are likely to
4 outweigh the risk posed by the pesticide resi-
5 due.

6 In making the determination under this subpara-
7 graph, the Administrator shall not consider the ef-
8 fects on any pesticide registrant, manufacturer, or
9 marketer of a pesticide.

10 “(3) LIMITATIONS.—(A) A tolerance may be is-
11 sued under the authority of paragraph (2)(E) only
12 if the Administrator has assessed the extent to
13 which efforts are being made to develop either an al-
14 ternative method of pest control or an alternative
15 pesticide chemical for use on such commodity or
16 food that would meet the requirements of paragraph
17 (2)(D).

18 “(B) A tolerance for a pesticide chemical resi-
19 due in or on a food shall not be established by the
20 Administrator unless the Administrator determines,
21 after consultation with the Secretary, that there is
22 a practical method for detecting and measuring the
23 levels of the pesticide chemical residue in or on the
24 food.

1 “(C) A tolerance for a pesticide chemical resi-
2 due in or on a food shall not be established at a level
3 lower than the limit of detection of the method for
4 detecting and measuring the pesticide chemical resi-
5 due specified by the Administrator under subpara-
6 graph (B).

7 “(4) INTERNATIONAL STANDARDS.—In estab-
8 lishing a tolerance for a pesticide chemical residue in
9 or on a food, the Administrator shall take into ac-
10 count any maximum residue level for the chemical in
11 or on the food that has been established by the
12 Codex Alimentarius Commission. The Administrator
13 shall determine whether the Codex maximum residue
14 level is adequate to protect the health of United
15 States’ consumers and whether the data supporting
16 the maximum residue level are valid, complete, and
17 reliable. If the Administrator determines not to
18 adopt a Codex maximum residue level, the Adminis-
19 trator shall publish a notice in the Federal Register
20 setting forth the reasons.

21 “(c) AUTHORITY AND STANDARD FOR EXEMP-
22 TIONS.—

23 “(1) AUTHORITY.—The Administrator may
24 issue a regulation establishing, modifying, or revok-
25 ing an exemption from the requirement for a toler-

1 ance for a pesticide chemical residue in or on a
2 food—

3 “(A) in response to a petition filed under
4 subsection (d), or

5 “(B) on the Administrator’s initiative
6 under subsection (e).

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

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

21 “(C) In making a determination under this sub-
22 paragraph, the Administrator shall take into ac-
23 count, among other relevant factors, the factors set
24 forth in subsection (b)(2)(C).

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

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

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

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

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

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

20 “(B) establishing or revoking an exemption
21 from the requirement of a tolerance for such a
22 residue.

23 “(2) PETITION CONTENTS.—

24 “(A) ESTABLISHMENT.—A petition under
25 paragraph (1) to establish a tolerance or ex-

1 emption for a pesticide chemical residue shall
2 be supported by such data and information as
3 are specified in regulations issued by the Ad-
4 ministrators, including—

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

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

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

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

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

1 mation as to the methods and controls
2 used in conducting those tests and inves-
3 tigations,

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

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

15 “(vii) practical methods for removing
16 any amount of the residue that would ex-
17 ceed any proposed tolerance,

18 “(viii) a proposed tolerance for the
19 pesticide chemical residue, if a tolerance is
20 proposed,

21 “(ix) all relevant data bearing on the
22 physical or other technical effect that the
23 pesticide chemical is intended to have and
24 the quantity of the pesticide chemical that
25 is required to produce the effect,

1 “(x) if the petition relates to a toler-
2 ance for a processed food, reports of inves-
3 tigations conducted using the processing
4 method(s) used to produce that food,

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

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

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

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

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

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

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

23 “(B) issue a proposed regulation under
24 subsection (e), and thereafter either issue a

1 final regulation under subsection (e) or an
2 order denying the petition; or

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

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

7 “(6) FURTHER PROCEEDINGS.—

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

20 “(B) An objection may include a request
21 for a public evidentiary hearing upon the objec-
22 tion. The Administrator shall, upon the initia-
23 tive of the Administrator or upon the request of
24 an interested person and after due notice, hold
25 a public evidentiary hearing if and to the extent

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

18 “(C) As soon as practicable after receiving
19 the arguments of the parties, the Administrator
20 shall issue an order stating the action taken
21 upon each such objection and setting forth any
22 revision to the regulation or prior order that the
23 Administrator has found to be warranted. If a
24 hearing was held under subparagraph (B), such
25 order and any revision to the regulation or prior

1 order shall, with respect to questions of fact at
2 issue in the hearing, be based only on substan-
3 tial evidence of record at such hearing, and
4 shall set forth in detail the findings of facts and
5 the conclusions of law or policy upon which the
6 order or regulation is based.

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

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

1 of such order, a petition praying that the order or
2 regulation be set aside in whole or in part.

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

17 “(C) If a party applies to the court for leave to
18 adduce additional evidence, and shows to the satis-
19 faction of the court that the additional evidence is
20 material and that there were reasonable grounds for
21 the failure to adduce the evidence in the proceeding
22 before the Administrator, the court may order that
23 the additional evidence (and evidence in rebuttal
24 thereof) shall be taken before the Administrator in
25 the manner and upon the terms and conditions the

1 court deems proper. The Administrator may modify
2 prior findings as to the facts by reason of the addi-
3 tional evidence so taken and may modify the order
4 or regulation accordingly. The Administrator shall
5 file with the court any such modified finding, order,
6 or regulation.

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

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

21 “(e) ACTION ON ADMINISTRATOR’S OWN INITIA-
22 TIVE.—

23 “(1) GENERAL RULE.—The Administrator may
24 issue a regulation—

1 “(A) establishing, modifying, or revoking a
2 tolerance for a pesticide chemical or a pesticide
3 chemical residue,

4 “(B) establishing or revoking an exemption
5 of a pesticide chemical residue from the require-
6 ment of a tolerance, or

7 “(C) establishing general procedures and
8 requirements to implement this section.

9 A regulation issued under this paragraph shall be-
10 come effective upon its publication.

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

23 “(f) SPECIAL DATA REQUIREMENTS.—

24 “(1) REQUIRING SUBMISSION OF ADDITIONAL
25 DATA.—If the Administrator determines that addi-

1 tional data or information are reasonably required to
2 support the continuation of a tolerance or exemption
3 that is in effect under this section for a pesticide
4 chemical residue on a food, the Administrator
5 shall—

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

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

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

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

24 “(ii) describing the type of data and
25 information required to be submitted to

1 the Administrator and stating why the
2 data and information could not be obtained
3 under the authority of section 3(c)(2)(B)
4 of the Federal Insecticide, Fungicide, and
5 Rodenticide Act or section 4 of the Toxic
6 Substances Control Act,

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

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

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

18 The Administrator may revise any such order to cor-
19 rect an error.

20 “(2) NONCOMPLIANCE.—If a submission re-
21 quired by a notice issued in accordance with para-
22 graph (1)(A) or an order issued under paragraph
23 (1)(B) is not made by the time specified in such no-
24 tice or order, the Administrator may by order pub-

1 lished in the Federal Register modify or revoke the
2 tolerance or exemption in question.

3 “(3) REVIEW.—An order issued under this sub-
4 section shall be effective upon publication and shall
5 be subject to review in accordance with paragraphs
6 (6) and (7) of subsection (d).

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

8 “(1) GENERAL RULE.—Data and information
9 that are submitted to the Administrator under this
10 section in support of a tolerance shall be entitled to
11 confidential treatment for reasons of business con-
12 fidentiality and to exclusive use and data compensa-
13 tion, to the same extent provided by sections 3 and
14 10 of the Federal Insecticide, Fungicide and
15 Rodenticide Act.

16 “(2) EXCEPTIONS.—Data that are entitled to
17 confidential treatment under paragraph (1) may
18 nonetheless be disclosed to the Congress of the Unit-
19 ed States, and may be disclosed, under such security
20 requirements as the Administrator may provide by
21 regulation, to—

22 “(A) employees of the United States au-
23 thorized by the Administrator to examine such
24 data in the carrying out of their official duties

1 under this Act or other Federal statutes in-
2 tended to protect the public health, or

3 “(B) contractors with the United States
4 authorized by the Administrator to examine
5 such data in the carrying out of contracts under
6 such statutes.

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

14 “(h) STATUS OF PREVIOUSLY ISSUED REGULA-
15 TIONS.—

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

1 “(2) REGULATIONS UNDER SECTION 409.—Reg-
2 ulations that established tolerances for substances
3 that are pesticide chemical residues on or in proc-
4 essed food, or that otherwise stated the conditions
5 under which such pesticide chemicals could be safely
6 used, and that were issued under section 409 on or
7 before the date of the enactment of this paragraph,
8 shall be deemed to be regulations issued under this
9 section and shall be subject to modification or rev-
10 ocation under subsection (d) or (e).

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

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

22 “(1) regarded by the Administrator or the Sec-
23 retary as generally recognized as safe for use within
24 the meaning of the provisions of section 408(a) or
25 201(s) as then in effect, or

1 “(2) regarded by the Secretary as a substance
2 described by section 201(s)(4),
3 such a pesticide chemical residue shall be regarded as ex-
4 empt from the requirement for a tolerance, as of the date
5 of enactment of this subsection. The Administrator shall
6 by regulation indicate which substances are described by
7 this subsection. An exemption under this subsection may
8 be revoked or modified as if it had been issued under sub-
9 section (c).

10 “(j) HARMONIZATION WITH ACTION UNDER OTHER
11 LAWS.—

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

1 food that are unsafe within the meaning of sub-
2 section (a).

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

23 “(A) the date by which each such cancella-
24 tion of a registration has become effective, or

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

4 “(3) SUSPENSION OF TOLERANCE OR EXEMP-
5 TION FOLLOWING SUSPENSION OF ASSOCIATED REG-
6 ISTRATIONS.—

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

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

15 “(4) TOLERANCES FOR UNAVOIDABLE RESI-
16 DUES.—In connection with action taken under para-
17 graph (2) or (3), or with respect to pesticides whose
18 registrations were canceled prior to the effective date
19 of this paragraph, if the Administrator determines
20 that a residue of the canceled or suspended pesticide
21 chemical will unavoidably persist in the environment
22 and thereby be present in or on a food, the Adminis-
23 trator may establish a tolerance for the pesticide
24 chemical residue at a level that permits such un-
25 avoidable residue to remain in such food. In estab-

1 lishing such a tolerance, the Administrator shall
2 take into account the factors set forth in subsection
3 (b)(2)(A)(iii) and shall use the procedures set forth
4 in subsection (e). The Administrator shall review
5 any such tolerance periodically and modify it as nec-
6 essary so that it allows only that level of the pes-
7 ticide chemical residue that is unavoidable.

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

18 “(A) the residue is present as the result of
19 an application or use of a pesticide at a time
20 and in a manner that was lawful under the
21 Federal Insecticide, Fungicide, and Rodenticide
22 Act; and

23 “(B) the residue does not exceed a level
24 that was authorized at the time of that applica-
25 tion or use to be present on the food under a

1 tolerance, exemption, food additive regulation,
2 or other sanction then in effect under this Act;
3 unless, in the case of any tolerance or exemption re-
4 voked, suspended, or modified under this subsection
5 or subsection (d) or (e), the Administrator has is-
6 sued a determination that consumption of the legally
7 treated food during the period of its likely availabil-
8 ity in commerce will pose an unreasonable dietary
9 risk.

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

18 “(1) the acceptance for filing of a petition sub-
19 mitted under subsection (d),

20 “(2) the promulgation of a regulation establish-
21 ing, modifying, or revoking a tolerance or establish-
22 ing or revoking an exemption from the requirement
23 of a tolerance under this section,

24 “(3) the acceptance for filing of objections
25 under subsection (d)(6), or

1 “(4) the certification and filing in court of a
2 transcript of the proceedings and the record under
3 subsection (d)(7),
4 may be conditioned upon the payment of such fees. The
5 regulations may further provide for waiver or refund of
6 fees in whole or in part when in the judgment of the Ad-
7 ministrator such a waiver or refund is equitable and not
8 contrary to the purposes of this subsection.

9 “(l) NATIONAL UNIFORMITY OF TOLERANCES.—

10 “(1) QUALIFYING PESTICIDE CHEMICAL RESI-
11 DUE.—For purposes of this subsection, the term
12 ‘qualifying pesticide chemical residue’ means a pes-
13 ticide chemical residue resulting from the use, in
14 production, processing, or storage of a food, of a
15 pesticide chemical that is an active ingredient and
16 that—

17 “(A) was first approved for such use in a
18 registration of a pesticide issued under section
19 3(c)(5) of the Federal Insecticide, Fungicide,
20 Rodenticide Act on or after April 25, 1985, on
21 the basis of data determined by the Adminis-
22 trator to meet all applicable requirements for
23 data prescribed by regulations in effect under
24 that Act on April 25, 1985; or

1 “(B) was approved for such use in a rereg-
2 istration eligibility determination issued under
3 section 4(g) of that Act on or after the date of
4 enactment of the Food Quality Protection Act
5 of 1993.

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

9 “(A) a tolerance or exemption from the re-
10 quirement for a tolerance for a qualifying pes-
11 ticide chemical residue that was—

12 “(i) issued under this section after the
13 date of enactment of the Food Quality
14 Protection Act of 1993;

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

22 “(B) any statement, issued by the Sec-
23 retary, of the residue level below which enforce-
24 ment action will not be taken under this Act
25 with respect to any qualifying pesticide chemi-

1 cal residue, if the Secretary finds that such pes-
2 ticide chemical residue level permitted by such
3 statement during the period to which such
4 statement applies protects human health.

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

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

1 ping, or other handling of a food because it contains
2 a pesticide residue (in excess of a prescribed limit),
3 or if it purports to require that a food containing a
4 pesticide residue be the subject of a warning or
5 other statement relating to the presence of the pes-
6 ticide residue in the food.

7 “(5) PETITION PROCEDURE.—

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

15 “(B) Any petition under subparagraph (A)
16 shall—

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

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

1 in such State to the pesticide chemical res-
2 idue.

3 “(C) Subject to paragraph (6), the Admin-
4 istrator may, by order, grant the authorization
5 described in subparagraph (A) if the Adminis-
6 trator determines that the proposed State regu-
7 latory limit—

8 “(i) is justified by compelling local
9 conditions;

10 “(ii) would not unduly burden inter-
11 state commerce; and

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

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

23 “(E) Any order of the Administrator
24 granting or denying the authorization described
25 in subparagraph (A) shall be subject to review

1 in the manner described in subsections (d)(6)
2 and (d)(7).

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

16 **SEC. 306. AUTHORIZATION FOR INCREASE MONITORING.**

17 There is authorized to be appropriated an additional
18 \$12,000,000 for increased monitoring by the Secretary of
19 Health and Human Services of pesticide residues in im-
20 ported and domestic food.

○

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