

103D CONGRESS
1ST SESSION

S. 1478

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to ensure that pesticide tolerances adequately safeguard the health of infants and children, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 21 (legislative day, SEPTEMBER 7), 1993

Mr. PRYOR (for himself, Mr. LUGAR, Mr. JOHNSTON, Mr. HEFLIN, Mrs. KASSEBAUM, Mr. COCHRAN, Mr. NICKLES, Mr. DOLE, Mr. COATS, Mr. HELMS, and Mr. BREAU) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to ensure that pesticide tolerances adequately safeguard the health of infants and children, 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”.

1 **TITLE I—DATA COLLECTION**
2 **AND PROCEDURES TO EN-**
3 **SURE THAT TOLERANCES**
4 **SAFEGUARD THE HEALTH OF**
5 **INFANTS AND CHILDREN**

6 **SEC. 101. IMPLEMENTATION OF NRC REPORT.**

7 (a) IN GENERAL.—The Administrator of the Envi-
8 ronmental Protection Agency, the Secretary of Agri-
9 culture, and the Secretary of Health and Human Services
10 shall coordinate the development and implementation of
11 procedures to ensure that pesticide tolerances adequately
12 safeguard the health of infants and children, based on the
13 conclusions and recommendations contained in the report
14 entitled “Pesticides in the Diets of Infants and Children”
15 of the National Research Council of the National Academy
16 of Sciences.

17 (b) PROCEDURES.—To the extent practicable, the
18 procedures referred to in subsection (a) shall include—

19 (1) collection of data on food consumption pat-
20 terns of infants and children;

21 (2) improved surveillance of pesticide residues,
22 including guidelines for the use of comparable ana-
23 lytical and standardized reporting methods, the in-
24 creased sampling of foods most likely consumed by
25 infants and children, and the development of more

1 complete information on the effects of food process-
2 ing on levels of pesticide residues;

3 (3) toxicity testing procedures that specifically
4 evaluate the vulnerability of infants and children;

5 (4) methods of risk assessment that take into
6 account unique characteristics of infants and chil-
7 dren; and

8 (5) other appropriate measures considered nec-
9 essary by the Administrator to ensure that pesticide
10 tolerances adequately safeguard the health of infants
11 and children.

12 **SEC. 102. COLLECTION OF PESTICIDE USE INFORMATION.**

13 (a) IN GENERAL.—The Secretary of Agriculture shall
14 collect data of Statewide or regional significance on the
15 use of pesticides to control pests and diseases of major
16 crops and crops of dietary significance, including fruits
17 and vegetables.

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

21 (c) COORDINATION.—The Secretary shall, as appro-
22 priate, coordinate with the Administrator of the Environ-
23 mental Protection Agency in the design of the surveys and
24 make available to the Administrator the aggregate results
25 of the surveys to assist the Administrator in developing

1 exposure calculations and benefits determinations with re-
2 spect to pesticide regulatory decisions.

3 **SEC. 103. INTEGRATED PEST MANAGEMENT.**

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

6 (1) by striking “(c) INTEGRATED PEST MAN-
7 AGEMENT.—The Administrator,” and inserting the
8 following:

9 “(c) INTEGRATED PEST MANAGEMENT.—

10 “(1) IN GENERAL.—The Administrator,”; and

11 (2) by adding at the end the following new
12 paragraph:

13 “(2) JOINT RESEARCH AND DEVELOPMENT.—

14 The Administrator and the Secretary of Agriculture
15 shall research, develop, and disseminate information
16 concerning integrated pest management techniques
17 and other pest control methods that enable produc-
18 ers to reduce or eliminate applications of pesticides
19 that pose a greater than negligible dietary risk to
20 humans, with a special focus on crops critical to a
21 balanced, healthy diet and that are considered as
22 minor crops in terms of acreage produced.”.

1 **TITLE II—CANCELLATION AND**
2 **SUSPENSION**

3 **SEC. 201. REFERENCE.**

4 Whenever in this title an amendment or repeal is ex-
5 pressed in terms of an amendment to, or repeal of, a sec-
6 tion or other provision, the reference shall be considered
7 to be made to a section or other provision of the Federal
8 Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136
9 et seq.).

10 **SEC. 202. CANCELLATION.**

11 Subsection (b) of section 6 (7 U.S.C. 136d(b)) is
12 amended to read as follows:

13 “(b) CANCELLATION AND CHANGE IN CLASSIFICA-
14 TION OR OTHER TERMS OR CONDITIONS OF REGISTRA-
15 TION.—

16 “(1) AUTHORITY.—Notwithstanding any other
17 provision of this Act, the Administrator may, by use
18 of informal rulemaking under this subsection, pre-
19 scribe requirements regarding the composition, pack-
20 aging, and labeling of a pesticide (or a group of pes-
21 ticides containing a common active or inert ingredi-
22 ent), may classify the pesticide, or may prohibit the
23 registration or continued registration of the pesticide
24 for some or all purposes, to the extent necessary to
25 ensure that the pesticide, when used in accordance

1 with widespread and commonly recognized practice,
2 does not generally cause unreasonable adverse ef-
3 fects on the environment.

4 “(2) BASIS FOR RULE.—

5 “(A) The Administrator may not initiate a
6 rulemaking under this subsection unless the
7 rulemaking is based on a validated test or other
8 significant evidence raising a prudent concern
9 that the pesticide causes unreasonable adverse
10 effects on the environment.

11 “(B)(i) The Administrator shall submit, to
12 a scientific peer review committee established
13 by the Administrator, the validated test or
14 other significant evidence on which the Admin-
15 istrator proposes to base a rulemaking under
16 paragraph (1).

17 “(ii) The scientific peer review committee
18 shall provide written recommendations to the
19 Administrator as to whether the test or evi-
20 dence reviewed satisfies the criteria under sub-
21 paragraph (A) for initiating a rulemaking under
22 paragraph (1).

23 “(iii) The scientific peer review committee
24 shall consist of employees of or consultants to
25 the Environmental Protection Agency who have

1 not been involved in a previous analysis of the
2 validated test or significant evidence presented
3 to the committee and who are experts in the
4 physical or biological disciplines involved in the
5 proposed rulemaking.

6 “(3) PRENOTICE PROCEDURES.—

7 “(A) The Administrator may not initiate a
8 rulemaking under paragraph (1) until the Ad-
9 ministrator has provided, to the registrant of
10 each affected pesticide, a notice that includes a
11 summary of the validated test or other signifi-
12 cant evidence on which the Administrator pro-
13 poses to base the rulemaking and the basis for
14 a determination that the test or evidence raises
15 a prudent concern that the pesticide causes un-
16 reasonable adverse effects on the environment.
17 A registrant may respond to a notice provided
18 under this subparagraph not later than 30 days
19 after receipt of the notice.

20 “(B) At the same time as the Adminis-
21 trator provides the notice to a registrant of the
22 pesticide under subparagraph (A), the Adminis-
23 trator shall also provide the notice to the Sec-
24 retary of Agriculture and the Secretary of
25 Health and Human Services. If an agricultural

1 commodity is affected, on receipt of the notice,
2 the Secretary of Agriculture shall prepare an
3 analysis of the benefit and use of the pesticide
4 and provide the analysis to the Administrator.

5 “(4) ADVANCE NOTICE TO PUBLIC.—

6 “(A) After receiving the recommendation
7 of the peer review committee established under
8 paragraph (2)(B), together with any comments
9 submitted by the Secretary of Agriculture, the
10 Secretary of Health and Human Services, and
11 a registrant, the Administrator shall—

12 “(i) issue an advance notice of pro-
13 posed rulemaking; or

14 “(ii) issue a notice of a proposed deci-
15 sion not to initiate a rulemaking under
16 paragraph (1).

17 “(B) The Administrator shall publish the
18 notice in the Federal Register and provide a pe-
19 riod of not less than 60 days for comment on
20 the notice. The notice shall contain a statement
21 of the basis and purpose of the notice and a
22 summary of—

23 “(i) the factual data on which the no-
24 tice is based;

1 “(ii) the major scientific assumptions
2 underlying the notice; and

3 “(iii) the notice provided under para-
4 graph (3) and any significant comments
5 received from a registrant, the Secretary of
6 Agriculture, and the Secretary of Health
7 and Human Services.

8 “(C) If the Administrator, after consider-
9 ing any comments received, decides not to issue
10 a notice of proposed rulemaking, the Adminis-
11 trator shall publish in the Federal Register a
12 notice setting forth the decision and the basis
13 for the decision.

14 “(5) DOCKET.—

15 “(A) For each rulemaking under para-
16 graph (1), the Administrator shall establish a
17 docket.

18 “(B) The docket shall include a copy of—

19 “(i) the notice provided under para-
20 graph (3);

21 “(ii) any notice issued under para-
22 graph (4);

23 “(iii) the notice of proposed rule-
24 making issued under paragraph (6);

1 “(iv) each timely comment filed with
2 the Administrator;

3 “(v) the report of the Scientific Advi-
4 sory Panel under paragraph (8);

5 “(vi) a record of each hearing held by
6 the Administrator in connection with the
7 rulemaking; and

8 “(vii) the final rule or decision to
9 withdraw the rule.

10 “(C) Information in the docket shall be
11 made available to the public consistent with sec-
12 tion 10.

13 “(D) No factual material that has not been
14 entered into the docket in a timely manner may
15 be relied on by the Administrator in issuing a
16 final rule or in withdrawing a proposed rule or
17 by a person in a judicial review proceeding, ex-
18 cept for—

19 “(i) information of which the Admin-
20 istrator may properly take official notice;
21 or

22 “(ii) information of which a court may
23 properly take judicial notice.

24 “(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 the basis and purpose of the pro-
7 posed rulemaking, a request for any additional
8 data needed, and a bibliography of all signifi-
9 cant scientific data and studies on which the
10 proposed rule is based. The statement of basis
11 and purpose shall include a 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 analysis and tentative con-
22 clusions of the Administrator regarding the
23 balancing of the risks and benefits.

24 “(B)(i) A registrant of the pesticide and a
25 person who submits comments on the proposed

1 rule shall make a report to the Administrator of
2 all scientific data and studies possessed by the
3 person concerning the risks and benefits of the
4 pesticide that is the subject of the rulemaking
5 that were not included in the bibliography in-
6 cluded in the notice required under subpara-
7 graph (A).

8 “(ii) If, after the date of the report made
9 under clause (i), the registrant or the person
10 receives additional scientific data or studies per-
11 tinent to the rulemaking that were not included
12 in the bibliography, the person shall make a re-
13 port of the scientific data and studies to the
14 Administrator promptly after receipt.

15 “(iii) If the Administrator receives reports
16 containing additional data concerning risks or
17 benefits, the Administrator shall revise the bib-
18 liography to reflect the data and make the re-
19 vised bibliography available to the public.

20 “(C)(i) The Administrator shall provide a
21 comment period of not less than 90 days after
22 the publication of the notice of proposed rule-
23 making.

1 “(ii) During the period, a person may sub-
2 mit comments, data, or documentary informa-
3 tion on the proposed rule.

4 “(iii) Promptly on receipt by the Adminis-
5 trator, all written comments and documentary
6 information on the proposed rule received from
7 a person for inclusion in the docket during the
8 comment period, shall be placed in the docket.

9 “(D)(i) At the same time as the Adminis-
10 trator publishes notice under subparagraph (A),
11 the Administrator shall provide the Secretary of
12 Agriculture and the Secretary of Health and
13 Human Services with a copy of the proposed
14 rule.

15 “(ii) Not later than 90 days after the pub-
16 lication of the notice of proposed rulemaking,
17 the Secretary of Agriculture and the Secretary
18 of Health and Human Services may provide
19 comments on the proposed rule.

20 “(iii) If an agricultural commodity is af-
21 fected, the Secretary of Agriculture shall pro-
22 vide to the Administrator an analysis of the im-
23 pact of the proposed action on the domestic and
24 global availability and prices of agricultural
25 commodities and retail food prices and any as-

1 sociated societal impacts (including impacts on
2 consumer nutrition and health and low-income
3 consumers).

4 “(7) INFORMAL HEARING.—

5 “(A)(i) A person who has submitted a
6 comment may, not later than 15 days after the
7 close of the comment period, request the Ad-
8 ministrator to conduct an informal hearing on
9 questions of fact pertaining to the proposed rule
10 or comments on the rule.

11 “(ii) The Administrator shall—

12 “(I) on receipt of the request, sched-
13 ule an informal hearing of not to exceed 20
14 days duration; and

15 “(II) not later than 60 days after the
16 close of the comment period, conduct the
17 hearing.

18 “(iii) The Administrator shall publish the
19 time, place, and purpose of the hearing in the
20 Federal Register.

21 “(iv) The informal hearing shall be limited
22 to addressing questions of fact raised by mate-
23 rials in the docket.

1 “(v) A transcript shall be made of any oral
2 presentation, discussion, or debate and included
3 in the docket.

4 “(B) The Administrator shall appoint a
5 presiding officer who shall have the authority to
6 administer oaths, regulate the course of the
7 hearing, conduct prehearing conferences, sched-
8 ule presentations, and exclude irrelevant, imma-
9 terial, or unduly repetitious evidence.

10 “(C)(i) The presiding officer shall conduct
11 the informal hearing in a manner that encour-
12 ages discussion and debate on questions of fact
13 regarding the docket.

14 “(ii) The Administrator shall designate 1
15 or more employees of the Environmental Pro-
16 tection Agency to participate in the hearing.

17 “(iii) A person who submitted a comment
18 on the proposed rule may participate in the
19 hearing and shall be entitled to present evidence
20 and argument to support the position of the
21 person or rebut a contrary position and may
22 choose to present materials in oral or written
23 form.

24 “(8) REVIEW BY SCIENTIFIC ADVISORY
25 PANEL.—

1 “(A) At the time the Administrator issues
2 a notice of proposed rulemaking under para-
3 graph (6), the Administrator shall provide a
4 copy of the notice to the Scientific Advisory
5 Panel established under section 25(d) (referred
6 to in this paragraph as the ‘Panel’).

7 “(B) If a person submits comments under
8 paragraph (6) in opposition to the proposed
9 rule, the Administrator shall request the com-
10 ments, evaluations, and recommendations of the
11 Panel as to the impact on health and the envi-
12 ronment of the proposed rule and on any dis-
13 puted issues of fact or scientific policy that ap-
14 pear to be of significance in the rulemaking.

15 “(C) The Panel may hold a public hearing
16 to discuss the proposed rule.

17 “(D) The Panel shall provide a report to
18 the Administrator not later than 30 days after
19 the close of the comment period (or, if a hear-
20 ing has been requested under paragraph (7),
21 not later than 30 days after the end of the
22 hearing).

23 “(E) The Administrator shall allow a rea-
24 sonable time for written public comment on the
25 report of the Panel. A copy of the report of the

1 Panel and any comments on the report shall be
2 included in the rulemaking docket.

3 “(9) FINAL ACTION.—

4 “(A) After considering all material in the
5 docket, the Administrator shall publish in the
6 Federal Register a final rule or a withdrawal of
7 the proposed rule.

8 “(B) The Administrator may not prohibit
9 a use of a pesticide if an alternative require-
10 ment will ensure that the pesticide, when used
11 in accordance with widespread and commonly
12 recognized practice, will not generally cause un-
13 reasonable adverse effects on the environment.

14 “(C) In taking a final action, the Adminis-
15 trator shall take into account the impact of the
16 action on production and prices of agricultural
17 commodities, retail food prices, and otherwise
18 on the agricultural economy.

19 “(D) The final rule or withdrawal of the
20 proposed rule shall be accompanied by a state-
21 ment that—

22 “(i) explains the reasons for the ac-
23 tion;

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

1 retary of Health and Human Services, and
2 to any report of the Scientific Advisory
3 Panel established under section 25(d);

4 “(iii) responds to each significant
5 comment contained in the docket; and

6 “(iv) in the case of a final rule—

7 “(I) explains the reason for any
8 major difference between the final
9 rule and the proposed rule;

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

15 “(III) explains any significant
16 disagreement the Administrator may
17 have with any comment, evaluation, or
18 recommendation contained in the re-
19 port under paragraph (8), the benefits
20 and use information described in
21 paragraph (6)(A)(iii), or the analysis
22 described in paragraph (6)(D) as the
23 analysis bears on the final rule.

24 “(E) A final rule issued under this sub-
25 section shall become effective on the date of the

1 publication of the final rule in the Federal Reg-
2 ister.

3 “(10) MODIFICATION OR CANCELLATION.—

4 “(A)(i) Subject to clause (ii), a final rule
5 shall state any requirement, classification, or
6 prohibition imposed by the rule, and shall state
7 that each affected registrant shall have a 30-
8 day period from the date of the publication of
9 the rule in the Federal Register to apply for an
10 amendment to the registration to comply with
11 the rule or to request voluntary cancellation of
12 the registration.

13 “(ii) If the rule unconditionally prohibits
14 all uses of a pesticide, the rule may provide that
15 cancellation of the registration of the pesticide
16 is effective beginning on the date of the publica-
17 tion of the rule.

18 “(iii) The final rule may prohibit or limit
19 distribution or sale by the registrant of the af-
20 fected pesticide to any other person in a State
21 during the 30-day period.

22 “(B) Notwithstanding any other provision
23 of this Act, if an application for an amendment
24 to the registration to make the registration
25 comply with a rule issued under subparagraph

1 (A) is not submitted within the 30-day period,
2 the Administrator may issue and publish in the
3 Federal Register an order canceling the reg-
4 istration, effective beginning on the date of the
5 publication of the order in the Federal Register.

6 “(11) DENIAL OF APPLICATIONS.—Notwith-
7 standing any other provision of this Act, no applica-
8 tion for initial or amended registration of a pesticide
9 under section 3 or 24(c) may be approved if the reg-
10 istration would be inconsistent with a rule in effect
11 under this subsection.

12 “(12) AMENDMENT OF RULE.—

13 “(A) A registrant, or other interested per-
14 son with the concurrence of the registrant, may
15 petition for the amendment or revocation of a
16 rule that has been issued under this subsection.

17 “(B) The petition shall state the factual
18 material and argument that form the basis for
19 the petition.

20 “(C) The Administrator shall publish a no-
21 tice of the petition in the Federal Register and
22 allow a 60-day comment period on the petition.

23 “(D) Not later than 180 days after publi-
24 cation of the notice, the Administrator shall de-
25 termine whether to deny the petition or to pro-

1 pose to amend or revoke the rule, and publish
2 the determination and the basis for the deter-
3 mination in the Federal Register.

4 “(E) In making the determination, the Ad-
5 ministrator shall give due regard to—

6 “(i) the desirability of finality;

7 “(ii) the opportunity that the peti-
8 tioner had to present the factual material
9 and argument in question in the prior rule-
10 making proceeding; and

11 “(iii) any new evidence submitted by
12 the petitioner.

13 “(F) If the Administrator proposes to
14 amend or revoke the rule, the procedures estab-
15 lished by paragraph (1) and paragraphs (6)
16 through (9) shall apply.

17 “(G) A denial of a petition shall be judi-
18 cially reviewable as provided in paragraph (13).

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

1 “(14) EXCEPTION TO REQUIREMENTS.—If the
2 Administrator finds it is necessary to issue a suspen-
3 sion order under subsection (c), the Administrator
4 may waive the requirements of paragraphs (3) and
5 (4).”.

6 **SEC. 203. PESTICIDES IN REVIEW.**

7 If the Administrator of the Environmental Protection
8 Agency, on or before January 1, 1993, publishes a docu-
9 ment instituting a special review proceeding or public in-
10 terim administrative review proceeding with respect to a
11 pesticide or an active ingredient of a pesticide, the Admin-
12 istrator may, in lieu of proceeding under section 6(b) of
13 the Federal Insecticide, Fungicide, and Rodenticide Act
14 (as amended by section 202 of this Act), elect to continue
15 the review proceeding and, on completion of the proceed-
16 ing, take such action as is warranted in accordance with
17 section 3(c)(6) and subsections (b) and (d) of section 6
18 of the Federal Insecticide, Fungicide, and Rodenticide Act
19 (as in effect on the day before the date of enactment of
20 this Act).

21 **SEC. 204. SUSPENSION.**

22 (a) ORDER.—Section 6(c)(1) (7 U.S.C. 136d(c)(1))
23 is amended by striking the second sentence and inserting
24 the following new sentence: “Except as provided in para-
25 graph (3), no order of suspension may be issued under

1 this subsection unless the Administrator has issued, or at
2 the same time issues, a proposed rule under subsection
3 (b).”.

4 (b) EMERGENCY ORDER.—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), if the Adminis-
9 trator proceeds expeditiously to issue a proposed rule.”.

10 **SEC. 205. TOLERANCE REEVALUATION AS PART OF REREG-**
11 **ISTRATION.**

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

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

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

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

3 “(ii) determine whether the tolerance
4 or exemption meets the requirements of
5 such 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 (21 U.S.C. 346a) as are warranted by the
15 determinations.”.

16 **SEC. 206. SCIENTIFIC ADVISORY PANEL.**

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

18 (1) by striking “(d) SCIENTIFIC ADVISORY
19 PANEL.—The Administrator shall” and inserting the
20 following:

21 “(d) SCIENTIFIC ADVISORY PANEL.—

22 “(1) IN GENERAL.—The Administrator shall”;

23 and

24 (2) by adding at the end the following new
25 paragraph:

1 “(2) SCIENCE REVIEW BOARD.—

2 “(A) There is established a Science Review
3 Board to consist of 60 scientists who shall be
4 available to the Scientific Advisory Panel to as-
5 sist in reviews conducted by the Panel.

6 “(B) The Scientific Advisory Panel shall
7 select the scientists from 60 nominations sub-
8 mitted by each of the National Science Founda-
9 tion and the National Institutes of Health.

10 “(C) A member of the Board shall be com-
11 pensated in the same manner as a member of
12 the Panel.”.

13 **SEC. 207. CONFORMING AMENDMENTS.**

14 (a) Paragraph (6) of section 3(c) (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)(i) Except as provided in subpara-
19 graph (B), if the Administrator proposes to
20 deny an application for registration because the
21 application does not satisfy the requirements of
22 paragraph (5), the Administrator shall notify
23 the applicant of the proposal and the reasons
24 for the denial (including the factual basis of the
25 proposal).

1 “(ii) Unless the applicant makes the nec-
2 essary corrections to the application and noti-
3 fies the Administrator of the corrections during
4 the 30-day period beginning on the day after
5 the date the applicant receives the notice, or
6 during the period the applicant submits a re-
7 quest for a hearing, the Administrator may
8 issue an order denying the application.

9 “(iii) If during the period referred to in
10 clause (ii), the Administrator does not receive
11 the corrections to the application or a request
12 for a hearing, the Administrator may issue an
13 order denying the application.

14 “(iv) The order denying the application
15 shall be published in the Federal Register and
16 shall not be subject to judicial review.

17 “(v) If during the period referred to in
18 clause (ii), the Administrator receives a request
19 for a hearing, a hearing shall be conducted
20 under section 6(d).

21 “(vi) If a hearing is held, a decision after
22 completion of the hearing shall be final and
23 shall be subject to judicial review under section
24 16(b)(1).

1 “(B)(i) The Administrator may deny an
2 application for registration because the applica-
3 tion does not comply with the requirements of
4 a rule issued under section 6(b).

5 “(ii) The Administrator shall notify the ap-
6 plicant of the denial.

7 “(iii) The notice shall explain why the ap-
8 plication does not comply with the requirements
9 and shall state that the applicant may petition
10 to amend or revoke the rule under section
11 6(b)(12).”.

12 (b) Section 3(c) (7 U.S.C. 136a(c)) is amended by
13 striking paragraph (8).

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

15 (1) in paragraph (1)(A), by striking “on the
16 initial classification and registered pesticides” and
17 inserting “under section 6(b). A registered pes-
18 ticide”; and

19 (2) in paragraph (2), by striking all that follows
20 “on the environment,” and inserting “the Adminis-
21 trator may initiate a proceeding under section
22 6(b).”.

23 (d) Section 4(e)(3)(B)(iii)(III) (7 U.S.C. 136a-
24 1(e)(3)(B)(iii)(III)) is amended—

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

3 (2) by inserting after “guidelines.” the follow-
4 ing new sentence: “If a hearing is held, a decision
5 after completion of the hearing shall be final.”.

6 (e) Section 6(c)(4) (7 U.S.C. 136d(c)(4)) is amended
7 by striking “Section 16 of this Act” and inserting “section
8 16(b)(1)”.

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

10 (1) by striking the first sentence and inserting
11 the following new sentence: “If a hearing is re-
12 quested pursuant to section 3(c)(2)(B)(iv), 3(c)(6),
13 or 4(e)(3)(B)(iii)(III), or subsection (c)(2) or (e)(2),
14 the hearing shall be held for the purpose of receiving
15 evidence relevant and material to the issues raised
16 by the request for the hearing.”; and

17 (2) by striking all that follows the eighth sen-
18 tence and inserting the following new sentence: “A
19 hearing under this subsection shall be held in ac-
20 cordance with sections 554, 556, and 557 of title 5,
21 United States Code. As soon as practicable after the
22 completion of the hearing, the Administrator shall
23 issue a final order setting forth the decision of the
24 Administrator. The order and decision shall be based
25 only on substantial evidence of the record of the

1 hearing, shall set forth detailed findings of fact on
2 which the order is based, and shall be subject to ju-
3 dicial review under section 16(b)(1).”.

4 (g) Section 16(a) (7 U.S.C. 136n(a)) is amended by
5 inserting after “a hearing” the following: “or a proceeding
6 under section 6(b)”.

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

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

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

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

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

18 “(2) REVIEW OF CERTAIN RULES.—

19 “(A) In the case of actual controversy as
20 to the validity of a rule issued by the Adminis-
21 trator under section 6(b)(9), a decision by the
22 Administrator under paragraph (4) or (9) of
23 section 6(b) not to issue a proposed rule or to
24 withdraw a proposed rule, or a denial of a peti-
25 tion to revoke or amend a final rule under sec-

1 tion 6(b)(12), a person who will be adversely af-
2 fected by the rule or decision and who has filed
3 comments in the proceeding leading to the rule
4 or decision may obtain judicial review by filing
5 a petition in the United States court of appeals
6 for the circuit in which the person resides or
7 has a place of business, not later than 60 days
8 after the entry of the order.

9 “(B) A copy of the petition shall be trans-
10 mitted to the Administrator or an officer des-
11 ignated by the Administrator.

12 “(C) On receipt of the copy of the petition,
13 the Administrator shall file in court the record
14 of the proceedings on which the Administrator
15 based the rule or decision, as provided in sec-
16 tion 2112 of title 28, United States Code.

17 “(D) On the filing of the petition, the
18 court shall have exclusive jurisdiction to affirm
19 or set aside the rule or decision in whole or in
20 part.

21 “(E) The standard of review shall be the
22 standard set forth in section 706 of title 5,
23 United States Code.

24 “(F) The judgment of the court under this
25 paragraph shall be final, subject to review by

1 the Supreme Court on certiorari or certification
2 as provided in section 1254 of title 28, United
3 States Code.

4 “(G) The commencement of proceedings
5 under this section shall not, unless specifically
6 ordered by the court to the contrary, operate as
7 a stay of an order.”.

8 (i) Section 25(a) (7 U.S.C. 136w(a)) is amended by
9 adding at the end the following new paragraph:

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

13 (j) Section 25(d)(1) (as designated by section 206)
14 is further amended—

15 (1) in the first sentence, by striking “of the ac-
16 tion proposed in notices of intent issued under sec-
17 tion 6(b) and”; and

18 (2) in the second sentence—

19 (A) by striking “notices of intent and”;
20 and

21 (B) by striking “6(b) or 25(a), as applica-
22 ble,” and inserting “25(a),”.

23 (k) The second sentence of section 25(e) (7 U.S.C.
24 136w(e)) is amended by inserting before the period at the

1 end the following: “, except for an action that may be
2 taken under section 6(b)”.

3 **SEC. 208. CONFORMING AMENDMENTS TO FIFRA TABLE OF**
4 **CONTENTS.**

5 The table of contents in section 1(b) (7 U.S.C. prec.
6 121) is amended—

7 (1) by striking the item relating to section
8 3(c)(6) and inserting the following new item:

“(6) Denial of application for registration.”;

9 (2) by striking the item relating to section
10 3(c)(8);

11 (3) by striking the item relating to section 6(b)
12 and inserting the following new items:

“(b) Cancellation and change in classification or other terms or
conditions of registration.

“(1) Authority.

“(2) Basis for rule.

“(3) Prenotice procedures.

“(4) Advance notice to public.

“(5) Docket.

“(6) Notice of proposed rulemaking.

“(7) Informal hearing.

“(8) Review by Scientific Advisory Panel.

“(9) Final action.

“(10) Modification or cancellation.

“(11) Denial of applications.

“(12) Amendment of rule.

“(13) Judicial review.

“(14) Exception to requirements.”;

13 (4) by striking the item relating to section
14 16(b) and inserting the following new items:

“(b) Review by court of appeals.
 “(1) Review of certain orders.
 “(2) Review of certain rules.”;

1 (5) by adding at the end of the items relating
 2 to section 25(a) the following new item:

“ (5) Exception.”;

3 (6) by striking the item relating to section
 4 25(d) and inserting the following new items:

“(d) Scientific Advisory Panel.
 “(1) In general.
 “(2) Science Review Board.”;

5 and

6 (7) by striking the item relating to section
 7 28(c) and inserting the following new items:

“(c) Integrated pest management.
 “(1) In general.
 “(2) Joint research and development.”.

8 **TITLE III—AMENDMENTS TO**
 9 **THE FEDERAL FOOD, DRUG,**
 10 **AND COSMETIC ACT**

11 **SEC. 301. REFERENCE.**

12 Whenever in this title an amendment is expressed in
 13 terms of an amendment to a section or other provision,
 14 the reference shall be considered to be made to a section
 15 or other provision of the Federal Food, Drug, and Cos-
 16 metic Act (21 U.S.C. 321 et seq.).

1 **SEC. 302. DEFINITIONS.**

2 (a) PESTICIDE CHEMICAL; PESTICIDE CHEMICAL
3 RESIDUE.—Section 201(q) (21 U.S.C. 321(q)) is amended
4 to read as follows:

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

6 “(A) any substance that is a pesticide within
7 the meaning of section 2(u) of the Federal Insecti-
8 cide, Fungicide, and Rodenticide Act (7 U.S.C.
9 136(u)),

10 “(B) any active ingredient of a pesticide within
11 the meaning of section 2(a) of the Federal Insecti-
12 cide, Fungicide, and Rodenticide Act (7 U.S.C.
13 136(a)), or

14 “(C) any inert ingredient of a pesticide within
15 the meaning of section 2(m) of the Federal Insecti-
16 cide, Fungicide, and Rodenticide Act (7 U.S.C.
17 136(m)).

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

21 “(A) a pesticide chemical, or

22 “(B) any other added substance that is present
23 in the commodity or food primarily as a result of the
24 metabolism or other degradation of a pesticide
25 chemical.

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

5 “(A) the substance’s occurrence as a residue on
6 a raw agricultural commodity or processed food is
7 attributable primarily to natural causes or to human
8 activities not involving the use of any substances for
9 a pesticidal purpose in the production, storage, proc-
10 essing, or transportation of any raw agricultural
11 commodity or processed food, and

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

17 (b) FOOD ADDITIVE.—Subparagraphs (1) and (2) of
18 section 201(s) (21 U.S.C. 321(s)) are amended to read
19 as follows:

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

22 “(2) a pesticide chemical; or”.

23 (c) PROCESSED FOOD.—Section 201 (21 U.S.C. 321)
24 is amended by adding at the end the following:

1 “(gg) 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 “(hh) 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 by in-
11 serting before the first period the following: “, or the viola-
12 tion of section 408(g)(2) or any regulation issued under
13 such section.”.

14 **SEC. 304. ADULTERATED FOOD.**

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

17 “(2) if—

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

1 “(B) it bears or contains a pesticide chemi-
2 cal residue that is unsafe within the meaning of
3 section 408(a); or

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

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

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

10 **SEC. 305. TOLERANCES AND EXEMPTIONS FOR PESTICIDE**
11 **CHEMICAL RESIDUES.**

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

14 **“SEC. 408. TOLERANCES AND EXEMPTIONS FOR PESTICIDE**
15 **CHEMICAL RESIDUES.**

16 “(a) REQUIREMENT FOR TOLERANCE OR EXEMP-
17 TION.—

18 “(1) DEFINITION.—For the purposes of this
19 section, the term ‘food,’ when used as a noun with-
20 out modification, shall mean a raw agricultural com-
21 modity or processed food.

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

1 “(A) a tolerance for such pesticide chemi-
2 cal residue in or on such food is in effect under
3 this section and the concentration of the residue
4 is within the limits of the tolerance; or

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

8 “(3) PROCESSED FOOD.—Notwithstanding
9 paragraph (2), the following provisions shall apply
10 with respect to processed food:

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

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

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

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

24 “(B) either—

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

11 “(ii) an exemption from the need for
12 a tolerance is in effect under this section
13 for residues of the precursor substance in
14 or on the food; and

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

20 “(5) EFFECT OF TOLERANCE OR EXEMP-
21 TION.—While a tolerance or exemption from the re-
22 quirement for a tolerance is in effect under this sec-
23 tion for a pesticide chemical residue with respect to
24 any food, the food shall not by reason of bearing or
25 containing any amount of such a residue be consid-

1 ered to be adulterated within the meaning of section
2 402(a)(1).

3 “(b) AUTHORITY AND STANDARD FOR TOLER-
4 ANCES.—

5 “(1) AUTHORITY.—The Administrator may
6 issue regulations establishing, modifying, or revoking
7 a tolerance for a pesticide chemical residue in or on
8 a food—

9 “(A) in response to a petition filed under
10 subsection (d); or

11 “(B) on the Administrator’s initiative
12 under subsection (e).

13 “(2) STANDARD.—

14 “(A) IN GENERAL.—A tolerance may not
15 be established for a pesticide chemical residue
16 in or on a food at a level that is higher than
17 a level that the Administrator determines is
18 adequate to protect the public health.

19 “(B) MODIFICATION OR REVOCATION OF A
20 TOLERANCE.—The Administrator shall modify
21 or revoke a tolerance if it is at a level higher
22 than the level that the Administrator deter-
23 mines is adequate to protect the public health.

24 “(C) DETERMINATION FACTORS.—In mak-
25 ing a determination under this paragraph, the

1 Administrator shall take into account, among
2 other relevant factors, the validity, complete-
3 ness, and reliability of the available data from
4 studies of the pesticide chemical residue, the
5 nature of any toxic effects shown to be caused
6 by the pesticide chemical in such studies, avail-
7 able information and reasonable assumptions
8 concerning the relationship of the results of
9 such studies to human risk, available informa-
10 tion and reasonable assumptions concerning the
11 dietary exposure levels of food consumers (and
12 major identifiable subgroups of food consumers,
13 including infants and children) to the pesticide
14 chemical residue, and available information and
15 reasonable assumptions concerning the varia-
16 bility of the sensitivities of major identifiable
17 groups, including infants and children, and
18 shall consider other factors to the extent re-
19 quired by subparagraph (F).

20 “(D) NEGLIGIBLE DIETARY RISK STAND-
21 ARD.—For purposes of subparagraph (A), a tol-
22 erance level for a pesticide chemical residue in
23 or on a food shall be considered to be adequate
24 to protect the public health if the dietary risk
25 posed to food consumers by such level of the

1 pesticide chemical residue is negligible. The Ad-
2 ministrator shall by regulation set forth the fac-
3 tors and methods for determining whether such
4 a risk is negligible.

5 “(E) CALCULATION OF DIETARY RISK.—
6 Where reliable data are available, the Adminis-
7 trator shall calculate the dietary risk posed to
8 food consumers by a pesticide chemical on the
9 basis of the percent of food actually treated
10 with the pesticide chemical and the actual resi-
11 due levels of the pesticide chemical that occur
12 in food. In particular, the Administrator shall
13 take into account aggregate pesticide use and
14 residue data collected by the Department of Ag-
15 riculture.

16 “(F) EXCEPTIONS TO THE NEGLIGIBLE DI-
17 ETARY RISK STANDARD.—For purposes of sub-
18 paragraph (A), a level of a pesticide chemical
19 residue in or on a food that poses a greater
20 than negligible dietary risk to consumers of the
21 food shall be considered to be adequate to pro-
22 tect the public health if the Administrator de-
23 termines that such risk is not unreasonable be-
24 cause—

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

8 “(ii) use of the pesticide avoids risks
9 to workers, the public, or the environment
10 that would be expected to result from the
11 use of another pesticide or pest control
12 method on the same food and that are
13 greater than the risks that result from die-
14 tary exposure to the pesticide chemical res-
15 idue; or

16 “(iii) the unavailability of the pes-
17 ticide would limit the availability to con-
18 sumers of an adequate, wholesome, and ec-
19 onomical food supply, taking into account
20 regional and domestic effects, and such ad-
21 verse effects are likely to outweigh the risk
22 posed by the pesticide residue.

23 In making the determination under this sub-
24 paragraph, the Administrator shall not consider

1 the effects on any pesticide registrant, manu-
2 facturer, or marketer of a pesticide.

3 “(3) LIMITATIONS.—

4 “(A) ISSUANCE OF TOLERANCE.—A toler-
5 ance may be issued under the authority of para-
6 graph (2)(f) only if the Administrator has as-
7 sessed the extent to which efforts are being
8 made to develop either an alternative method of
9 pest control or an alternative pesticide chemical
10 for use on such commodity or food that would
11 meet the requirements of paragraph (2)(D).

12 “(B) ESTABLISHMENT OF A TOLER-
13 ANCE.—A tolerance for a pesticide chemical
14 residue in or on a food shall not be established
15 by the Administrator unless the Administrator
16 determines, after consultation with the Sec-
17 retary, that there is a practical method for de-
18 tecting and measuring the levels of the pesticide
19 chemical residue in or on the food.

20 “(C) ESTABLISHMENT OF A TOLERANCE
21 LEVEL.—A tolerance for a pesticide chemical
22 residue in or on a food shall not be established
23 at a level lower than the limit of detection of
24 the method for detecting and measuring the

1 pesticide chemical residue specified by the Ad-
2 ministrator under subparagraph (B).

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

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

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

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

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

3 “(2) STANDARD.—

4 “(A) IN GENERAL.—An exemption from
5 the requirement for a tolerance for a pesticide
6 chemical residue in or on a food may be estab-
7 lished only if the Administrator determines that
8 a tolerance is not needed to protect the public
9 health, in view of the levels of dietary exposure
10 to the pesticide chemical residue that could rea-
11 sonably be expected to occur.

12 “(B) REVOCATION OF EXEMPTION.—An
13 exemption from the requirement for a tolerance
14 for a pesticide chemical residue in or on a food
15 shall be revoked if the Administrator, in re-
16 sponse to a petition for the revocation of the ex-
17 emption or at the Administrator’s own initiative
18 determines that the exemption does not satisfy
19 the criterion of subparagraph (A).

20 “(C) DETERMINATION FACTORS.—In mak-
21 ing a determination under this subparagraph,
22 the Administrator shall take into account,
23 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; and

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 such 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 or methods used to produce such
5 food;

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

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

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

20 “(B) MODIFICATION OR REVOCATION.—
21 The Administrator may by regulation establish
22 the requirements for information and data to
23 support a petition to modify or revoke a toler-
24 ance or to revoke an exemption from the re-
25 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) OBJECTIONS.—Not later than 60
9 days after a regulation or order is issued under
10 paragraph (4), subsection (e)(1), or subsection
11 (f)(1), any person may file objections thereto
12 with the Administrator, specifying with particu-
13 larity the provisions of the regulation or order
14 considered to be objectionable and stating rea-
15 sonable grounds therefor. If the regulation or
16 order was issued in response to a petition under
17 paragraph (d)(1), a copy of each objection filed
18 by a person other than the petitioner shall be
19 served by the Administrator on the petitioner.

20 “(B) PUBLIC EVIDENTIARY HEARING.—An
21 objection may include a request for a public evi-
22 dentiary hearing upon the objection. The Ad-
23 ministrator shall, upon the initiative of the Ad-
24 ministrator or upon the request of an interested
25 person and after due notice, hold a public evi-

1 dentiary hearing if and to the extent the Ad-
2 ministrator determines that such a public hear-
3 ing is necessary to receive factual evidence rel-
4 evant to material issues of fact raised by the
5 objections. The presiding officer in such a hear-
6 ing may authorize a party to obtain discovery
7 from other persons and may upon a showing of
8 good cause made by a party issue a subpoena
9 to compel testimony or production of documents
10 from any person. The presiding officer shall
11 apply the Federal Rules of Civil Procedure in
12 making any order for the protection of the wit-
13 ness or the content of documents produced and
14 shall order the payment of reasonable fees and
15 expenses as a condition to requiring testimony
16 of the witness. On contest, such a subpoena
17 may be enforced by a Federal district court.

18 “(C) ISSUANCE OF AN ORDER.—After re-
19 ceiving the arguments of the parties, the Ad-
20 ministrator shall, as soon as practicable, issue
21 an order stating the action taken upon each
22 such objection and setting forth any revision to
23 the regulation or prior order that the Adminis-
24 trator has found to be warranted. If a hearing
25 was held under subparagraph (B), such order

1 and any revision to the regulation or prior order
2 shall, with respect to questions of fact at issue
3 in the hearing, be based only on substantial evi-
4 dence of record at such hearing, and shall set
5 forth in detail the findings of facts and the con-
6 clusions of law or policy upon which the order
7 or regulation is based.

8 “(D) EFFECTIVE DATE OF AN ORDER.—

9 An order issued under this paragraph ruling on
10 an objection shall not take effect before the
11 90th day after its publication unless the Admin-
12 istrator finds that emergency conditions exist
13 necessitating an earlier effective date, in which
14 event the Administrator shall specify in the
15 order the Administrator’s findings as to such
16 conditions.

17 “(7) JUDICIAL REVIEW.—

18 “(A) FILING OF PETITION.—In a case of
19 actual controversy as to the validity of any
20 order issued under paragraph (6) or any regula-
21 tion that is the subject of such an order, any
22 person who will be adversely affected by such
23 order or regulation may obtain judicial review
24 by filing in the United States Court of Appeals
25 for the circuit wherein such person resides or

1 has its principal place of business, or in the
2 United States Court of Appeals for the District
3 of Columbia Circuit, not later than 60 days
4 after publication of such order, a petition pray-
5 ing that the order or regulation be set aside in
6 whole or in part.

7 “(B) FILING OF RECORD OF PROCEED-
8 INGS.—A copy of the petition shall be forthwith
9 transmitted by the clerk of the court to the Ad-
10 ministrator, or any officer designated by the
11 Administrator for that purpose, and thereupon
12 the Administrator shall file in the court the
13 record of the proceedings on which the Admin-
14 istrator based the order or regulation, as pro-
15 vided in section 2112 of title 28, United States
16 Code. Upon the filing of such a petition, the
17 court shall have exclusive jurisdiction to affirm
18 or set aside the order or regulation complained
19 of in whole or in part. The findings of the Ad-
20 ministrator with respect to questions of fact
21 shall be sustained only if supported by substan-
22 tial evidence when considered on the record as
23 a whole.

24 “(C) ADDITIONAL EVIDENCE.—If a party
25 applies to the court for leave to adduce addi-

1 tional evidence, and shows to the satisfaction of
2 the court that the additional evidence is mate-
3 rial and that there were reasonable grounds for
4 the failure to adduce the evidence in the pro-
5 ceeding before the Administrator, the court may
6 order that the additional evidence (and evidence
7 in rebuttal thereof) shall be taken before the
8 Administrator in the manner and upon the
9 terms and conditions the court deems proper.
10 The Administrator may modify prior findings
11 as to the facts by reason of the additional evi-
12 dence so taken and may modify the order or
13 regulation accordingly. The Administrator shall
14 file with the court any such modified finding,
15 order, or regulation.

16 “(D) FINAL JUDGMENT.—The judgment of
17 the court affirming or setting aside, in whole or
18 in part, any order under paragraph (6) and any
19 regulation that is the subject of such an order
20 shall be final, subject to review by the Supreme
21 Court of the United States as provided in sec-
22 tion 1254 of title 28 of the United States Code.
23 The commencement of proceedings under this
24 paragraph shall not, unless specifically ordered

1 by the court to the contrary, operate as a stay
2 of a regulation or order.

3 “(E) LIMITATIONS ON JUDICIAL RE-
4 VIEW.—Any issue as to which review is or was
5 obtainable under paragraph (6) and this para-
6 graph shall not be the subject of judicial review
7 under any other provision of law.

8 “(e) ACTION ON ADMINISTRATOR’S OWN INITIA-
9 TIVE.—

10 “(1) GENERAL RULE.—The Administrator may
11 issue a regulation—

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

15 “(B) establishing or revoking an exemption
16 of a pesticide chemical residue from the require-
17 ment of a tolerance; or

18 “(C) establishing general procedures and
19 requirements to implement this section.

20 A regulation issued under this paragraph shall be-
21 come effective upon its publication.

22 “(2) NOTICE.—Before issuing a final regulation
23 under paragraph (1), the Administrator shall issue
24 a notice of proposed rulemaking and provide a pe-
25 riod of not less than 60 days for public comment on

1 the proposed regulation, except that a shorter period
2 for comment may be provided if the Administrator
3 for good cause finds that it would be contrary to the
4 public interest to do so and states the reasons for
5 the finding in the notice of proposed rulemaking.
6 The Administrator shall provide an opportunity for
7 a public hearing during the rulemaking under proce-
8 dures provided in subsection (d)(6)(B).

9 “(f) SPECIAL DATA REQUIREMENTS.—

10 “(1) REQUIRING SUBMISSION OF ADDITIONAL
11 DATA.—If the Administrator determines that addi-
12 tional data or information are reasonably required to
13 support the continuation of a tolerance or exemption
14 that is in effect under this section for a pesticide
15 chemical residue on a food, the Administrator
16 shall—

17 “(A) issue a notice requiring the persons
18 holding the pesticide registrations associated
19 with such tolerance or exemption to submit the
20 data or information under section 3(c)(2)(B) of
21 the Federal Insecticide, Fungicide, and
22 Rodenticide Act (7 U.S.C. 136a(c)(2)(B));

23 “(B) issue a rule requiring that testing be
24 conducted on a substance or mixture under sec-

1 tion 4 of the Toxic Substances Control Act (15
2 U.S.C. 2603); or

3 “(C) publish in the Federal Register, after
4 first providing notice and an opportunity for
5 comment of not less than 90 days duration, an
6 order—

7 “(i) requiring the submission to the
8 Administrator by one or more interested
9 persons of a notice identifying the person
10 or persons who will submit the required
11 data and information;

12 “(ii) describing the type of data and
13 information required to be submitted to
14 the Administrator and stating why the
15 data and information could not be obtained
16 under the authority of section 3(c)(2)(B)
17 of the Federal Insecticide, Fungicide, and
18 Rodenticide Act (7 U.S.C. 136a(c)(2)(B))
19 or section 4 of the Toxic Substances Con-
20 trol Act (15 U.S.C. 2603);

21 “(iii) describing the reports to the Ad-
22 ministrator required to be prepared during
23 and after the collection of the data and in-
24 formation;

1 “(iv) requiring the submission to the
2 Administrator of the data, information,
3 and reports referred to in clauses (ii) and
4 (iii); and

5 “(v) establishing dates by which the
6 submissions described in clauses (i) and
7 (iv) must be made.

8 The Administrator may revise any such order to cor-
9 rect an error.

10 “(2) NONCOMPLIANCE.—If a submission re-
11 quired by a notice issued in accordance with para-
12 graph (1)(A) or an order issued under paragraph
13 (1)(B) is not made by the time specified in such no-
14 tice or order, the Administrator may by order pub-
15 lished in the Federal Register modify or revoke the
16 tolerance or exemption in question.

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

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

22 “(1) GENERAL RULE.—Data and information
23 that are submitted to the Administrator under this
24 section in support of a tolerance shall be entitled to
25 confidential treatment for reasons of business con-

1 confidentiality and to exclusive use and data compensa-
2 tion, to the same extent provided by sections 3 and
3 10 of the Federal Insecticide, Fungicide, and
4 Rodenticide Act (7 U.S.C. 136a and 136h).

5 “(2) EXCEPTIONS.—Data that are entitled to
6 confidential treatment under paragraph (1) may be
7 disclosed to the Congress, and may be disclosed,
8 under such security requirements as the Adminis-
9 trator may provide by regulation, to—

10 “(A) employees of the United States who
11 are authorized by the Administrator to examine
12 such data in the carrying out of their official
13 duties under this Act or other Federal laws in-
14 tended to protect the public health; or

15 “(B) contractors with the United States
16 authorized by the Administrator to examine
17 such data in the carrying out of contracts under
18 such statutes.

19 “(3) SUMMARIES.—Notwithstanding any provi-
20 sion of this subsection or other law, the Adminis-
21 trator may publish the informative summary re-
22 quired by subsection (d)(2)(A)(i) and may, in issu-
23 ing a proposed or final regulation or order under
24 this section, publish an informative summary of the
25 data relating to the regulation or order.

1 “(h) STATUS OF PREVIOUSLY ISSUED REGULA-
2 TIONS.—

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

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

22 “(3) REGULATIONS UNDER SECTION 408.—Reg-
23 ulations that established tolerances or exemptions
24 under this section that were issued on or before the
25 date of the enactment of this paragraph shall remain

1 in effect unless modified or revoked under subsection
2 (d) or (e).

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

8 “(1) regarded by the Administrator or the Sec-
9 retary as generally recognized as safe for use within
10 the meaning of the provisions of section 408(a) or
11 201(s) as then in effect; or

12 “(2) regarded by the Secretary as a substance
13 described by section 201(s)(4),

14 such a pesticide chemical residue shall be regarded as ex-
15 empt from the requirement for a tolerance, as of the date
16 of enactment of this subsection. The Administrator shall
17 by regulation indicate which substances are described by
18 this subsection. An exemption under this subsection may
19 be revoked or modified as if it had been issued under sub-
20 section (c).

21 “(j) HARMONIZATION WITH ACTION UNDER OTHER
22 LAWS.—

23 “(1) LIMITATION.—Notwithstanding any other
24 provision of this Act, a final rule under this section
25 that revokes, modifies, or suspends a tolerance or

1 exemption for a pesticide chemical residue in or on
2 a food may be issued only if the Administrator has
3 first taken any necessary action under the Federal
4 Insecticide, Fungicide, and Rodenticide Act (7
5 U.S.C. 136 et seq.), with respect to the registration
6 of the pesticide whose use results in such residue to
7 ensure that any authorized use of the pesticide in
8 producing, storing, processing, or transporting food
9 that occurs after the issuance of such final rule
10 under this section will not result in pesticide chemi-
11 cal residues on such food that are unsafe within the
12 meaning of subsection (a).

13 “(2) REVOCATION OF TOLERANCE OR EXEMP-
14 TION FOLLOWING CANCELLATION OF ASSOCIATED
15 REGISTRATIONS.—If the Administrator, acting under
16 the Federal Insecticide, Fungicide, and Rodenticide
17 Act (7 U.S.C. 136 et seq.), cancels the registration
18 of each pesticide that contains a particular pesticide
19 chemical and that is labeled for use on a particular
20 food, or requires that the registration of each such
21 pesticide be modified to prohibit its use in connec-
22 tion with the production, storage, or transportation
23 of such food, due in whole or in part to dietary risks
24 to humans posed by residues of such pesticide chemi-
25 cal on such food, the Administrator shall revoke any

1 tolerance or exemption that allows the presence of
2 such pesticide chemical, or any pesticide chemical
3 residue that results from its use, in or on such food.
4 The Administrator shall use the procedures set forth
5 in subsection (e) in taking action under this para-
6 graph. A revocation under this paragraph shall be-
7 come effective not later than 180 days after—

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

10 “(B) the date on which the use of the can-
11 celed pesticide becomes unlawful under the
12 terms of the cancellation,

13 whichever is later.

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

17 “(A) SUSPENSION.—If the Administrator,
18 acting under the Federal Insecticide, Fungicide,
19 and Rodenticide Act (7 U.S.C. 136 et seq.),
20 suspends the use of each registered pesticide
21 that contains a particular pesticide chemical
22 and that is labeled for use on a particular food,
23 due in whole or in part to dietary risks to hu-
24 mans posed by residues of such pesticide chemi-
25 cal on such food, the Administrator shall sus-

1 pend any tolerance or exemption that allows the
2 presence of such pesticide chemical, or any pes-
3 ticide chemical residue that results from its use,
4 in or on such food. The Administrator shall use
5 the procedures set forth in subsection (e) in
6 taking action under this paragraph. A suspen-
7 sion under this paragraph shall become effective
8 not later than 60 days after the date by which
9 each such suspension of use has become effec-
10 tive.

11 “(B) EFFECT OF SUSPENSION.—The sus-
12 pension of a tolerance or exemption under sub-
13 paragraph (A) shall be effective as long as the
14 use of each associated registration of a pesticide
15 is suspended under the Federal Insecticide,
16 Fungicide, and Rodenticide Act (7 U.S.C. 136
17 et seq.). While a suspension of a tolerance or
18 exemption is effective the tolerance or exemp-
19 tion shall not be considered to be in effect. If
20 the suspension of use of the pesticide under
21 such Act is terminated, leaving the registration
22 of the pesticide for such use in effect under
23 such Act, the Administrator shall rescind any
24 associated suspension of a tolerance or exemp-
25 tion.

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

19 “(5) PESTICIDE RESIDUES RESULTING FROM
20 LAWFUL APPLICATION OF PESTICIDE.—Notwith-
21 standing any other provision of this Act, if a toler-
22 ance or exemption for a pesticide chemical residue in
23 or on a food has been revoked, suspended, or modi-
24 fied under this section, an article of that food shall
25 not be considered unsafe solely because of the pres-

1 ence of such pesticide chemical residue in or on such
2 food if it is shown to the satisfaction of the Sec-
3 retary that—

4 “(A) the residue is present as the result of
5 an application or use of a pesticide at a time
6 and in a manner that was lawful under the
7 Federal Insecticide, Fungicide, and Rodenticide
8 Act (7 U.S.C. 136 et seq.); and

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

21 “(k) FEES.—The Administrator shall by regulation
22 require the payment of such fees as will in the aggregate,
23 in the judgment of the Administrator, be sufficient over
24 a reasonable term to provide, equip, and maintain an ade-
25 quate service for the performance of the Administrator’s

1 functions under this section. Under the regulations, the
2 performance of the Administrator's services or other func-
3 tions under this section, including—

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

6 “(2) the promulgation of a regulation establish-
7 ing, modifying, or revoking a tolerance or establish-
8 ing or revoking an exemption from the requirement
9 of a tolerance under this section;

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

12 “(4) the certification and filing in court of a
13 transcript of the proceedings and the record under
14 subsection (d)(7),

15 may be conditioned upon the payment of such fees. The
16 regulations may further provide for waiver or refund of
17 fees in whole or in part when in the judgment of the Ad-
18 ministrator such a waiver or refund is equitable and not
19 contrary to the purposes of this subsection.

20 “(l) NATIONAL UNIFORMITY OF TOLERANCES.—

21 “(1) QUALIFYING PESTICIDE CHEMICAL RESI-
22 DUE.—For purposes of this subsection, the term
23 ‘qualifying pesticide chemical residue’ means a pes-
24 ticide chemical residue resulting from the use, in
25 production, processing, or storage of a food, of a

1 pesticide chemical that is an active ingredient and
2 that—

3 “(A) was first approved for such use in a
4 registration of a pesticide issued under section
5 3(c)(5) of the Federal Insecticide, Fungicide,
6 Rodenticide Act (7 U.S.C. 136a(c)(5)) on or
7 after April 25, 1985, on the basis of data deter-
8 mined by the Administrator to meet all applica-
9 ble requirements for data prescribed by regula-
10 tions in effect under such Act on April 25,
11 1985; or

12 “(B) was approved for such use in a rereg-
13 istration eligibility determination issued under
14 section 4(g) of the Federal Insecticide, Fun-
15 gicide, and Rodenticide Act (7 U.S.C. 136a-
16 1(g)) on or after the date of enactment of the
17 Food Quality Protection Act of 1993.

18 “(2) QUALIFYING FEDERAL DETERMINATION.—

19 For purposes of this subsection, the term ‘qualifying
20 Federal determination’ means—

21 “(A) a tolerance or exemption from the re-
22 quirement for a tolerance for a qualifying pes-
23 ticide chemical residue that was—

1 “(i) issued under this section after the
2 date of enactment of the Food Quality
3 Protection Act of 1993; and

4 “(ii) issued (or, pursuant to sub-
5 section (h) or (i), deemed to have been is-
6 sued) under this section, and determined
7 by the Administrator to meet the standard
8 under subsection (b)(2) (in the case of a
9 tolerance) or (c)(2) (in the case of an ex-
10 emption); and

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

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

1 reviewable in accordance with paragraphs (6) and
2 (7) of subsection (d).

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

21 “(5) PETITION PROCEDURE.—

22 “(A) IN GENERAL.—Any State may peti-
23 tion the Administrator for authorization to es-
24 tablish in such State a regulatory limit on a
25 qualifying pesticide chemical residue in or on

1 any food that is not identical to the qualifying
2 Federal determination applicable to such quali-
3 fying pesticide chemical residue.

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

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

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

17 “(C) ORDER.—Subject to paragraph (6),
18 the Administrator may, by order, grant the au-
19 thorization described in subparagraph (A) if the
20 Administrator determines that the proposed
21 State regulatory limit—

22 “(i) is justified by compelling local
23 conditions;

24 “(ii) would not unduly burden inter-
25 state commerce; and

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

3 “(D) CONSIDERATION OF PETITION AS PE-
4 TITION FOR TOLERANCE OR EXEMPTIONS.—In
5 lieu of any action authorized under subpara-
6 graph (C), the Administrator may treat a peti-
7 tion under this paragraph as a petition under
8 subsection (d) to revoke or modify a tolerance
9 or to revoke an exemption. If the Administrator
10 determines to treat a petition under this para-
11 graph as a petition under subsection (d), the
12 Administrator shall thereafter act on the peti-
13 tion pursuant to subsection (d).

14 “(E) REVIEW OF ORDER.—Any order of
15 the Administrator granting or denying the au-
16 thorization described in subparagraph (A) shall
17 be subject to review in the manner described in
18 subsections (d)(6) and (d)(7).

19 “(6) RESIDUES FROM LAWFUL APPLICATION.—
20 No State or political subdivision may enforce any
21 regulatory limit on the level of a pesticide chemical
22 residue that may appear in or on any food if, at the
23 time of the application of the pesticide that resulted
24 in such residue, the sale of such food with such resi-
25 due level was lawful under this Act and under the

1 law of such State, unless the State demonstrates
 2 that consumption of the food containing such pes-
 3 ticide residue level during the period of the food's
 4 likely availability in the State will pose an unreason-
 5 able dietary risk to the health of persons within such
 6 State.”.

7 **SEC. 305. CONFORMING AMENDMENT.**

8 Section 512(a)(1) (21 U.S.C. 360b(a)(1)) is amended
 9 by striking “section 402(a)(2)(D)” and inserting “section
 10 402(a)(2)(C)(ii)”.

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

12 There is authorized to be appropriated \$12,000,000
 13 in addition to other amounts appropriated for increased
 14 monitoring by the Secretary of Health and Human Serv-
 15 ices of pesticide residues in imported and domestic food.

○

S 1478 IS—2

S 1478 IS—3

S 1478 IS—4

S 1478 IS—5