104TH CONGRESS 1ST SESSION H. R. 1627

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

IN THE HOUSE OF REPRESENTATIVES

May 12, 1995

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

A BILL

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

1 Be it enacted by the Senate and House of Representa-

2 tives of the United States of America in Congress assembled,

3 SECTION 1. SHORT TITLE.

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

6 TITLE I—CANCELLATION AND 7 SUSPENSION

8 SEC. 101. REFERENCE.

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

14 SEC. 102. CANCELLATION.

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

17 "(b) CANCELLATION AND CHANGE IN CLASSIFICA18 TION OR OTHER TERMS OR CONDITIONS OF REGISTRA19 TION.—

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

of informal rulemaking under this subsection, pre-1 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 practice, does not generally cause unreasonable ad-10 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.—

"(A) The Administrator may not initiate a
rulemaking under paragraph (1) until the Administrator has furnished to the registrant of
each affected pesticide a notice that includes a
summary of the validated test or other significant evidence upon which the Administrator

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

8 "(B) At the same time that the Adminis-9 trator furnishes notice to registrants of the pesticide under subparagraph (A), the Adminis-10 11 trator shall also furnish such notice to the Secretary of Agriculture and the Secretary of 12 Health and Human Services. Upon receipt of 13 such notification, the Secretary of Agriculture, 14 15 when an agricultural commodity is affected, shall prepare an analysis of the benefit and use 16 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 Adminis22 trator shall either—

23 "(i) issue a notice of proposed rule24 making under paragraph (5); or

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

3 "(4) DOCKET.—For each rulemaking under paragraph (1), the Administrator shall establish a 4 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 the Scientific Advisory Panel under paragraph (7), 9 10 of a record of each hearing held by the Administrator in connection with the rulemaking of the deci-11 sion of the hearing examiner under paragraph (6), 12 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 of section 10. No factual material that has not been 16 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— "(A) information of which the Adminis-21 22 trator may properly take official notice; or "(B) information of which a court may 23

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

"(C) The Administrator shall provide a 14 15 comment period of not less than 90 days after the publication of the notice of proposed rule-16 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 comments and documentary information on the pro-21 22 posed rule received from any person for inclusion in the docket during the comment period, 23 shall be place in the docket. 24

- "(D) At the same time that the Adminis-1 2 trator publishes notice under subparagraph (A), 3 the Administrator shall provide the Secretary of 4 Agriculture and the Secretary of Health and Human Services with a copy of the proposed 5 rule. Not later than 90 days after the publica-6 7 tion of the notice of proposed rulemaking, the Secretary of Agriculture and the Secretary of 8 9 Health and Human Services may provide comments on such proposed rule. When an agricul-10 11 tural commodity is affected, the Secretary of 12 Agriculture shall provide to the Administrator an analysis of the impact of the proposed action 13 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.—

"(A) Any person who has submitted a
comment may, not later than 15 days after the
close of the comment period, request of the Administrator a hearing on questions of fact,
based on information submitted under paragraph (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 days after the close of the comment period. The 5 6 Administrator shall announce the time, place, 7 and purpose of the hearing in the Federal Register. The hearing shall be limited to addressing 8 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.

"(B) The Administrator shall appoint a 13 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).

"(C) The hearing examiner shall conduct
the hearing in a manner that encourages discussion and debate on questions of fact regarding the docket, and conforms with the deadlines
set in this paragraph. The Administrator shall

1 designate one or more employees of the Envi-2 ronmental Protection Agency to participate in the hearing. Any person who submitted a com-3 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 may choose to present materials in oral or writ-8 ten form. The presentation of evidence and ar-9 gument shall not delay the conclusion of the 10 11 hearing beyond 20 days of its commencement. "(D) Subject to subparagraph (B), an in-12 13 terested person is entitled— "(i) to present such person's position 14 15 orally or by documentary submissions (or both); and 16 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 cross-examination of persons as the hear-21 22 ing examiner determines (I) to be appropriate, and (II) to be required for a full 23 24 and true disclosure with respect to such is-25 sues.

"(E) As soon as practicable after comple-1 2 tion of the hearing but not later than 180 days after the close of the public comment period, 3 4 the hearing examiner shall issue a decision. Such decision shall be based only on substantial 5 evidence of record of such hearing (including 6 7 the report of the Scientific Advisory Panel) and shall set forth detailed findings of fact upon 8 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), the Administrator shall provide a copy of such notice 13 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 to be of significance in the hearing. The Panel may 21 22 hold a public hearing to discuss the proposed rule. The Panel shall provide a report to the hearing ex-23 24 aminer (or Administrator if no hearing is requested) 25 not later than 120 days after the close of comment period. The Administrator shall allow a reasonable
 time for written public comment on the Panel's re port. A copy of the Panel's report and any com ments shall be included in the rulemaking docket.

"(8) FINAL ACTION.—Not later than 365 days 5 after issuing a notice of proposed rulemaking and 6 7 after considering all material in the docket, the Administrator shall publish in the Federal Register ei-8 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 widespread and commonly recognized practice, will 13 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.—

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

"(B) Notwithstanding any other provision 13 of this Act, if an application for an amendment 14 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.

"(10) DENIAL OF APPLICATIONS.—Notwithstanding any other provision of this Act, no application for initial or amended registration of any pesticide under section 3 or 24(c) may be approved if

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

"(11) AMENDMENT OF RULE.—A registrant, or 3 4 other interested person with the concurrence of the registrant, may petition for the amendment or rev-5 6 ocation of a rule that has been issued under this 7 subsection. The petition shall state the factual material and argument that form the basis for the peti-8 9 tion. The Administrator shall publish a notice of the petition in the Federal Register and allow a 60-day 10 11 comment period thereon. Not later than 180 days 12 after publication of the notice, the Administrator shall determine whether to deny the petition or to 13 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 evidence submitted by the petitioner. If the Adminis-21 22 trator proposes to amend or revoke the rule, then the procedures established by paragraph (1) and 23 24 paragraphs (5) through (8) apply. A denial of a petition shall be judicially reviewable as provided in
 paragraph (12).

"(12) JUDICIAL REVIEW.—A decision not to
initiate a rulemaking published under paragraph (3),
a final rule or a withdrawal of a proposed rule published under paragraph (8) or a denial of a petition
under paragraph (11) shall be judicially reviewable
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, has published a document instituting a special review pro-11 ceeding or public interim administrative review proceeding 12 13 with respect to a particular pesticide or active ingredient thereof, the Administrator may, in lieu of proceeding 14 15 under section 6(b) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Food Quality 16 Protection Act of 1995, elect to continue such review pro-17 ceeding and, upon its completion, take action as warranted 18 in accordance with sections 3(c)(6), 6(b), and 6(d) as 19 those sections were in effect on the day before the date 20 of enactment of the Food Quality Protection Act of 1995. 21 22 SEC. 104. SUSPENSION.

(a) SECTION 6(c)(1).—The second sentence of section 6(c)(1) (7 U.S.C. 136d(c)(1)) is amended to read:
"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 REREG12 ISTRATION.

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

"(E) As soon as the Administrator has 15 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 containing a particular active ingredient, the Ad-21 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 1 U.S.C. 346a); 2 "(ii) determine whether such tolerance 3 4 or exemption meets the requirements of that Act: 5 "(iii) 6 determine whether additional 7 tolerances or exemptions should be issued; "(iv) publish in the Federal Register a 8 notice setting forth the determinations 9 made under this subparagraph; and 10 "(v) commence promptly such pro-11 ceedings under this Act and section 408 of 12 13 the Federal Food, Drug, and Cosmetic Act 14 as are warranted by such determinations.". 15 SEC. 106. SCIENTIFIC ADVISORY PANEL. The first sentence of section 25(d) (7 U.S.C. 16 136w(d)) is amended— 17 18 (1) by striking "The Administrator shall" and 19 inserting "(1) IN GENERAL.—The Administrator 20 shall": and 21 (2) by adding at the end the following: "(2) SCIENCE REVIEW BOARD.—There is estab-22 23 lished a Science Review Board to consist of 60 sci-24 entists who shall be available to the Scientific Advisory Panel to assist in reviews conducted by the 25

Panel. The Scientific Advisory Panel shall select the
 scientists from 60 nominations submitted each by
 the National Science Foundation and the National
 Institutes of Health. Members of the Board shall be
 compensated in the same manner as members of the
 Panel.".

7 SEC. 107 CONFORMING AMENDMENTS.

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

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

"(A) Except as provided in subparagraph 12 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 30day period beginning with the day after the 21 22 date the applicant receives the notice, or unless during that time the applicant submits a re-23 24 quest for a hearing, the Administrator may issue an order denying the application. If dur-25

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

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

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

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

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

7 (2) in paragraph (2), by striking "the Adminis8 trator shall notify the registrant" and all that fol9 lows through the end of the paragraph, and insert10 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 follow17 ing: "If a hearing is held, a decision after completion
18 of such hearing shall be final.".

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

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

(1) by amending the first sentence to read asfollows: "If a hearing is requested pursuant to sec-

1	tion $3(c)(2)(B)(iv)$, $3(c)(6)$, $4(e)(3)(B)(iii)(III)$, $6(b)$,
2	6(c)(2), or $6(e)(2)$, such hearing shall be held for the
3	purpose of receiving evidence relevant and material
4	to the issues raised by the request for hearing."; and
5	(2) by striking the ninth sentence and all that
6	follows through the end of the subsection and insert-
7	ing the following: "A hearing under this subsection
8	shall be held in accordance with the provisions of
9	sections 554, 556, and 557 of title 5, United States
10	Code.''.
11	(g) SECTION 16(b).—Section 16(b) (17 U.S.C.
12	136n(b)) is amended—
13	(1) by striking "(b) REVIEW BY COURT OF AP-
14	PEALS.—In the case of" and inserting the following:
15	"(b) Review by Court of Appeals.—
16	"(1) Review of certain orders.—In the
17	case of";
18	(2) by striking "under this section" in the sixth
19	sentence of paragraph (1) (as so designated) and in-
20	serting ''under this paragraph'', and
21	(3) by adding at the end the following new
22	paragraph:
23	"(2) REVIEW OF CERTAIN RULES.—In the case
24	of actual controversy as to the validity of any rule
25	issued by the Administrator under section 6(b)(8),

1 any decision by the Administrator under section 2 6(b)(8) not to issue a proposed rule or to withdraw a proposed rule, or any denial of a petition to revoke 3 4 or amend a final rule under section 6(b)(11), any person who will be adversely affected by such rule or 5 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 Administrator or any officer designated by the Administrator 21 22 for that purpose, and thereupon the Administrator shall file in court the record of the proceedings on 23 24 which the Administrator based such rule or decision, 25 as provided in section 2112 of title 28, United

States Code. Upon the filing of such petition the 1 2 court shall have exclusive jurisdiction to affirm or set aside such rule or decision in whole or in part. 3 The standard of review shall be that set forth in sec-4 tion 706 of title 5, United States Code. The judg-5 6 ment of the court under this paragraph shall be 7 final, subject to review by the Supreme Court upon certiorari or certification as provided in section 1254 8 of title 28, United States Code. The commencement 9 of proceedings under this section shall not, unless 10 11 specifically ordered by the court to the contrary, operate as a stay of an order.". 12 SECTION 25(a).—Section 25(a) 13 (h) (7 U.S.C.

13 (ii) SECTION 23(a).—Section 23(a) (7 0.3.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 notices21 of intent issued under subsection 6(b) and"; and

(2) in the second sentence by striking "noticesof 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) by striking the period at the end of the sec ond sentence; and

3 (2) by inserting at the end of the second sen4 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".

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

17 SEC. 202. MINOR CROP PROTECTION.

18 (a) DEFINITION.—Section 2 (7 U.S.C. 136) is19 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 agricul22 tural crop or site, or for the protection of public health
23 where—

24 "(1) the total United States acreage for the25 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.".

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

"(ii) The period of exclusive data use 6 for data submitted to support the applica-7 tion for the original registration of a pes-8 ticide under clause (i) shall be extended 9 one additional year for each 3 minor uses 10 11 registered after the date of enactment of this clause and, before the expiration of 12 13 the period of exclusive use under this clause, up to a total of 3 additional years 14 15 for all minor uses registered by the Administrator if the Administrator in consulta-16 17 tion with the Secretary of Agriculture determines that, based on information pro-18 19 vided by an applicant for registration or a 20 registrant, that— 21 "(I) there are insufficient effica-22 cious alternative registered pesticides

available for the use; or

	~ 0
1	"(II) the alternatives to the pes-
2	ticide pose greater risks to the envi-
3	ronment or human health; or
4	''(III) the pesticide plays or will
5	play a significant part in managing
6	pest resistance; or
7	''(IV) the pesticide plays or will
8	play a significant part in an inte-
9	grated pest management program.
10	The registration of a pesticide for a minor
11	use on a crop grouping established by the
12	Administrator shall be considered for pur-
13	poses of this clause one minor use for each
14	representative crop for which data are pro-
15	vided in the crop grouping. Any additional
16	exclusive use period under this clause shall
17	be modified as appropriate or terminated if
18	the registrant voluntarily cancels the prod-
19	uct or deletes from the registration the
20	minor uses which formed the basis for the
21	extension of the additional exclusive use
22	period or if the Administrator determines
23	that the registrant is not actually market-
24	ing the product for such minor uses.".

1	(c) Time Extensions for Development of
2	Minor Use Data.—
3	(1) DATA CALL-IN.—Section $3(c)(2)(B)$ (7)
4	U.S.C. $136a(c)(2)(B)$ is amended by adding at the
5	end the following:
6	''(vi) Upon the request of a registrant
7	the Administrator shall, in the case of a
8	minor use, extend the deadline for the pro-
9	duction of residue chemistry data under
10	this subparagraph for data required solely
11	to support that minor use until the final
12	deadline for submission of data under sec-
13	tion 4 for the other use of the pesticide es-
14	tablished as of the date of enactment of
15	the Minor Use Crop Protection Act of
16	1995, if—
17	"(I) the data to support other
18	uses of the pesticide on a food are
19	being provided;
20	''(II) the registrant, in submit-
21	ting a request for such an extension,
22	provides a schedule, including interim
23	dates to measure progress, to assure
24	that the data production will be com-

30

tension period;

1

2

pleted before the expiration of the ex-

	1
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
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1	registration of the affected products
2	with the minor use and shall inform
3	the public of such action. Notwith-
4	standing the provisions of this clause,
5	the Administrator may take action to
6	modify or revoke the extension under
7	this clause if the Administrator deter-
8	mines that the extension for the minor
9	use may cause an unreasonable ad-
10	verse effect on the environment. In
11	such circumstance, the Administrator
12	shall provide, in writing to the reg-
13	istrant, a notice revoking the exten-
14	sion of time for submission of data.
15	Such data shall instead be due in ac-
16	cordance with the date established by
17	the Administrator for the submission
18	of the data.".
19	(2) REREGISTRATION.—Sections $4(d)(4)(B)$,
20	4(e)(2)(B), and $4(f)(2)(B)$ (7 U.S.C. 136a–
21	1(d)(4)(B), $(e)(2)(B)$, and $(f)(2)(B)$) are each
22	amended by adding at the end the following: "Upon
23	the request of a registrant, the Administrator shall,
24	in the case of a minor use, extend the deadline for
25	the production of residue chemistry data under this

1	subparagraph for data required solely to support
2	that minor use until the final deadline for submis-
3	sion of data under this section for the other uses of
4	the pesticide established as of the date of enactment
5	of the Minor Use Crop Protection Act of 1995 if-
6	"(i) the data to support other uses of the
7	pesticide on a food are being provided;
8	''(ii) the registrant, in submitting a request
9	for such an extension provides a schedule, in-
10	cluding interim dates to measure progress, to
11	assure that the data production will be com-
12	pleted before the expiration of the extension
13	period;
14	"(iii) the Administrator has determined
15	that such extension will not significantly delay
16	the Administrator's schedule for issuing a re-
17	registration eligibility determination required
18	under this section; and
19	"(iv) the Administrator has determined in
20	writing that based on existing data, such exten-
21	sion would not significantly increase the risk of
22	any unreasonable adverse effect on the environ-
23	ment. If the Administrator grants an extension
24	under this subparagraph, the Administrator
25	shall monitor the development of the data and

1	shall ensure that the registrant is meeting the
2	schedule for the production of the data. If the
3	Administrator determines that the registrant is
4	not meeting or has not met the schedule for the
5	production of such data, the Administrator may
6	proceed in accordance with clause (iv) of section
7	3(c)(2)(B) or other provisions of this section, as
8	appropriate, regarding the continued registra-
9	tion of the affected products with the minor use
10	and shall inform the public of such action. Not-
11	withstanding the provisions of this subpara-
12	graph, the Administrator may take action to
13	modify or revoke the extension under this sub-
14	paragraph if the Administrator determines that
15	the extension for the minor use may cause an
16	unreasonable adverse effect on the environment.
17	In such circumstance, the Administrator shall
18	provide, in writing to the registrant, a notice re-
19	voking the extension of time for submission of
20	data. Such data shall instead be due in accord-
21	ance with the date then established by the Ad-
22	ministrator for submission of the data.".
23	(d) MINOR USE WAIVER.—Section 3(c)(2) (7 U.S.C.
24	136a(c)(2)) is amended—

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

1	(2) by inserting "Additional data.—" after
2	"(B)";
3	(3) by inserting "SIMPLIFIED PROCEDURES.—"
4	after "(C)"; 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.—

"(i) The Administrator shall, as expe-1 2 ditiously as possible, review and act on any complete application— 3 "(I) that proposes the initial reg-4 istration of a new pesticide active in-5 gredient if the active ingredient is 6 7 proposed to be registered solely for minor uses, or proposes a registration 8 9 amendment solely for minor uses to 10 an existing registration; or "(II) for a registration or a reg-11 istration amendment that proposes 12 significant minor uses. 13 14 "(ii) For the purposes of clause (i)— "(I) the term 'as expeditiously as 15 possible' means that the Adminis-16 17 trator shall to the greatest extent 18 practicable complete a review and 19 evaluation of all data, submitted with a complete application, within 12 20 months after the submission of the 21 22 complete application, and the failure 23 of the Administrator to complete such a review and evaluation under clause 24

- 36
- 1(i) shall not be subject to judicial re-2view; and

"(II) the term 'significant minor 3 4 uses' means 3 or more minor uses 5 proposed for every non-minor use, a minor use that would, in the judgment 6 7 of the Administrator, serve as a replacement for any use which has been 8 9 canceled in the 5 years preceding the receipt of the application, or a minor 10 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 MINOR USE DATA.—If a registrant makes a re-16 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 request, the registrant shall have a full time pe-21 22 riod for providing such data. For purposes of this subparagraph, the term 'full time period' 23 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.—

(1) REREGISTRATION.—

5

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

this paragraph unless the Administrator deter-1 mines that the absence of the data is significant 2 enough to cause human health or environmental 3 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 in the Federal Register a notice of the receipt 8 9 of the request and the effective date upon which the uses not being supported will be voluntarily 10 11 deleted from the registration pursuant to sec-12 tion 6(f)(1). If the Administrator grants an extension under this paragraph, the Adminis-13 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 registration of the affected products with the minor 23 and other uses and shall inform the public of 24 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.".

(B) Section 4(e)(3)(A) (7 U.S.C. 136a-12 1(e)(3)(A) is amended by adding at the end 13 the following: "If the registrant does not com-14 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 established as of the date of enactment of the Minor 3 4 Use Crop Protection Act of 1995, for the submission of data under this section for the sup-5 6 port uses identified pursuant to this subpara-7 graph unless the Administrator determines that the absence of the data is significant enough 8 to cause human health or environmental con-9 cerns. On the basis of such determination the 10 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 development of the data for the uses being sup-21 22 ported and shall ensure that the registrant is meeting the schedule for the production of such 23 24 data. If the Administrator determines that the 25 registrant is not meeting or has not met the

schedule for the production of such data, the 1 2 Administrator may proceed in accordance with section 3(c)(2)(B)(iv) regarding the continued 3 4 registration of the affected products with the minor and other uses and shall inform the pub-5 6 lic of such action in accordance with section 7 6(f)(2). Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the 8 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 extension and establish a new effective date by which 16 17 the minor use shall be deleted from the reg-18 istration.". 19 (2)DATA.—Section 3(c)(2)(B)(7 U.S.C. 20 136a(c)(2)(B), as amended by subsection (c), is further amended by adding at the end the following: 21 22 "(vii) If the registrant does not commit to support a specific minor use of the pesticide, 23

but is supporting and providing data in a timelyand adequate fashion to support uses of the

pesticide on a food, or if all uses of the pes-1 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 minor use until the final deadline established as 10 11 of the date of enactment of the Minor Use Crop 12 Production Act of 1995, for the submission of data under section 4 for the supported uses 13 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

6(f)(1). If the Administrator grants an exten-1 2 sion under this clause, the Administrator shall monitor the development of the data for the 3 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 has not met the schedule for the production of 8 9 such data, the Administrator may proceed in accordance with clause (iv) of this subpara-10 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 the minor use shall be deleted from the reg istration.".

3 (g) UTILIZATION OF DATA FOR VOLUNTARILY CAN4 CELED CHEMICALS.—Section 6(f) (7 U.S.C. 136d(f)) is
5 amended by adding at the end the following:

6 "(4) UTILIZATION OF DATA FOR VOLUNTARILY 7 CANCELED CHEMICALS.—When an application is filed with the Administrator for the registration of 8 9 a pesticide for a minor use and another registrant subsequently voluntarily cancels its registration for 10 11 an identical or substantially similar pesticide for an identical or substantially similar use, the Adminis-12 trator shall process, review, and evaluate the pend-13 ing application as if the voluntary cancellation had 14 15 not yet taken place, except that the Administrator shall not take such action if the Administrator deter-16 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 MINOR25 USE PROGRAM.—The Federal Insecticide, Fungicide, and

Rodenticide Act (7 U.S.C. 136 et seq.) is amended by re designating sections 30 and 31 as sections 32 and 33, re 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 program within the Office of Pesticide Programs. Such of-8 9 fice shall be responsible for coordinating the development 10 of minor use programs and policies and consulting with growers regarding minor use issues and registrations and 11 amendments which are submitted to the Environmental 12 Protection Agency.". 13

(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 USE20PROGRAM.

"(a) IN GENERAL.—The Secretary of Agriculture
(hereinafter in this section referred to as the 'Secretary')
shall ensure the coordination of the responsibilities of the
Department of Agriculture related to minor uses of pesticides, 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 given those entities that do not directly receive funds 3 4 from the sale of products registered on minor uses. 5 Any entity that seeks such funding under this paragraph shall be required to match such funds with an 6 7 equal amount of its own funds. Any data developed through the matching fund program shall be jointly 8 9 owned by the Department of Agriculture and by the entity that receives such funding. Any data devel-10 11 oped under this subsection shall be subject to the provisions of section 3(c)(1)(F). All compensation 12 received by the Department of Agriculture in return 13 14 for the use of such data under the matching fund

program shall be returned to a revolving fund which
will support the matching fund program.
"(2) AUTHORIZATION.—There is authorized to

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 ex20 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.

(b) PROCEDURES.—To the extent practicable, the
procedures referred to in subsection (a) shall include the
collection of data on food consumption patterns of a statistically 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 sur8 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 Administrator, shall implement research, demonstration, 18 19 and education programs to support adoption of integrated 20 pest management. Integrated Pest Management is a sustainable approach to managing pests by combining biologi-21 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 available to pesticide users, including Federal agencies. Federal 26 HR 1627 IH

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

5 TITLE IV—AMENDMENTS TO THE FED6 ERAL FOOD, DRUG, AND COSMETIC 7 ACT

8 SEC. 401. REFERENCE.

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

14 SEC. 402. DEFINITIONS.

(a) Section 201(q) (21 U.S.C. 321(q)) is amended toread as follows:

17 (q)(1) The term 'pesticide chemical' means—

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

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

"(2) The term 'pesticide chemical residue' means a
 residue in or on raw agricultural commodity or processed
 food of—

4 "(A) a pesticide chemical; or

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

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

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

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

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

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

5 "(2) a pesticide chemical; or".

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

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

13 "(cc) The term 'Administrator' means the Adminis14 trator of the United States Environmental Protection
15 Agency.".

16 SEC. 403. PROHIBITED ACTS.

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

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

(2) by inserting at the end ", or the violation
of section 408(g)(2) or any regulation issued under
that section.".

22 SEC. 404. ADULTERATED FOOD.

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

1	"(2)(A) if it bears or contains any added poi-
2	sonous or added deleterious substance (other than a
3	substance that is a pesticide chemical residue in or
4	on a raw agricultural commodity or processed food,
5	a food additive, a color additive, or a new animal
6	drug) that is unsafe within the meaning of section
7	406;
8	"(B) if it bears or contains a pesticide chemical
9	residue that is unsafe within the meaning of section
10	408(a); or
11	"(C) if it is or if it bears or contains—
12	"(i) any food additive that is unsafe within
13	the meaning of section 409; or
14	"(ii) a new animal drug (or conversion
15	product thereof) that is unsafe within the
16	meaning of section 512; or".
17	SEC. 405. TOLERANCES AND EXEMPTIONS FOR PESTICIDE
18	CHEMICAL RESIDUES.
19	Section 408 (21 U.S.C. 346a) is amended to read as
20	follows:
21	"TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMI-
22	CAL RESIDUES
23	"Sec. 408. (a) Requirement for Tolerance or
24	EXEMPTION.—

1	"(1) GENERAL RULE.—For the purposes of this
2	section, the term 'food,' when used as a noun with-
3	out modification, shall mean a raw agricultural com-
4	modity or processed food. Except as provided in
5	paragraph (2) or (3), any pesticide chemical residue
6	in or on a food shall be deemed unsafe for the pur-
7	pose of section 402(a)(2)(B) unless—
8	"(A) a tolerance for such pesticide chemi-
9	cal residue in or on such food is in effect under
10	this section and the concentration of the residue
11	is within the limits of the tolerance; or
12	''(B) an exemption from the requirement
13	of a tolerance is in effect under this section for
14	the pesticide chemical residue.
15	"(2) PROCESSED FOOD.—Notwithstanding
16	paragraph (1)—
17	"(A) if a tolerance is in effect under this
18	section for a pesticide chemical residue in or on
19	a raw agricultural commodity, a pesticide chem-
20	ical residue that is present in or on a processed
21	food because the food is made from that raw
22	agricultural commodity shall not be considered
23	unsafe within the meaning of section
24	402(a)(2)(B) despite the lack of a tolerance for
25	the pesticide chemical residue in or on the proc-

essed food if the concentration of the pesticide chemical residue in the processed food when ready for consumption or use is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity.

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

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

24 "(A) the Administrator has not determined25 that the degradation product is likely to pose

1	any potential health risk from dietary exposure
2	that is of a different type than, or of a greater
3	significance than, any risk posed by dietary ex-
4	posure to the precursor substance; and
5	"(B) either—
6	"(i) a tolerance is in effect under this
7	section for residues of the precursor sub-
8	stance in or on the food, and the combined
9	level of residues of the degradation product
10	and the precursor substance in or on the
11	food is at or below the stoichiometrically
12	equivalent level that would be permitted by
13	the tolerance if the residue consisted only
14	of the precursor substance rather than the
15	degradation product; or
16	"(ii) an exemption from the need for
17	a tolerance is in effect under this section
18	for residues of the precursor substance in
19	or on the food; and
20	"(C) the tolerance or exemption for resi-
21	dues of the precursor substance does not state
22	that it applies only to particular named sub-
23	stances or states that it does not apply to resi-
24	dues of the degradation product.

1	"(4) Effect of tolerance or exemp-
2	TION.—While a tolerance or exemption from the re-
3	quirement for a tolerance is in effect under this sec-
4	tion for a pesticide chemical residue with respect to
5	any food, the food shall not by reason of bearing or
6	containing any amount of such a residue be consid-
7	ered to be adulterated within the meaning of section
8	402(a)(1).
9	"(b) Authority and Standard for Toler-
10	ANCES.—
11	"(1) AUTHORITY.—The Administrator may
12	issue regulations establishing, modifying, or revoking
13	a tolerance for a pesticide chemical residue in or on
14	a food—
15	"(A) in response to a petition filed under
16	subsection (d); or
17	''(B) on the Administrator's initiative
18	under subsection (e).
19	"(2) STANDARD.—(A) A tolerance may not be
20	established for a pesticide chemical residue in or on
21	a food at a level that is higher than a level that the
22	Administrator determines is adequate to protect the
23	public health.
24	"(B) The Administrator shall modify or revoke
25	a tolerance if it is at a level higher than the level

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

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

"(D) For purposes of subparagraph (A), a tolerance level for a pesticide chemical residue in or on
a food shall be deemed to be adequate to protect the
public health if the dietary risk posed to food con-

sumers by such level of the pesticide chemical residue is negligible. The Administrator shall by regulation set forth the factors and methods, including
tests which are appropriate for the determination of
dietary risk and most likely dietary exposure, for the
determination of negligible dietary risk.

"(E) Procedures shall be developed and implemented that ensure that pesticide tolerances adequately safeguard the health of infants and children.

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

19 "(G) For purposes of subparagraph (A), a level 20 of a pesticide chemical residue in or on a food that poses a greater than negligible dietary risk to con-21 22 sumers of the food shall be deemed to be adequate to protect the public health if the Administrator de-23 24 that such risk termines is not unreasonable 25 because"(i) use of the pesticide that produces the residue protects humans or the environment from adverse effects on public health or welfare that would, directly or indirectly, result in greater risk to the public or the environment than the dietary risk from the pesticide chemical residue; or

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

15 "(iii) the availability of the pesticide would
16 enable domestic growers to maintain the avail17 ability of an adequate, wholesome, and economi18 cal food supply for consumers, taking into ac19 count national and regional effects.

In making the determination under this subparagraph, the Administrator shall not consider the effects on any pesticide registrant, manufacturer, or marketer of a pesticide.

24 "(3) LIMITATIONS.—(A) A tolerance may be is25 sued under the authority of paragraph (2)(E) only

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

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

15 "(C) A tolerance for a pesticide chemical resi16 due in or on a food shall not be established at a level
17 lower than the limit of detection of the method for
18 detecting and measuring the pesticide chemical resi19 due specified by the Administrator under subpara20 graph (B).

"(4) INTERNATIONAL STANDARDS.—In establishing a tolerance for a pesticide chemical residue in
or on a food, the Administrator shall determine
whether a maximum residue level for the chemical
has been established by the Codex Alimentarius

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

16 "(c) Authority and Standard for Exemp-17 tions.—

18 "(1) AUTHORITY.—The Administrator may
19 issue a regulation establishing, modifying, or revok20 ing an exemption from the requirement for a toler21 ance for a pesticide chemical residue in or on a
22 food—

23 "(A) in response to a petition filed under24 subsection (d); or

1 "(B) on the Administrator's initiative 2 under subsection (e).

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

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

"(C) In making a determination under this
paragraph, the Administrator shall take into account, among other relevant factors, the factors set
forth in subsection (b)(2)(C).

21 "(3) LIMITATION.—An exemption from the re22 quirement for a tolerance for a pesticide chemical
23 residue in or on a food shall not be established by
24 the Administrator unless the Administrator deter25 mines, after consultation with the Secretary—

1	"(A) that there is a practical method for
2	detecting and measuring the levels of such pes-
3	ticide chemical residue in or on such food; or
4	"(B) that there is no need for such a
5	method, and states the reasons for such deter-
6	mination in the order issuing the regulation es-
7	tablishing or modifying the regulation.
8	"(d) Petition for Tolerance or Exemption.—
9	"(1) Petitions and petitioners.—Any per-
10	son may file with the Administrator a petition pro-
11	posing the issuance of a regulation—
12	''(A) establishing, modifying, or revoking a
13	tolerance for a pesticide chemical residue in or
14	on a food; or
15	''(B) establishing or revoking an exemption
16	from the requirement of a tolerance for such a
17	residue.
18	"(2) Petition contents.—
19	"(A) ESTABLISHMENT.—A petition under
20	paragraph (1) to establish a tolerance or ex-
21	emption for a pesticide chemical residue shall
22	be supported by such data and information as
23	are specified in regulations issued by the Ad-
24	ministrator, including—

1	"(i)(I) an informative summary of the
2	petition and of the data, information, and
3	arguments submitted or cited in support of
4	the petition;
5	"(II) a statement that the petitioner
6	agrees that such summary or any informa-
7	tion it contains may be published as a part
8	of the notice of filing of the petition to be
9	published under this subsection and as
10	part of a proposed or final regulation is-
11	sued under this section;
12	''(ii) the name, chemical identity, and
13	composition of the pesticide chemical resi-
14	due and of the pesticide chemical that pro-
15	duces the residue;
16	"(iii) data showing the recommended
17	amount, frequency, method, and time of
18	application of that pesticide chemical;
19	"(iv) full reports of tests and inves-
20	tigations made with respect to the safety of
21	the pesticide chemical, including full infor-
22	mation as to the methods and controls
23	used in conducting those tests and inves-
24	tigations;

1	"(v) full reports of tests and inves-
2	tigations made with respect to the nature
3	and amount of the pesticide chemical resi-
4	due that is likely to remain in or on the
5	food, including a description of the analyt-
6	ical methods used;
7	"(vi) a practical method for detecting
8	and measuring the levels of the pesticide
9	chemical residue in or on the food, or a
10	statement why such a method is not need-
11	ed;
12	"(vii) practical methods for removing
13	any amount of the residue that would ex-
14	ceed any proposed tolerance;
15	"(viii) a proposed tolerance for the
16	pesticide chemical residue, if a tolerance is
17	proposed;
18	"(ix) all relevant data bearing on the
19	physical or other technical effect that the
20	pesticide chemical is intended to have and
21	the quantity of the pesticide chemical that
22	is required to produce the effect;
23	"(x) if the petition relates to a toler-
24	ance for a processed food, reports of inves-

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1	tigations conducted using the processing
2	method(s) used to produce that food;
3	"(xi) such information as the Admin-
4	istrator may require to make the deter-
5	mination under subsection $(b)(2)(E)$; and
6	''(xii) such other data and information
7	as the Administrator requires by regulation
8	to support the petition.
9	If information or data required by this subpara-
10	graph is available to the Administrator, the per-
11	son submitting the petition may cite the avail-
12	ability of the information or data in lieu of sub-
13	mitting it. The Administrator may require a pe-
14	tition to be accompanied by samples of the pes-
15	ticide chemical with respect to which the peti-
16	tion is filed.
17	"(B) MODIFICATION OR REVOCATION.—
18	The Administrator may by regulation establish
19	the requirements for information and data to
20	support a petition to modify or revoke a toler-
21	ance or to revoke an exemption from the re-
22	quirement for a tolerance.
23	"(3) NOTICE.—A notice of the filing of a peti-
24	tion that the Administrator determines has met the
25	requirements of paragraph (2) shall be published by

the Administrator within 30 days after such deter-1 2 mination. The notice shall announce the availability of a description of the analytical methods available 3 to the Administrator for the detection and measure-4 ment of the pesticide chemical residue with respect 5 to which the petition is filed or shall set forth the 6 7 petitioner's statement of why such a method is not needed. The notice shall include the summary re-8 quired by paragraph (2)(A)(i). 9 "(4) ACTIONS BY THE ADMINISTRATOR.—The 10 Administrator shall, after giving due consideration 11 to a petition filed under paragraph (1) and any 12 13 other information available to the Administrator— "(A) issue a final regulation (which may 14 15 vary from that sought by the petition) establishing, modifying, or revoking a tolerance for 16 17 the pesticide chemical residue or an exemption 18 of the pesticide chemical residue from the re-19 quirement of a tolerance; "(B) issue a proposed regulation under 20 21 subsection (e), and thereafter either issue a 22 final regulation under subsection (e) or an

23 order denying the petition; or

"(C) issue an order denying the petition.

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

"(6) Further proceedings.—

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

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

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

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

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

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

24 "(B) A copy of the petition shall be forthwith25 transmitted by the clerk of the court to the Adminis-

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

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

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

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

17 "(e) Action on Administrator's Own Initia-18 Tive.—

19 "(1) GENERAL RULE.—The Administrator may20 issue a regulation—

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

1	''(B) establishing or revoking an exemption
2	of a pesticide chemical residue from the require-
3	ment of a tolerance; or
4	''(C) establishing general procedures and
5	requirements to implement this section.
6	A regulation issued under this paragraph shall be-
7	come effective upon its publication.
8	''(2) NOTICE.—Before issuing a final regulation
9	under paragraph (1), the Administrator shall issue
10	a notice of proposed rulemaking and provide a pe-
11	riod of not less than 60 days for public comment on
12	the proposed regulation, except that a shorter period
13	for comment may be provided if the Administrator
14	for good cause finds that it would be contrary to the
15	public interest to do so and states the reasons for
16	the finding in the notice of proposed rulemaking.
17	The Administrator shall provide an opportunity for
18	a public hearing during the rulemaking under proce-
19	dures provided in subsection $(d)(6)(B)$.
20	"(f) Special Data Requirements.—

21 "(1) REQUIRING SUBMISSION OF ADDITIONAL
22 DATA.—If the Administrator determines that addi23 tional data or information are reasonably required to
24 support the continuation of a tolerance or exemption
25 that is in effect under this section for a pesticide

chemical residue on a food, the Administrator

2	shall—
3	''(A) issue a notice requiring the persons
4	holding the pesticide registrations associated
5	with such tolerance or exemption to submit the
6	data or information under section $3(c)(2)(B)$ of
7	the Federal Insecticide, Fungicide, and
8	Rodenticide Act;
9	''(B) issue a rule requiring that testing be
10	conducted on a substance or mixture under sec-
11	tion 4 of the Toxic Substances Control Act; or
12	''(C) publish in the Federal Register, after
13	first providing notice and an opportunity for
14	comment of not less than 90 days' duration, an

15 order—

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

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

1	of the Federal Insecticide, Fungicide, and
2	Rodenticide Act or section 4 of the Toxic
3	Substances Control Act;
4	''(iii) describing the reports of the Ad-
5	ministrator required to be prepared during
6	and after the collection of the data and in-
7	formation;
8	''(iv) requiring the submission to the
9	Administrator of the data, information,
10	and reports referred to in clauses (ii) and
11	(iii); and
12	"(v) establishing dates by which the
13	submissions described in clauses (i) and
14	(iv) must be made.
15	The Administrator may revise any such order
16	to correct an error.
17	"(2) NONCOMPLIANCE.—If a submission re-
18	quired by a notice issued in accordance with para-
19	graph (1)(A) or an order issued under paragraph
20	(1)(B) is not made by the time specified in such no-
21	tice or order, the Administrator may by order pub-
22	lished in the Federal Register modify or revoke the
23	tolerance or exemption in question.
24	"(3) REVIEW.—An order issued under this subsection
25	shall be effective upon publication and shall be subject to

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

3 "(g) Confidentiality and Use of Data.—

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

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

"(A) employees of the United States authorized by the Administrator to examine such
data in the carrying out of their official duties
under this Act or other Federal statutes intended to protect the public health; or

23 "(B) contractors with the United States24 authorized by the Administrator to examine

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

"(3) SUMMARIES.—Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) and may, in issuing a proposed or final regulation or order under
this section, publish an informative summary of the
data relating to the regulation or order.

10 "(h) Status of Previously Issued Regula-11 tions.—

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

21 "(2) REGULATIONS UNDER SECTION 409.—Reg22 ulations that established tolerances for substances
23 that are pesticide chemical residues on or in proc24 essed food, or that otherwise stated the conditions
25 under which such pesticide chemicals could be safely

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used, and that were issued under section 409 on or
before the date of the enactment of this paragraph,
shall be deemed to be regulations issued under this
section and shall be subject to modification or revocation under subsection (d) or (e).

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

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

17 "(1) regarded by the Administrator or the Sec18 retary as generally recognized as safe for use within
19 the meaning of the provisions of section 408(a) or
20 201(s) as then in effect; or

21 "(2) regarded by the Secretary as a substance 22 described by section 201(s)(4), such a pesticide 23 chemical residue shall be regarded as exempt from 24 the requirement for a tolerance, as of the date of en-25 actment of this subsection. The Administrator shall by regulation indicate which substances are described by this subsection. All exemption under this
subsection may be revoked or modified as if it had
been issued under subsection (c).

5 "(j) HARMONIZATION WITH ACTION UNDER OTHER6 LAWS.—

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

"(2) REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED
REGISTRATIONS.—If the Administrator, acting under
the Federal Insecticide, Fungicide, and Rodenticide

Act, cancels the registration of each pesticide that 1 2 contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that 3 4 the registration of each such pesticide be modified to prohibit its use in connection with the production, 5 storage, or transportation of such food, due in whole 6 7 or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Ad-8 ministrator shall revoke any tolerance or exemption 9 that allows the presence of the pesticide chemical, or 10 any pesticide chemical residue that results from its 11 12 use, in or on that food. The Administrator shall use 13 the procedures set forth in subsection (e) in taking 14 action under this paragraph. A revocation under this 15 paragraph shall become effective not later than 180 days after-16 17 "(A) the date by which each such cancella-18 tion of a registration has become effective; or

19 "(B) the date on which the use of the can20 celed pesticide becomes unlawful under the
21 terms of the cancellation, whichever is later.

22 "(3) SUSPENSION OF TOLERANCE OR EXEMP23 TION FOLLOWING SUSPENSION OF ASSOCIATED REG24 ISTRATIONS.—

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

"(B) EFFECT OF SUSPENSION.—The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective

the tolerance or exemption shall not be considered to be in effect. If the suspension of use of
the pesticide under that Act is terminated, leaving the registration of the pesticide for such use
in effect under that Act, the Administrator
shall rescind any associated suspension of tolerance or exemption.

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

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

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

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

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

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

13 "(2) the promulgation of a regulation establish14 ing, modifying, or revoking a tolerance or establish15 ing or revoking an exemption from the requirement
16 of a tolerance under this section;

17 "(3) the acceptance for filing of objections18 under subsection (d)(6); or

"(4) the certification and filing in court of a
transcript of the proceedings and the record under
subsection (d)(7);

22 may be conditioned upon the payment of such fees. The 23 regulations may further provide for waiver or refund of 24 fees in whole or in part when in the judgment of the Ad1 ministrator such a waiver or refund is equitable and not2 contrary to the purposes of this subsection.

3 "(I) NATIONAL UNIFORMITY OF TOLERANCES.—

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

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

"(B) was approved for such use in a reregistration eligibility determination issued under
section 4(g) of that Act on or after the date of
enactment of the Food Quality Protection Act
of 1995.

1	"(2) Qualifying federal determination.—
2	For purposes of this subsection, the term 'qualifying
3	Federal determination' means—
4	"(A) a tolerance or exemption from the re-
5	quirement for a tolerance for a qualifying pes-
6	ticide chemical residue that was—
7	"(i) issued under this section after the
8	date of enactment of the Food Quality
9	Protection Act of 1995; (or)
10	''(ii) issued (or, pursuant to sub-
11	section (h) or (i), deemed to have been is-
12	sued) under this section, and determined
13	by the Administrator to meet the standard
14	under subsection $(b)(2)$ (in the case of a
15	tolerance) or $(c)(2)$ (in the case of an ex-
16	emption); and
17	"(B) any statement, issued by the Sec-
18	retary, of the residue level below which enforce-
19	ment action will not be taken under this Act
20	with respect to any qualifying pesticide chemi-
21	cal residue, if the Secretary finds that such pes-
22	ticide chemical residue level permitted by such
23	statement during the period to which such
24	statement applies protects human health.

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

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

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1	other statement relating to the presence of the pes-
2	ticide residue in the food.
3	"(5) Petition procedure.—
4	"(A) Any State may petition the Adminis-
5	trator for authorization to establish in such
6	State a regulatory limit on a qualifying pes-
7	ticide chemical residue in or on any food that
8	is not identical to the qualifying Federal deter-
9	mination applicable to such qualifying pesticide
10	chemical residue.
11	''(B) Any petition under subparagraph (A)
12	shall—
13	''(i) satisfy any requirements pre-
14	scribed, by rule, by the Administrator; and
15	"(ii) be supported by scientific data
16	about the pesticide chemical residue that is
17	the subject of the petition or about chemi-
18	cally related pesticide chemical residues,
19	data on the consumption within such State
20	of food bearing the pesticide chemical resi-
21	due, and data on exposure of humans with-
22	in such State to the pesticide chemical res-
23	idue.
24	"(C) Subject to paragraph (6), the Admin-
25	istrator may, by order, grant the authorization

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1	described in subparagraph (A) if the Adminis-
2	trator determines that the proposed State regu-
3	latory limit—
4	''(i) is justified by compelling local
5	conditions;
6	''(ii) would not unduly burden inter-
7	state commerce; and
8	''(iii) would not cause any food to be
9	in violation of Federal law.
10	''(D) In lieu of any action authorized
11	under subparagraph (C), the Administrator
12	may treat a petition under this paragraph as a
13	petition under subsection (d) to revoke or mod-
14	ify a tolerance or to revoke an exemption. If the
15	Administrator determines to treat a petition
16	under this paragraph as a petition under sub-
17	section (d), the Administrator shall thereafter
18	act on the petition pursuant to subsection (d).
19	"(E) Any order of the Administrator
20	granting or denying the authorization described
21	in subparagraph (A) shall be subject to review
22	in the manner described in subsections (d)(6)
23	and (d)(7).
24	"(6) Residues from lawful application.—
25	No State or political subdivision may enforce any

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

12 SEC. 406. AUTHORIZATION FOR INCREASE MONITORING.

There is authorized to be appropriated an additional \$12,000,000 for increased monitoring by the Secretary of Health and Human Services of pesticide residues in imported and domestic food.

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