

Union Calendar No. 364

104TH CONGRESS
2^D Session

H. R. 1627

[Report No. 104-669, Parts I and II]

A BILL

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

JULY 23, 1996

Reported from the Committee on Commerce with an
amendment, committed to the Committee of the Whole
House on the State of the Union, and ordered to be
printed

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

IN THE HOUSE OF REPRESENTATIVES

MAY 12, 1995

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

JULY 11, 1996

Reported from the Committee on Agriculture with amendments

[Omit the part struck through and insert the part printed in *italic*]

JULY 23, 1996

Additional sponsors: Mr. HAYES, Mr. PETERSON of Minnesota, Mr. COBLE, Mr. MCINTOSH, Mr. BALLENGER, Mr. BUNN of Oregon, Mr. LAUGHLIN, Mr. FUNDERBURK, Mr. PICKETT, Mr. BARR of Georgia, Mr. FAZIO of California, Mr. COLLINS of Georgia, Mr. SOLOMON, Mr. GEKAS, Mr. BONO, Mr. JONES, Mr. BAKER of California, Mr. GUTKNECHT, Mr. SISISKY, Mr. KLUG, Mr. GALLEGLY, Mr. JACOBS, Mr. BURTON of Indiana, Mr. ARCHER, Mr. CAMP, Mr. CHRISTENSEN, Mr. COBURN, Mr. HERGER, Mr. KANJORSKI, Mr. COSTELLO, Mr. FRANKS of Connecticut, Mr. THORNTON, Mr. HEFNER, Mr. THOMAS, Mr. BROWNBAC, Mr. ROGERS, Mr. HEINEMAN, Mr. DORNAN, Mr. WATTS of Oklahoma, Mr. LINDER, Mr. GOODLING, Mr. ROHRBACHER, Mr. CRANE, Mr. FORD, Mr. SPENCE, Mr. PARKER, Mr. LEWIS of California, Mr. STOCKMAN, Mr. DAVIS, Mr. MCKEON, Mr. WICKER, Mr. TIAHRT, Mr. HILLIARD, Mr. THOMPSON, Mr. HOBSON, Mr. HOUGHTON, Mr. BONILLA, Mr. BUNNING of Kentucky, Mr. LEACH, Ms. DUNN of Washington, Mr. MATSUI, Mr. SPRATT, Mrs. SMITH of Washington, Mr. CLYBURN, Mr. TANNER, Mr. PETERSON of Florida, Mr. MICA, Mr. PACKARD, Mr. PETE GEREN of Texas, Mr. EHRLICH, Mr. BATEMAN, Mr. CHAPMAN, Mr. MILLER of Florida, Mr. SKELTON, Mr. RIGGS, Mr. VOLKMER, Mr. MCCOLLUM, Mr. FARR of California, Mr. TATE, Mr. PAYNE OF VIRGINIA, Mr. HUNTER, Mr. CRAMER, Mr. BREWSTER, Mr. WELLER, Mr. MCINNIS, Mrs. MYRICK, Mr. HILLEARY, Mrs. CUBIN, Mr. GILCHREST, Mr. NUSSLE, Mr. WILLIAMS, Mr. KNOLLENBERG, Mr. LARGENT, Mr. ENGEL, Mr. LIVINGSTON, Mr. ROTH, Mr. LIGHTFOOT, Mr. CALLAHAN, Mr. LIPINSKI, Mr. DELAY, Mr. SHUSTER, Mr. GOSS, Mr. ROYCE, Mr. BEVILL, Mr. DEAL of Georgia, Mr. WELDON of Florida, Mr. SOUDER, Mr. ANDREWS, Mr. DREIER, Mr. BARTLETT of Maryland, Mr. CUNNINGHAM, Mr. STEARNS, Mr. BACHUS, Mr. SCARBOROUGH, Mrs. FOWLER, Mr. TRAFICANT, Mr. PORTER, Mr. BASS, Mr. ENGLISH of Pennsylvania, Mrs. VUCANOVICH, Mr. CASTLE, Mr. KIM, Mr. SMITH of Texas, Ms. PRYCE, Mr. PETRI, Mr. HANSEN, Mr. ISTOOK, Mr. WATT of North Carolina, Mr. LONGLEY, Mr. HAMILTON, Mr. MANTON, Mr. MYERS of Indiana, Mr. LATOURETTE, Mrs. CLAYTON, Mr. BARCIA of Michigan, Mr. BOEHLERT, Mr. DICKS, Mr. WAMP, Mr. MCDADE, Mr. GRAHAM, Mr. KOLBE, Mr. NEY, Mrs. ROUKEMA, Mr. CAMPBELL, Mr. GILMAN, Mr. DINGELL, and Mr. WAXMAN

JULY 23, 1996

Reported from the Committee on Commerce with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Omit the part in bold brackets and insert the part printed in boldface roman]

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Food Quality Protection Act of 1995”.

TITLE I—CANCELLATION AND SUSPENSION

SEC. 101. REFERENCE.

Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Insecticide, Fungicide, and Rodenticide Act.

SEC. 102. CANCELLATION.

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

“(b) CANCELLATION AND CHANGE IN CLASSIFICATION OR OTHER TERMS OR CONDITIONS OF REGISTRATION.—

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

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

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

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

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

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

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

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

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

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

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

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

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

25 ~~“(5) NOTICE OF PROPOSED RULEMAKING.—~~

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

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

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

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

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

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

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

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

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

19 “(6) HEARING.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 “(D) in the case of a final rule—

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

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

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

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

24 “(9) MODIFICATION OR CANCELLATION.—

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

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

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

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

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

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

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

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

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

22 **SEC. 104. SUSPENSION.**

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

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

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

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

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

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

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

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

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

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

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

“(v) commence promptly such proceedings under this Act and section 408 of the Federal Food, Drug, and Cosmetic Act as are warranted by such determinations.”.

SEC. 106. SCIENTIFIC ADVISORY PANEL.

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

(1) by striking “The Administrator shall” and inserting “(1) IN GENERAL.—The Administrator shall”; and

(2) by adding at the end the following:

“(2) SCIENCE REVIEW BOARD.—There is established a Science Review Board to consist of 60 scientists who shall be available to the Scientific Advisory Panel to assist in reviews conducted by the

1 Panel. The Scientific Advisory Panel shall select the
 2 scientists from 60 nominations submitted each by
 3 the National Science Foundation and the National
 4 Institutes of Health. Members of the Board shall be
 5 compensated in the same manner as members of the
 6 Panel.”.

7 **SEC. 107 CONFORMING AMENDMENTS.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 **TITLE II—MINOR USE CROP PROTECTION**
7 **ACT OF 1995**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 subparagraph for data required solely to support
2 that minor use until the final deadline for submis-
3 sion of data under this section for the other uses of
4 the pesticide established as of the date of enactment
5 of the Food Quality Protection Act of 1996 if—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 “(C) ~~MINOR USE REGISTRATION.—~~

1 “(i) The Administrator shall, as expe-
2 ditiously as possible, review and act on any
3 complete application—

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

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

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

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

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

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

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

1 beginning with the data of receipt by the reg-
2 istrant of the Administrator's notice of denial.”.

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

5 (1) REREGISTRATION.—

6 (A) Sections 4(d)(6) and 4(f)(3) (7 U.S.C.
7 136a-1(d)(6) and (f)(3)) are each amended by
8 adding at the end the following: “If the reg-
9 istrant does not commit to support a specific
10 minor use of the pesticide, but is supporting
11 and providing data in a timely and adequate
12 fashion to support uses of the pesticide on a
13 food, or if all uses of the pesticide are nonfood
14 uses and the registrant does not commit to sup-
15 port a specific minor use of the pesticide but is
16 supporting and providing data in a timely and
17 adequate fashion to support other nonfood uses
18 of the pesticide, the Administrator, at the writ-
19 ten request of the registrant, shall not take any
20 action pursuant to this paragraph in regard to
21 such unsupported minor use until the final
22 deadline established as of the date of enactment
23 of the Minor Use Crop Protection Act of 1995,
24 for the submission of data under this section
25 for the supported uses identified pursuant to

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 “(b) MATCHING FUND PROGRAM.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 **SECTION 1. SHORT TITLE.**

6 *This Act may be cited as the “Food Quality Protection*
 7 *Act of 1996”.*

8 **TITLE I—SUSPENSION-**
 9 **APPLICATORS**

10 **SEC. 101. REFERENCE.**

11 *Whenever in this title an amendment or repeal is ex-*
 12 *pressed in terms of an amendment to, or repeal of, a section*
 13 *or other provision, the reference shall be considered to be*
 14 *made to a section or other provision of the Federal Insecti-*
 15 *cide, Fungicide, and Rodenticide Act.*

16 **Subtitle A—Suspension**

17 **SEC. 102. SUSPENSION.**

18 (a) SECTION 6(c)(1).—*The second sentence of section*
 19 *6(c)(1) (7 U.S.C. 136d(c)(1)) is amended to read: “Except*
 20 *as provided in paragraph (3), no order of suspension may*
 21 *be issued under this subsection unless the Administrator has*
 22 *issued, or at the same time issues, a notice of intention to*
 23 *cancel the registration or change the classification of the*
 24 *pesticide under subsection (b).”.*

1 (b) *SECTION 6(c)(3).—Section 6(c)(3) (7 U.S.C.*
 2 *136d(c)(3)) is amended by inserting after the first sentence*
 3 *the following new sentence: “The Administrator may issue*
 4 *an emergency order under this paragraph before issuing a*
 5 *notice of intention to cancel the registration or change the*
 6 *classification of the pesticide under subsection (b) and the*
 7 *Administrator shall proceed to issue the notice under sub-*
 8 *section (b) within 90 days of issuing an emergency order.*
 9 *If the Administrator does not issue a notice under sub-*
 10 *section (b) within 90 days of issuing an emergency order,*
 11 *the emergency order shall expire.”.*

12 **SEC. 103. TOLERANCE REEVALUATION AS PART OF REREG-**
 13 **ISTRATION.**

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

16 “(E) As soon as the Administrator has suf-
 17 ficient information with respect to the dietary
 18 risk of a particular active ingredient, but in any
 19 event no later than the time the Administrator
 20 makes a determination under subparagraph (C)
 21 or (D) with respect to pesticides containing a
 22 particular active ingredient, the Administrator
 23 shall—

24 “(i) reassess each associated tolerance
 25 and exemption from the requirement for a

1 *tolerance issued under section 408 of the*
2 *Federal Food, Drug, and Cosmetic Act (21*
3 *U.S.C. 346a) taking into account available*
4 *information and reasonable assumptions*
5 *concerning the dietary exposure levels of*
6 *food consumers (and major identifiable sub-*
7 *groups of food consumers, including infants*
8 *and children) to residue of the pesticide in*
9 *food and available information and reason-*
10 *able assumptions concerning the variability*
11 *of the sensitivities of major identifiable*
12 *groups, including infants and children;*

13 “(ii) *determine whether such tolerance*
14 *or exemption meets the requirements of that*
15 *Act;*

16 “(iii) *determine whether additional tol-*
17 *erances or exemptions should be issued;*

18 “(iv) *publish in the Federal Register a*
19 *notice setting forth the determinations made*
20 *under this subparagraph; and*

21 “(v) *commence promptly such proceed-*
22 *ings under this Act and section 408 of the*
23 *Federal Food, Drug, and Cosmetic Act as*
24 *are warranted by such determinations.”.*

1 **SEC. 104. SCIENTIFIC ADVISORY PANEL.**

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

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

5 *“(1) IN GENERAL.—The Administrator shall”;*
 6 *and*

7 *(2) by adding at the end the following:*

8 *“(2) SCIENCE REVIEW BOARD.—There is estab-*
 9 *lished a Science Review Board to consist of 60 sci-*
 10 *entists who shall be available to the Scientific Advi-*
 11 *sory Panel to assist in reviews conducted by the*
 12 *Panel. Members of the Board shall be selected in the*
 13 *same manner as members of temporary subpanels cre-*
 14 *ated under paragraph (1). Members of the Board shall*
 15 *be compensated in the same manner as members of*
 16 *the Panel.”.*

17 **SEC. 105. NITROGEN STABILIZER.**

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

20 *(1) in subsection (a)—*

21 *(A) in paragraph (1) by striking “or” after*
 22 *“defoliant,” and inserting “; or nitrogen sta-*
 23 *bilizer” after “desiccant”;*

24 *(B) at the end of paragraph (3) by striking*
 25 *“and”;*

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

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

4 “(5) in the case of a nitrogen stabilizer, an in-
5 gredient which will prevent or hinder the process of
6 nitrification, denitrification, ammonia volatilization,
7 or urease production through action affecting soil bac-
8 teria.”;

9 (2) in subsection (u), by striking “and” before
10 “(2)” and by inserting “and (3) any nitrogen sta-
11 bilizer,” after “desiccant,”; and

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

13 “(hh) NITROGEN STABILIZER.—The term ‘nitrogen
14 stabilizer’ means any substance or mixture of substances in-
15 tended for preventing or hindering the process of nitrifica-
16 tion, denitrification, ammonia volatilization, or urease pro-
17 duction through action upon soil bacteria. Such term shall
18 not include—

19 “(1) dicyandiamide;

20 “(2) ammonium thiosulfate; or

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

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

24 “(B) that was in commercial agronomic use
25 prior to January 1, 1992, with respect to which

1 *after January 1, 1992, the distributor or seller*
 2 *of the substance or mixture has made no specific*
 3 *claim of prevention or hindering of the process*
 4 *of nitrification, denitrification, ammonia vola-*
 5 *tilization urease production regardless of the ac-*
 6 *tual use or purpose for, or future use or purpose*
 7 *for, the substance or mixture.*

8 *Statements made in materials required to be submitted to*
 9 *any State legislative or regulatory authority, or required*
 10 *by such authority to be included in the labeling or other*
 11 *literature accompanying any such substance or mixture*
 12 *shall not be deemed a specific claim within the meaning*
 13 *of this subsection.”.*

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

16 “(4) *MIXTURES OF NITROGEN STABILIZERS AND*
 17 *FERTILIZER PRODUCTS.—Any mixture or other com-*
 18 *bination of—*

19 “(A) *1 or more nitrogen stabilizers reg-*
 20 *istered under this Act; and*

21 “(B) *1 or more fertilizer products,*
 22 *shall not be subject to the provisions of this section or*
 23 *sections 4, 5, 7, 15, and 17(a)(2) if the mixture or*
 24 *other combination is accompanied by the labeling re-*
 25 *quired under this Act for the nitrogen stabilizer con-*

1 *tained in the mixture or other combination, the mix-*
 2 *ture or combination is mixed or combined in accord-*
 3 *ance with such labeling, and the mixture or combina-*
 4 *tion does not contain any active ingredient other than*
 5 *the nitrogen stabilizer.”.*

6 **SEC. 106. AUTHORITY OF STATES.**

7 (a) *DEFINITIONS.*—Section 2 (7 U.S.C. 136), as
 8 *amended by section 105, is further amended—*

9 (1) *in subsection (aa), by adding at the end the*
 10 *following new sentence: “The term ‘State’ does not in-*
 11 *clude a local government, as defined in subsection*
 12 *(ii), and is not intended to grant any authority or*
 13 *to otherwise refer to local governments or political*
 14 *subdivisions of a State.”; and*

15 (2) *by adding at the end the following:*

16 “(ii) *LOCAL GOVERNMENT.*—The term ‘local govern-
 17 *ment’ means any political subdivision of a State including*
 18 *counties, townships, cities, towns, parishes, and boroughs,*
 19 *whether home rule entities or not, or any local agency or*
 20 *body of any type which has an organized existence, govern-*
 21 *mental character, and substantial autonomy including*
 22 *independent or autonomous school districts, housing au-*
 23 *thorities, and other special districts.”.*

1 (b) *RECORDS*.—Section 8(b) (7 U.S.C. 136f(b)) is
 2 amended by striking “or political subdivision” in the first
 3 sentence.

4 (c) *DELEGATION AND COOPERATION*.—Section 22(b)
 5 (7 U.S.C. 136t(b)) is amended by striking “or any political
 6 subdivision thereof”.

7 (d) *AUTHORITY OF STATES*.—Section 24 (7 U.S.C.
 8 136v) is amended by adding at the end the following:

9 “(d) *LOCAL REGULATION*.—Subject to subsection (e),
 10 a local government shall not impose or continue in effect
 11 any requirement or regulation regarding pesticides or de-
 12 vices.

13 “(e) *LOCALLY SPECIFIC STATE REGULATION*.—Noth-
 14 ing in this section shall prohibit a State from enforcing
 15 laws, enacting laws, or implementing regulations applica-
 16 ble to local governments regarding the sale or use of any
 17 federally registered pesticide or device.”.

18 (e) *AUTHORITY OF ADMINISTRATOR*.—The first sen-
 19 tence of section 25(e) (7 U.S.C. 136w(e)) is amended by
 20 striking “or political subdivision thereof”.

21 **SEC. 107. PERIODIC REGISTRATION REVIEW.**

22 (a) *SECTION 6*.—Section 6 (7 U.S.C. 136d) is amend-
 23 ed—

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

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

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

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

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

13 “(g) *REGISTRATION REVIEW.*—

14 “(1)(A) *GENERAL RULE.*—The registrations of
15 pesticides are to be periodically reviewed. The Admin-
16 istrator shall by regulation establish a procedure for
17 accomplishing the periodic review of registrations.
18 The goal of these regulations shall be a review of a
19 pesticide’s registration every 15 years. No registration
20 shall be canceled as a result of the registration review
21 process unless the Administrator follows the proce-
22 dures and substantive requirements of section 6.

23 “(B) *LIMITATION.*—Nothing in this subsection
24 shall prohibit the Administrator from undertaking
25 any other review of a pesticide pursuant to this Act.

1 “(2)(A) *DATA*.—*The Administrator shall use the*
 2 *authority in subsection (c)(2)(B) to require the sub-*
 3 *mission of data when such data are necessary for a*
 4 *registration review.*

5 “(B) *DATA SUBMISSION, COMPENSATION, AND*
 6 *EXEMPTION*.—*For purposes of this subsection, the pro-*
 7 *visions of subsections (c)(1), (c)(2)(B), and (c)(2)(D)*
 8 *shall be utilized for and be applicable to any data re-*
 9 *quired for registration review.”.*

10 ***Subtitle B—Training for Maintenance***
 11 ***Applicators and Service***
 12 ***Technicians***

13 ***SEC. 120. MAINTENANCE APPLICATORS AND SERVICE TECH-***
 14 ***NICIANS DEFINITIONS.***

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

17 “(jj) *MAINTENANCE APPLICATOR*.—*The term ‘mainte-*
 18 *nance applicator’ means any individual who, in the prin-*
 19 *cipal course of such individual’s employment, uses, or su-*
 20 *pervises the use of, a pesticide not classified for restricted*
 21 *use (other than a ready to use consumer products pes-*
 22 *ticides); for the purpose of providing structural pest control*
 23 *or lawn pest control including janitors, general mainte-*
 24 *nance personnel, sanitation personnel, and grounds mainte-*
 25 *nance personnel. The term ‘maintenance applicator’ does*

1 *not include private applicators as defined in section 2(e)(2);*
 2 *individuals who use antimicrobial pesticides, sanitizers or*
 3 *disinfectants; individuals employed by Federal, State, and*
 4 *local governments or any political subdivisions thereof, or*
 5 *individuals who use pesticides not classified for restricted*
 6 *use in or around their homes, boats, sod farms, nurseries,*
 7 *greenhouses, or other noncommercial property.*

8 “(kk) *SERVICE TECHNICIAN.*—*The term ‘service tech-*
 9 *nician’ means any individual who uses or supervises the*
 10 *use of pesticides (other than a ready to use consumer prod-*
 11 *ucts pesticide) for the purpose of providing structural pest*
 12 *control or lawn pest control on the property of another for*
 13 *a fee. The term ‘service technician’ does not include individ-*
 14 *uals who use antimicrobial pesticides, sanitizers or dis-*
 15 *infectants; or who otherwise apply ready to use consumer*
 16 *products pesticides.”.*

17 **SEC. 121. MINIMUM REQUIREMENTS FOR TRAINING OF**
 18 **MAINTENANCE APPLICATORS AND SERVICE**
 19 **TECHNICIANS.**

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

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

24 (2) *by adding after section 29 the following:*

1 **“SEC. 30. MINIMUM REQUIREMENTS FOR TRAINING OF**
 2 **MAINTENANCE APPLICATORS AND SERVICE**
 3 **TECHNICIANS.**

4 *“Each State may establish minimum requirements for*
 5 *training of maintenance applicators and service techni-*
 6 *cians. Such training may include instruction in the safe*
 7 *and effective handling and use of pesticides in accordance*
 8 *with the Environmental Protection Agency approved label-*
 9 *ing, and instruction in integrated pest management tech-*
 10 *niques. The authority of the Administrator with respect to*
 11 *minimum requirements for training of maintenance appli-*
 12 *cators and service technicians shall be limited to ensuring*
 13 *that each State understands the provisions of this section.”.*

14 **TITLE II—MINOR USE CROP PRO-**
 15 **TECTION, ANTIMICROBIAL**
 16 **PESTICIDE REGISTRATION**
 17 **REFORM, AND PUBLIC**
 18 **HEALTH PESTICIDES**

19 **SEC. 201. REFERENCE.**

20 *Whenever in this title an amendment or repeal is ex-*
 21 *pressed in terms of an amendment to, or repeal of, a section*
 22 *or other provision, the reference shall be considered to be*
 23 *made to a section or other provision of the Federal Insecti-*
 24 *cide, Fungicide, and Rodenticide Act.*

1 ***Subtitle A—Minor Use Crop***
2 ***Protection***

3 **SEC. 210. MINOR CROP PROTECTION.**

4 (a) *DEFINITION.*—Section 2 (7 U.S.C. 136), as amend-
5 ed by section 120, is further amended by adding at the end
6 the following:

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

11 “(1) the total United States acreage for the crop
12 is less than 300,000 acres, as determined by the Sec-
13 retary of Agriculture; or

14 “(2) the Administrator, in consultation with the
15 Secretary of Agriculture, determines that, based on
16 information provided by an applicant for registration
17 or a registrant, the use does not provide sufficient eco-
18 nomic incentive to support the initial registration or
19 continuing registration of a pesticide for such use
20 and—

21 “(A) there are insufficient efficacious alter-
22 native registered pesticides available for the use;

23 “(B) the alternatives to the pesticide use
24 pose greater risks to the environment or human
25 health;

1 “(C) the minor use pesticide plays or will
2 play a significant part in managing pest resist-
3 ance; or

4 “(D) the minor use pesticide plays or will
5 play a significant part in an integrated pest
6 management program.

7 *The status as a minor use under this subsection shall con-*
8 *tinue as long as the Administrator has not determined that,*
9 *based on existing data, such use may cause an unreasonable*
10 *adverse effect on the environment and the use otherwise*
11 *qualifies for such status.”.*

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

14 (1) *by redesignating clauses (ii) and (iii) as*
15 *clauses (iii) and (iv), respectively; and*

16 (2) *by inserting after clause (i) the following:*

17 “(ii) *The period of exclusive data use*
18 *provided under clause (i) shall be extended*
19 *1 additional year for each 3 minor uses reg-*
20 *istered after the date of enactment of this*
21 *clause and within 7 years of the commence-*
22 *ment of the exclusive use period, up to a*
23 *total of 3 additional years for all minor*
24 *uses registered by the Administrator if the*
25 *Administrator, in consultation with the*

1 *Secretary of Agriculture, determines that,*
2 *based on information provided by an appli-*
3 *cant for registration or a registrant, that—*

4 *“(I) there are insufficient effica-*
5 *cious alternative registered pesticides*
6 *available for the use;*

7 *“(II) the alternatives to the minor*
8 *use pesticide pose greater risks to the*
9 *environment or human health;*

10 *“(III) the minor use pesticide*
11 *plays or will play a significant part in*
12 *managing pest resistance; or*

13 *“(IV) the minor use pesticide*
14 *plays or will play a significant part in*
15 *an integrated pest management pro-*
16 *gram.*

17 *The registration of a pesticide for a minor*
18 *use on a crop grouping established by the*
19 *Administrator shall be considered for pur-*
20 *poses of this clause 1 minor use for each*
21 *representative crop for which data are pro-*
22 *vided in the crop grouping. Any additional*
23 *exclusive use period under this clause shall*
24 *be modified as appropriate or terminated if*
25 *the registrant voluntarily cancels the prod-*

1 *uct or deletes from the registration the*
2 *minor uses which formed the basis for the*
3 *extension of the additional exclusive use pe-*
4 *riod or if the Administrator determines that*
5 *the registrant is not actually marketing the*
6 *product for such minor uses.”;*

7 *(3) in clause (iv), as amended by paragraph (1),*
8 *by striking “and (ii)” and inserting “, (ii), and*
9 *(iii)”;* and

10 *(4) at the end of the section, as amended by*
11 *paragraph (1), by adding the following:*

12 *“(v) The period of exclusive use pro-*
13 *vided under clause (ii) shall not take into*
14 *effect until 1 year after enactment of this*
15 *clause, except where an applicant or reg-*
16 *istrant is applying for the registration of a*
17 *pesticide containing an active ingredient*
18 *not previously registered.*

19 *“(vi) With respect to data submitted*
20 *after the date of enactment of this clause by*
21 *an applicant or registrant to support an*
22 *amendment adding a new use to an existing*
23 *registration that does not retain any period*
24 *of exclusive use, if such data relates solely*
25 *to a minor use of a pesticide, such data*

1 shall not, without the written permission of
2 the original data submitter, be considered
3 by the Administrator to support an appli-
4 cation for a minor use by another person
5 during the period of 10 years following the
6 date of submission of such data. The appli-
7 cant or registrant at the time the new
8 minor use is requested shall notify the Ad-
9 ministrator that to the best of their knowl-
10 edge the exclusive use period for the pes-
11 ticide has expired and that the data per-
12 taining solely to the minor use of a pes-
13 ticide is eligible for the provisions of this
14 paragraph. If the minor use registration
15 which is supported by data submitted pur-
16 suant to this subsection is voluntarily can-
17 celed or if such data are subsequently used
18 to support a nonminor use, the data shall
19 no longer be subject to the exclusive use pro-
20 visions of this clause but shall instead be
21 considered by the Administrator in accord-
22 ance with the provisions of clause (i), as
23 appropriate.”.

24 (c) *TIME EXTENSIONS FOR DEVELOPMENT OF MINOR*

25 *USE DATA.*—

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

4 “(vi) *Upon the request of a registrant*
5 *the Administrator shall, in the case of a*
6 *minor use, extend the deadline for the pro-*
7 *duction of residue chemistry data under this*
8 *subparagraph for data required solely to*
9 *support that minor use until the final dead-*
10 *line for submission of data under section 4*
11 *for the other uses of the pesticide established*
12 *as of the date of enactment of the Minor Use*
13 *Crop Protection Act of 1996, if—*

14 “(I) *the data to support other uses*
15 *of the pesticide on a food are being*
16 *provided;*

17 “(II) *the registrant, in submitting*
18 *a request for such an extension, pro-*
19 *vides a schedule, including interim*
20 *dates to measure progress, to assure*
21 *that the data production will be com-*
22 *pleted before the expiration of the ex-*
23 *tension period;*

24 “(III) *the Administrator has de-*
25 *termined that such extension will not*

1 *significantly delay the Administrator's*
2 *schedule for issuing a reregistration*
3 *eligibility determination required*
4 *under section 4; and*

5 *“(IV) the Administrator has de-*
6 *termined that based on existing data,*
7 *such extension would not significantly*
8 *increase the risk of any unreasonable*
9 *adverse effect on the environment. If*
10 *the Administrator grants an extension*
11 *under this clause, the Administrator*
12 *shall monitor the development of the*
13 *data and shall ensure that the reg-*
14 *istrant is meeting the schedule for the*
15 *production of the data. If the Adminis-*
16 *trator determines that the registrant is*
17 *not meeting or has not met the sched-*
18 *ule for the production of such data, the*
19 *Administrator may proceed in accord-*
20 *ance with clause (iv) regarding the*
21 *continued registration of the affected*
22 *products with the minor use and shall*
23 *inform the public of such action. Not-*
24 *withstanding the provisions of this*
25 *clause, the Administrator may take ac-*

1 *tion to modify or revoke the extension*
2 *under this clause if the Administrator*
3 *determines that the extension for the*
4 *minor use may cause an unreasonable*
5 *adverse effect on the environment. In*
6 *such circumstance, the Administrator*
7 *shall provide, in writing to the reg-*
8 *istrant, a notice revoking the extension*
9 *of time for submission of data. Such*
10 *data shall instead be due in accordance*
11 *with the date established by the Ad-*
12 *ministrator for the submission of the*
13 *data.”.*

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

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

3 “(ii) the registrant, in submitting a request
4 for such an extension provides a schedule, includ-
5 ing interim dates to measure progress, to assure
6 that the data production will be completed before
7 the expiration of the extension period;

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

13 “(iv) the Administrator has determined
14 that based on existing data, such extension
15 would not significantly increase the risk of
16 any unreasonable adverse effect on the envi-
17 ronment. If the Administrator grants an ex-
18 tension under this subparagraph, the Ad-
19 ministrator shall monitor the development
20 of the data and shall ensure that the reg-
21 istrant is meeting the schedule for the pro-
22 duction of the data. If the Administrator
23 determines that the registrant is not meet-
24 ing or has not met the schedule for the pro-
25 duction of such data, the Administrator

1 *may proceed in accordance with clause (iv)*
 2 *of section 3(c)(2)(B) or other provisions of*
 3 *this section, as appropriate, regarding the*
 4 *continued registration of the affected prod-*
 5 *ucts with the minor use and shall inform*
 6 *the public of such action. Notwithstanding*
 7 *the provisions of this subparagraph, the Ad-*
 8 *ministrator may take action to modify or*
 9 *revoke the extension under this subpara-*
 10 *graph if the Administrator determines that*
 11 *the extension for the minor use may cause*
 12 *an unreasonable adverse affect on the envi-*
 13 *ronment. In such circumstance, the Admin-*
 14 *istrator shall provide written notice to the*
 15 *registrant revoking the extension of time for*
 16 *submission of data. Such data shall instead*
 17 *be due in accordance with the date then es-*
 18 *tablished by the Administrator for submis-*
 19 *sion of the data.”.*

20 *(d) MINOR USE WAIVER.—Section 3(c)(2) (7 U.S.C.*
 21 *136a(c)(2)) is amended—*

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

23 *(2) by inserting “ADDITIONAL DATA.—” after*

24 *“(B)”;*

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

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

4 “(E) MINOR USE WAIVER.—In handling the
 5 registration of a pesticide for a minor use, the
 6 Administrator may waive otherwise applicable
 7 data requirements if the Administrator deter-
 8 mines that the absence of such data will not pre-
 9 vent the Administrator from determining—

10 “(i) the incremental risk presented by
 11 the minor use of the pesticide; and

12 “(ii) that such risk, if any, would not
 13 be an unreasonable adverse effect on the en-
 14 vironment.”.

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

17 (1) by inserting after “(A)” the following: “IN
 18 GENERAL.—”;

19 (2) by inserting after “(B)” the following:
 20 “IDENTICAL OR SUBSTANTIALLY SIMILAR.—”; and

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

22 “(C) MINOR USE REGISTRATION.—

23 “(i) The Administrator shall, as expe-
 24 ditiously as possible, review and act on any
 25 complete application—

1 “(I) that proposes the initial reg-
2 istration of a new pesticide active in-
3 gredient if the active ingredient is pro-
4 posed to be registered solely for minor
5 uses, or proposes a registration amend-
6 ment solely for minor uses to an exist-
7 ing registration; or

8 “(II) for a registration or a reg-
9 istration amendment that proposes sig-
10 nificant minor uses.

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

12 “(I) the term ‘as expeditiously as
13 possible’ means that the Administrator
14 shall, to the greatest extent practicable,
15 complete a review and evaluation of all
16 data, submitted with a complete appli-
17 cation, within 12 months after the sub-
18 mission of the complete application,
19 and the failure of the Administrator to
20 complete such a review and evaluation
21 under clause (i) shall not be subject to
22 judicial review; and

23 “(II) the term ‘significant minor
24 uses’ means 3 or more minor uses pro-
25 posed for every nonminor use, a minor

1 use that would, in the judgment of the
2 Administrator, serve as a replacement
3 for any use which has been canceled in
4 the 5 years preceding the receipt of the
5 application, or a minor use that in the
6 opinion of the Administrator would
7 avoid the reissuance of an emergency
8 exemption under section 18 for that
9 minor use.

10 “(D) ADEQUATE TIME FOR SUBMISSION OF
11 MINOR USE DATA.—If a registrant makes a re-
12 quest for a minor use waiver, regarding data re-
13 quired by the Administrator, pursuant to para-
14 graph (2)(E), and if the Administrator denies in
15 whole or in part such data waiver request, the
16 registrant shall have a full-time period for pro-
17 viding such data. For purposes of this subpara-
18 graph, the term ‘full-time period’ means the time
19 period originally established by the Adminis-
20 trator for submission of such data, beginning
21 with the date of receipt by the registrant of the
22 Administrator’s notice of denial.”.

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

25 (1) REREGISTRATION.—

(A) Sections 4(d)(6) and 4(f)(3) (7 U.S.C. 136a–1(d)(6) and (f)(3)) are each amended by adding at the end the following: “If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Food Quality Protection Act of 1996, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon re-

1 *ceipt of the request from the registrant, the Ad-*
2 *ministrator shall publish in the Federal Register*
3 *a notice of the receipt of the request and the ef-*
4 *fective date upon which the uses not being sup-*
5 *ported will be voluntarily deleted from the reg-*
6 *istration pursuant to section 6(f)(1). If the Ad-*
7 *ministrator grants an extension under this para-*
8 *graph, the Administrator shall monitor the devel-*
9 *opment of the data for the uses being supported*
10 *and shall ensure that the registrant is meeting*
11 *the schedule for the production of such data. If*
12 *the Administrator determines that the registrant*
13 *is not meeting or has not met the schedule for*
14 *the production of such data, the Administrator*
15 *may proceed in accordance with section*
16 *3(c)(2)(B)(iv) regarding the continued registra-*
17 *tion of the affected products with the minor and*
18 *other uses and shall inform the public of such*
19 *action in accordance with section 6(f)(2). Not-*
20 *withstanding this subparagraph, the Adminis-*
21 *trator may deny, modify, or revoke the tem-*
22 *porary extension under this paragraph if the Ad-*
23 *ministrator determines that the continuation of*
24 *the minor use may cause an unreasonable ad-*
25 *verse effect on the environment. In the event of*

1 *modification or revocation, the Administrator*
2 *shall provide, in writing, to the registrant a no-*
3 *tice revoking the temporary extension and estab-*
4 *lish a new effective date by which the minor use*
5 *shall be deleted from the registration.”.*

6 *(B) Section 4(e)(3)(A) (7 U.S.C. 136a–*
7 *1(e)(3)(A)) is amended by adding at the end the*
8 *following: “If the registrant does not commit to*
9 *support a specific minor use of the pesticide, but*
10 *is supporting and providing data in a timely*
11 *and adequate fashion to support uses of the pes-*
12 *ticide on a food, or if all uses of the pesticide are*
13 *nonfood uses and the registrant does not commit*
14 *to support a specific minor use of the pesticide*
15 *but is supporting and providing data in a time-*
16 *ly and adequate fashion to support other nonfood*
17 *uses of the pesticide, the Administrator, at the*
18 *written request of the registrant, shall not take*
19 *any action pursuant to this subparagraph in re-*
20 *gard to such unsupported minor use until the*
21 *final deadline established as of the date of enact-*
22 *ment of the Food Quality Protection Act of 1996,*
23 *for the submission of data under this section for*
24 *the supported uses identified pursuant to this*
25 *subparagraph unless the Administrator deter-*

1 *mines that the absence of the data is significant*
2 *enough to cause human health or environmental*
3 *concerns. On the basis of such determination, the*
4 *Administrator may refuse the request for exten-*
5 *sion by the registrant. Upon receipt of the re-*
6 *quest from the registrant, the Administrator*
7 *shall publish in the Federal Register a notice of*
8 *the receipt of the request and the effective date*
9 *upon which the uses not being supported will be*
10 *voluntarily deleted from the registration pursu-*
11 *ant to section 6(f)(1). If the Administrator*
12 *grants an extension under this subparagraph, the*
13 *Administrator shall monitor the development of*
14 *the data for the uses being supported and shall*
15 *ensure that the registrant is meeting the schedule*
16 *for the production of such data. If the Adminis-*
17 *trator determines that the registrant is not meet-*
18 *ing or has not met the schedule for the produc-*
19 *tion of such data, the Administrator may pro-*
20 *ceed in accordance with section 3(c)(2)(B)(iv) re-*
21 *garding the continued registration of the affected*
22 *products with the minor and other uses and shall*
23 *inform the public of such action in accordance*
24 *with section 6(f)(2). Notwithstanding this sub-*
25 *paragraph, the Administrator may deny, modify,*

1 *or revoke the temporary extension under this*
2 *subparagraph if the Administrator determines*
3 *that the continuation of the minor use may*
4 *cause an unreasonable adverse effect on the envi-*
5 *ronment. In The event of modification or revoca-*
6 *tion, the Administrator shall provide, in writing,*
7 *to the registrant a notice revoking the temporary*
8 *extension and establish a new effective date by*
9 *which the minor use shall be deleted from the*
10 *registration.”.*

11 (2) *DATA.—Section 3(c)(2)(B) (7 U.S.C.*
12 *136a(c)(2)(B)), as amended by subsection (c)(1), is*
13 *further amended by adding at the end the following:*

14 *“(vii) If the registrant does not commit*
15 *to support a specific minor use of the pes-*
16 *ticide, but is supporting and providing data*
17 *in a timely and adequate fashion to support*
18 *uses of the pesticide on a food, or if all uses*
19 *of the pesticide are nonfood uses and the*
20 *registrant does not commit to support a*
21 *specific minor use of the pesticide but is*
22 *supporting and providing data in a timely*
23 *and adequate fashion to support other*
24 *nonfood uses of the pesticide, the Adminis-*
25 *trator, at the written request of the reg-*

1 *istrant, shall not take any action pursuant*
2 *to this clause in regard to such unsupported*
3 *minor use until the final deadline estab-*
4 *lished as of the date of enactment of the*
5 *Food Quality Protection Act of 1996, for the*
6 *submission of data under section 4 for the*
7 *supported use identified pursuant to this*
8 *clause unless the Administrator determines*
9 *that the absence of the data is significant*
10 *enough to cause human health or environ-*
11 *mental concerns. On the basis of such deter-*
12 *mination, the Administrator may refuse the*
13 *request for extension by the registrant.*
14 *Upon receipt of the request from the reg-*
15 *istrant, the Administrator shall publish in*
16 *the Federal Register a notice of the receipt*
17 *of the request and the effective date upon*
18 *which the uses not being supported will be*
19 *voluntarily deleted from the registration*
20 *pursuant to section 6(f)(1). If the Adminis-*
21 *trator grants an extension under this*
22 *clause, the Administrator shall monitor the*
23 *development of the data for the uses being*
24 *supported and shall ensure that the reg-*
25 *istrant is meeting the schedule for the pro-*

1 *duction of such data. If the Administrator*
2 *determines that the registrant is not meet-*
3 *ing or has not met the schedule for the pro-*
4 *duction of such data, the Administrator*
5 *may proceed in accordance with clause (iv)*
6 *of this subparagraph regarding the contin-*
7 *ued registration of the affected products*
8 *with the minor and other uses and shall in-*
9 *form the public of such action in accordance*
10 *with section 6(f)(2). Notwithstanding the*
11 *provisions of this clause, the Administrator*
12 *may deny, modify, or revoke the temporary*
13 *extension under this subparagraph if the*
14 *Administrator determines that the continu-*
15 *ation of the minor use may cause an unrea-*
16 *sonable adverse effect on the environment.*
17 *In the event of modification or revocation,*
18 *the Administrator shall provide, in writing,*
19 *to the registrant a notice revoking the tem-*
20 *porary extension and establish a new effec-*
21 *tive date by which the minor use shall be*
22 *deleted from the registration.”.*

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

24 *(1) in paragraph (1)(C)(ii) by striking “90-day”*
25 *each place it appears and inserting “180-day”; and*

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

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

6 “(4) *UTILIZATION OF DATA FOR VOLUNTARILY*
7 *CANCELED PESTICIDE.*—When an application is filed
8 with the Administrator for the registration of a pes-
9 ticide for a minor use and another registrant subse-
10 quently voluntarily cancels its registration for an
11 identical or substantially similar pesticide for an
12 identical or substantially similar use, the Adminis-
13 trator shall process, review, and evaluate the pending
14 application as if the voluntary cancellation had not
15 yet taken place except that the Administrator shall
16 not take such action if the Administrator determines
17 that such minor use may cause an unreasonable ad-
18 verse effect on the environment. In order to rely on
19 this subsection, the applicant must certify that it
20 agrees to satisfy any outstanding data requirements
21 necessary to support the reregistration of the pesticide
22 in accordance with the data submission schedule es-
23 tablished by the Administrator.”.

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

1 *Rodenticide Act (7 U.S.C. 136 et seq.), as amended by sec-*
 2 *tion 121, is amended by adding after section 30 the follow-*
 3 *ing:*

4 **“SEC. 31. ENVIRONMENTAL PROTECTION AGENCY MINOR**
 5 **USE PROGRAM.**

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

14 “(b) *The Office of Pesticide Programs shall prepare a*
 15 *public report concerning the progress made on the registra-*
 16 *tion of minor uses, including implementation of the exclu-*
 17 *sive use as an incentive for registering new minor uses,*
 18 *within 3 years of the passage of the Food Quality Protection*
 19 *Act of 1996.”.*

20 (j) *DEPARTMENT OF AGRICULTURE MINOR USE PRO-*
 21 *GRAM.—The Federal Insecticide, Fungicide, and*
 22 *Rodenticide Act (7 U.S.C. 136 et seq.), as amended by sub-*
 23 *section (i), is amended by adding after section 31 the follow-*
 24 *ing:*

1 **“SEC. 32. DEPARTMENT OF AGRICULTURE MINOR USE PRO-**
 2 **GRAM.**

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

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

14 “(2) *supporting integrated pest management re-*
 15 *search;*

16 “(3) *consulting with growers to develop data for*
 17 *minor uses; and*

18 “(4) *providing assistance for minor use registra-*
 19 *tions, tolerances, and reregistrations with the Envi-*
 20 *ronmental Protection Agency.*

21 “(b)(1) *MINOR USE PESTICIDE DATA.*—

22 “(A) *GRANT AUTHORITY.*—*The Secretary, in*
 23 *consultation with the Administrator, shall establish a*
 24 *program to make grants for the development of data*
 25 *to support minor use pesticide registrations and re-*
 26 *registrations. The amount of any such grant shall not*

1 exceed $\frac{1}{2}$ of the cost of the project for which the grant
2 is made.

3 “(B) *APPLICANTS*.—Any person who wants to
4 develop data to support minor use pesticide registra-
5 tions and reregistrations may apply for a grant
6 under subparagraph (A). Priority shall be given to an
7 applicant for such a grant who does not directly re-
8 ceive funds from the sale of pesticides registered for
9 minor uses.

10 “(C) *DATA OWNERSHIP*.—Any data that is devel-
11 oped under a grant under subparagraph (A) shall be
12 jointly owned by the Department of Agriculture and
13 the person who received the grant. Such a person shall
14 enter into an agreement with the Secretary under
15 which such person shall share any fee paid to such
16 person under section 3(c)(1)(F).

17 “(2) *MINOR USE PESTICIDE DATA REVOLVING FUND*.—

18 “(A) *ESTABLISHMENT*.—There is established in
19 the Treasury of the United States a revolving fund to
20 be known as the Minor Use Pesticide Data Revolving
21 Fund. The Fund shall be available without fiscal year
22 limitation to carry out the authorized purposes of this
23 subsection.

24 “(B) *CONTENTS OF THE FUND*.—There shall be
25 deposited in the Fund—

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

3 “(ii) fees collected by the Secretary for any
4 data developed under a grant under paragraph
5 (1)(A).

6 “(C) *AUTHORIZATIONS OF APPROPRIATIONS.*—
7 *There are authorized to be appropriated for each fis-*
8 *cal year to carry out the purposes of this subsection*
9 *\$10,000,000 to remain available until expended.”.*

10 ***Subtitle B—Antimicrobial Pesticide***
11 ***Registration Reform***

12 ***SEC. 221. DEFINITIONS.***

13 *Section 2 (7 U.S.C. 136), as amended by section*
14 *210(a) is further amended—*

15 *(1) in subsection (u), by adding at the end the*
16 *following: “The term ‘pesticide’ does not include liq-*
17 *uid chemical sterilant products (including any*
18 *sterilant or subordinate disinfectant claims on such*
19 *products) for use on a critical or semi-critical device,*
20 *as defined in section 201 of the Federal Food, Drug,*
21 *and Cosmetic Act (21 U.S.C. 321). For purposes of*
22 *the preceding sentence, the term ‘critical device’ in-*
23 *cludes any device which is introduced directly into*
24 *the human body, either into or in contact with the*
25 *bloodstream or normally sterile areas of the body and*

1 *the term ‘semi-critical device’ includes any device*
 2 *which contacts intact mucous membranes but which*
 3 *does not ordinarily penetrate the blood barrier or oth-*
 4 *erwise enter normally sterile areas of the body.”; and*

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

6 *“(mm) ANTIMICROBIAL PESTICIDE.—*

7 *“(1) IN GENERAL.—The term ‘antimicrobial pes-*
 8 *ticide’ means a pesticide that—*

9 *“(A) is intended to—*

10 *“(i) disinfect, sanitize, reduce, or miti-*
 11 *gate growth or development of micro-*
 12 *biological organisms; or*

13 *“(ii) protect inanimate objects, indus-*
 14 *trial processes or systems, surfaces, water,*
 15 *or other chemical substances from contami-*
 16 *nation, fouling, or deterioration caused by*
 17 *bacteria, viruses, fungi, protozoa, algae, or*
 18 *slime; and*

19 *“(B) in the intended use is exempt from, or*
 20 *otherwise not subject to, a tolerance under section*
 21 *408 of the Federal Food, Drug, and Cosmetic Act*
 22 *(21 U.S.C. 346a and 348) or a food additive reg-*
 23 *ulation under section 409 of such Act.*

24 *“(2) EXCLUDED PRODUCTS.—The term*
 25 *‘antimicrobial pesticide’ does not include —*

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

5 “(B) an agricultural fungicide product; or

6 “(C) an aquatic herbicide product.

7 “(3) INCLUDED PRODUCTS.—The term
8 ‘antimicrobial pesticide’ does include any other chem-
9 ical sterilant product (other than liquid chemical
10 sterilant products exempt under subsection (u)), any
11 other disinfectant product, any other industrial
12 microbiocide product, and any other preservative
13 product that is not excluded by paragraph (2).”.

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

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

18 “(viii)(I) If data required to support reg-
19 istration of a pesticide under subparagraph (A)
20 is requested by a Federal or State regulatory au-
21 thority, the Administrator shall, to the extent
22 practicable, coordinate data requirements, test
23 protocols, timetables, and standards of review
24 and reduce burdens and redundancy caused to

1 *the registrant by multiple requirements on the*
 2 *registrant.*

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

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

11 **SEC. 223. LABEL AND LABELING.**

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

14 *“(9) LABELING.—*

15 *“(A) ADDITIONAL STATEMENTS.—Subject to*
 16 *subparagraphs (B) and (C), it shall not be a vio-*
 17 *lation of this Act for a registrant to modify the*
 18 *labeling of an antimicrobial pesticide product to*
 19 *include relevant information on product efficacy,*
 20 *product composition, container composition or*
 21 *design, or other characteristics that do not relate*
 22 *to any pesticidal claim or pesticidal activity.*

23 *“(B) REQUIREMENTS.—Proposed labeling*
 24 *information under subparagraph (A) shall not be*
 25 *false or misleading, shall not conflict with or de-*

tract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

“(C) NOTIFICATION AND DISAPPROVAL.—

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

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

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

“(ii) DISAPPROVAL.—Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

1 “(iii) *RESTRICTION ON SALE.*—A reg-
2 istrant may not sell or distribute a product
3 bearing a disapproved modification.

4 “(iv) *OBJECTION.*—A registrant may
5 file an objection in writing to a disapproval
6 under clause (ii) not later than 30 days
7 after receipt of notification of the dis-
8 approval.

9 “(v) *FINAL ACTION.*—A decision by the
10 Administrator following receipt and consid-
11 eration of an objection filed under clause
12 (iv) shall be considered a final agency ac-
13 tion.

14 “(D) *USE DILUTION.*—The label or labeling
15 required under this Act for an antimicrobial pes-
16 ticide that is or may be diluted for use may have
17 a different statement of caution or protective
18 measures for use of the recommended diluted so-
19 lution of the pesticide than for use of a con-
20 centrate of the pesticide if the Administrator de-
21 termines that—

22 “(i) adequate data have been submitted
23 to support the statement proposed for the
24 diluted solution uses; and

1 “(ii) the label or labeling provides ade-
 2 quate protection for exposure to the diluted
 3 solution of the pesticide.”.

4 **SEC. 224. REGISTRATION REQUIREMENTS FOR**
 5 **ANTIMICROBIAL PESTICIDES.**

6 Section 3 (7 U.S.C. 136a), as amended by section
 7 107(b), is further amended by adding at the end the follow-
 8 ing:

9 “(h) REGISTRATION REQUIREMENTS FOR
 10 ANTIMICROBIAL PESTICIDES.—

11 “(1) EVALUATION OF PROCESS.—To the maxi-
 12 mum extent practicable consistent with the degrees of
 13 risk presented by a antimicrobial pesticide and the
 14 type of review appropriate to evaluate the risks, the
 15 Administrator shall identify and evaluate reforms to
 16 the antimicrobial registration process that would re-
 17 duce review periods existing as of the date of enact-
 18 ment of this subsection for antimicrobial pesticide
 19 product registration applications and applications for
 20 amended registration of antimicrobial pesticide prod-
 21 ucts, including—

22 “(A) new antimicrobial active ingredients;

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

24 “(C) substantially similar or identical
 25 antimicrobial pesticides; and

1 “(D) amendments to antimicrobial pesticide
2 registrations.

3 “(2) REVIEW TIME PERIOD REDUCTION GOAL.—
4 Each reform identified under paragraph (1) shall be
5 designed to achieve the goal of reducing the review pe-
6 riod following submission of a complete application,
7 consistent with the degree of risk, to a period of not
8 more than—

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

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

13 “(C) 120 days for any other new
14 antimicrobial product;

15 “(D) 90 days for a substantially similar or
16 identical antimicrobial product;

17 “(E) 90 days for an amendment to an
18 antimicrobial registration that does not require
19 scientific review of data; and

20 “(F) 90 to 180 days for an amendment to
21 an antimicrobial registration that requires sci-
22 entific review of data and that is not otherwise
23 described in this paragraph.

24 “(3) IMPLEMENTATION.—

25 “(A) PROPOSED RULEMAKING.—

1 “(i) *ISSUANCE.*—Not later than 270
2 *days after the date of enactment of this sub-*
3 *section, the Administrator shall publish in*
4 *the Federal Register proposed regulations to*
5 *accelerate and improve the review of*
6 *antimicrobial pesticide products designed to*
7 *implement, to the extent practicable, the*
8 *goals set forth in paragraph (2).*

9 “(ii) *REQUIREMENTS.*—Proposed regu-
10 *lations issued under clause (i) shall—*

11 “(I) *define the various classes of*
12 *antimicrobial use patterns, including*
13 *household, industrial, and institutional*
14 *disinfectants and sanitizing pesticides,*
15 *preservatives, water treatment, and*
16 *pulp and paper mill additives, and*
17 *other such products intended to dis-*
18 *infect, sanitize, reduce, or mitigate*
19 *growth or development of micro-*
20 *biological organisms, or protect inani-*
21 *mate objects, industrial processes or*
22 *systems, surfaces, water, or other chem-*
23 *ical substances from contamination,*
24 *fouling, or deterioration caused by bac-*

1 *teria, viruses, fungi, protozoa, algae, or*
2 *slime;*

3 “(II) *differentiate the types of re-*
4 *view undertaken for antimicrobial pes-*
5 *ticides;*

6 “(III) *conform the degree and*
7 *type of review to the risks and benefits*
8 *presented by antimicrobial pesticides*
9 *and the function of review under this*
10 *Act, considering the use patterns of the*
11 *product, toxicity, expected exposure,*
12 *and product type;*

13 “(IV) *ensure that the registration*
14 *process is sufficient to maintain*
15 *antimicrobial pesticide efficacy and*
16 *that antimicrobial pesticide products*
17 *continue to meet product performance*
18 *standards and effectiveness levels for*
19 *each type of label claim made; and*

20 “(V) *implement effective and reli-*
21 *able deadlines for process management.*

22 “(iii) *COMMENTS.—In developing the*
23 *proposed regulations, the Administrator*
24 *shall solicit the views from registrants and*

1 *other affected parties to maximize the effec-*
2 *tiveness of the rule development process.*

3 *“(B) FINAL REGULATIONS.—*

4 *“(i) ISSUANCE.—The Administrator*
5 *shall issue final regulations not later than*
6 *240 days after the close of the comment pe-*
7 *riod for the proposed regulations.*

8 *“(ii) FAILURE TO MEET GOAL.—If a*
9 *goal described in paragraph (2) is not met*
10 *by the final regulations, the Administrator*
11 *shall identify the goal, explain why the goal*
12 *was not attained, describe the element of the*
13 *regulations included instead, and identify*
14 *future steps to attain the goal.*

15 *“(iii) REQUIREMENTS.—In issuing*
16 *final regulations, the Administrator shall—*

17 *“(I) consider the establishment of*
18 *a certification process for regulatory*
19 *actions involving risks that can be re-*
20 *sponsibly managed, consistent with the*
21 *degree of risk, in the most cost-efficient*
22 *manner;*

23 *“(II) consider the establishment of*
24 *a certification process by approved lab-*

1 *oratories as an adjunct to the review*
2 *process;*

3 *“(III) use all appropriate and*
4 *cost-effective review mechanisms, in-*
5 *cluding—*

6 *“(aa) expanded use of notifi-*
7 *cation and non-notification proce-*
8 *dures;*

9 *“(bb) revised procedures for*
10 *application review; and*

11 *“(cc) allocation of appro-*
12 *priate resources to ensure stream-*
13 *lined management of*
14 *antimicrobial pesticide registra-*
15 *tions; and*

16 *“(IV) clarify criteria for deter-*
17 *mination of the completeness of an ap-*
18 *plication.*

19 *“(C) EXPEDITED REVIEW.—This subsection*
20 *does not affect the requirements or extend the*
21 *deadlines or review periods contained in sub-*
22 *section (c)(3).*

23 *“(D) ALTERNATIVE REVIEW PERIODS.—If*
24 *the final regulations to carry out this paragraph*
25 *are not effective 630 days after the date of enact-*

1 *ment of this subsection, until the final regula-*
2 *tions become effective, the review period, begin-*
3 *ning on the date of receipt by the Agency of a*
4 *complete application, shall be—*

5 *“(i) 2 years for a new antimicrobial*
6 *active ingredient pesticide registration;*

7 *“(ii) 1 year for a new antimicrobial*
8 *use of a registered active ingredient;*

9 *“(iii) 180 days for any other new*
10 *antimicrobial product;*

11 *“(iv) 90 days for a substantially simi-*
12 *lar or identical antimicrobial product;*

13 *“(v) 90 days for an amendment to an*
14 *antimicrobial registration that does not re-*
15 *quire scientific review of data; and*

16 *“(vi) 240 days for an amendment to*
17 *an antimicrobial registration that requires*
18 *scientific review of data and that is not oth-*
19 *erwise described in this subparagraph.*

20 *“(E) WOOD PRESERVATIVES.—An applica-*
21 *tion for the registration, or for an amendment to*
22 *the registration, of a wood preservative product*
23 *for which a claim of pesticidal activity listed in*
24 *section 2(mm) is made (regardless of any other*
25 *pesticidal claim that is made with respect to the*

1 *product) shall be reviewed by the Administrator*
2 *within the same period as that established under*
3 *this paragraph for an antimicrobial pesticide*
4 *product application, consistent with the degree of*
5 *risk posed by the use of the wood preservative*
6 *product, if the application requires the applicant*
7 *to satisfy the same data requirements as are re-*
8 *quired to support an application for a wood pre-*
9 *servative product that is an antimicrobial pes-*
10 *ticide.*

11 “(F) NOTIFICATION.—

12 “(i) IN GENERAL.—Subject to clause
13 (iii), the Administrator shall notify an ap-
14 plicant whether an application has been
15 granted or denied not later than the final
16 day of the appropriate review period under
17 this paragraph, unless the applicant and
18 the Administrator agree to a later date.

19 “(ii) FINAL DECISION.—If the Admin-
20 istrator fails to notify an applicant within
21 the period of time required under clause (i),
22 the failure shall be considered an agency ac-
23 tion unlawfully withheld or unreasonably
24 delayed for purposes of judicial review

1 *under chapter 7 of title 5, United States*
2 *Code.*

3 “(iii) *EXEMPTION.—This subpara-*
4 *graph does not apply to an application for*
5 *an antimicrobial pesticide that is filed*
6 *under subsection (c)(3)(B) prior to 90 days*
7 *after the date of enactment of this sub-*
8 *section.*

9 “(4) *ANNUAL REPORT.—*

10 “(A) *SUBMISSION.—Beginning on the date*
11 *of enactment of this subsection and ending on the*
12 *date that the goals under paragraph (2) are*
13 *achieved, the Administrator shall, not later than*
14 *March 1 of each year, prepare and submit an*
15 *annual report to the Committee on Agriculture*
16 *of the House of Representatives and the Commit-*
17 *tee on Agriculture, Nutrition, and Forestry of the*
18 *Senate.*

19 “(B) *REQUIREMENTS.—A report submitted*
20 *under subparagraph (A) shall include a descrip-*
21 *tion of—*

22 “(i) *measures taken to reduce the back-*
23 *log of pending registration applications;*

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

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

4 **SEC. 225. DISPOSAL OF HOUSEHOLD, INDUSTRIAL, OR IN-**
5 **STITUTIONAL ANTIMICROBIAL PRODUCTS.**

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

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

9 “(1) *IN GENERAL.*—Nothing in”; and

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

11 “(2) *ANTIMICROBIAL PRODUCTS.*—A household,
12 industrial, or institutional antimicrobial product that
13 is not subject to regulation under the Solid Waste
14 Disposal Act (42 U.S.C. 6901 et seq.) shall not be sub-
15 ject to the provisions of subsections (a), (e), and (f),
16 unless the Administrator determines that such prod-
17 uct must be subject to such provisions to prevent an
18 unreasonable adverse effect on the environment.”.

19 **Subtitle C—Public Health**
20 **Pesticides**

21 **SEC. 230. DEFINITIONS.**

22 (a) *ADVERSE EFFECTS.*—Section 2(bb) (7 U.S.C.
23 136(bb)) is amended by adding at the end the following:

24 “The Administrator shall consider the risks and benefits of
25 public health pesticides separate from the risks and benefits

1 *of other pesticides. In weighing any regulatory action con-*
 2 *cerning a public health pesticide under this Act, the Admin-*
 3 *istrator shall weigh any risks of the pesticide against the*
 4 *health risks such as the diseases transmitted by the vector*
 5 *to be controlled by the pesticide.”.*

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

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

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

23 **SEC. 231. REGISTRATION.**

24 Section 3(c)(2)(A) (7 U.S.C. 136a(c)(2)(A)) is amend-
 25 ed—

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

4 (2) by striking “potential exposure of man and
 5 the environment to the pesticide” and inserting “po-
 6 tential beneficial or adverse effects on man and the
 7 environment”.

8 **SEC. 232. REREGISTRATION.**

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

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

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

23 (2) in subsection (i)(5), by redesignating sub-
 24 paragraphs (F) and (G) as subparagraphs (G) and

1 (H), respectively, and by adding after subparagraph
2 (E) the following:

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

12 (3) in subsection (i)(7)(B), by striking “or to de-
13 termine” and inserting “, to determine” and by in-
14 serting before the period the following: “, or to deter-
15 mine the volume usage for public health pesticides”;
16 and

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

21 “(iii) proposes the initial or amended
22 registration of an end use pesticide that, if
23 registered as proposed, would be used for a
24 public health pesticide.”.

1 **SEC. 233. CANCELLATION.**

2 Section 6(b) (7 U.S.C. 136d(b)) is amended by adding
3 after the eighth sentence the following: “When a public
4 health use is affected, the Secretary of Health and Human
5 Services should provide available benefits and use informa-
6 tion, or an analysis thereof, in accordance with the proce-
7 dures followed and subject to the same conditions as the Sec-
8 retary of Agriculture in the case of agricultural pesticides.”.

9 **SEC. 234. VIEWS OF THE SECRETARY OF HEALTH AND**
10 **HUMAN SERVICES.**

11 Section 21 (7 U.S.C. 136s) is amended by redesignat-
12 ing subsections (b) and (c) as subsections (c) and (d), re-
13 spectively, and by adding after subsection (a) the following:
14 “(b) SECRETARY OF HEALTH AND HUMAN SERV-
15 ICES.—The Administrator, before publishing regulations
16 under this Act for any public health pesticide, shall solicit
17 the views of the Secretary of Health and Human Services
18 in the same manner as the views of the Secretary of Agri-
19 culture are solicited under section 25(a)(2).”.

20 **SEC. 235. AUTHORITY OF ADMINISTRATOR.**

21 Section 25(a)(1) (7 U.S.C. 136w(a)(1)) is amended—
22 (1) by inserting after “various classes of pes-
23 ticides” the following: “, including public health pes-
24 ticides,”; and

1 (2) by striking “and nonagricultural pesticides”
 2 and inserting “, nonagricultural, and public health
 3 pesticides”.

4 **SEC. 236. IDENTIFICATION OF PESTS.**

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

7 “(d) *PUBLIC HEALTH PESTS.*—The Administrator, in
 8 coordination with the Secretary of Agriculture and the Sec-
 9 retary of Health and Human Services, shall identify pests
 10 of significant public health importance and, in coordina-
 11 tion with the Public Health Service, develop and implement
 12 programs to improve and facilitate the safe and necessary
 13 use of chemical, biological, and other methods to combat and
 14 control such pests of public health importance.”.

15 **SEC. 237. PUBLIC HEALTH DATA.**

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

18 “(m) *AUTHORIZATION OF FUNDS TO DEVELOP PUB-*
 19 *LIC HEALTH DATA.*—

20 “(1) *DEFINITION.*—For the purposes of this sec-
 21 tion, ‘Secretary’ means the Secretary of Health and
 22 Human Services, acting through the Public Health
 23 Service.

24 “(2) *CONSULTATION.*—In the case of a pesticide
 25 registered for use in public health programs for vector

1 *control or for other uses the Administrator determines*
2 *to be human health protection uses, the Administrator*
3 *shall, upon timely request by the registrant or any*
4 *other interested person, or on the Administrator's own*
5 *initiative may, consult with the Secretary prior to*
6 *taking final action to suspend registration under sec-*
7 *tion 3(c)(2)(B)(iv), or cancel a registration under sec-*
8 *tion 4, 6(e), or 6(f). In consultation with the Sec-*
9 *retary, the Administrator shall prescribe the form and*
10 *content of requests under this section.*

11 “(3) *BENEFITS TO SUPPORT FAMILY.*—*The Ad-*
12 *ministrator, after consulting with the Secretary, shall*
13 *make a determination whether the potential benefits*
14 *of continued use of the pesticide for public health or*
15 *health protection purposes are of such significance as*
16 *to warrant a commitment by the Secretary to conduct*
17 *or to arrange for the conduct of the studies required*
18 *by the Administrator to support continued registra-*
19 *tion under section 3 or registration under section 4.*

20 “(4) *ADDITIONAL TIME.*—*If the Administrator*
21 *determines that such a commitment is warranted and*
22 *in the public interest, the Administrator shall notify*
23 *the Secretary and shall, to the extent necessary,*
24 *amend a notice issued under section 3(c)(2)(B) to*

1 *specify additional reasonable time periods for submis-*
2 *sion of the data.*

3 “(5) *ARRANGEMENTS.*—*The Secretary shall make*
4 *such arrangements for the conduct of required studies*
5 *as the Secretary finds necessary and appropriate to*
6 *permit submission of data in accordance with the*
7 *time periods prescribed by the Administrator. Such*
8 *arrangements may include Public Health Service in-*
9 *tramural research activities, grants, contracts, or co-*
10 *operative agreements with academic, public health, or*
11 *other organizations qualified by experience and train-*
12 *ing to conduct such studies.*

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

21 “(7) *AUTHORIZATION OF APPROPRIATIONS.*—
22 *There is authorized to be appropriated to carry out*
23 *the purposes of this section \$12,000,000 for fiscal year*
24 *1997, and such sums as may be necessary for succeed-*
25 *ing fiscal years.’’.*

1 ***Subtitle D—Expedited Registration***
 2 ***of Reduced Risk Pesticides***

3 ***SEC. 250. EXPEDITED REGISTRATION OF PESTICIDES .***

4 *Section 3(c) (7 U.S.C. 136a(c)), as amended by section*
 5 *223, is amended—*

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

8 *“(G) If the applicant is requesting that the*
 9 *registration or amendment to the registration of*
 10 *a pesticide be expedited, an explanation of the*
 11 *basis for the request must be submitted, in ac-*
 12 *cordance with paragraph (10) of this sub-*
 13 *section.”; and*

14 *(2) by adding at the end the following:*

15 *“(10) EXPEDITED REGISTRATION OF PES-*
 16 *TICIDES.—*

17 *“(A) Not later than 1 year after the date of*
 18 *enactment of this paragraph, the Administrator*
 19 *shall, utilizing public comment, develop proce-*
 20 *dures and guidelines, and expedite the review of*
 21 *an application for registration of a pesticide or*
 22 *an amendment to a registration that satisfies*
 23 *such guidelines.*

24 *“(B) Any application for registration or an*
 25 *amendment, including biological and conven-*

1 *tional pesticides, will be considered for expedited*
2 *review under this paragraph. An application for*
3 *registration or an amendment shall qualify for*
4 *expedited review if use of the pesticide proposed*
5 *by the application may reasonably be expected to*
6 *accomplish 1 or more of the following:*

7 *“(i) Reduce the risks of pesticides to*
8 *human health.*

9 *“(ii) Reduce the risks of pesticides to*
10 *nontarget organisms.*

11 *“(iii) Reduce the potential for con-*
12 *tamination of groundwater, surface water,*
13 *or other valued environmental resources.*

14 *“(iv) Broaden the adoption of inte-*
15 *grated pest management strategies, or make*
16 *such strategies more available or more effec-*
17 *tive.*

18 *“(C) The Administrator, not later than 30*
19 *days after receipt of an application for expedited*
20 *review, shall notify the applicant whether the ap-*
21 *plication is complete. If it is found to be incom-*
22 *plete, the Administrator may either reject the re-*
23 *quest for expedited review or ask the applicant*
24 *for additional information to satisfy the guide-*
25 *lines developed under subparagraph (A).”.*

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

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

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

15 (b) *PROCEDURES.*—To the extent practicable, the pro-
16 cedures referred to in subsection (a) shall include the collec-
17 tion of data on food consumption patterns of a statistically
18 valid sample of infants and children.

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

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

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

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

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

12 (c) *COORDINATION.*—*The Secretary of Agriculture*
 13 *shall, as appropriate, coordinate with the Administrator of*
 14 *the Environmental Protection Agency in the design of the*
 15 *surveys and make available to the Administrator the aggre-*
 16 *gate results of the surveys to assist the Administrator.*

17 **SEC. 303. INTEGRATED PEST MANAGEMENT.**

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

1 *information on Integrated Pest Management widely avail-*
2 *able to pesticide users, including Federal agencies. Federal*
3 *agencies shall use Integrated Pest Management techniques*
4 *in carrying out pest management activities and shall pro-*
5 *mote Integrated Pest Management through procurement*
6 *and regulatory policies, and other activities.*

7 **SEC. 304. COORDINATION OF CANCELLATION.**

8 *Section 2(bb) (7 U.S.C. 136(bb)) is amended—*
9 *(1) by inserting “(1)” after “means”; and*
10 *(2) by striking the period at the end of the first*
11 *sentence and inserting “, or (2) a human dietary risk*
12 *from residues that result from a use of a pesticide in*
13 *or on any food inconsistent with the standard the Ad-*
14 *ministrator determines is adequate to protect the pub-*
15 *lic health under section 408 of the Federal Food,*
16 *Drug, and Cosmetic Act (21 U.S.C. 346a).”.*

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

18 *(a) The Secretary of Agriculture shall, in consultation*
19 *with the Administrator of the Environmental Protection*
20 *Agency, prepare a report to Congress evaluating the current*
21 *status and potential improvements in Federal pesticide use*
22 *information gathering activities. This report shall at least*
23 *include—*
24 *(1) an analysis of the quality and reliability of*
25 *the information collected by the Department of Agri-*

1 *culture, the Environmental Protection Agency, and*
 2 *other Federal agencies regarding the agricultural use*
 3 *of pesticides; and*

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

10 *(b) The Secretary shall submit this report to Congress*
 11 *not later than 1 year following the date of enactment of*
 12 *this section.*

13 **[TITLE IV—AMENDMENTS TO THE FED-**
 14 **ERAL FOOD, DRUG, AND COSMETIC**
 15 **ACT**

16 **[SEC. 401. REFERENCE.**

17 **[**Whenever in this title an amendment is expressed
 18 in terms of an amendment to a section or other provision,
 19 or refers to a section or other provision, the reference shall
 20 be considered to be made to a section or other provision
 21 of the Federal Food, Drug, and Cosmetic Act.

22 **[SEC. 402. DEFINITIONS.**

23 **[**(a) Section 201(q) (21 U.S.C. 321(q)) is amended
 24 to read as follows:

25 **[**“(q)(1) The term ‘pesticide chemical’ means—

1 【“(A) any substance that is a pesticide within
2 the meaning of the Federal Insecticide, Fungicide,
3 and Rodenticide Act; or

4 【“(B) any active ingredient of a pesticide with-
5 in the meaning of the Federal Insecticide, Fungicide,
6 and Rodenticide Act.

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

10 【“(A) a pesticide chemical; or

11 【“(B) any other added substance that is
12 present in the commodity or food primarily as a re-
13 sult of the metabolism or other degradation of a pes-
14 ticide chemical.

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

19 【“(A) its occurrence as a residue on a raw agri-
20 cultural commodity or processed food is attributable
21 primarily to natural causes or to human activities
22 not involving the use of any substances for a pes-
23 ticial purpose in the production, storage, process-
24 ing, or transportation of any raw agricultural com-
25 modity or processed food; and

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

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

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

10 【“(2) a pesticide chemical; or”.

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

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

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

21 **【SEC. 403. PROHIBITED ACTS.**

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

23 【(1) by striking the period at the end; and

1 【(2) by inserting at the end “, or the violation
2 of section 408(g)(2) or any regulation issued under
3 that section.”.

4 **【SEC. 404. ADULTERATED FOOD.**

5 【Section 402(a)(2) (21 U.S.C. 342(a)(2)) is amended
6 to read as follows:

7 【“(2)(A) if it bears or contains any added poi-
8 sonous or added deleterious substance (other than a
9 substance that is a pesticide chemical residue in or
10 on a raw agricultural commodity or processed food,
11 a food additive, a color additive, or a new animal
12 drug) that is unsafe within the meaning of section
13 406;

14 【“(B) if it bears or contains a pesticide chemi-
15 cal residue that is unsafe within the meaning of sec-
16 tion 408(a); or

17 【“(C) if it is or if it bears or contains—

18 【“(i) any food additive that is unsafe with-
19 in the meaning of section 409; or

20 【“(ii) a new animal drug (or conversion
21 product thereof) that is unsafe within the
22 meaning of section 512; or”.

1 **[SEC. 405. TOLERANCES AND EXEMPTIONS FOR PESTICIDE**
2 **CHEMICAL RESIDUES.**

3 **[**Section 408 (21 U.S.C. 346a) is amended to read
4 as follows:

5 **[“TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMI-**
6 **CAL RESIDUES**

7 **[“SEC. 408. (a) REQUIREMENT FOR TOLERANCE OR**
8 **EXEMPTION.—**

9 **[“(1) GENERAL RULE.—**For the purposes of
10 this section, the term ‘food,’ when used as a noun
11 without modification, shall mean a raw agricultural
12 commodity or processed food. Except as provided in
13 paragraph (2) or (3), any pesticide chemical residue
14 in or on a food shall be deemed unsafe for the pur-
15 pose of section 402(a)(2)(B) unless—

16 **[“(A) a tolerance for such pesticide chemi-**
17 **cal residue in or on such food is in effect under**
18 **this section and the concentration of the residue**
19 **is within the limits of the tolerance; or**

20 **[“(B) an exemption from the requirement**
21 **of a tolerance is in effect under this section for**
22 **the pesticide chemical residue.**

23 **[“(2) PROCESSED FOOD.—**Notwithstanding
24 paragraph (1)—

25 **[“(A) if a tolerance is in effect under this**
26 **section for a pesticide chemical residue in or on**

1 a raw agricultural commodity, a pesticide chem-
2 ical residue that is present in or on a processed
3 food because the food is made from that raw
4 agricultural commodity shall not be considered
5 unsafe within the meaning of section
6 402(a)(2)(B) despite the lack of a tolerance for
7 the pesticide chemical residue in or on the proc-
8 essed food if the concentration of the pesticide
9 chemical residue in the processed food when
10 ready for consumption or use is not greater
11 than the tolerance prescribed for the pesticide
12 chemical residue in the raw agricultural com-
13 modity.

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

22 **【“(3) RESIDUES OF DEGRADATION PROD-**
23 UCTS.—If a pesticide chemical residue is present in
24 or on a food because it is a metabolite or other deg-
25 radation product of a precursor substance that itself

1 is a pesticide chemical or pesticide chemical residue,
2 such a residue shall not be considered to be unsafe
3 within the meaning of section 402(a)(2)(B) despite
4 the lack of a tolerance or exemption from the need
5 for a tolerance for such residue in or on such food
6 if—

7 【“(A) the Administrator has not deter-
8 mined that the degradation product is likely to
9 pose any potential health risk from dietary ex-
10 posure that is of a different type than, or of a
11 greater significance than, any risk posed by die-
12 tary exposure to the precursor substance; and

13 【“(B) either—

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

1 【“(ii) an exemption from the need for
2 a tolerance is in effect under this section
3 for residues of the precursor substance in
4 or on the food; and

5 【“(C) the tolerance or exemption for resi-
6 dues of the precursor substance does not state
7 that it applies only to particular named sub-
8 stances or states that it does not apply to resi-
9 dues of the degradation product.

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

18 【“(b) AUTHORITY AND STANDARD FOR TOLER-
19 ANCES.—

20 【“(1) AUTHORITY.—The Administrator may
21 issue regulations establishing, modifying, or revoking
22 a tolerance for a pesticide chemical residue in or on
23 a 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.—(A) A tolerance may not be
4 established for a pesticide chemical residue in or on
5 a food at a level that is higher than a level that the
6 Administrator determines is adequate to protect the
7 public health.

8 【“(B) The Administrator shall modify or revoke
9 a tolerance if it is at a level higher than the level
10 that the Administrator determines is adequate to
11 protect the public health.

12 【“(C) In making a determination under this
13 paragraph the Administrator shall take into account,
14 among other relevant factors, the validity, complete-
15 ness, and reliability of the available data from stud-
16 ies of the pesticide chemical residue, the nature of
17 any toxic effects shown to be caused by the pesticide
18 chemical in such studies, available information and
19 reasonable assumptions concerning the relationship
20 of the results of such studies to human risk, avail-
21 able information and reasonable assumptions con-
22 cerning the dietary exposure levels of food consum-
23 ers (and major identifiable subgroups of food con-
24 sumers, including infants and children) to the pes-
25 ticide chemical residue, and available information

1 and reasonable assumptions concerning the varia-
2 bility of the sensitivities of major identifiable groups,
3 including infants and children, and shall consider
4 other factors to the extent required by subparagraph
5 (F).

6 【“(D) For purposes of subparagraph (A), a tol-
7 erance level for a pesticide chemical residue in or on
8 a food shall be deemed to be adequate to protect the
9 public health if the dietary risk posed to food con-
10 sumers by such level of the pesticide chemical resi-
11 due is negligible. The Administrator shall by regula-
12 tion set forth the factors and methods, including
13 tests which are appropriate for the determination of
14 dietary risk and most likely dietary exposure, for the
15 determination of negligible dietary risk.

16 【“(E) Procedures shall be developed and imple-
17 mented that ensure that pesticide tolerances ade-
18 quately safeguard the health of infants and children.

19 【“(F) Where reliable data are available, the
20 Administrator shall calculate the dietary risk posed
21 to food consumers by a pesticide chemical on the
22 basis of the percent of food actually treated with the
23 pesticide chemical and the actual residue levels of
24 the pesticide chemical that occur in food. In particu-
25 lar, the Administrator shall take into account aggre-

1 gate pesticide use and residue data collected by the
2 Department of Agriculture.

3 【“(G) For purposes of subparagraph (A), a
4 level of a pesticide chemical residue in or on a food
5 that poses a greater than negligible dietary risk to
6 consumers of the food shall be deemed to be ade-
7 quate to protect the public health if the Adminis-
8 trator determines that such risk is not unreasonable
9 because—

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 that are considered to be greater
22 than the risks that result from dietary exposure
23 to the pesticide chemical residue; or

24 【“(iii) the availability of the pesticide
25 would enable domestic growers to maintain the

1 availability of an adequate, wholesome, and eco-
2 nomical food supply for consumers, taking into
3 account national and regional effects.

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

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

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

24 【“(C) A tolerance for a pesticide chemical resi-
25 due in or on a food shall not be established at a level

1 lower than the limit of detection of the method for
2 detecting and measuring the pesticide chemical resi-
3 due specified by the Administrator under subpara-
4 graph (B).

5 【“(4) INTERNATIONAL STANDARDS.—In estab-
6 lishing a tolerance for a pesticide chemical residue in
7 or on a food, the Administrator shall determine
8 whether a maximum residue level for the chemical
9 has been established by the Codex Alimentarius
10 Commission. If a Codex maximum residue level has
11 been established for the chemical and the Adminis-
12 trator does not propose to adopt the Codex level, the
13 Administrator shall publish for public comment a
14 notice explaining the reasons for departing from the
15 Codex level. If the Administrator determines not to
16 adopt a Codex level, the Administrator shall publish
17 as part of the final tolerance decision a determina-
18 tion with supporting data that the Codex level is not
19 supported by adequate and reliable scientific data, or
20 is inadequate to protect the health of the United
21 States’ consumers and that the effect of the toler-
22 ance on the availability to consumers of an adequate,
23 wholesome and economical food supply, does not out-
24 weigh the risk posed by the pesticide residue.

1 【“(c) AUTHORITY AND STANDARD FOR EXEMP-
2 TIONS.—

3 【“(1) AUTHORITY.—The Administrator may
4 issue a regulation establishing, modifying, or revok-
5 ing an exemption from the requirement for a toler-
6 ance for a pesticide chemical residue in or on a
7 food—

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

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

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

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

1 【“(C) In making a determination under this
2 paragraph, the Administrator shall take into ac-
3 count, among other relevant factors, the factors set
4 forth in subsection (b)(2)(C).

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

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

13 【“(B) that there is no need for such a
14 method, and states the reasons for such deter-
15 mination in the order issuing the regulation es-
16 tablishing or modifying the regulation.

17 【“(d) PETITION FOR TOLERANCE OR EXEMPTION.—

18 【“(1) PETITIONS AND PETITIONERS.—Any per-
19 son may file with the Administrator a petition pro-
20 posing the issuance of a regulation—

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

1 【“(B) establishing or revoking an exemp-
2 tion from the requirement of a tolerance for
3 such a residue.

4 【“(2) PETITION CONTENTS.—

5 【“(A) ESTABLISHMENT.—A petition under
6 paragraph (1) to establish a tolerance or ex-
7 emption for a pesticide chemical residue shall
8 be supported by such data and information as
9 are specified in regulations issued by the Ad-
10 ministrators, including—

11 【“(i)(I) an informative summary of
12 the petition and of the data, information,
13 and arguments submitted or cited in sup-
14 port of the petition;

15 【“(II) a statement that the petitioner
16 agrees that such summary or any informa-
17 tion it contains may be published as a part
18 of the notice of filing of the petition to be
19 published under this subsection and as
20 part of a proposed or final regulation is-
21 sued under this section;

22 【“(ii) the name, chemical identity,
23 and composition of the pesticide chemical
24 residue and of the pesticide chemical that
25 produces the residue;

1 【“(iii) data showing the recommended
2 amount, frequency, method, and time of
3 application of that pesticide chemical;

4 【“(iv) full reports of tests and inves-
5 tigations made with respect to the safety of
6 the pesticide chemical, including full infor-
7 mation as to the methods and controls
8 used in conducting those tests and inves-
9 tigations;

10 【“(v) full reports of tests and inves-
11 tigations made with respect to the nature
12 and amount of the pesticide chemical resi-
13 due that is likely to remain in or on the
14 food, including a description of the analyt-
15 ical methods used;

16 【“(vi) a practical method for detect-
17 ing and measuring the levels of the pes-
18 ticide chemical residue in or on the food,
19 or a statement why such a method is not
20 needed;

21 【“(vii) practical methods for removing
22 any amount of the residue that would ex-
23 ceed any proposed tolerance;

1 【“(viii) a proposed tolerance for the
2 pesticide chemical residue, if a tolerance is
3 proposed;

4 【“(ix) all relevant data bearing on the
5 physical or other technical effect that the
6 pesticide chemical is intended to have and
7 the quantity of the pesticide chemical that
8 is required to produce the effect;

9 【“(x) if the petition relates to a toler-
10 ance for a processed food, reports of inves-
11 tigations conducted using the processing
12 method(s) used to produce that food;

13 【“(xi) such information as the Admin-
14 istrator may require to make the deter-
15 mination under subsection (b)(2)(E); and

16 【“(xii) such other data and informa-
17 tion as the Administrator requires by regu-
18 lation to support the petition.

19 If information or data required by this subpara-
20 graph is available to the Administrator, the per-
21 son submitting the petition may cite the avail-
22 ability of the information or data in lieu of sub-
23 mitting it. The Administrator may require a pe-
24 tition to be accompanied by samples of the pes-

1 pesticide chemical with respect to which the peti-
2 tion is filed.

3 **【“(B) MODIFICATION OR REVOCATION.—**

4 The Administrator may by regulation establish
5 the requirements for information and data to
6 support a petition to modify or revoke a toler-
7 ance or to revoke an exemption from the re-
8 quirement for a tolerance.

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

21 **【“(4) ACTIONS BY THE ADMINISTRATOR.—**The
22 Administrator shall, after giving due consideration
23 to a petition filed under paragraph (1) and any
24 other information available to the Administrator—

1 【“(A) issue a final regulation (which may
2 vary from that sought by the petition) estab-
3 lishing, modifying, or revoking a tolerance for
4 the pesticide chemical residue or an exemption
5 of the pesticide chemical residue from the re-
6 quirement of a tolerance;

7 【“(B) issue a proposed regulation under
8 subsection (e), and thereafter either issue a
9 final regulation under subsection (e) or an
10 order denying the petition; or

11 【“(C) issue an order denying the petition.

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

15 【“(6) FURTHER PROCEEDINGS.—

16 【“(A) Within 60 days after a regulation or
17 order is issued under paragraph (4), subsection
18 (e)(1), or subsection (f)(1), any person may file
19 objections thereto with the Administrator, speci-
20 fying with particularity the provisions of the
21 regulation or order deemed objectionable and
22 stating reasonable grounds therefor. If the reg-
23 ulation or order was issued in response to a pe-
24 tition under paragraph (d)(1), a copy of each
25 objection filed by a person other than the peti-

1 tioner shall be served by the Administrator on
2 the petitioner.

3 【“(B) An objection may include a request
4 for a public evidentiary hearing upon the objec-
5 tion. The Administrator shall, upon the initia-
6 tive of the Administrator or upon the request of
7 an interested person and after due notice, hold
8 a public evidentiary hearing if and to the extent
9 the Administrator determines that such a public
10 hearing is necessary to receive factual evidence
11 relevant to material issues of fact raised by the
12 objections. The presiding officer in such a hear-
13 ing may authorize a party to obtain discovery
14 from other persons and may upon a showing of
15 good cause made by a party issue a subpoena
16 to compel testimony or production of documents
17 from any person. The presiding officer shall be
18 governed by the Federal Rules of Civil Proce-
19 dure in making any order for the protection of
20 the witness or the content of documents pro-
21 duced and shall order the payment of a reason-
22 able fees and expenses as a condition to requir-
23 ing testimony of the witness. On contest, such
24 a subpoena may be enforced by a Federal dis-
25 trict court.

1 【“(C) As soon as practicable after receiv-
2 ing the arguments of the parties, the Adminis-
3 trator shall issue an order stating the action
4 taken upon each such objection and setting
5 forth any revision to the regulation or prior
6 order that the Administrator has found to be
7 warranted. If a hearing was held under sub-
8 paragraph (B), such order and any revision to
9 the regulation or prior order shall, with respect
10 to questions of fact at issue in the hearing, be
11 based only on substantial evidence of record at
12 such hearing, and shall set forth in detail the
13 findings of facts and the conclusions of law or
14 policy upon which the order or regulation is
15 based.

16 【“(D) An order issued under this para-
17 graph ruling on an objection shall not take ef-
18 fect before the 90th day after its publication
19 unless the Administrator finds that emergency
20 conditions exist necessitating an earlier effective
21 date, in which event the Administrator shall
22 specify in the order the Administrator’s find-
23 ings as to such conditions.

24 【“(7) JUDICIAL REVIEW.—(A) In a case of ac-
25 tual controversy as to the validity of any order is-

1 sued under paragraph (6) or any regulation that is
2 the subject of such an order, any person who will be
3 adversely affected by such order or regulation may
4 obtain judicial review by filing in the United States
5 Court of Appeals for the circuit wherein that person
6 resides or has its principal place of business, or in
7 the United States Court of Appeals for the District
8 of Columbia Circuit, within 60 days after publication
9 of such order, a petition praying that the order or
10 regulation be set aside in whole or in part.

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

1 【“(C) If a party applies to the court for leave
2 to adduce additional evidence, and shows to the sat-
3 isfaction of the court that the additional evidence is
4 material and that there were reasonable grounds for
5 the failure to adduce the evidence in the proceeding
6 before the Administrator, the court may order that
7 the additional evidence (and evidence in rebuttal
8 thereof) shall be taken before the Administrator in
9 the manner and upon the terms and conditions the
10 court deems proper. The Administrator may modify
11 prior findings as to the facts by reason of the addi-
12 tional evidence so taken and may modify the order
13 or regulation accordingly. The Administrator shall
14 file with the court any such modified finding, order,
15 or regulation.

16 【“(D) The judgment of the court affirming or
17 setting aside, in whole or in part, any order under
18 paragraph (6) and any regulation which is the sub-
19 ject of such an order shall be final, subject to review
20 by the Supreme Court of the United States as pro-
21 vided in section 1254 of title 28 of the United States
22 Code. The commencement of proceedings under this
23 paragraph shall not, unless specifically ordered by
24 the court to the contrary, operate as a stay of a reg-
25 ulation or order.

1 【“(E) Any issue as to which review is or was
2 obtainable under paragraph (6) and this paragraph
3 shall not be the subject of judicial review under any
4 other provision of law.

5 【“(e) ACTION ON ADMINISTRATOR’S OWN INITIA-
6 TIVE.—

7 【“(1) GENERAL RULE.—The Administrator
8 may issue a regulation—

9 【“(A) establishing, modifying, or revoking
10 a tolerance for a pesticide chemical or a pes-
11 ticide chemical residue;

12 【“(B) establishing or revoking an exemp-
13 tion of a pesticide chemical residue from the re-
14 quirement of a tolerance; or

15 【“(C) establishing general procedures and
16 requirements to implement this section.

17 A regulation issued under this paragraph shall be-
18 come effective upon its publication.

19 【“(2) NOTICE.—Before issuing a final regula-
20 tion under paragraph (1), the Administrator shall
21 issue a notice of proposed rulemaking and provide a
22 period of not less than 60 days for public comment
23 on the proposed regulation, except that a shorter pe-
24 riod for comment may be provided if the Adminis-
25 trator for good cause finds that it would be contrary

1 to the public interest to do so and states the reasons
2 for the finding in the notice of proposed rulemaking.
3 The Administrator shall provide an opportunity for
4 a public hearing during the rulemaking under proce-
5 dures provided in subsection (d)(6)(B).

6 **【“(f) SPECIAL DATA REQUIREMENTS.—**

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

14 **【“(A) issue a notice requiring the persons**
15 **holding the pesticide registrations associated**
16 **with such tolerance or exemption to submit the**
17 **data or information under section 3(c)(2)(B) of**
18 **the Federal Insecticide, Fungicide, and**
19 **Rodenticide Act;**

20 **【“(B) issue a rule requiring that testing**
21 **be conducted on a substance or mixture under**
22 **section 4 of the Toxic Substances Control Act;**
23 **or**

24 **【“(C) publish in the Federal Register,**
25 **after first providing notice and an opportunity**

1 for comment of not less than 90 days' duration,
2 an order—

3 【“(i) requiring the submission to the
4 Administrator by one or more interested
5 persons of a notice identifying the person
6 or persons who will submit the required
7 data and information;

8 【“(ii) describing the type of data and
9 information requiring to be submitted to
10 the Administrator and stating why the
11 data and information could not be obtained
12 under the authority of section 3(c)(2)(B)
13 of the Federal Insecticide, Fungicide, and
14 Rodenticide Act or section 4 of the Toxic
15 Substances Control Act;

16 【“(iii) describing the reports of the
17 Administrator required to be prepared dur-
18 ing and after the collection of the data and
19 information;

20 【“(iv) requiring the submission to the
21 Administrator of the data, information,
22 and reports referred to in clauses (ii) and
23 (iii); and

1 【“(v) establishing dates by which the
2 submissions described in clauses (i) and
3 (iv) must be made.

4 The Administrator may revise any such order
5 to correct an error.

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

13 【“(3) REVIEW.—An order issued under this
14 subsection shall be effective upon publication and
15 shall be subject to review in accordance with para-
16 graphs (6) and (7) of subsection (d).

17 【“(g) CONFIDENTIALITY AND USE OF DATA.—

18 【“(1) GENERAL RULE.—Data and information
19 that are submitted to the Administrator under this
20 section in support of a tolerance or an exemption
21 from a tolerance shall be entitled to confidential
22 treatment for reasons of business confidentiality and
23 to exclusive use and data compensation, to the same
24 extent provided by sections 3 and 10 of the Federal
25 Insecticide, Fungicide, and Rodenticide Act.

1 【“(2) EXCEPTIONS.—Data that are entitled to
2 confidential treatment under paragraph (1) may
3 nonetheless be disclosed to the Congress of the
4 United States, and may be disclosed, under such se-
5 curity requirements as the Administrator may pro-
6 vide by regulation, to—

7 【“(A) employees of the United States au-
8 thorized by the Administrator to examine such
9 data in the carrying out of their official duties
10 under this Act or other Federal statutes in-
11 tended to protect the public health; or

12 【“(B) contractors with the United States
13 authorized by the Administrator to examine
14 such data in the carrying out of contracts under
15 such statutes.

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

23 【“(h) STATUS OF PREVIOUSLY ISSUED REGULA-
24 TIONS.—

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

10 【“(2) REGULATIONS UNDER SECTION 409.—
11 Regulations that established tolerances for sub-
12 stances that are pesticide chemical residues on or in
13 processed food, or that otherwise stated the condi-
14 tions under which such pesticide chemicals could be
15 safely used, and that were issued under section 409
16 on or before the date of the enactment of this para-
17 graph, shall be deemed to be regulations issued
18 under this section and shall be subject to modifica-
19 tion or revocation under subsection (d) or (e).

20 【“(3) REGULATIONS UNDER SECTION 408.—
21 Regulations that established tolerances or exemp-
22 tions under this section that were issued on or be-
23 fore the date of the enactment of this paragraph
24 shall remain in effect unless modified or revoked
25 under subsection (d) or (e).

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

6 【“(1) regarded by the Administrator or the
7 Secretary as generally recognized as safe for use
8 within the meaning of the provisions of section
9 408(a) or 201(s) as then in effect; or

10 【“(2) regarded by the Secretary as a substance
11 described by section 201(s)(4), such a pesticide
12 chemical residue shall be regarded as exempt from
13 the requirement for a tolerance, as of the date of en-
14 actment of this subsection. The Administrator shall
15 by regulation indicate which substances are de-
16 scribed by this subsection. All exemption under this
17 subsection may be revoked or modified as if it had
18 been issued under subsection (c).

19 【“(j) HARMONIZATION WITH ACTION UNDER OTHER
20 LAWS.—

21 【“(1) LIMITATION.—Notwithstanding any other
22 provision of this Act, a final rule under this section
23 that revokes, modifies, or suspends a tolerance or
24 exemption for a pesticide chemical residue in or on
25 a food may be issued only if the Administrator has

1 first taken any necessary action under the Federal
2 Insecticide, Fungicide, and Rodenticide Act with re-
3 spect to the registration of the pesticide(s) whose
4 use results in such residue to ensure that any au-
5 thorized use of the pesticide in producing, storing,
6 processing, or transporting food that occurs after
7 the issuance of such final rule under this section will
8 not result in pesticide chemical residues on such
9 food that are unsafe within the meaning of sub-
10 section (a).

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

1 use, in or on that food. The Administrator shall use
2 the procedures set forth in subsection (e) in taking
3 action under this paragraph. A revocation under this
4 paragraph shall become effective not later than 180
5 days after—

6 【“(A) the date by which each such can-
7 cellation of a registration has become effective;
8 or

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

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

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

1 sults from its use, in or on that food. The Ad-
2 ministrator shall use the procedures set forth in
3 subsection (e) in taking action under this para-
4 graph. A suspension under this paragraph shall
5 become effective not later than 60 days after
6 the date by which each such suspension of use
7 has become effective.

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

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

1 of this paragraph, if the Administrator determines
2 that a residue of the canceled or suspended pesticide
3 chemical will unavoidably persist in the environment
4 and thereby be present in or on a food, the Adminis-
5 trator may establish a tolerance for the pesticide
6 chemical residue at a level that permits such un-
7 avoidable residue to remain in such food. In estab-
8 lishing such a tolerance, the Administrator shall
9 take into account the factors set forth in subsection
10 (b)(2)(A)(iii) and shall use the procedures set forth
11 in subsection (e). The Administrator shall review
12 any such tolerance periodically and modify it as nec-
13 essary so that it allows only that level of the pes-
14 ticide chemical residue that is unavoidable.

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

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

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

18 【“(k) FEES.—The Administrator shall by regulation
19 require the payment of such fees as will in the aggregate,
20 in the judgment of the Administrator, be sufficient over
21 a reasonable term to provide, equip, and maintain an ade-
22 quate service for the performance of the Administrator’s
23 functions under this section. Under the regulations, the
24 performance of the Administrator’s services or other func-
25 tions under this section, including—

1 【“(1) the acceptance for filing of a petition
2 submitted under subsection (d);

3 【“(2) the promulgation of a regulation estab-
4 lishing, modifying, or revoking a tolerance or estab-
5 lishing or revoking an exemption from the require-
6 ment of a tolerance under this section;

7 【“(3) the acceptance for filing of objections
8 under subsection (d)(6); or

9 【“(4) the certification and filing in court of a
10 transcript of the proceedings and the record under
11 subsection (d)(7);

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

17 【“(1) NATIONAL UNIFORMITY OF TOLERANCES.—

18 【“(1) QUALIFYING PESTICIDE CHEMICAL RESI-
19 DUE.—For purposes of this subsection, the term
20 ‘qualifying pesticide chemical residue’ means a pes-
21 ticide chemical residue resulting from the use, in
22 production, processing, or storage of a food, of a
23 pesticide chemical that is an active ingredient and
24 that—

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

9 【“(B) was approved for such use in a re-
 10 registration eligibility determination issued
 11 under section 4(g) of that Act on or after the
 12 date of enactment of the Food Quality Protec-
 13 tion Act of 1995.

14 【“(2) QUALIFYING FEDERAL DETERMINA-
 15 TION.—For purposes of this subsection, the term
 16 ‘qualifying Federal determination’ means—

17 【“(A) a tolerance or exemption from the
 18 requirement for a tolerance for a qualifying pes-
 19 ticide chemical residue that was—

20 【“(i) issued under this section after
 21 the date of enactment of the Food Quality
 22 Protection Act of 1995; (or)

23 【“(ii) issued (or, pursuant to sub-
 24 section (h) or (i), deemed to have been is-
 25 sued) under this section, and determined

1 by the Administrator to meet the standard
2 under subsection (b)(2) (in the case of a
3 tolerance) or (c)(2) (in the case of an ex-
4 emption); and

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

13 【“(3) LIMITATION.—The Administrator may
14 make the determination described in paragraph
15 (2)(A)(ii) only by issuing a rule in accordance with
16 the procedure set forth in subsection (d) or (e) and
17 only if the Administrator issues a proposed rule and
18 allows a period of not less than 30 days for comment
19 on the proposed rule. Any such rule shall be
20 reviewable in accordance with subsections (d)(6) and
21 (d)(7).

22 【“(4) STATE AUTHORITY.—Except as provided
23 in paragraph (5), no State or political subdivision
24 may establish or enforce any regulatory limit on a
25 qualifying pesticide chemical residue in or on any

1 food if a qualifying Federal determination applies to
2 the presence of such pesticide chemical residue in or
3 on such food, unless such State regulatory limit is
4 identical to such qualifying Federal determination. A
5 State or political subdivision shall be deemed to es-
6 tablish or enforce a regulatory limit on a pesticide
7 chemical residue in or on food if it purports to pro-
8 hibit or penalize the production, processing, ship-
9 ping, or other handling of a food because it contains
10 a pesticide residue (in excess of a prescribed limit),
11 or if it purports to require that a food containing a
12 pesticide residue be the subject of a warning or
13 other statement relating to the presence of the pes-
14 ticide residue in the food.

15 **【“(5) PETITION PROCEDURE.—**

16 **【“(A) Any State may petition the Admin-**
17 **istrator for authorization to establish in such**
18 **State a regulatory limit on a qualifying pes-**
19 **ticide chemical residue in or on any food that**
20 **is not identical to the qualifying Federal deter-**
21 **mination applicable to such qualifying pesticide**
22 **chemical residue.**

23 **【“(B) Any petition under subparagraph**
24 **(A) shall—**

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

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

12 【“(C) Subject to paragraph (6), the Ad-
13 ministrator may, by order, grant the authoriza-
14 tion described in subparagraph (A) if the Ad-
15 ministrator determines that the proposed State
16 regulatory limit—

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

19 【“(ii) would not unduly burden inter-
20 state commerce; and

21 【“(iii) would not cause any food to be
22 in violation of Federal law.

23 【“(D) In lieu of any action authorized
24 under subparagraph (C), the Administrator
25 may treat a petition under this paragraph as a

1 petition under subsection (d) to revoke or mod-
2 ify a tolerance or to revoke an exemption. If the
3 Administrator determines to treat a petition
4 under this paragraph as a petition under sub-
5 section (d), the Administrator shall thereafter
6 act on the petition pursuant to subsection (d).

7 【“(E) Any order of the Administrator
8 granting or denying the authorization described
9 in subparagraph (A) shall be subject to review
10 in the manner described in subsections (d)(6)
11 and (d)(7).

12 【“(6) RESIDUES FROM LAWFUL APPLICA-
13 TION.—No State or political subdivision may enforce
14 any regulatory limit on the level of a pesticide chem-
15 ical residue that may appear in or on any food if,
16 at the time of the application of the pesticide that
17 resulted in such residue, the sale of such food with
18 such residue level was lawful under this Act and
19 under the law of such State, unless the State dem-
20 onstrates that consumption of the food containing
21 such pesticide residue level during the period of the
22 food’s likely availability in the State will pose an un-
23 reasonable dietary risk to the health of persons with-
24 in such State.”.

1 **[SEC. 406. AUTHORIZATION FOR INCREASE MONITORING.**

2 **[There is authorized to be appropriated an additional**
3 **\$12,000,000 for increased monitoring by the Secretary of**
4 **Health and Human Services of pesticide residues in im-**
5 **ported and domestic food.]**

6 **TITLE IV—AMENDMENTS TO THE**
7 **FEDERAL FOOD, DRUG, AND**
8 **COSMETIC ACT**

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

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

12 **(b) REFERENCE.—Whenever in this title an**
13 **amendment or repeal is expressed in terms of**
14 **an amendment to, or repeal of, a section or**
15 **other provision, the reference shall be consid-**
16 **ered to be made to a section or other provi-**
17 **sion of the Federal Food, Drug, and Cosmetic**
18 **Act.**

19 **SEC. 402. DEFINITIONS.**

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

22 **“(q)(1) The term ‘pesticide chemical’**
23 **means any substance that is a pesticide with-**
24 **in the meaning of the Federal Insecticide,**
25 **Fungicide, and Rodenticide Act, including all**
26 **active and inert ingredients of such pesticide.**

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

4 **“(A) a pesticide chemical; or**

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

10 **“(3) Notwithstanding paragraphs (1) and**
11 **(2), the Administrator may by regulation ex-**
12 **cept a substance from the definition of ‘pes-**
13 **ticide chemical’ or ‘pesticide chemical resi-**
14 **due’ if—**

15 **“(A) its occurrence as a residue on or**
16 **in a raw agricultural commodity or proc-**
17 **essed food is attributable primarily to**
18 **natural causes or to human activities not**
19 **involving the use of any substances for a**
20 **pesticidal purpose in the production,**
21 **storage, processing, or transportation of**
22 **any raw agricultural commodity or proc-**
23 **essed food; and**

24 **“(B) the Administrator, after con-**
25 **sultation with the Secretary, determines**

1 that the substance more appropriately
2 should be regulated under one or more
3 provisions of this Act other than sections
4 402(a)(2)(B) and 408.”.

5 (b) SECTION 201(s).—Paragraphs (1) and (2)
6 of section 201(s) (21 U.S.C. 321(s)) are amend-
7 ed to read as follows:

8 “(1) a pesticide chemical residue in or
9 on a raw agricultural commodity or proc-
10 essed food; or

11 “(2) a pesticide chemical; or”.

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

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

21 “(hh) The term ‘Administrator’ means the
22 Administrator of the United States Environ-
23 mental Protection Agency.”.

1 SEC. 403. PROHIBITED ACTS.

2 Section 301(j) (21 U.S.C. 331(j)) is amended
3 in the first sentence by inserting before the
4 period the following: “; or the violating of sec-
5 tion 408(i)(2) or any regulation issued under
6 that section.”.

7 SEC. 404. ADULTERATED FOOD.

8 Section 402(a) (21 U.S.C. 342(a)) is amend-
9 ed by striking “(2)(A) if it bears” and all that
10 follows through “(3) if it consists” and insert-
11 ing the following: “(2)(A) if it bears or con-
12 tains any added poisonous or added delete-
13 rious substance (other than a substance that
14 is a pesticide chemical residue in or on a raw
15 agricultural commodity or processed food, a
16 food additive, a color additive, or a new ani-
17 mal drug) that is unsafe within the meaning
18 of section 406; or (B) if it bears or contains a
19 pesticide chemical residue that is unsafe
20 within the meaning of section 408(a); or (C) if
21 it is or if it bears or contains (i) any food addi-
22 tive that is unsafe within the meaning of sec-
23 tion 409; or (ii) a new animal drug (or conver-
24 sion product thereof) that is unsafe within the
25 meaning of section 512; or (3) if it consists”.

1 SEC. 405. TOLERANCES AND EXEMPTIONS FOR PESTICIDE
2 CHEMICAL RESIDUES.

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

5 “TOLERANCES AND EXEMPTIONS FOR PESTICIDE
6 CHEMICAL RESIDUES

7 “SEC. 408. (a) REQUIREMENT FOR TOLER-
8 ANCE OR EXEMPTION.—

9 “(1) GENERAL RULE.—Except as pro-
10 vided in paragraph (2) or (3), any pes-
11 ticide chemical residue in or on a food
12 shall be deemed unsafe for the purpose of
13 section 402(a)(2)(B) unless—

14 “(A) a tolerance for such pesticide
15 chemical residue in or on such food is
16 in effect under this section and the
17 quantity of the residue is within the
18 limits of the tolerance; or

19 “(B) an exemption from the re-
20 quirement of a tolerance is in effect
21 under this section for the pesticide
22 chemical residue.

23 For the purposes of this section, the term
24 ‘food’, when used as a noun without
25 modification, shall mean a raw agricul-
26 tural commodity or processed food.

1 **“(2) PROCESSED FOOD.—Notwithstand-**
2 **ing paragraph (1)—**

3 **“(A) if a tolerance is in effect**
4 **under this section for a pesticide**
5 **chemical residue in or on a raw agri-**
6 **cultural commodity, a pesticide chem-**
7 **ical residue that is present in or on a**
8 **processed food because the food is**
9 **made from that raw agricultural com-**
10 **modity shall not be considered unsafe**
11 **within the meaning of section**
12 **402(a)(2)(B) despite the lack of a tol-**
13 **erance for the pesticide chemical res-**
14 **idue in or on the processed food if the**
15 **pesticide chemical has been used in**
16 **or on the raw agricultural commodity**
17 **in conformity with a tolerance under**
18 **this section, such residue in or on the**
19 **raw agricultural commodity has been**
20 **removed to the extent possible in**
21 **good manufacturing practice, and the**
22 **concentration of the pesticide chemi-**
23 **cal residue in the processed food is**
24 **not greater than the tolerance pre-**
25 **scribed for the pesticide chemical res-**

1 idue in the raw agricultural commod-
2 ity; or

3 “(B) if an exemption for the re-
4 quirement for a tolerance is in effect
5 under this section for a pesticide
6 chemical residue in or on a raw agri-
7 cultural commodity, a pesticide chem-
8 ical residue that is present in or on a
9 processed food because the food is
10 made from that raw agricultural com-
11 modity shall not be considered unsafe
12 within the meaning of section
13 402(a)(2)(B).

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

1 “(A) the Administrator has not de-
2 termined that the degradation prod-
3 uct is likely to pose any potential
4 health risk from dietary exposure
5 that is of a different type than, or of
6 a greater significance than, any risk
7 posed by dietary exposure to the pre-
8 cursor substance;

9 “(B) either—

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

23 “(ii) an exemption from the
24 need for a tolerance is in effect
25 under this section for residues of

1 the precursor substance in or on
2 the food; and

3 “(C) the tolerance or exemption
4 for residues of the precursor sub-
5 stance does not state that it applies
6 only to particular named substances
7 and does not state that it does not
8 apply to residues of the degradation
9 product.

10 “(4) EFFECT OF TOLERANCE OR EXEMP-
11 TION.—While a tolerance or exemption
12 from the requirement for a tolerance is in
13 effect under this section for a pesticide
14 chemical residue with respect to any
15 food, the food shall not by reason of bear-
16 ing or containing any amount of such a
17 residue be considered to be adulterated
18 within the meaning of section 402(a)(1).

19 “(b) AUTHORITY AND STANDARD FOR TOLER-
20 ANCE.—

21 “(1) AUTHORITY.—The Administrator
22 may issue regulations establishing, modi-
23 fying, or revoking a tolerance for a pes-
24 ticide chemical residue in or on a food—

1 “(A) in response to a petition filed
2 under subsection (d); or

3 “(B) on the Administrator’s own
4 initiative under subsection (e).

5 As used in this section, the term ‘modify’
6 shall not mean expanding the tolerance
7 to cover additional foods.

8 “(2) STANDARD.—

9 “(A) GENERAL RULE.—

10 “(i) STANDARD.—The Adminis-
11 trator may establish or leave in
12 effect a tolerance for a pesticide
13 chemical residue in or on a food
14 only if the Administrator deter-
15 mines that the tolerance is safe.
16 The Administrator shall modify or
17 revoke a tolerance if the Adminis-
18 trator determines it is not safe.

19 “(ii) DETERMINATION OF SAFE-
20 TY.—As used in this section, the
21 term ‘safe’, with respect to a toler-
22 ance for a pesticide chemical resi-
23 due’, means that the Adminis-
24 trator has determined that there
25 is a reasonable certainty that no

1 harm will result from aggregate
2 exposure to the pesticide chemi-
3 cal residue, including all antici-
4 pated dietary exposures and all
5 other exposures for which there
6 is reliable information.

7 “(iii) RULE OF CONSTRUCTION.—
8 With respect to a tolerance, a pes-
9 ticide chemical residue meeting
10 the standard under clause (i) is
11 not an eligible pesticide chemical
12 residue for purposes of subpara-
13 graph (B).

14 “(B) TOLERANCES FOR ELIGIBLE PES-
15 TICIDE CHEMICAL RESIDUES.—

16 “(i) DEFINITION.—As used in
17 this subparagraph, the term ‘eligi-
18 ble pesticide chemical residue’
19 means a pesticide chemical resi-
20 due as to which—

21 “(I) the Administrator is
22 not able to identify a level of
23 exposure to the residue at
24 which the residue will not
25 cause or contribute to a

1 known or anticipated harm to
2 human health (referred to in
3 this section as a ‘nonthreshold
4 effect’);

5 “(II) the lifetime risk of
6 experiencing the nonthresh-
7 old effect is appropriately as-
8 sessed by quantitative risk as-
9 sessment; and

10 “(III) with regard to any
11 known or anticipated harm to
12 human health for which the
13 Administrator is able to iden-
14 tify a level at which the resi-
15 due will not cause such harm
16 (referred to in this section as
17 a ‘threshold effect’), the Ad-
18 ministrator determines that
19 the level of aggregate expo-
20 sure is safe.

21 “(ii) DETERMINATION OF TOLER-
22 ANCE.—Notwithstanding subpara-
23 graph (A)(i), a tolerance for an eli-
24 gible pesticide chemical residue

1 **may be left in effect or modified**
2 **under this subparagraph if—**

3 **“(I) at least one of the con-**
4 **ditions described in clause**
5 **(iii) is met; and**

6 **“(II) both of the condi-**
7 **tions described in clause (iv)**
8 **are met.**

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

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

22 **“(II) Use of the pesticide**
23 **chemical that produces the**
24 **residue is necessary to avoid**
25 **a significant disruption in do-**

1 mestic production of an ade-
2 quate, wholesome, and eco-
3 nomical food supply.

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

10 “(I) The yearly risk associ-
11 ated with the nonthreshold ef-
12 fect from aggregate exposure
13 to the residue does not exceed
14 10 times the yearly risk that
15 would be allowed under sub-
16 paragraph (A) for such effect.

17 “(II) The tolerance is lim-
18 ited so as to ensure that the
19 risk over a lifetime associated
20 with the nonthreshold effect
21 from aggregate exposure to
22 the residue is not greater
23 than twice the lifetime risk
24 that would be allowed under

1 subparagraph (A) for such ef-
2 fect.

3 “(v) REVIEW.—Five years after
4 the date on which the Adminis-
5 trator makes a determination to
6 leave in effect or modify a toler-
7 ance under this subparagraph,
8 and thereafter as the Adminis-
9 trator deems appropriate, the Ad-
10 ministrators shall determine, after
11 notice and opportunity for com-
12 ment, whether it has been dem-
13 onstrated to the Administrator
14 that a condition described in
15 clause (iii)(I) or clause (iii)(II)
16 continues to exist with respect to
17 the tolerance and that the yearly
18 and lifetime risks from aggregate
19 exposure to such residue con-
20 tinue to comply with the limits
21 specified in clause (iv). If the Ad-
22 ministrators determine by such
23 date that such demonstration has
24 not been made, the Administrator
25 shall, not later than 180 days after

1 the date of such determination,
2 issue a regulation under sub-
3 section (e)(1) to modify or revoke
4 the tolerance.

5 “(vi) INFANTS AND CHILDREN.—
6 Any tolerance under this subpara-
7 graph shall meet the require-
8 ments of subparagraph (C).

9 “(C) EXPOSURE OF INFANTS AND
10 CHILDREN.—In establishing, modify-
11 ing, leaving in effect, or revoking a
12 tolerance or exemption for a pesticide
13 chemical residue, the Administrator—

14 “(i) shall assess the risk of the
15 pesticide chemical residue based
16 on—

17 “(I) available information
18 about consumption patterns
19 among infants and children
20 that are likely to result in dis-
21 proportionately high con-
22 sumption of foods containing
23 or bearing such residue
24 among infants and children in

1 **comparison to the general**
2 **population;**

3 **“(II) available information**
4 **concerning the special suscep-**
5 **tibility of infants and children**
6 **to the pesticide chemical resi-**
7 **dues, including neurological**
8 **differences between infants**
9 **and children and adults, and**
10 **effects of in utero exposure to**
11 **pesticide chemicals; and**

12 **“(III) available informa-**
13 **tion concerning the cumu-**
14 **lative effects on infants and**
15 **children of such residues and**
16 **other substances that have a**
17 **common mechanism of tox-**
18 **icity; and**

19 **“(ii) shall—**

20 **“(I) ensure that there is a**
21 **reasonable certainty that no**
22 **harm will result to infants**
23 **and children from aggregate**
24 **exposure to the pesticide**
25 **chemical residue; and**

1 **“(II) publish a specific de-**
2 **termination regarding the**
3 **safety of the pesticide chemi-**
4 **cal residue for infants and**
5 **children.**

6 **The Secretary of Health and Human**
7 **Services and the Secretary of Agri-**
8 **culture, in consultation with the Ad-**
9 **ministrator, shall conduct surveys to**
10 **document dietary exposure to pes-**
11 **ticides among infants and children.**
12 **In the case of threshold effects, for**
13 **purposes of clause (ii)(I) an addi-**
14 **tional tenfold margin of safety for the**
15 **pesticide chemical residue and other**
16 **sources of exposure shall be applied**
17 **for infants and children to take into**
18 **account potential pre- and post-natal**
19 **toxicity and completeness of the data**
20 **with respect to exposure and toxicity**
21 **to infants and children. Notwith-**
22 **standing such requirement for an ad-**
23 **ditional margin of safety, the Admin-**
24 **istrator may use a different margin of**
25 **safety for the pesticide chemical resi-**

1 due only if, on the basis of reliable
2 data, such margin will be safe for in-
3 fants and children.

4 “(D) FACTORS.—In establishing,
5 modifying, leaving in effect, or revok-
6 ing a tolerance or exemption for a
7 pesticide chemical residue, the Ad-
8 ministrator shall consider, among
9 other relevant factors—

10 “(i) the validity, completeness,
11 and reliability of the available
12 data from studies of the pesticide
13 chemical and pesticide chemical
14 residue;

15 “(ii) the nature of any toxic ef-
16 fect shown to be caused by the
17 pesticide chemical or pesticide
18 chemical residue in such studies;

19 “(iii) available information
20 concerning the relationship of the
21 results of such studies to human
22 risk;

23 “(iv) available information
24 concerning the dietary consump-
25 tion patterns of consumers (and

1 major identifiable subgroups of
2 consumers);

3 “(v) available information
4 concerning the cumulative effects
5 of such residues and other sub-
6 stances that have a common
7 mechanism of toxicity;

8 “(vi) available information
9 concerning the aggregate expo-
10 sure levels of consumers (and
11 major identifiable subgroups of
12 consumers) to the pesticide chem-
13 ical residue and to other related
14 substances, including dietary ex-
15 posure under the tolerance and
16 all other tolerances in effect for
17 the pesticide chemical residue,
18 and exposure from other non-oc-
19 cupational sources;

20 “(vii) available information
21 concerning the variability of the
22 sensitivities of major identifiable
23 subgroups of consumers;

24 “(viii) such information as the
25 Administrator may require on

1 whether the pesticide chemical
2 may have an effect in humans
3 that is similar to an effect pro-
4 duced by a naturally occurring
5 estrogen or other endocrine ef-
6 fects; and

7 “(ix) safety factors which in
8 the opinion of experts qualified
9 by scientific training and experi-
10 ence to evaluate the safety of food
11 additives are generally recog-
12 nized as appropriate for the use
13 of animal experimentation data.

14 “(E) DATA AND INFORMATION RE-
15 GARDING ANTICIPATED AND ACTUAL RESI-
16 DUE LEVELS.—

17 “(i) AUTHORITY.—In establishing,
18 modifying, leaving in effect, or revok-
19 ing a tolerance for a pesticide chemi-
20 cal residue, the Administrator may
21 consider available data and informa-
22 tion on the anticipated residue levels
23 of the pesticide chemical in or on
24 food and the actual residue levels of
25 the pesticide chemical that have been

1 **measured in food, including residue**
2 **data collected by the Food and Drug**
3 **Administration.**

4 **“(ii) REQUIREMENT.—If the Admin-**
5 **istrator relies on anticipated or ac-**
6 **tual residue levels in establishing,**
7 **modifying, or leaving in effect a toler-**
8 **ance, the Administrator shall pursu-**
9 **ant to subsection (f)(1) require that**
10 **data be provided five years after the**
11 **date on which the tolerance is estab-**
12 **lished, modified, or left in effect, and**
13 **thereafter as the Administrator**
14 **deems appropriate, demonstrating**
15 **that such residue levels are not above**
16 **the levels so relied on. If such data**
17 **are not so provided, or if the data do**
18 **not demonstrate that the residue lev-**
19 **els are not above the levels so relied**
20 **on, the Administrator shall, not later**
21 **than 180 days after the date on which**
22 **the data were required to be pro-**
23 **vided, issue a regulation under sub-**
24 **section (e)(1), or an order under sub-**

1 section (f)(2), as appropriate, to mod-
2 ify or revoke the tolerance.

3 “(F) PERCENT OF FOOD ACTUALLY
4 TREATED.—In establishing, modifying,
5 leaving in effect, or revoking a toler-
6 ance for a pesticide chemical residue,
7 the Administrator may, when assess-
8 ing chronic dietary risk, consider
9 available data and information on the
10 percent of food actually treated with
11 the pesticide chemical (including ag-
12 gregate pesticide use data collected
13 by the Department of Agriculture)
14 only if the Administrator—

15 “(i) finds that the data are re-
16 liable and provide a valid basis to
17 show what percentage of the food
18 derived from such crop is likely
19 to contain such pesticide chemi-
20 cal residue;

21 “(ii) finds that the exposure
22 estimate does not understate ex-
23 posure for any significant sub-
24 population group;

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

8 “(iv) provides for the periodic
9 reevaluation of the estimate of
10 anticipated dietary exposure.

11 **“(3) DETECTION METHODS.—**

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

22 **“(B) DETECTION LIMIT.—**A toler-
23 ance for a pesticide chemical residue
24 in or on a food shall not be estab-
25 lished at or modified to a level lower

1 than the limit of detection of the
2 method for detecting and measuring
3 the pesticide chemical residue speci-
4 fied by the Administrator under sub-
5 paragraph (A).

6 “(4) INTERNATIONAL STANDARDS.—In es-
7 tablishing a tolerance for a pesticide
8 chemical residue in or on a food, the Ad-
9 ministrator shall determine whether a
10 maximum residue level for the pesticide
11 chemical has been established by the
12 Codex Alimentarius Commission. If a
13 Codex maximum residue level has been
14 established for the pesticide chemical
15 and the Administrator does not propose
16 to adopt the Codex level, the Adminis-
17 trator shall publish for public comment a
18 notice explaining the reasons for depart-
19 ing from the Codex level.

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

22 “(1) AUTHORITY.—The Administrator
23 may issue a regulation establishing,
24 modifying, or revoking an exemption
25 from the requirement for a tolerance for

1 **a pesticide chemical residue in or on**
2 **food—**

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

5 **“(B) on the Administrator’s initia-**
6 **tive under subsection (e).**

7 **“(2) STANDARD.—**

8 **“(A) GENERAL RULE.—**

9 **“(i) STANDARD.—The Adminis-**
10 **trator may establish or leave in**
11 **effect an exemption from the re-**
12 **quirement for a tolerance for a**
13 **pesticide chemical residue in or**
14 **on food only if the Administrator**
15 **determines that the exemption is**
16 **safe. The Administrator shall**
17 **modify or revoke an exemption if**
18 **the Administrator determines it is**
19 **not safe.**

20 **“(ii) DETERMINATION OF SAFE-**
21 **TY.—The term ‘safe’, with respect**
22 **to an exemption for a pesticide**
23 **chemical residue, means that the**
24 **Administrator has determined**
25 **that there is a reasonable cer-**

1 tainty that no harm will result
2 from aggregate exposure to the
3 pesticide chemical residue, in-
4 cluding all anticipated dietary ex-
5 posures and all other exposures
6 for which there is reliable infor-
7 mation.

8 “(B) FACTORS.—In making a deter-
9 mination under this paragraph, the
10 Administrator shall take into ac-
11 count, among other relevant consid-
12 erations, the considerations set forth
13 in subparagraphs (C) and (D) of sub-
14 section (b)(2).

15 “(3) LIMITATION.—An exemption from
16 the requirement for a tolerance for a pes-
17 ticide chemical residue in or on food
18 shall not be established or modified by
19 the Administrator unless the Adminis-
20 trator determines, after consultation with
21 the Secretary—

22 “(A) that there is a practical
23 method for detecting and measuring
24 the levels of such pesticide chemical
25 residue in or on food; or

1 **“(B) that there is no need for such**
2 **a method, and states the reasons for**
3 **such determination in issuing the**
4 **regulation establishing or modifying**
5 **the exemption.**

6 **“(d) PETITION FOR TOLERANCE OR EXEMP-**
7 **TION.—**

8 **“(1) PETITIONS AND PETITIONERS.—Any**
9 **person may file with the Administrator a**
10 **petition proposing the issuance of a regu-**
11 **lation—**

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

15 **“(B) establishing, modifying, or**
16 **revoking an exemption from the re-**
17 **quirement of a tolerance for such a**
18 **residue.**

19 **“(2) PETITION CONTENTS.—**

20 **“(A) ESTABLISHMENT.—A petition**
21 **under paragraph (1) to establish a tol-**
22 **erance or exemption for a pesticide**
23 **chemical residue shall be supported**
24 **by such data and information as are**

1 specified in regulations issued by the
2 Administrator, including—

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

8 “(II) a statement that the peti-
9 tioner agrees that such summary
10 or any information it contains
11 may be published as a part of the
12 notice of filing of the petition to
13 be published under this sub-
14 section and as part of a proposed
15 or final regulation issued under
16 this section;

17 “(ii) the name, chemical iden-
18 tity, and composition of the pes-
19 ticide chemical residue and of the
20 pesticide chemical that produces
21 the residue;

22 “(iii) data showing the rec-
23 ommended amount, frequency,
24 method, and time of application
25 of that pesticide chemical;

1 “(iv) full reports of tests and
2 investigations made with respect
3 to the safety of the pesticide
4 chemical, including full informa-
5 tion as to the methods and con-
6 trols used in conducting those
7 tests and investigations;

8 “(v) full reports of tests and
9 investigations made with respect
10 to the nature and amount of the
11 pesticide chemical residue that is
12 likely to remain in or on the food,
13 including a description of the an-
14 alytical methods used;

15 “(vi) a practical method for
16 detecting and measuring the lev-
17 els of the pesticide chemical resi-
18 due in or on the food, or for ex-
19 emptions, a statement why such a
20 method is not needed;

21 “(vii) a proposed tolerance for
22 the pesticide chemical residue, if
23 a tolerance is proposed;

24 “(viii) if the petition relates to
25 a tolerance for a processed food,

1 reports of investigations con-
2 ducted using the processing
3 method(s) used to produce that
4 food;

5 “(ix) such information as the
6 Administrator may require to
7 make the determination under
8 subsection (b)(2)(C);

9 “(x) such information as the
10 Administrator may require on
11 whether the pesticide chemical
12 may have an effect in humans
13 that is similar to an effect pro-
14 duced by a naturally occurring
15 estrogen or other endocrine ef-
16 fects;

17 “(xi) information regarding
18 exposure to the pesticide chemi-
19 cal residue due to any tolerance
20 or exemption already granted for
21 such residue;

22 “(xii) practical methods for re-
23 moving any amount of the residue
24 that would exceed any proposed
25 tolerance; and

1 “(xiii) such other data and in-
2 formation as the Administrator
3 requires by regulation to support
4 the petition.

5 If information or data required by
6 this subparagraph is available to the
7 Administrator, the person submitting
8 the petition may cite the availability
9 of the information or data in lieu of
10 submitting it. The Administrator may
11 require a petition to be accompanied
12 by samples of the pesticide chemical
13 with respect to which the petition is
14 filed.

15 “(B) MODIFICATION OR REVOCATION.—The Administrator may by reg-
16 ulation establish the requirements for
17 information and data to support a pe-
18 tition to modify or revoke a tolerance
19 or to modify or revoke an exemption
20 from the requirement for a tolerance.

21 “(3) NOTICE.—A notice of the filing of
22 a petition that the Administrator deter-
23 mines has met the requirements of para-
24 graph (2) shall be published by the Ad-
25

1 **ministrator within 30 days after such de-**
2 **termination. The notice shall announce**
3 **the availability of a description of the an-**
4 **alytical methods available to the Admin-**
5 **istrator for the detection and measure-**
6 **ment of the pesticide chemical residue**
7 **with respect to which the petition is filed**
8 **or shall set forth the petitioner's state-**
9 **ment of why such a method is not need-**
10 **ed. The notice shall include the summary**
11 **required by paragraph (2)(A)(i)(I).**

12 **“(4) ACTIONS BY THE ADMINISTRATOR.—**

13 **“(A) IN GENERAL.—The Adminis-**
14 **trator shall, after giving due consid-**
15 **eration to a petition filed under para-**
16 **graph (1) and any other information**
17 **available to the Administrator—**

18 **“(i) issue a final regulation**
19 **(which may vary from that sought**
20 **by the petition) establishing,**
21 **modifying, or revoking a toler-**
22 **ance for the pesticide chemical**
23 **residue or an exemption of the**
24 **pesticide chemical residue from**
25 **the requirement of a tolerance**

1 (which final regulation shall be is-
2 sued without further notice and
3 without further period for public
4 comment);

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

9 “(iii) issue an order denying
10 the petition.

11 “(B) PRIORITIES.—The Adminis-
12 trator shall give priority to petitions
13 for the establishment or modification
14 of a tolerance or exemption for a pes-
15 ticide chemical residue that appears
16 to pose a significantly lower risk to
17 human health from dietary exposure
18 than pesticide chemical residues that
19 have tolerances in effect for the same
20 or similar uses.

21 “(C) EXPEDITED REVIEW OF CERTAIN
22 PETITIONS.—

23 “(i) DATE CERTAIN FOR RE-
24 VIEW.—If a person files a complete
25 petition with the Administrator

1 proposing the issuance of a regu-
2 lation establishing a tolerance or
3 exemption for a pesticide chemi-
4 cal residue that presents a lower
5 risk to human health than a pes-
6 ticide chemical residue for which
7 a tolerance has been left in effect
8 or modified under subsection
9 (b)(2)(B), the Administrator shall
10 complete action on such petition
11 under this paragraph within 1
12 year.

13 “(ii) REQUIRED DETERMINA-
14 TIONS.—If the Administrator is-
15 sues a final regulation establish-
16 ing a tolerance or exemption for a
17 safer pesticide chemical residue
18 under clause (i), the Adminis-
19 trator shall, not later than 180
20 days after the date on which the
21 regulation is issued, determine
22 whether a condition described in
23 subclause (I) or (II) of subsection
24 (b)(2)(B)(iii) continues to exist
25 with respect to a tolerance that

1 has been left in effect or modified
2 under subsection (b)(2)(B). If such
3 condition does not continue to
4 exist, the Administrator shall, not
5 later than 180 days after the date
6 on which the determination
7 under the preceding sentence is
8 made, issue a regulation under
9 subsection (e)(1) to modify or re-
10 voke the tolerance.

11 “(e) ACTION ON ADMINISTRATOR’S OWN INI-
12 TIATIVE.—

13 “(1) GENERAL RULE.—The Adminis-
14 trator may issue a regulation—

15 “(A) establishing, modifying, sus-
16 pending under subsection (l)(3), or re-
17 voking a tolerance for a pesticide
18 chemical or a pesticide chemical resi-
19 due;

20 “(B) establishing, modifying, sus-
21 pending under subsection (l)(3), or re-
22 voking an exemption of a pesticide
23 chemical residue from the require-
24 ment of a tolerance; or

1 “(C) establishing general proce-
2 dures and requirements to implement
3 this section.

4 “(2) NOTICE.—Before issuing a final
5 regulation under paragraph (1), the Ad-
6 ministrator shall issue a notice of pro-
7 posed rulemaking and provide a period
8 of not less than 60 days for public com-
9 ment on the proposed regulation, except
10 that a shorter period for comment may
11 be provided if the Administrator for good
12 cause finds that it would be in the public
13 interest to do so and states the reasons
14 for the finding in the notice of proposed
15 rulemaking.

16 “(f) SPECIAL DATA REQUIREMENTS.—

17 “(1) REQUIRING SUBMISSION OF ADDI-
18 TIONAL DATA.—If the Administrator deter-
19 mines that additional data or information
20 are reasonably required to support the
21 continuation of a tolerance or exemption
22 that is in effect under this section for a
23 pesticide chemical residue on a food, the
24 Administrator shall—

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

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

12 “(C) publish in the Federal Reg-
13 ister, after first providing notice and
14 an opportunity for comment of not
15 less than 60 days’ duration, an
16 order—

17 “(i) requiring the submission
18 to the Administrator by one or
19 more interested persons of a no-
20 tice identifying the person or per-
21 sons who will submit the required
22 data and information;

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

1 and stating why the data and in-
2 formation could not be obtained
3 under the authority of section
4 3(c)(2)(B) of the Federal Insecti-
5 cide, Fungicide, and Rodenticide
6 Act or section 4 of the Toxic Sub-
7 stances Control Act;

8 “(iii) describing the reports of
9 the Administrator required to be
10 prepared during and after the
11 collection of the data and infor-
12 mation;

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

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

21 The Administrator may under sub-
22 paragraph (C) revise any such order
23 to correct an error. The Adminis-
24 trator may under this paragraph re-
25 quire data or information pertaining

1 to whether the pesticide chemical
2 may have an effect in humans that is
3 similar to an effect produced by a
4 naturally occurring estrogen or other
5 endocrine effects.

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

20 “(g) EFFECTIVE DATE, OBJECTIONS, HEAR-
21 INGS, AND ADMINISTRATIVE REVIEW.—

22 “(1) EFFECTIVE DATE.—A regulation or
23 order issued under subsection (d)(4),
24 (e)(1), or (f)(2) shall take effect upon pub-
25 lication unless the regulation or order

1 specifies otherwise. The Administrator
2 may stay the effectiveness of the regula-
3 tion or order if, after issuance of such
4 regulation or order, objections are filed
5 with respect to such regulation or order
6 pursuant to paragraph (2).

7 “(2) FURTHER PROCEEDINGS.—

8 “(A) OBJECTIONS.—Within 60 days
9 after a regulation or order is issued
10 under subsection (d)(4), (e)(1)(A),
11 (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C), any
12 person may file objections thereto
13 with the Administrator, specifying
14 with particularity the provisions of
15 the regulation or order deemed objec-
16 tionable and stating reasonable
17 grounds therefor. If the regulation or
18 order was issued in response to a pe-
19 tition under subsection (d)(1), a copy
20 of each objection filed by a person
21 other than the petitioner shall be
22 served by the Administrator on the
23 petitioner.

24 “(B) HEARING.—An objection may
25 include a request for a public evi-

1 dentiary hearing upon the objection.
2 The Administrator shall, upon the ini-
3 tiative of the Administrator or upon
4 the request of an interested person
5 and after due notice, hold a public
6 evidentiary hearing if and to the ex-
7 tent the Administrator determines
8 that such a public hearing is nec-
9 essary to receive factual evidence rel-
10 evant to material issues of fact raised
11 by the objections. The presiding offi-
12 cer in such a hearing may authorize a
13 party to obtain discovery from other
14 persons and may upon a showing of
15 good cause made by a party issue a
16 subpoena to compel testimony or pro-
17 duction of documents from any per-
18 son. The presiding officer shall be
19 governed by the Federal Rules of
20 Civil Procedure in making any order
21 for the protection of the witness or
22 the content of documents produced
23 and shall order the payment of a rea-
24 sonable fees and expenses as a condi-
25 tion to requiring testimony of the wit-

1 ness. On contest, such a subpoena
2 may be enforced by a Federal district
3 court.

4 “(C) FINAL DECISION.—As soon as
5 practicable after receiving the argu-
6 ments of the parties, the Adminis-
7 trator shall issue an order stating the
8 action taken upon each such objec-
9 tion and setting forth any revision to
10 the regulation or prior order that the
11 Administrator has found to be war-
12 ranted. If a hearing was held under
13 subparagraph (B), such order and any
14 revision to the regulation or prior
15 order shall, with respect to questions
16 of fact at issue in the hearing, be
17 based only on substantial evidence of
18 record at such hearing, and shall set
19 forth in detail the findings of facts
20 and the conclusions of law or policy
21 upon which the order or regulation is
22 based.

23 “(h) JUDICIAL REVIEW.—

24 “(1) PETITION.—In a case of actual
25 controversy as to the validity of any reg-

1 **ulation issued under subsection (e)(1)(C),**
2 **or any order issued under subsection**
3 **(f)(1)(C) or (g)(2)(C), or any regulation**
4 **that is the subject of such an order, any**
5 **person who will be adversely affected by**
6 **such order or regulation may obtain judi-**
7 **cial review by filing in the United States**
8 **Court of Appeals for the circuit wherein**
9 **that person resides or has its principal**
10 **place of business, or in the United States**
11 **Court of Appeals for the District of Co-**
12 **lumbia Circuit, within 60 days after pub-**
13 **lication of such order or regulation, a pe-**
14 **tition praying that the order or regula-**
15 **tion be set aside in whole or in part.**

16 **“(2) RECORD AND JURISDICTION.—A**
17 **copy of the petition under paragraph (1)**
18 **shall be forthwith transmitted by the**
19 **clerk of the court to the Administrator,**
20 **or any officer designated by the Adminis-**
21 **trator for that purpose, and thereupon**
22 **the Administrator shall file in the court**
23 **the record of the proceedings on which**
24 **the Administrator based the order or reg-**
25 **ulation, as provided in section 2112 of**

1 title 28, United States Code. Upon the fil-
2 ing of such a petition, the court shall
3 have exclusive jurisdiction to affirm or
4 set aside the order or regulation com-
5 plained of in whole or in part. As to or-
6 ders issued following a public evidentiary
7 hearing, the findings of the Adminis-
8 trator with respect to questions of fact
9 shall be sustained only if supported by
10 substantial evidence when considered on
11 the record as a whole.

12 “(3) ADDITIONAL EVIDENCE.—If a party
13 applies to the court for leave to adduce
14 additional evidence and shows to the sat-
15 isfaction of the court that the additional
16 evidence is material and that there were
17 reasonable grounds for the failure to ad-
18 duce the evidence in the proceeding be-
19 fore the Administrator, the court may
20 order that the additional evidence (and
21 evidence in rebuttal thereof) shall be
22 taken before the Administrator in the
23 manner and upon the terms and condi-
24 tions the court deems proper. The Admin-
25 istrator may modify prior findings as to

1 the facts by reason of the additional evi-
2 dence so taken and may modify the order
3 or regulation accordingly. The Adminis-
4 trator shall file with the court any such
5 modified finding, order, or regulation.

6 “(4) FINAL JUDGMENT; SUPREME COURT
7 REVIEW.—The judgment of the court af-
8 firming or setting aside, in whole or in
9 part, any regulation or any order and any
10 regulation which is the subject of such an
11 order shall be final, subject to review by
12 the Supreme Court of the United States
13 as provided in section 1254 of title 28 of
14 the United States Code. The commence-
15 ment of proceedings under this sub-
16 section shall not, unless specifically or-
17 dered by the court to the contrary, oper-
18 ate as a stay of a regulation or order.

19 “(5) APPLICATION.—Any issue as to
20 which review is or was obtainable under
21 this subsection shall not be the subject of
22 judicial review under any other provision
23 of law.

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

1 **“(1) GENERAL RULE.—Data and infor-**
2 **mation that are or have been submitted**
3 **to the Administrator under this section**
4 **or section 409 in support of a tolerance or**
5 **an exemption from a tolerance shall be**
6 **entitled to confidential treatment for rea-**
7 **sons of business confidentiality and to ex-**
8 **clusive use and data compensation to the**
9 **same extent provided by sections 3 and**
10 **10 of the Federal Insecticide, Fungicide,**
11 **and Rodenticide Act.**

12 **“(2) EXCEPTIONS.—**

13 **“(A) IN GENERAL.—Data and infor-**
14 **mation that are entitled to confiden-**
15 **tial treatment under paragraph (1)**
16 **may be disclosed, under such security**
17 **requirements as the Administrator**
18 **may provide by regulation, to—**

19 **“(i) employees of the United**
20 **States authorized by the Adminis-**
21 **trator to examine such data and**
22 **information in the carrying out of**
23 **their official duties under this Act**
24 **or other Federal statutes in-**

1 tended to protect the public
2 health; or

3 “(ii) contractors with the
4 United States authorized by the
5 Administrator to examine such
6 data and information in the car-
7 rying out of contracts under this
8 Act or such statutes.

9 “(B) CONGRESS.—This subsection
10 does not authorize the withholding of
11 data or information from either
12 House of Congress or from, to the ex-
13 tent of matter within its jurisdiction,
14 any committee or subcommittee of
15 such committee or any joint commit-
16 tee of Congress or any subcommittee
17 of such joint committee.

18 “(3) SUMMARIES.—Notwithstanding
19 any provision of this subsection or other
20 law, the Administrator may publish the
21 informative summary required by sub-
22 section (d)(2)(A)(i) and may, in issuing a
23 proposed or final regulation or order
24 under this section, publish an inform-

1 **ative summary of the data relating to the**
2 **regulation or order.**

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

5 **“(1) REGULATIONS UNDER SECTION 406.—**
6 **Regulations affecting pesticide chemical**
7 **residues in or on raw agricultural com-**
8 **modities promulgated, in accordance**
9 **with section 701(e), under the authority**
10 **of section 406(a) upon the basis of public**
11 **hearings instituted before January 1,**
12 **1953, shall be deemed to be regulations**
13 **issued under this section and shall be**
14 **subject to modification or revocation**
15 **under subsections (d) and (e), and shall**
16 **be subject to review under subsection (q).**

17 **“(2) REGULATIONS UNDER SECTION 409.—**
18 **Regulations that established tolerances**
19 **for substances that are pesticide chemi-**
20 **cal residues in or on processed food, or**
21 **that otherwise stated the conditions**
22 **under which such pesticide chemicals**
23 **could be safely used, and that were is-**
24 **sued under section 409 on or before the**
25 **date of the enactment of this paragraph,**

1 shall be deemed to be regulations issued
2 under this section and shall be subject to
3 modification or revocation under sub-
4 section (d) or (e), and shall be subject to
5 review under subsection (q).

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

14 “(k) TRANSITIONAL PROVISION.—If, on the
15 day before the date of the enactment of this
16 subsection, a substance that is a pesticide
17 chemical was, with respect to a particular
18 pesticidal use of the substance and any result-
19 ing pesticide chemical residue in or on a par-
20 ticular food—

21 “(1) regarded by the Administrator or
22 the Secretary as generally recognized as
23 safe for use within the meaning of the
24 provisions of subsection (a) or section
25 201(s) as then in effect; or

1 “(2) regarded by the Secretary as a
2 substance described by section 201(s)(4);
3 such a pesticide chemical residue shall be re-
4 garded as exempt from the requirement for a
5 tolerance, as of the date of enactment of this
6 subsection. The Administrator shall by regu-
7 lation indicate which substances are de-
8 scribed by this subsection. Any exemption
9 under this subsection may be modified or re-
10 voked as if it had been issued under sub-
11 section (c).

12 “(1) HARMONIZATION WITH ACTION UNDER
13 OTHER LAWS.—

14 “(1) COORDINATION WITH FIFRA.—To the
15 extent practicable and consistent with
16 the review deadlines in subsection (q), in
17 issuing a final rule under this subsection
18 that suspends or revokes a tolerance or
19 exemption for a pesticide chemical resi-
20 due in or on food, the Administrator shall
21 coordinate such action with any related
22 necessary action under the Federal Insec-
23 ticide, Fungicide, and Rodenticide Act.

24 “(2) REVOCATION OF TOLERANCE OR EX-
25 EMPTION FOLLOWING CANCELLATION OF AS-

1 **SOCIATED REGISTRATIONS.—If the Adminis-**
2 **trator, acting under the Federal Insecti-**
3 **cide, Fungicide, and Rodenticide Act,**
4 **cancels the registration of each pesticide**
5 **that contains a particular pesticide chem-**
6 **ical and that is labeled for use on a par-**
7 **ticular food, or requires that the registra-**
8 **tion of each such pesticide be modified to**
9 **prohibit its use in connection with the**
10 **production, storage, or transportation of**
11 **such food, due in whole or in part to die-**
12 **tary risks to humans posed by residues of**
13 **that pesticide chemical on that food, the**
14 **Administrator shall revoke any tolerance**
15 **or exemption that allows the presence of**
16 **the pesticide chemical, or any pesticide**
17 **chemical residue that results from its**
18 **use, in or on that food. Subsection (e)**
19 **shall apply to actions taken under this**
20 **paragraph. A revocation under this para-**
21 **graph shall become effective not later**
22 **than 180 days after—**

23 **“(A) the date by which each such**
24 **cancellation of a registration has be-**
25 **come effective; or**

1 “(B) the date on which the use of
2 the canceled pesticide becomes un-
3 lawful under the terms of the can-
4 cellation, whichever is later.

5 “(3) SUSPENSION OF TOLERANCE OR EX-
6 EMPTION FOLLOWING SUSPENSION OF ASSOCI-
7 ATED REGISTRATIONS.—

8 “(A) SUSPENSION.—If the Adminis-
9 trator, acting under the Federal In-
10 secticide, Fungicide, and Rodenticide
11 Act, suspends the use of each reg-
12 istered pesticide that contains a par-
13 ticular pesticide chemical and that is
14 labeled for use on a particular food,
15 due in whole or in part to dietary
16 risks to humans posed by residues of
17 that pesticide chemical on that food,
18 the Administrator shall suspend any
19 tolerance or exemption that allows
20 the presence of the pesticide chemi-
21 cal, or any pesticide chemical residue
22 that results from its use, in or on that
23 food. Subsection (e) shall apply to ac-
24 tions taken under this paragraph. A
25 suspension under this paragraph

1 shall become effective not later than
2 60 days after the date by which each
3 such suspension of use has become ef-
4 fective.

5 “(B) EFFECT OF SUSPENSION.—The
6 suspension of a tolerance or exemp-
7 tion under subparagraph (A) shall be
8 effective as long as the use of each as-
9 sociated registration of a pesticide is
10 suspended under the Federal Insecti-
11 cide, Fungicide, and Rodenticide Act.
12 While a suspension of a tolerance or
13 exemption is effective the tolerance
14 or exemption shall not be considered
15 to be in effect. If the suspension of
16 use of the pesticide under that Act is
17 terminated, leaving the registration
18 of the pesticide for such use in effect
19 under that Act, the Administrator
20 shall rescind any associated suspen-
21 sion of tolerance or exemption.

22 “(4) TOLERANCES FOR UNAVOIDABLE
23 RESIDUES.—In connection with action
24 taken under paragraph (2) or (3), or with
25 respect to pesticides whose registrations

1 were suspended or canceled prior to the
2 date of the enactment of this paragraph
3 under the Federal Insecticide, Fungicide,
4 and Rodenticide Act, if the Administrator
5 determines that a residue of the canceled
6 or suspended pesticide chemical will un-
7 avoidably persist in the environment and
8 thereby be present in or on a food, the
9 Administrator may establish a tolerance
10 for the pesticide chemical residue. In es-
11 tablishing such a tolerance, the Adminis-
12 trator shall take into account both the
13 factors set forth in subsection (b)(2) and
14 the unavailability of the residue. Sub-
15 section (e) shall apply to the establish-
16 ment of such tolerance. The Adminis-
17 trator shall review any such tolerance pe-
18 riodically and modify it as necessary so
19 that it allows no greater level of the pes-
20 ticide chemical residue than is unavail-
21 able.

22 “(5) PESTICIDE RESIDUES RESULTING
23 FROM LAWFUL APPLICATION OF PESTICIDE.—
24 Notwithstanding any other provision of
25 this Act, if a tolerance or exemption for a

1 pesticide chemical residue in or on a food
2 has been revoked, suspended, or modified
3 under this section, an article of that food
4 shall not be deemed unsafe solely be-
5 cause of the presence of such pesticide
6 chemical residue in or on such food if it
7 is shown to the satisfaction of the Sec-
8 retary that—

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

15 “(B) the residue does not exceed a
16 level that was authorized at the time
17 of that application or use to be
18 present on the food under a toler-
19 ance, exemption, food additive regu-
20 lation, or other sanction then in ef-
21 fect under this Act;

22 unless, in the case of any tolerance or ex-
23 emption revoked, suspended, or modified
24 under this subsection or subsection (d) or
25 (e), the Administrator has issued a deter-

1 mination that consumption of the legally
2 treated food during the period of its like-
3 ly availability in commerce will pose an
4 unreasonable dietary risk.

5 “(6) TOLERANCE FOR USE OF PESTICIDES
6 UNDER AN EMERGENCY EXEMPTION.—If the
7 Administrator grants an exemption
8 under section 18 of the Federal Insecti-
9 cide, Fungicide, and Rodenticide Act (7
10 U.S.C. 136p) for a pesticide chemical, the
11 Administrator shall establish a tolerance
12 or exemption from the requirement for a
13 tolerance for the pesticide chemical resi-
14 due. Such a tolerance or exemption from
15 a tolerance shall have an expiration date.
16 The Administrator may establish such a
17 tolerance or exemption without provid-
18 ing notice or a period for comment on the
19 tolerance or exemption. The Adminis-
20 trator shall promulgate regulations with-
21 in 365 days after the date of the enact-
22 ment of this paragraph governing the es-
23 tablishment of tolerances and exemptions
24 under this paragraph. Such regulations
25 shall be consistent with the safety stand-

1 ard under subsections (b)(2) and (c)(2)
2 and with section 18 of the Federal Insec-
3 ticide, Fungicide, and Rodenticide Act.

4 “(m) FEES.—

5 “(1) AMOUNT.—The Administrator
6 shall by regulation require the payment
7 of such fees as will in the aggregate, in
8 the judgment of the Administrator, be
9 sufficient over a reasonable term to pro-
10 vide, equip, and maintain an adequate
11 service for the performance of the Ad-
12 ministrator’s functions under this sec-
13 tion. Under the regulations, the perform-
14 ance of the Administrator’s services or
15 other functions under this section, in-
16 cluding—

17 “(A) the acceptance for filing of a
18 petition submitted under subsection
19 (d);

20 “(B) establishing, modifying, leav-
21 ing in effect, or revoking a tolerance
22 or establishing, modifying, leaving in
23 effect, or revoking an exemption from
24 the requirement for a tolerance
25 under this section;

1 **“(C) the acceptance for filing of**
2 **objections under subsection (g); or**

3 **“(D) the certification and filing in**
4 **court of a transcript of the proceed-**
5 **ings and the record under subsection**
6 **(h);**

7 **may be conditioned upon the payment of**
8 **such fees. The regulations may further**
9 **provide for waiver or refund of fees in**
10 **whole or in part when in the judgment of**
11 **the Administrator such a waiver or re-**
12 **fund is equitable and not contrary to the**
13 **purposes of this subsection.**

14 **“(2) DEPOSIT.—All fees collected under**
15 **paragraph (1) shall be deposited in the**
16 **Reregistration and Expedited Processing**
17 **Fund created by section 4(k) of the Fed-**
18 **eral Insecticide, Fungicide, and**
19 **Rodenticide Act. Such fees shall be avail-**
20 **able to the Administrator, without fiscal**
21 **year limitation, for the performance of**
22 **the Administrator’s services or functions**
23 **as specified in paragraph (1).**

24 **“(n) NATIONAL UNIFORMITY OF TOLER-**
25 **ANCES.—**

1 **“(1) QUALIFYING PESTICIDE CHEMICAL**
2 **RESIDUE.—For purposes of this sub-**
3 **section, the term ‘qualifying pesticide**
4 **chemical residue’ means a pesticide**
5 **chemical residue resulting from the use,**
6 **in production, processing, or storage of a**
7 **food, of a pesticide chemical that is an ac-**
8 **tive ingredient and that—**

9 **“(A) was first approved for such**
10 **use in a registration of a pesticide is-**
11 **sued under section 3(c)(5) of the Fed-**
12 **eral Insecticide, Fungicide,**
13 **Rodenticide Act on or after April 25,**
14 **1985, on the basis of data determined**
15 **by the Administrator to meet all ap-**
16 **plicable requirements for data pre-**
17 **scribed by regulations in effect under**
18 **that Act on April 25, 1985; or**

19 **“(B) was approved for such use in**
20 **a reregistration eligibility determina-**
21 **tion issued under section 4(g) of that**
22 **Act on or after the date of enactment**
23 **of this subsection.**

24 **“(2) QUALIFYING FEDERAL DETERMINA-**
25 **TION.—For purposes of this subsection,**

1 the term ‘qualifying Federal determina-
2 tion’ means a tolerance or exemption
3 from the requirement for a tolerance for
4 a qualifying pesticide chemical residue
5 that—

6 “(A) is issued under this section
7 after the date of the enactment of this
8 subsection and determined by the Ad-
9 ministrator to meet the standard
10 under subsection (b)(2)(A) (in the
11 case of a tolerance) or (c)(2) (in the
12 case of an exemption); or

13 “(B)(i) pursuant to subsection (j)
14 is remaining in effect or is deemed to
15 have been issued under this section,
16 or is regarded under subsection (k) as
17 exempt from the requirement for a
18 tolerance; and

19 “(ii) is determined by the Admin-
20 istrator to meet the standard under
21 subsection (b)(2)(A) (in the case of a
22 tolerance) or (c)(2) (in the case of an
23 exemption).

24 “(3) LIMITATION.—The Administrator
25 may make the determination described in

1 paragraph (2)(B)(ii) only by issuing a rule
2 in accordance with the procedure set
3 forth in subsection (d) or (e) and only if
4 the Administrator issues a proposed rule
5 and allows a period of not less than 30
6 days for comment on the proposed rule.
7 Any such rule shall be reviewable in ac-
8 cordance with subsections (g) and (h).

9 “(4) STATE AUTHORITY.—Except as pro-
10 vided in paragraphs (5), (6), and (8) no
11 State or political subdivision may estab-
12 lish or enforce any regulatory limit on a
13 qualifying pesticide chemical residue in
14 or on any food if a qualifying Federal de-
15 termination applies to the presence of
16 such pesticide chemical residue in or on
17 such food, unless such State regulatory
18 limit is identical to such qualifying Fed-
19 eral determination. A State or political
20 subdivision shall be deemed to establish
21 or enforce a regulatory limit on a pes-
22 ticide chemical residue in or on a food if
23 it purports to prohibit or penalize the
24 production, processing, shipping, or
25 other handling of a food because it con-

1 **tains a pesticide residue (in excess of a**
2 **prescribed limit).**

3 **“(5) PETITION PROCEDURE.—**

4 **“(A) IN GENERAL.—Any State may**
5 **petition the Administrator for author-**
6 **ization to establish in such State a**
7 **regulatory limit on a qualifying pes-**
8 **ticide chemical residue in or on any**
9 **food that is not identical to the quali-**
10 **fying Federal determination applica-**
11 **ble to such qualifying pesticide chem-**
12 **ical residue.**

13 **“(B) PETITION REQUIREMENTS.—Any**
14 **petition under subparagraph (A)**
15 **shall—**

16 **“(i) satisfy any requirements**
17 **prescribed, by rule, by the Admin-**
18 **istrator; and**

19 **“(ii) be supported by scientific**
20 **data about the pesticide chemical**
21 **residue that is the subject of the**
22 **petition or about chemically re-**
23 **lated pesticide chemical residues,**
24 **data on the consumption within**
25 **such State of food bearing the**

1 pesticide chemical residue, and
2 data on exposure of humans with-
3 in such State to the pesticide
4 chemical residue.

5 “(C) AUTHORIZATION.—The Admin-
6 istrator may, by order, grant the au-
7 thorization described in subpara-
8 graph (A) if the Administrator deter-
9 mines that the proposed State regu-
10 latory limit—

11 “(i) is justified by compelling
12 local conditions; and

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

15 “(D) TREATMENT.—In lieu of any
16 action authorized under subpara-
17 graph (C), the Administrator may
18 treat a petition under this paragraph
19 as a petition under subsection (d) to
20 modify or revoke a tolerance or an
21 exemption. If the Administrator de-
22 termines to treat a petition under
23 this paragraph as a petition under
24 subsection (d), the Administrator

1 shall thereafter act on the petition
2 pursuant to subsection (d).

3 “(E) REVIEW.—Any order of the
4 Administrator granting or denying
5 the authorization described in sub-
6 paragraph (A) shall be subject to re-
7 view in the manner described in sub-
8 sections (g) and (h).

9 “(6) URGENT PETITION PROCEDURE.—
10 Any State petition to the Administrator
11 pursuant to paragraph (5) that dem-
12 onstrates that consumption of a food con-
13 taining such pesticide residue level dur-
14 ing the period of the food’s likely avail-
15 ability in the State will pose a significant
16 public health threat from acute exposure
17 shall be considered an urgent petition. If
18 an order by the Administrator to grant or
19 deny the requested authorization in an
20 urgent petition is not made within 30
21 days of receipt of the petition, the peti-
22 tioning State may establish and enforce a
23 temporary regulatory limit on a qualify-
24 ing pesticide chemical residue in or on
25 the food. The temporary regulatory limit

1 shall be validated or terminated by the
2 Administrator's final order on the peti-
3 tion.

4 “(7) RESIDUES FROM LAWFUL APPLICA-
5 TION.—No State or political subdivision
6 may enforce any regulatory limit on the
7 level of a pesticide chemical residue that
8 may appear in or on any food if, at the
9 time of the application of the pesticide
10 that resulted in such residue, the sale of
11 such food with such residue level was
12 lawful under this section and under the
13 law of such State, unless the State dem-
14 onstrates that consumption of the food
15 containing such pesticide residue level
16 during the period of the food's likely
17 availability in the State will pose an un-
18 reasonable dietary risk to the health of
19 persons within such State.

20 “(8) SAVINGS.—Nothing in this Act pre-
21 empts the authority of any State or politi-
22 cal subdivision to require that a food con-
23 taining a pesticide chemical residue bear
24 or be the subject of a warning or other
25 statement relating to the presence of the

1 pesticide chemical residue in or on such
2 food.

3 “(o) CONSUMER RIGHT TO KNOW.—Not later
4 than 2 years after the date of the enactment
5 of the Food Quality Protection Act of 1996,
6 and annually thereafter, the Administrator
7 shall, in consultation with the Secretary of
8 Agriculture and the Secretary of Health and
9 Human Services, publish in a format under-
10 standable to a lay person, and distribute to
11 large retail grocers for public display (in a
12 manner determined by the grocer), the follow-
13 ing information, at a minimum:

14 “(1) A discussion of the risks and ben-
15 efits of pesticide chemical residues in or
16 on food purchased by consumers.

17 “(2) A listing of actions taken under
18 subparagraph (B) of subsection (b)(2)
19 that may result in pesticide chemical res-
20 idues in or on food that present a yearly
21 or lifetime risk above the risk allowed
22 under subparagraph (A) of such sub-
23 section, and the food on which the pes-
24 ticide chemicals producing the residues
25 are used.

1 **“(3) Recommendations to consumers**
2 **for reducing dietary exposure to pes-**
3 **ticide chemical residues in a manner con-**
4 **sistent with maintaining a healthy diet,**
5 **including a list of food that may reason-**
6 **ably substitute for food listed under para-**
7 **graph (2).**

8 **Nothing in this subsection shall prevent retail**
9 **grocers from providing additional informa-**
10 **tion.**

11 **“(p) ESTROGENIC SUBSTANCES SCREENING**
12 **PROGRAM.—**

13 **“(1) DEVELOPMENT.—Not later than 2**
14 **years after the date of enactment of this**
15 **section, the Administrator shall in con-**
16 **sultation with the Secretary of Health**
17 **and Human Services develop a screening**
18 **program, using appropriate validated**
19 **test systems and other scientifically rel-**
20 **evant information, to determine whether**
21 **certain substances may have an effect in**
22 **humans that is similar to an effect pro-**
23 **duced by a naturally occurring estrogen,**
24 **or such other endocrine effect as the Ad-**
25 **ministrator may designate.**

1 **“(2) IMPLEMENTATION.—Not later than**
2 **3 years after the date of enactment of this**
3 **section, after obtaining public comment**
4 **and review of the screening program de-**
5 **scribed in paragraph (1) by the scientific**
6 **advisory panel established under section**
7 **25(d) of the Federal Insecticide, Fun-**
8 **gicide, and Rodenticide Act or the**
9 **science advisory board established by**
10 **section 8 of the Environmental Research,**
11 **Development, and Demonstration Act of**
12 **1978 (42 U.S.C. 4365), the Administrator**
13 **shall implement the program.**

14 **“(3) SUBSTANCES.—In carrying out the**
15 **screening program described in para-**
16 **graph (1), the Administrator—**

17 **“(A) shall provide for the testing**
18 **of all pesticide chemicals; and**

19 **“(B) may provide for the testing**
20 **of any other substance that may have**
21 **an effect that is cumulative to an ef-**
22 **fect of a pesticide chemical if the Ad-**
23 **ministrator determines that a sub-**
24 **stantial population may be exposed to**
25 **such substance.**

1 **“(4) EXEMPTION.—Notwithstanding**
2 **paragraph (3), the Administrator may, by**
3 **order, exempt from the requirements of**
4 **this section a biologic substance or other**
5 **substance if the Administrator deter-**
6 **mines that the substance is anticipated**
7 **not to produce any effect in humans simi-**
8 **lar to an effect produced by a naturally**
9 **occurring estrogen.**

10 **“(5) COLLECTION OF INFORMATION.—**

11 **“(A) IN GENERAL.—The Adminis-**
12 **trator shall issue an order to a reg-**
13 **istrant of a substance for which test-**
14 **ing is required under this subsection,**
15 **or to a person who manufactures or**
16 **imports a substance for which testing**
17 **is required under this subsection, to**
18 **conduct testing in accordance with**
19 **the screening program described in**
20 **paragraph (1), and submit informa-**
21 **tion obtained from the testing to the**
22 **Administrator, within a reasonable**
23 **time period that the Administrator**
24 **determines is sufficient for the gen-**
25 **eration of the information.**

1 **“(B) PROCEDURES.—To the extent**
2 **practicable the Administrator shall**
3 **minimize duplicative testing of the**
4 **same substance for the same endo-**
5 **crine effect, develop, as appropriate,**
6 **procedures for fair and equitable**
7 **sharing of test costs, and develop, as**
8 **necessary, procedures for handling of**
9 **confidential business information.**

10 **“(C) FAILURE OF REGISTRANTS TO**
11 **SUBMIT INFORMATION.—**

12 **“(i) SUSPENSION.—If a reg-**
13 **istrant of a substance referred to**
14 **in paragraph (3)(A) fails to com-**
15 **ply with an order under subpara-**
16 **graph (A) of this paragraph, the**
17 **Administrator shall issue a notice**
18 **of intent to suspend the sale or**
19 **distribution of the substance by**
20 **the registrant. Any suspension**
21 **proposed under this paragraph**
22 **shall become final at the end of**
23 **the 30-day period beginning on**
24 **the date that the registrant re-**
25 **ceives the notice of intent to sus-**

1 pend, unless during that period a
2 person adversely affected by the
3 notice requests a hearing or the
4 Administrator determines that
5 the registrant has complied fully
6 with this paragraph.

7 “(ii) HEARING.—If a person re-
8 quests a hearing under clause (i),
9 the hearing shall be conducted in
10 accordance with section 554 of
11 title 5, United States Code. The
12 only matter for resolution at the
13 hearing shall be whether the reg-
14 istrant has failed to comply with
15 an order under subparagraph (A)
16 of this paragraph. A decision by
17 the Administrator after comple-
18 tion of a hearing shall be consid-
19 ered to be a final agency action.

20 “(iii) TERMINATION OF SUSPEN-
21 SIONS.—The Administrator shall
22 terminate a suspension under this
23 subparagraph issued with respect
24 to a registrant if the Adminis-
25 trator determines that the reg-

1 istrant has complied fully with
2 this paragraph.

3 “(D) NONCOMPLIANCE BY OTHER
4 PERSONS.—Any person (other than a
5 registrant) who fails to comply with
6 an order under subparagraph (A)
7 shall be liable for the same penalties
8 and sanctions as are provided under
9 section 16 of the Toxic Substances
10 Control Act (15 U.S.C. 2601 and fol-
11 lowing) in the case of a violation re-
12 ferred to in that section. Such pen-
13 alties and sanctions shall be assessed
14 and imposed in the same manner as
15 provided in such section 16.

16 “(6) AGENCY ACTION.—In the case of
17 any substance that is found, as a result of
18 testing and evaluation under this section,
19 to have an endocrine effect on humans,
20 the Administrator shall, as appropriate,
21 take action under such statutory author-
22 ity as is available to the Administrator,
23 including consideration under other sec-
24 tions of this Act, as is necessary to ensure
25 the protection of public health.

1 **“(7) REPORT TO CONGRESS.—Not later**
2 **than 4 years after the date of enactment**
3 **of this section, the Administrator shall**
4 **prepare and submit to Congress a report**
5 **containing—**

6 **“(A) the findings of the Adminis-**
7 **trator resulting from the screening**
8 **program described in paragraph (1);**

9 **“(B) recommendations for further**
10 **testing needed to evaluate the impact**
11 **on human health of the substances**
12 **tested under the screening program;**
13 **and**

14 **“(C) recommendations for any**
15 **further actions (including any action**
16 **described in paragraph (6)) that the**
17 **Administrator determines are appro-**
18 **priate based on the findings.**

19 **“(q) SCHEDULE FOR REVIEW.—**

20 **“(1) IN GENERAL.—The Administrator**
21 **shall review tolerances and exemptions**
22 **for pesticide chemical residues in effect**
23 **on the day before the date of the enact-**
24 **ment of the Food Quality Protection Act**

1 of 1996, as expeditiously as practicable,
2 assuring that—

3 “(A) 33 percent of such tolerances
4 and exemptions are reviewed within
5 3 years of the date of enactment of
6 such Act;

7 “(B) 66 percent of such tolerances
8 and exemptions are reviewed within
9 6 years of the date of enactment of
10 such Act; and

11 “(C) 100 percent of such toler-
12 ances and exemptions are reviewed
13 within 10 years of the date of enact-
14 ment of such Act.

15 In conducting a review of a tolerance or
16 exemption, the Administrator shall deter-
17 mine whether the tolerance or exemption
18 meets the requirements of subsection
19 (b)(2) or (c)(2) and shall, by the deadline
20 for the review of the tolerance or exemp-
21 tion, issue a regulation under subsection
22 (d)(4) or (e)(1) to modify or revoke the
23 tolerance or exemption if the tolerance or
24 exemption does not meet such require-
25 ments.

1 **“(2) PRIORITIES.—In determining pri-**
2 **orities for reviewing tolerances and ex-**
3 **emptions under paragraph (1), the Ad-**
4 **ministrator shall give priority to the re-**
5 **view of the tolerances or exemptions that**
6 **appear to pose the greatest risk to public**
7 **health.**

8 **“(3) PUBLICATION OF SCHEDULE.—Not**
9 **later than 12 months after the date of the**
10 **enactment of the Food Quality Protection**
11 **Act of 1996, the Administrator shall pub-**
12 **lish a schedule for review of tolerances**
13 **and exemptions established prior to the**
14 **date of the enactment of the Food Quality**
15 **Protection Act of 1996. The determination**
16 **of priorities for the review of tolerances**
17 **and exemptions pursuant to this sub-**
18 **section is not a rulemaking and shall not**
19 **be subject to judicial review, except that**
20 **failure to take final action pursuant to**
21 **the schedule established by this para-**
22 **graph shall be subject to judicial review.**

23 **“(r) TEMPORARY TOLERANCE OR EXEMP-**
24 **TION.—The Administrator may, upon the re-**
25 **quest of any person who has obtained an ex-**

1 **perimental permit for a pesticide chemical**
2 **under the Federal Insecticide, Fungicide, and**
3 **Rodenticide Act or upon the Administrator’s**
4 **own initiative, establish a temporary toler-**
5 **ance or exemption for the pesticide chemical**
6 **residue for the uses covered by the permit.**
7 **Subsections (b)(2), (d) and (c)(2), (e) shall**
8 **apply to actions taken under this subsection.**

9 “(s) SAVINGS CLAUSE.—Nothing in this sec-
10 **tion shall be construed to amend or modify**
11 **the provisions of the Toxic Substances Con-**
12 **trol Act or the Federal Insecticide, Fungicide,**
13 **and Rodenticide Act.”.**

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

15 **For the fiscal years 1997 through 1999,**
16 **there is authorized to be appropriated in the**
17 **aggregate an additional \$12,000,000 for in-**
18 **creased monitoring by the Secretary of**
19 **Health and Human Services of pesticide resi-**
20 **dues in imported and domestic food.**

21 **SEC. 407. ALTERNATIVE ENFORCEMENT.**

22 **Section 303(g) (21 U.S.C. 333(f)) is amend-**
23 **ed—**

1 (1) by redesignating paragraphs (2),
2 (3), and (4) as paragraphs (3), (4), and (5),
3 respectively,

4 (2) by inserting after paragraph (1)
5 the following:

6 “(2)(A) Any person who introduces into
7 interstate commerce or delivers for introduc-
8 tion into interstate commerce an article of
9 food that is adulterated within the meaning of
10 section 402(a)(2)(B) shall be subject to a civil
11 money penalty of not more than \$50,000 in the
12 case of an individual and \$250,000 in the case
13 of any other person for such introduction or
14 delivery, not to exceed \$500,000 for all such
15 violations adjudicated in a single proceeding.

16 “(B) This paragraph shall not apply to any
17 person who grew the article of food that is
18 adulterated. If the Secretary assesses a civil
19 penalty against any person under this para-
20 graph, the Secretary may not use the criminal
21 authorities under this section to sanction
22 such person for the introduction or delivery
23 for introduction into interstate commerce of
24 the article of food that is adulterated. If the
25 Secretary assesses a civil penalty against any

1 person under this paragraph, the Secretary
2 may not use the seizure authorities of section
3 304 or the injunction authorities of section
4 302 with respect to the article of food that is
5 adulterated.

6 “(C) In a hearing to assess a civil penalty
7 under this paragraph, the presiding officer
8 shall have the same authority with regard to
9 compelling testimony or production of docu-
10 ments as a presiding officer has under section
11 408(g)(2)(B). The third sentence of paragraph
12 (3)(A) shall not apply to any investigation
13 under this paragraph.”;

14 (3) in paragraph (3), as so redesign-
15 nated, by striking “paragraph (1)” each
16 place it occurs and inserting “paragraph
17 (1) or (2)”;

18 (4) in paragraph (4), as so redesign-
19 nated, by striking “(2)(A)” and inserting
20 “(3)(A)”;

21 (5) in paragraph (5), as so redesign-
22 nated, by striking “(3)” each place it oc-
23 curs and inserting “(4)”.

TITLE V—FEES

SEC. 501. REREGISTRATION FEES.

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

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

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

“(i) in each of the fiscal years 1998, 1999, and 2000, the Administrator is authorized to collect up to an additional \$2,000,000 in a manner consistent with subsection (k)(5) and the recommendations of the Inspector General of the Environmental Protection Agency. The total fees that may be collected under this clause shall not exceed \$6,000,000.”.

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

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

“(2) SOURCE AND USE.—

“(A) All moneys derived from fees collected by the Administrator under subsection (i) shall

1 *be deposited in the fund and shall be available*
2 *to the Administrator, without fiscal year limita-*
3 *tion, specifically to offset the costs of reregistra-*
4 *tion and expedited processing of the applications*
5 *specified in paragraph (3). Such moneys derived*
6 *from fees may not be expended in any fiscal year*
7 *to the extent such moneys derived from fees*
8 *would exceed money appropriated for use by the*
9 *Administrator and expended in such year for*
10 *such costs of reregistration and expedited proc-*
11 *essing of such applications. The Administrator*
12 *shall, prior to expending any such moneys de-*
13 *rived from fees—*

14 *“(i) effective October 1, 1997, adopt*
15 *specific and cost accounting rules and pro-*
16 *cedures as approved by the General Ac-*
17 *counting Office and the Inspector General of*
18 *the Environmental Protection Agency to en-*
19 *sure that moneys derived from fees are allo-*
20 *cated solely to the costs of reregistration and*
21 *expedited processing of the applications*
22 *specified in paragraph (3) in the same por-*
23 *tion as appropriated funds;*

24 *“(ii) prohibit the use of such moneys*
25 *derived from fees to pay for any costs other*

1 *than those necessary to achieve reregistra-*
 2 *tion and expedited processing of the appli-*
 3 *cations specified in paragraph (3); and*

4 *“(iii) ensure that personnel and facil-*
 5 *ity costs associated with the functions to be*
 6 *carried out under this paragraph do not ex-*
 7 *ceed agency averages for comparable person-*
 8 *nel and facility costs.*

9 *“(B) The Administrator shall also—*

10 *“(i) complete the review of unreviewed*
 11 *reregistration studies required to support*
 12 *the reregistration eligibility decisions sched-*
 13 *uled for completion in accordance with sub-*
 14 *section (l)(2); and*

15 *“(ii) contract for such outside assist-*
 16 *ance as may be necessary for review of re-*
 17 *quired studies, using a generally accepted*
 18 *competitive process for the selection of ven-*
 19 *dors of such assistance.”.*

20 *(d) SECTION 4(k)(3).—Section 4(k)(3) (7 U.S.C.*
 21 *136a–1(k)(3)) is amended—*

22 *(1) in subparagraph (A), by striking out “for*
 23 *each of the fiscal years 1992, 1993, and 1994, 1/7th of*
 24 *the maintenance fees collected, up to 2 million each*
 25 *year” and inserting in lieu thereof “for each of the*

1 *fiscal years 1997 through 2001, not more than $\frac{1}{7}$ of*
2 *the maintenance fees collected in such fiscal year”;*
3 *and*

4 *(2) by adding a new subparagraph (C) to read*
5 *as follows:*

6 *“(C) The Administrator shall complete the*
7 *processing of the unprocessed expedited review*
8 *applications within 5 years from the date of en-*
9 *actment of the Food Quality Protection Act of*
10 *1996.”.*

11 *(e) SECTION 4(k)(5).—Section 4(k)(5) (7 U.S.C. 136a–*
12 *1(k)(5)) is amended to read as follows:*

13 *“(5) ACCOUNTING AND PERFORMANCE.—The Ad-*
14 *ministrator shall take all steps necessary to ensure*
15 *that expenditures from fees authorized by subsection*
16 *(i)(5)(C)(ii) are used only to carry out the goals es-*
17 *tablished under subsection (l). The Reregistration and*
18 *Expedited Processing Fund shall be designated as an*
19 *Environmental Protection Agency component for pur-*
20 *poses of section 3515(c) of title 31, United States*
21 *Code. The annual audit required under section 3521*
22 *of such title of the financial statements of activities*
23 *under this Act under section 3515(b) of such title*
24 *shall include an audit of the fees collected under sub-*
25 *section (i)(5)(C) and disbursed, of the amount appro-*

1 *priated to match such fees, and of the Administrator's*
2 *attainment of performance measure and goals estab-*
3 *lished under subsection (l). Such an audit shall also*
4 *include a review of the reasonableness of the overhead*
5 *allocation and adequacy of disclosures of direct and*
6 *indirect costs associated with carrying out the rereg-*
7 *istration and expedited processing of the applications*
8 *specified in paragraph (3), and the basis for and ac-*
9 *curacy of all costs paid with moneys derived from*
10 *such fees. The Inspector General shall conduct the an-*
11 *nuual audit and report the findings and recommenda-*
12 *tions of such audit to the Administrator and to the*
13 *Committees on Agriculture of the House of Represent-*
14 *atives and the Senate. The cost of such audit shall be*
15 *paid for out of the fees collected under subsection*
16 *(i)(5)(C).''.*

17 *(f) GOALS.—Subsections (l) and (m) of section 4 (7*
18 *U.S.C. 136a–1), as amended by section 237, are redesi-*
19 *gnated as subsections (m) and (n) respectively and the fol-*
20 *lowing is inserted after subsection (k):*

21 *“(l) PERFORMANCE MEASURES AND GOAL.—The Ad-*
22 *ministrator shall establish and publish annually in the*
23 *Federal Register performance measures and goals. Such*
24 *measures and goals shall include—*

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

10 “(2) the future schedule for reregistrations, in-
 11 cluding the projection for such schedules that will be
 12 issued under subsection (g)(2) (A) and (B) in the cur-
 13 rent fiscal year and the succeeding fiscal year; and

14 “(3) the projected year of completion of the rereg-
 15 istrations under this section.”.

16 ***TITLE VI—INDIAN TRIBES***

17 ***SEC. 601. AUTHORITY OF INDIAN TRIBES.***

18 (a) *IN GENERAL.*—Section 24 (7 U.S.C. 136v) is
 19 amended—

20 (1) in subsection (a), by inserting before the
 21 comma the following: “and an Indian tribe may only
 22 regulate the sale or use of any federally registered pes-
 23 ticide or device within the boundaries of a Federal
 24 Indian reservation for such tribe if at least 50 percent

1 of the lands in such reservation are owned by mem-
2 bers of the tribe or the tribe”;

3 (2) in subsections (b) and (c), by inserting “or
4 Indian tribe” after “State” each time it occurs; and
5 (3) in the section heading, by inserting before the
6 period the following: “**AND INDIAN TRIBES**”.

7 (b) *ENFORCEMENT*.—Section 26 (7 U.S.C. 136w–1) is
8 amended—

9 (1) in subsection (a), by inserting “and an In-
10 dian tribe with respect to violations which occur
11 within the boundaries of a Federal Indian reservation
12 for such tribe, but only if at least 50 percent of the
13 lands in such reservation are owned by members of
14 the tribe or the tribe” after “violations” and by in-
15 serting “or Indian tribe” after “State” each place it
16 occurs;

17 (2) in subsection (b), by inserting “or Indian
18 tribe” after “State” in the first sentence;

19 (3) in subsection (c), by inserting “or Indian
20 tribes” after “States”; and

21 (4) in the section heading, by inserting “**AND**
22 **INDIAN TRIBE**” after “**STATE**”.