104TH CONGRESS 1ST SESSION

S. 1166

To amend the Federal Insecticide, Fungicide, and Rodenticide Act, to improve the registration of pesticides, to provide minor use crop protection, to improve pesticide tolerances to safeguard infants and children, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 10 (legislative day, JULY 10), 1995

Mr. Lugar (for himself, Mr. Pryor, Mrs. Kassebaum, Mr. Inouye, Mr. Cochran, Mr. Kerrey, Mr. Dole, Mr. Heflin, Mr. Gorton, and Mr. Breaux) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

- To amend the Federal Insecticide, Fungicide, and Rodenticide Act, to improve the registration of pesticides, to provide minor use crop protection, to improve pesticide tolerances to safeguard infants and children, and for other purposes.
 - 1 Be it enacted by the Senate and House of Representa-
 - 2 tives of the United States of America in Congress assembled,
 - 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
 - 4 (a) SHORT TITLE.—This Act may be cited as the
 - 5 "Food Quality Protection Act of 1995".

1 (b) Table of Contents of

2 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—AMENDMENTS TO THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Sec. 101. Reference.

Subtitle A-Registration of Pesticides

- Sec. 111. Tolerance reevaluation as part of reregistration.
- Sec. 112. Scientific advisory panel.
- Sec. 113. Coordination of cancellation.

Subtitle B-Minor Use Crop Protection

- Sec. 121. Definition of minor use.
- Sec. 122. Exclusive use of minor use pesticides.
- Sec. 123. Time extensions for development of minor use data.
- Sec. 124. Minor use waiver.
- Sec. 125. Expedition of minor use registrations.
- Sec. 126. Utilization of data for voluntarily canceled chemicals.
- Sec. 127. Minor use programs.

Subtitle C—Conforming Amendments

Sec. 131. FIFRA table of contents.

TITLE II—DATA COLLECTION AND IMPROVED PROCEDURES TO ENSURE THAT TOLERANCES SAFEGUARD THE HEALTH OF INFANTS AND CHILDREN

- Sec. 201. Implementation of NAS report.
- Sec. 202. Collection of pesticide use information.
- Sec. 203. Integrated pest management.

TITLE III—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

- Sec. 301. Reference.
- Sec. 302. Definitions.
- Sec. 303. Prohibited acts.
- Sec. 304. Adulterated food.
- Sec. 305. Tolerances and exemptions for pesticide chemical residues.
- Sec. 306. Authorization for increase monitoring.

1	TITLE I—AMENDMENTS TO THE
2	FEDERAL INSECTICIDE, FUN-
3	GICIDE, AND RODENTICIDE
4	ACT
5	SEC. 101. REFERENCE.
6	Except as otherwise expressly provided, whenever in
7	this title an amendment or repeal is expressed in terms
8	of an amendment to, or repeal of, a section or other provi-
9	sion, the reference shall be considered to be made to a
10	section or other provision of the Federal Insecticide, Fun-
11	gicide, and Rodenticide Act (7 U.S.C. 136 et seq.).
12	Subtitle A—Registration of
13	Pesticides
14	SEC. 111. TOLERANCE REEVALUATION AS PART OF REREG
15	ISTRATION.
16	Section 4(g)(2) (7 U.S.C. 136a-1(g)(2)) is amended
17	by adding at the end the following:
18	"(E) As soon as the Administrator has
19	sufficient information with respect to the die-
20	tary risk of a particular active ingredient, but
21	in any event not later than the date on which
22	the Administrator makes a determination under
23	subparagraph (C) or (D) with respect to a pes-
24	ticide containing a particular active ingredient,
25	the Administrator shall—

1	"(i) reassess each associated tolerance
2	and exemption from the requirement for a
3	tolerance issued under section 408 of the
4	Federal Food, Drug, and Cosmetic Act (21
5	U.S.C. 346a), taking into account available
6	information and reasonable assumptions
7	concerning the dietary exposure levels of
8	food consumers (and major identifiable
9	subgroups of food consumers, including in-
10	fants and children) to residue of the pes-
11	ticide in food and available information
12	and reasonable assumptions concerning the
13	variability of the sensitivities of major
14	identifiable groups, including infants and
15	children;
16	"(ii) determine whether the tolerance
17	or exemption meets the requirements of
18	the Act;
19	"(iii) determine whether additional
20	tolerances or exemptions should be issued;
21	"(iv) publish in the Federal Register a
22	notice setting forth the determinations
23	made under this subparagraph; and
24	"(v) commence promptly such pro-
25	ceedings under this Act and section 408 of

1	the Endand Enad Drug and Commette Act
1	the Federal Food, Drug, and Cosmetic Act
2	(21 U.S.C. 346a) as are warranted by the
3	determinations.".
4	SEC. 112. SCIENTIFIC ADVISORY PANEL.
5	Section 25(d) (7 U.S.C. 136w(d)) is amended—
6	(1) in the first sentence, by striking "(d) Sci-
7	ENTIFIC ADVISORY PANEL.—The Administrator
8	shall" and inserting the following:
9	"(d) Scientific Advisory Panel.—
10	"(1) IN GENERAL.—The Administrator shall";
11	and
12	(2) by adding at the end the following:
13	"(2) Science review board.—
14	"(A) There is established a science review
15	board consisting of 60 scientists who shall be
16	available to the scientific advisory panel to as-
17	sist in reviews conducted by the panel.
18	"(B) The scientific advisory panel shall se-
19	lect the scientists from 60 nominations submit-
20	ted by each of the National Science Foundation
21	and the National Institutes of Health.
22	"(C) A member of the board shall be com-
23	pensated in the same manner as a member of
24	the panel.".

1	SEC. 113. COORDINATION OF CANCELLATION.
2	Section 2(bb) (7 U.S.C. 136(bb)) is amended—
3	(1) by striking "means any unreasonable risk"
4	and inserting "means—
5	"(1) any unreasonable risk"; and
6	(2) by striking the period at the end and insert-
7	ing "; and; and
8	(3) by adding at the end the following:
9	"(2) a human dietary risk from residue that re-
10	sults from a use of a pesticide in or on any food in-
11	consistent with the standard the Administrator de-
12	termines is adequate to protect the public health
13	under section 408 of the Federal Food, Drug, and
14	Cosmetic Act (21 U.S.C. 346a).".
15	Subtitle B—Minor Use Crop
16	Protection
17	SEC. 121. DEFINITION OF MINOR USE.
18	Section 2 (7 U.S.C. 136) is amended by adding at
19	the end the following:
20	"(hh) MINOR USE.—The term 'minor use' means the
21	use of a pesticide on an animal, on a commercial agricul-
22	tural crop or site, or for the protection of public health
23	if—
24	"(1)(A) in the case of the use of the pesticide
25	on a commercial agricultural crop or site, the total
26	quantity of acreage devoted to the crop in the Unit-

1	ed States is less than 300,000 acres, as determined
2	by the Secretary; or
3	"(B) the Administrator, in consultation with
4	the Secretary of Agriculture, determines that, based
5	on information provided by an applicant for registra-
6	tion or a registrant—
7	"(i) the use does not provide a sufficient
8	economic incentive to support the initial reg-
9	istration or continuing registration of a pes-
10	ticide for the use; and
11	"(ii)(I) there are not a sufficient number
12	of efficacious alternative registered pesticides
13	available for the use; or
14	"(II) any 1 of the alternatives to the pes-
15	ticide pose a greater risk to the environment or
16	human health than the pesticide; or
17	"(III) the pesticide plays, or will play, a
18	significant part in managing pest resistance; or
19	"(IV) the pesticide plays, or will play, a
20	significant part in an integrated pest manage-
21	ment program; and
22	"(2) the Administrator does not determine that,
23	based on data existing on the date of the determina-
24	tion, the use may cause unreasonable adverse effects
25	on the environment.".

SEC. 122. EXCLUSIVE USE OF MINOR USE PESTICIDES. 2 Section 3(c)(1)(F) (7 U.S.C. 136a(c)(1)(F)) 3 amended— 4 (1) in clause (i)— (A) by striking "(i) With respect" and in-5 serting "(i)(I) With respect"; 6 7 (B) by striking "a period of ten years fol-8 lowing the date the Administrator first registers the pesticide" and inserting "the exclusive data 9 10 use period determined under subclause (II)"; 11 and 12 (C) by adding at the end the following: "(II) Except as provided in subclauses 13 (III) and (IV), the exclusive data use pe-14 15 riod under subclause (I) shall be 10 years 16 beginning on the date the Administrator first registers the pesticide. 17 18 "(III) Subject to subclauses (IV), (V), 19 and (VI), the exclusive data use period 20 under subclause (II) shall be extended 1 21 year for each 3 minor uses registered after 22 the date of enactment of this subclause 23 and before the date that is 7 years after 24 the date the Administrator first registers 25 the pesticide, if the Administrator in con-

sultation with the Secretary of Agriculture,

26

1	determines that, based on information pro-
2	vided by an applicant for registration or a
3	registrant—
4	"(aa) there are not a sufficient
5	number of efficacious alternative reg-
6	istered pesticides available for the use;
7	or
8	"(bb) any 1 of the alternatives to
9	the pesticide pose a greater risk to the
10	environment or human health than
11	the pesticide; or
12	"(cc) the pesticide plays, or will
13	play, a significant part in managing
14	pest resistance; or
15	"(dd) the pesticide plays, or will
16	play, a significant part in an inte-
17	grated pest management program.
18	"(IV) Notwithstanding subclause
19	(III), the exclusive data use period estab-
20	lished under this clause may not exceed 13
21	years.
22	"(V) For purposes of subclause (III),
23	the registration of a pesticide for a minor
24	use on a crop grouping established by the
25	Administrator shall be considered 1 minor

1	use for each representative crop for which
2	data are provided in the crop grouping.
3	"(VI) An extension under subclause
4	(III) shall be reduced or terminated if the
5	applicant for registration or the registrant
6	voluntarily cancels the pesticide or deletes
7	from the registration a minor use that
8	formed the basis for the extension, or if
9	the Administrator determines that the ap-
10	plicant or registrant is not actually mar-
11	keting the pesticide for a minor use that
12	formed the basis for the extension."; and
13	(2) by adding at the end the following:
14	"(iv) The period of exclusive use pro-
15	vided under clause (i)(III) shall not take
16	effect until 1 year after enactment of this
17	clause, except where an applicant or reg-
18	istrant is applying for the registration of a
19	pesticide containing an active ingredient
20	not previously registered.
21	"(v) With respect to data submitted
22	after the date of enactment of this clause
23	by an applicant or registrant to support an
24	amendment adding a new use to an exist-
25	ing registration that does not retain any

period of exclusive use, if the data relate solely to a minor use of a pesticide, the data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of the data. The applicant or registrant at the time at which the new minor use is requested shall notify the Administrator that, to the best of the applicant's or registrant's knowledge, the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide are eligible for exclusive use protection under this paragraph. If the minor use registration that is supported by data submitted pursuant to this subsection is voluntarily canceled or if the data are subsequently used to support a nonminor use, the data shall not be subject to the exclusive use protection provided under this paragraph but shall instead be considered by the Adminis-

1	trator in accordance with clause (i), as ap-
2	propriate.''.
3	SEC. 123. TIME EXTENSIONS FOR DEVELOPMENT OF MINOR
4	USE DATA.
5	(a) IN GENERAL.—Section 3 (7 U.S.C. 136a) is
6	amended by adding at the end the following:
7	"(g) Time Extension for Development of
8	MINOR USE DATA.—
9	"(1) Supported use.—In the case of a minor
10	use, the Administrator shall, on the request of a reg-
11	istrant and subject to paragraph (3), extend the
12	time for the production of residue chemistry data
13	under subsection $(c)(2)(B)$ and subsections $(d)(4)$,
14	(e)(2), and (f)(2) of section 4 for data required sole-
15	ly to support the minor use until the final date
16	under section 4 for submitting data on any other use
17	established not later than the date of enactment of
18	this subsection.
19	"(2) Nonsupported use.—
20	"(A) If a registrant does not commit to
21	support a minor use of a pesticide, the Admin-
22	istrator shall, on the request of the registrant
23	and subject to paragraph (3), extend the time
24	for taking any action under subsection
25	(c)(2)(B) or subsection $(d)(6)$, $(e)(3)(A)$, or

1	(f)(3) of section 4 regarding the minor use until
2	the final date under section 4 for submitting
3	data on any other use established not later than
4	the date of enactment of this subsection.
5	"(B) On receipt of the request from the
6	registrant, the Administrator shall publish in
7	the Federal Register a notice of the receipt of
8	the request and the effective date on which the
9	uses not being supported will be deleted from
10	the registration under section $6(f)(1)$.
11	"(3) Conditions.—Paragraphs (1) and (2)
12	shall apply only if—
13	"(A) the registrant commits to support
14	and provide data for—
15	"(i) any use of the pesticide on a food;
16	or
17	"(ii) any other use, if all uses of the
18	pesticide are for uses other than food;
19	"(B)(i) the registrant provides a schedule
20	for producing the data referred to in subpara-
21	graph (A) with the request for an extension;
22	"(ii) the schedule includes interim dates
23	for measuring progress; and
24	"(iii) the Administrator determines that
25	the registrant is able to produce the data re-

1	ferred to in subparagraph (A) before a final
2	date established by the Administrator;
3	"(C) the Administrator determines that
4	the extension would not significantly delay issu-
5	ance of a determination of eligibility for rereg-
6	istration under section 4; and
7	"(D) the Administrator determines that,
8	based on data existing on the date of the deter-
9	mination, the extension would not significantly
10	increase the risk of unreasonable adverse effects
11	on the environment.
12	"(4) Monitoring.—If the Administrator
13	grants an extension under paragraph (1) or (2), the
14	Administrator shall—
15	"(A) monitor the development of any data
16	the registrant committed to under paragraph
17	(3)(A); and
18	"(B) ensure that the registrant is meeting
19	the schedule provided under paragraph (3)(B)
20	for producing the data.
21	"(5) Noncompliance.—If the Administrator
22	determines that a registrant is not meeting a sched-
23	ule provided by the registrant under paragraph
24	(3)(B), the Administrator may—

1	"(A) revoke any extension to which the
2	schedule applies; and
3	"(B) proceed in accordance with subsection
4	(c)(2)(B)(iv).
5	"(6) Modification or revocation.—The Ad-
6	ministrator may modify or revoke an extension
7	under this subsection if the Administrator deter-
8	mines that the extension could cause unreasonable
9	adverse effects on the environment. If the Adminis-
10	trator modifies or revokes an extension under this
11	paragraph, the Administrator shall provide written
12	notice to the registrant of the modification or rev-
13	ocation.".
14	(b) Conforming Amendments.—
15	(1) Section 3(c)(2)(B) (7 U.S.C. 136a(c)(2)(B))
16	is amended by adding at the end the following:
17	"(vi) Subsection (g) shall apply to this sub-
18	paragraph.''.
19	(2) Subsections (d)(4), (e)(2), and (f)(2) of sec-
20	tion 4 (7 U.S.C. 136a-1) are each amended by add-
21	ing at the end the following:
22	"(C) Section 3(g) shall apply to this para-
23	graph.".
24	(3) Subsections (d)(6) and (f)(3) of section 4 (7)
25	U.S.C. 136a-1) are each amended by striking "The

1	Administrator shall" and inserting "Subject to sec-
2	tion 3(g), the Administrator shall''.
3	(4) Section 4(e)(3)(A) (7 U.S.C. 136a-
4	1(e)(3)(A)) is amended by striking "If the reg-
5	istrant" and inserting "Subject to section 3(g), if
6	the registrant".
7	SEC. 124. MINOR USE WAIVER.
8	Section 3(c)(2) (7 U.S.C. 136a(c)(2)) is amended by
9	adding at the end the following:
10	"(E) In the case of the registration of a
11	pesticide for a minor use, the Administrator
12	may waive otherwise applicable data require-
13	ments if the Administrator determines that the
14	absence of the data will not prevent the Admin-
15	istrator from determining—
16	"(i) the incremental risk presented by
17	the minor use of the pesticide; and
18	"(ii) whether the minor use of the
19	pesticide would have unreasonable adverse
20	effects on the environment.".
21	SEC. 125. EXPEDITION OF MINOR USE REGISTRATIONS.
22	Section 3(c)(3) (7 U.S.C. 136a(c)(3)) is amended by
23	adding at the end the following:

1	"(C)(i) As expeditiously as practicable
2	after receipt, the Administrator shall review and
3	act on a complete application that—
4	"(I) proposes the initial registration
5	of a new pesticide active ingredient, if the
6	active ingredient is proposed to be reg-
7	istered solely for a minor use, or proposes
8	a registration amendment to an existing
9	registration solely for a minor use; or
10	"(II) for a registration or a registra-
11	tion amendment, proposes a significant
12	minor use.
13	"(ii) As used in clause (i):
14	"(I) The term 'as expeditiously as
15	practicable' means the Administrator shall,
16	to the greatest extent practicable, complete
17	a review and evaluation of all data submit-
18	ted with the application not later than 1
19	year after submission of the application.
20	"(II) The term 'significant minor use'
21	means—
22	"(aa) 3 or more proposed minor
23	uses for each proposed use that is not
24	minor;

1	"(bb) a minor use that the Ad-
2	ministrator determines could replace a
3	use that was canceled not earlier than
4	5 years preceding the receipt of the
5	application; or
6	"(cc) a minor use that the Ad-
7	ministrator determines would avoid
8	the reissuance of an emergency ex-
9	emption under section 18 for the
10	minor use.
11	"(iii) Review and action on an application
12	under clause (i) shall not be subject to judicial
13	review.
14	"(D) On receipt by the registrant of a de-
15	nial of a request to waive a data requirement
16	under paragraph (2)(E), the registrant shall
17	have the full time period originally established
18	by the Administrator for submission of the
19	data, beginning on the date of receipt by the
20	registrant of the denial.".
21	SEC. 126. UTILIZATION OF DATA FOR VOLUNTARILY CAN-
22	CELED CHEMICALS.
23	Section 6(f) (7 U.S.C. 136d) is amended—
24	(1) in paragraph $(1)(C)(ii)$ by striking "90-
25	day" and inserting "180-day" each place it appears:

1	(2) in paragraph (3)(A) by striking "90-day"
2	and inserting "180-day"; and
3	(3) by adding at the end the following:
4	"(4) Utilization of data for voluntarily
5	CANCELED CHEMICALS.—The Administrator shall
6	process, review, and evaluate the application for a
7	voluntarily canceled pesticide as if the registrant had
8	not canceled the registration, if—
9	"(A) another application is pending on the
10	effective date of the voluntary cancellation for
11	the registration of a pesticide that is—
12	"(i) for a minor use;
13	"(ii) identical or substantially similar
14	to the canceled pesticide; and
15	"(iii) for an identical or substantially
16	similar use as the canceled pesticide;
17	"(B) the Administrator determines that
18	the minor use will not cause unreasonable ad-
19	verse effects on the environment; and
20	"(C) the applicant under subparagraph (A)
21	certifies that the applicant will satisfy any out-
22	standing data requirement necessary to support
23	the reregistration of the pesticide, in accordance
24	with any data submission schedule established
25	by the Administrator.".

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1	SEC. 127. MINOR USE PROGRAMS
2	The Act is amended—
_	(1) 1 1 1

- 3 (1) by redesignating sections 30 and 31 (7
- 4 U.S.C. 136x and 136y) as sections 33 and 34, re-
- 5 spectively; and
- 6 (2) by inserting after section 29 (7 U.S.C.
- 7 136w–4) the following:
- 8 "SEC. 30. ENVIRONMENTAL PROTECTION AGENCY MINOR
- 9 **USE PROGRAM.**
- 10 "(a) ESTABLISHMENT.—The Administrator shall es-
- 11 tablish a minor use program in the Office of Pesticide Pro-
- 12 grams.
- 13 "(b) RESPONSIBILITIES.—In carrying out the pro-
- 14 gram established under subsection (a), the Administrator
- 15 shall—
- 16 "(1) coordinate the development of minor use
- 17 programs and policies; and
- 18 "(2) consult with growers regarding a minor
- use issue, registration, or amendment that is submit-
- ted to the Environmental Protection Agency.
- $21\,$ "SEC. 31. DEPARTMENT OF AGRICULTURE MINOR USE PRO-
- 22 GRAM.
- 23 "(a) Establishment.—The Secretary of Agri-
- 24 culture shall establish a minor use program.
- 25 "(b) RESPONSIBILITIES.—In carrying out the pro-
- 26 gram established under subsection (a), the Secretary shall

coordinate the responsibilities of the Department of Agriculture related to the minor use of a pesticide, including— 3 "(1) carrying out the Inter-Regional Research Project Number 4 established under section 2(e) of Public Law 89–106 (7 U.S.C. 450i(e)); 5 "(2) carrying out the national pesticide resist-6 7 ance monitoring program established under section 1651(d) of the Food, Agriculture, Conservation, and 8 Trade Act of 1990 (7 U.S.C. 5882(d)); 9 "(3) supporting integrated pest management 10 11 research; "(4) consulting with growers to develop data for 12 13 minor uses: and "(5) providing assistance for minor use reg-14 15 istrations, tolerances, and reregistrations with the 16 Environmental Protection Agency. "SEC. 32. MINOR USE MATCHING FUND PROGRAM. 18 ESTABLISHMENT.—The Secretary of Agriculture, in consultation with the Administrator, shall es-19 tablish and administer a minor use matching fund pro-21 gram. "(b) RESPONSIBILITIES.—In carrying out the pro-22 gram, the Secretary shall— 23 "(1) ensure the continued availability of minor 24

25

use pesticides; and

- 1 "(2) develop data to support minor use pes-
- 2 ticide registrations and reregistrations.
- 3 "(c) ELIGIBILITY.—Any person that desires to de-
- 4 velop data to support a minor use registration shall be
- 5 eligible to participate in the program.
- 6 "(d) PRIORITY.—In carrying out the program, the
- 7 Secretary shall provide a priority for funding to a person
- 8 that does not directly receive funds from the sale of a
- 9 product registered for a minor use.
- 10 "(e) MATCHING FUNDS.—To be eligible for funds
- 11 under the program, a person shall match the amount of
- 12 funds provided under the program with an equal amount
- 13 of non-Federal funds.
- 14 "(f) OWNERSHIP OF DATA.—Any data developed
- 15 through the program shall be jointly owned by the Depart-
- 16 ment of Agriculture and the person that receives funds
- 17 under this section.
- 18 "(g) STATEMENT.—Any data developed under this
- 19 subsection shall be submitted in a statement that complies
- 20 with section 3(c)(1)(F).
- 21 "(h) Compensation.—Any compensation received
- 22 by the Department of Agriculture for the use of data de-
- 23 veloped under this section shall be placed in a revolving
- 24 fund. The fund shall be available, without fiscal year limi-
- 25 tation, to carry out the program.

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"(i) AUTHORIZATION FOR APPROPRIATIONS.—There
 1
    are authorized to be appropriated to carry out this section
    $10,000,000 for each fiscal year.".
 3
              Subtitle C—Conforming
 4
                        Amendments
    SEC. 131. FIFRA TABLE OF CONTENTS.
 7
         The table of contents in section 1(b) (7 U.S.C. prec.
 8
    121) is amended—
              (1) by adding at the end of the items relating
 9
         to section 2 the following:
10
        "(hh) Minor use.";
11
              (2) by adding at the end of the items relating
         to section 3 the following:
12
        "(g) Time extension for development of minor use data.
           "(1) Supported use.
           "(2) Nonsupported use.
           "(3) Conditions.
           "(4) Monitoring.
           "(5) Noncompliance.
           "(6) Modification or revocation.";
13
              (3) by adding at the end of the items relating
         to section 6(f) the following:
14
           "(4) Utilization of data for voluntarily canceled chemicals.";
              (4) by striking the item relating to section
15
16
         25(d) and inserting the following:
        "(d) Scientific advisory panel.
           "(1) In general.
           "(2) Science review board.";
17
         and
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(5) by striking the items relating to sections 30 1 2 and 31 and inserting the following: "Sec. 30. Environmental Protection Agency minor use program. '(a) Establishment. "(b) Responsibilities. "Sec. 31. Department of Agriculture minor use program. '(a) Establishment. "(b) Responsibilities. "Sec. 32. Minor use matching fund program. "(a) Establishment. "(b) Responsibilities. "(c) Eligibility. "(d) Priority. "(e) Matching funds. "(f) Ownership of data. "(g) Statement. "(h) Compensation. "(i) Authorization for appropriations. "Sec. 33. Severability. "Sec. 34. Authorization for appropriations.". **COLLECTION** II—DATA TITLE **IMPROVED** PROCE-AND 4 **ENSURE DURES** TO 5 **TOLERANCES** SAFEGUARD 6 HEALTH **INFANTS** OF THE 7 AND CHILDREN 8 9 SEC. 201. IMPLEMENTATION OF NAS REPORT. 10 (a) IN GENERAL.—The Administrator of the Envi-11 ronmental Protection Agency, the Secretary of Agriculture, and the Secretary of Health and Human Services shall coordinate the development and implementation of procedures to ensure that pesticide tolerances adequately safeguard the health of infants and children, based on the

conclusions and recommendations contained in the report

17 entitled "Pesticides in the Diets of Infants and Children"

1	of the National Research Council of the National Academy
2	of Sciences.
3	(b) PROCEDURES.—To the maximum extent prac-
4	ticable, the procedures referred to in subsection (a) shall
5	include—
6	(1) collection of data on food consumption pat-
7	terns of infants and children;
8	(2) improved surveillance of pesticide residues,
9	including guidelines for the use of comparable ana-
10	lytical and standardized reporting methods, the in-
11	creased sampling of foods most likely consumed by
12	infants and children, and the development of more
13	complete information on the effects of food process-
14	ing on levels of pesticide residues;
15	(3) toxicity testing procedures that take into ac-
16	count the vulnerability of infants and children;
17	(4) methods of risk assessment that take into
18	account unique characteristics of infants and chil-
19	dren; and
20	(5) other appropriate measures considered nec-
21	essary by the Administrator to ensure that pesticide
22	tolerances adequately safeguard the health of infants

and children.

1 SEC. 202. COLLECTION OF PESTICIDE USE INFORMATION.

- 2 (a) IN GENERAL.—The Secretary of Agriculture shall
- 3 collect data of Statewide or regional significance on the
- 4 use of pesticides to control pests and diseases of major
- 5 crops and crops of dietary significance, including fruits
- 6 and vegetables.
- 7 (b) COLLECTION.—The data shall be collected by sur-
- 8 veys of farmers or from other sources offering statistically
- 9 reliable data.
- 10 (c) COORDINATION.—The Secretary shall, as appro-
- 11 priate, coordinate with the Administrator of the Environ-
- 12 mental Protection Agency in the design of the surveys and
- 13 make available to the Administrator the aggregate results
- 14 of the surveys to assist the Administrator in developing
- 15 exposure calculations and benefits determinations with re-
- 16 spect to pesticide regulatory decisions.

17 SEC. 203. INTEGRATED PEST MANAGEMENT.

- 18 (a) Definition.—In this section, the term "inte-
- 19 grated pest management" means a sustainable approach
- 20 to managing pests by combining biological, cultural, phys-
- 21 ical, and chemical tools in a way that minimizes economic,
- 22 health, and environmental risks.
- 23 (b) Implementation.—The Secretary of Agri-
- 24 culture, in cooperation with the Administrator of the Envi-
- 25 ronmental Protection Agency, shall implement research,

- 1 demonstration, and education programs to support adop-
- 2 tion of integrated pest management.
- 3 (c) FEDERAL AGENCIES.—Federal agencies shall use
- 4 integrated pest management techniques to carry out pest
- 5 management activities and shall promote integrated pest
- 6 management through procurement and regulatory policy
- 7 and through other activities.
- 8 (d) Information.—The Secretary of Agriculture
- 9 and the Administrator of the Environmental Protection
- 10 Agency shall make information on integrated pest man-
- 11 agement widely available to pesticide users, including Fed-
- 12 eral agencies that use pesticides.

13 TITLE III—AMENDMENTS TO

- 14 THE FEDERAL FOOD, DRUG,
- 15 AND COSMETIC ACT
- 16 SEC. 301. REFERENCE.
- 17 Whenever in this title an amendment is expressed in
- 18 terms of an amendment to a section or other provision,
- 19 or refers to a section or other provision, the reference shall
- 20 be considered to be made to a section or other provision
- 21 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
- 22 321 et seq.).

SEC. 302. DEFINITIONS.

- 2 (a) Pesticide, Chemical; Pesticide Chemical
- 3 Residue.—Section 201(q) (21 U.S.C. 321(q)) is amended
- 4 to read as follows:
- 5 ''(q)(1) The term 'pesticide chemical' means—
- 6 "(A) any substance that is a pesticide within
- 7 the meaning of section 2(u) of the Federal Insecti-
- 8 cide, Fungicide, and Rodenticide Act (7 U.S.C. 136
- 9 (u)),
- 10 "(B) any active ingredient of a pesticide within
- the meaning of section 2(a) of the Federal Insecti-
- cide, Fungicide, and Rodenticide Act. (7 U.S.C.
- 13 136(a)), or
- 14 "(C) any inert ingredient of a pesticide within
- the meaning of section 2(m) of the Federal Insecti-
- cide, Fungicide, and Rodenticide Act. (7 U.S.C. 136
- 17 (m)).
- 18 ''(2) The term 'pesticide chemical residue' means a
- 19 residue in or on raw agricultural commodity or processed
- 20 food of—
- 21 "(A) a pesticide chemical, or
- "(B) any other added substance that is present
- in the commodity or food primarily as a result of the
- 24 metabolism or other degradation of a pesticide
- chemical.

- "(3) Notwithstanding subparagraphs (1) and (2), the 1 Administrator may by regulation except a substance from the definition of 'pesticide chemical' or 'pesticide chemical 3 residue' if— 4 "(A) the substance's occurrence as a residue on 5 a raw agricultural commodity or processed food is 6 7 attributable primarily to natural causes or to human activities not involving the use of any substances for 8 9 a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural 10 11 commodity or processed food, and "(B) the Administrator, after consultation with 12 the Secretary, determines that the substance more 13 appropriately should be regulated under one or more 14 15 provisions of this Act other than sections 402(a)(2)(B) and 408.". 16 17 (b) FOOD ADDITIVE.—Subparagraphs (1) and (2) of section 201(s) (21 U.S.C. 321(s)) are amended to read 18 as follows: 19 20 "(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or 21 22 "(2) a pesticide chemical; or". 23 (c) Processed Food; Administrator.—Section
- 24 201 (21 U.S.C. 321) is amended by adding at the end 25 the following new subsections:

- 1 "(gg) The term 'processed food' means any food
- 2 other than a raw agricultural commodity and includes any
- 3 raw agricultural commodity that has been subject to proc-
- 4 essing, such as canning, cooking, freezing, dehydration, or
- 5 milling.
- 6 "(hh) The term 'Administrator' means the Adminis-
- 7 trator of the United States Environmental Protection
- 8 Agency.".

9 SEC. 303. PROHIBITED ACTS.

- 10 Section 301(j) (21 U.S.C. 331(j)) is amended by in-
- 11 serting before the period at the end of the first sentence
- 12 the following: ", or the violation of section 408(g) or any
- 13 regulation issued under that subsection".

14 SEC. 304. ADULTERATED FOOD.

- 15 Section 402(a)(2) (21 U.S.C. 342(a)(2)) is amended
- 16 to read as follows: "(2)(A) if it bears or contains any
- 17 added poisonous or added deleterious substance (other
- 18 than a substance that is a pesticide chemical residue in
- 19 or on a raw agricultural commodity or processed food, a
- 20 food additive, a color additive, or a new animal drug) that
- 21 is unsafe within the meaning of section 406; (B) if it bears
- 22 or contains a pesticide chemical residue that is unsafe
- 23 within the meaning of section 408(a); or (C) if it is or
- 24 if it bears or contains (i) any food additive that is unsafe
- 25 within the meaning of section 409 or (ii) a new animal

1	drug (or conversion product thereof) that is unsafe within
2	the meaning of section 512; or".
3	SEC. 305. TOLERANCES AND EXEMPTIONS FOR PESTICIDE
4	CHEMICAL RESIDUES.
5	Section 408 (21 U.S.C. 346a) is amended to read as
6	follows:
7	"SEC. 408. TOLERANCES AND EXEMPTIONS FOR PESTICIDE
8	CHEMICAL RESIDUES.
9	"(a) Requirement for Tolerance or Exemp-
10	TION.—
11	"(1) Definition.—For the purposes of this
12	section, the term 'food', when used as a noun with-
13	out modification, means a raw agricultural commod-
14	ity or processed food.
15	"(2) General rule.—Except as provided in
16	paragraph (3) or (4), any pesticide chemical residue
17	in or on a food shall be deemed unsafe for the pur-
18	pose of section 402(a)(2)(B) unless—
19	"(A) a tolerance for such pesticide chemi-
20	cal residue in or on such food is in effect under
21	this section and the concentration of the residue
22	is within the limits of the tolerance; or
23	"(B) an exemption from the requirement
24	of a tolerance is in effect under this section for
25	the pesticide chemical residue.

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

"(A) Tolerance requirement.—If a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance for the pesticide chemical residue in or on the processed 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) EXEMPTION FROM TOLERANCE RE-QUIREMENT.—If an exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw

agricultural commodity shall not be considered 1 the 2 unsafe within meaning of section 402(a)(2)(B). 3 "(4) RESIDUES OF DEGRADATION PRODUCTS.— 5 If a pesticide chemical residue is present in or on a 6 food because the residue is a metabolite or other 7 degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical 8 9 residue, the residue shall not be considered to be un-10 safe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance or exemption from the 11 need for a tolerance for the residue in or on the food 12 if— 13 "(A) the Administrator has not determined 14 15 that the degradation product is likely to pose 16 any potential health risk from dietary exposure 17 that is of a different type than, or of a greater 18 significance than, any risk posed by dietary ex-19 posure to the precursor substance; and 20 "(B) either— 21 "(i) a tolerance is in effect under this 22 section for residues of the precursor sub-23 stance in or on the food, and the combined level of residues of the degradation product 24

and the precursor substance in or on the

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1	food is at or below the stoichiometrically
2	equivalent level that would be permitted by
3	the tolerance if the residue consisted only
4	of the precursor substance rather than the
5	degradation product; or
6	"(ii) an exemption from the need for
7	a tolerance is in effect under this section
8	for residues of the precursor substance in
9	or on the food; and
10	"(C) the tolerance or exemption for resi-
11	dues of the precursor substance does not state
12	that the tolerance or exemption applies only to
13	particular named substances or states that the
14	tolerance or exemption does not apply to resi-
15	dues of the degradation product.
16	"(5) Effect of tolerance or exemp-
17	TION.—While a tolerance or exemption from the re-
18	quirement for a tolerance is in effect under this sec-
19	tion for a pesticide chemical residue with respect to
20	any food, the food shall not by reason of bearing or

24 "(b) Authority and Standard for Toler-25 ances.—

containing any amount of such a residue be consid-

ered to be adulterated within the meaning of section

402(a)(1).

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1	"(1) AUTHORITY.—The Administrator may
2	issue regulations establishing, modifying, or revoking
3	a tolerance for a pesticide chemical residue in or on
4	a food—
5	"(A) in response to a petition filed under
6	subsection (d); or
7	"(B) on the Administrator's initiative
8	under subsection (e).
9	"(2) Standard.—
10	"(A) In General.—A tolerance may not
11	be established for a pesticide chemical residue
12	in or on a food at a level that is higher than
13	a level that the Administrator determines is
14	adequate to protect the public health.
15	"(B) Modification or revocation of a
16	TOLERANCE.—The Administrator shall modify
17	or revoke a tolerance if the tolerance is at a
18	level higher than the level that the Adminis-
19	trator determines is adequate to protect the
20	public health.
21	"(C) DETERMINATION FACTORS.—In mak-
22	ing a determination under this paragraph, the
23	Administrator shall take into account, among
24	other relevant factors, the validity, complete-
25	ness, and reliability of the available data from

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studies of the pesticide chemical residue, the nature of any toxic effects shown to be caused by the pesticide chemical in the studies, available information and reasonable assumptions concerning the relationship of the results of the studies to human risk, available information and reasonable assumptions concerning the dietary exposure levels of food consumers (and major identifiable subgroups of food consumers, including infants and children) to the pesticide chemical residue, and available information and reasonable assumptions concerning the variability of the sensitivities of major identifiable subgroups, including infants and children, and shall consider other factors to the extent required by subparagraph (F).

"(D) NEGLIGIBLE DIETARY RISK STAND-ARD.—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 consumers by the level of the pesticide chemical residue is negligible. The Administrator shall by regulation set forth the factors and methods, including tests that are ap-

propriate for the determination of dietary risk and most likely dietary exposure, for the determination of negligible dietary risk.

- "(E) Infants and children.—Procedures shall be developed and implemented that ensure that pesticide tolerances adequately safeguard the health of infants and children.
- "(F) CALCULATION OF DIETARY RISK.—
 Where reliable data are available, the Administrator shall calculate the dietary risk posed to food consumers by a pesticide chemical on the basis of the percent of food actually treated with the pesticide chemical and the actual residue levels of the pesticide chemical that occur in food. In particular, the Administrator shall take into account aggregate pesticide use and residue data collected by the Department of Agriculture.
- "(G) EXCEPTIONS TO THE NEGLIGIBLE DI-ETARY RISK STANDARD.—For purposes of subparagraph (A), a level of a pesticide chemical residue in or on a food that poses a greater than negligible dietary risk to consumers of the food shall be considered to be adequate to protect the public health if the Administrator de-

1	termines that the risk is not unreasonable be-
2	cause—
3	"(i) use of the pesticide that produces
4	the residue protects humans or the envi-
5	ronment from adverse effects on public
6	health or welfare that would, directly or in-
7	directly, result in a greater risk to the pub-
8	lic or the environment than the dietary risk
9	from the pesticide chemical residue;
10	"(ii) use of the pesticide avoids
11	risks—
12	"(I) to workers, the public, or the
13	environment that would be expected to
14	result from the use of another pes-
15	ticide or pest control method on the
16	same food; and
17	"(II) that are greater than the
18	risks that result from dietary exposure
19	to the pesticide chemical residue; or
20	"(iii) the availability of the pesticide
21	would maintain the availability to consum-
22	ers of an adequate, wholesome, and eco-
23	nomical food supply taking into account
24	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.

"(3) Limitations.—

"(A) ISSUANCE OF TOLERANCE.—A tolerance may be issued under the authority of paragraph (2)(G) only 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) ESTABLISHMENT OF A TOLER-ANCE.—A tolerance for a pesticide chemical residue in or on a food shall not be established by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

"(C) ESTABLISHMENT OF A TOLERANCE LEVEL.—A tolerance for a pesticide chemical residue in or on a food shall not be established at a level lower than the limit of detection of

the method for detecting and measuring the pesticide chemical residue as determined by the Administrator under subparagraph (B).

- "(4) International standards.—In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall take into account any maximum residue level for the chemical in or on the food that has been established by the Codex Alimentarius Commission. The Administrator shall determine whether the Codex maximum residue level is adequate to protect the health of consumers in the United States and whether the data supporting the maximum residue level are valid, complete, and reliable. If the Administrator determines not to adopt a Codex level, the Administrator shall publish a notice in the Federal Register setting forth the reasons for the determination.
- 18 "(c) Authority and Standard for Exemp-19 tions.—
- issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on a food—

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1	"(A) in response to a petition filed under
2	subsection (d), or
3	"(B) on the Administrator's initiative
4	under subsection (e).
5	"(2) Standard.—
6	"(A) In General.—An exemption from
7	the requirement for a tolerance for a pesticide
8	chemical residue in or on a food may be estab-
9	lished only if the Administrator determines that
10	a tolerance is not needed to protect the public
11	health, in view of the levels of dietary exposure
12	to the pesticide chemical residue that could rea-
13	sonably be expected to occur.
14	"(B) REVOCATION OF EXEMPTION.—An
15	exemption from the requirement for a tolerance
16	for a pesticide chemical residue in or on a food
17	shall be revoked if the Administrator, in re-
18	sponse to a petition for the revocation of the ex-
19	emption, or at the Administrator's own initia-
20	tive, determines that the exemption does not
21	satisfy the criterion of subparagraph (A).
22	"(C) DETERMINATION FACTORS.—In mak-
23	ing a determination under this paragraph, the

Administrator shall take into account, among

1	other relevant factors, the factors set forth in
2	subsection $(b)(2)(C)$.
3	"(3) Limitation.—An exemption from the re-
4	quirement for a tolerance for a pesticide chemical
5	residue in or on a food shall not be established by
6	the Administrator unless the Administrator deter-
7	mines, after consultation with the Secretary—
8	"(A) that there is a practical method for
9	detecting and measuring the levels of the pes-
10	ticide chemical residue in or on the food; or
11	"(B) that there is no need for such a
12	method, and states the reasons for the deter-
13	mination in the order issuing the regulation es-
14	tablishing or modifying the regulation.
15	"(d) Petition for Tolerance of Exemption.—
16	"(1) Filing.—Any person may file with the
17	Administrator a petition proposing the issuance of a
18	regulation—
19	"(A) establishing, modifying, or revoking a
20	tolerance for a pesticide chemical residue in or
21	on a food; or
22	"(B) establishing or revoking an exemption
23	from the requirement of a tolerance for such a
24	residue.
25	"(2) Petition contents.—

1	"(A) IN GENERAL.—A petition under para-
2	graph (1) to establish a tolerance or exemption
3	for a pesticide chemical residue shall be sup-
4	ported by such data and information as are
5	specified in regulations issued by the Adminis-
6	trator, including—
7	"(i)(I) an informative summary of the
8	petition and of the data, information, and
9	arguments submitted or cited in support of
10	the petition; and
11	"(II) a statement that the petitioner
12	agrees that the summary or any informa-
13	tion the summary contains may be pub-
14	lished as a part of the notice of filing of
15	the petition to be published under this sub-
16	section and as part of a proposed or final
17	regulation issued under this section;
18	"(ii) the name, chemical identity, and
19	composition of the pesticide chemical resi-
20	due and of the pesticide chemical that pro-
21	duces the residue;
22	"(iii) data showing the recommended
23	amount, frequency, method, and time of
24	application of that pesticide chemical:

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

1	pesticide chemical is intended to have and
2	the quantity of the pesticide chemical that
3	is required to produce the effect;
4	"(x) if the petition relates to a toler-
5	ance for a processed food, reports of inves-
6	tigations conducted using the processing
7	method or methods used to produce that
8	food;
9	"(xi) such information as the Admin-
10	istrator may require to make the deter-
11	mination under subsection $(b)(2)(E)$; and
12	"(xii) such other data and information
13	as the Administrator requires by regulation
14	to support the petition.
15	If information or data required by this subpara-
16	graph is available to the Administrator, the per-
17	son submitting the petition may cite the avail-
18	ability of the information or data in lieu of sub-
19	mitting the information or data. The Adminis-
20	trator may require a petition to be accompanied
21	by samples of the pesticide chemical with re-
22	spect to which the petition is filed.
23	"(B) Modification or revocation.—
24	The Administrator may by regulation establish
25	the requirements for information and data to

support a petition to modify or revoke a tolerance or to revoke an exemption from the requirement for a tolerance.

"(3) Notice.—A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the statement of the petitioner of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i).

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

"(A) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance;

"(B) issue a proposed regulation under subsection (e), and thereafter either issue a final regulation under subsection (e) or an order denying the petition; or "(C) issue an order denying the petition. "(5) Effective date.—A regulation issued under paragraph (4) shall take effect upon publica-tion.

"(6) Further proceedings.—

"(A) Objections.—Not later than 60 days after a regulation or order is issued under paragraph (4), subsection (e)(1), or subsection (f)(1), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order considered objectionable and stating reasonable grounds therefore. If the regulation or order was issued in response to a petition filed under paragraph (1), a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

"(B) Public evidentiary hearing.—An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Ad-

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ministrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that the public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in the hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpoena may be enforced by a Federal district court.

"(C) ISSUANCE OF AN ORDER.—After receiving the arguments of the parties, the Administrator shall, as soon as practicable, issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Adminis-

trator has found to be warranted. If a hearing was held under subparagraph (B), the order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at the 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) EFFECTIVE DATE OF AN ORDER.— An order issued under this paragraph ruling on an objection shall not take effect before the 90th day after the publication of the order unless the Administrator finds that emergency conditions exist necessitating an earlier effective date, in which event the Administrator shall specify in the order the findings of the Administrator as to such conditions.

"(7) Judicial review.—

"(A) FILING.—In a case of actual controversy as to the validity of any order issued under paragraph (6) or any regulation that is the subject of such an order, any person who will be adversely affected by the order or regulation may obtain judicial review by filing in the

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United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, not later than 60 days after publication of such order, a petition praying that the order or regulation be set aside in whole or in part.

"(B) FILING OF RECORD OF PROCEED-INGS.—A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28, United States Code. Upon the filing of the petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

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

"(D) FINAL JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any order under paragraph (6) and any regulation that is the subject of the order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this

1	paragraph shall not, unless specifically ordered
2	by the court to the contrary, operate as a stay
3	of a regulation or order.
4	"(E) Limitations on judicial re-
5	VIEW.—Any issue as to which review is or was
6	obtainable under paragraph (6) and this para-
7	graph shall not be the subject of judicial review
8	under any other provision of law.
9	"(e) Action on Administrator's Own Initia-
10	TIVE.—
11	"(1) GENERAL RULE.—The Administrator may
12	issue a regulation—
13	"(A) establishing, modifying, or revoking a
14	tolerance for a pesticide chemical or a pesticide
15	chemical residue;
16	"(B) establishing or revoking an exemption
17	of a pesticide chemical residue from the require-
18	ment of a tolerance; or
19	"(C) establishing general procedures and
20	requirements to implement this section.
21	A regulation issued under this paragraph shall be-
22	come effective upon the publication of the regulation.
23	"(2) NOTICE.—Before issuing a final regulation
24	under paragraph (1), the Administrator shall issue
25	a notice of proposed rulemaking and provide a pe-

riod of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking. The Administrator shall provide an opportunity for a public hearing during the rulemaking under procedures provided in subsection (d)(6)(B).

"(f) Special Data Requirements.—

"(1) REQUIRING SUBMISSION OF ADDITIONAL DATA.—If the Administrator determines that additional data or information is reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

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

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

1	tion 4 of the Toxic Substances Control Act (15
2	U.S.C. 2603); or
3	"(C) publish in the Federal Register, after
4	first providing notice and an opportunity for
5	comment of not less than 90 days' duration, an
6	order—
7	"(i) requiring the submission to the
8	Administrator by one or more interested
9	persons of a notice identifying the person
10	or persons who will submit the required
11	data and information;
12	"(ii) describing the type of data and
13	information required to be submitted to
14	the Administrator and stating why the
15	data and information could not be obtained
16	under the authority of section $3(c)(2)(B)$
17	of the Federal Insecticide, Fungicide, and
18	Rodenticide Act (7 U.S.C. $136a(c)(2)(B)$)
19	or section 4 of the Toxic Substances Con-
20	trol Act (15 U.S.C. 2603);
21	"(iii) describing the reports to the Ad-
22	ministrator required to be prepared during
23	and after the collection of the data and in-
24	formation;

1	"(iv) requiring the submission to the
2	Administrator of the data, information,
3	and reports referred to in clauses (ii) and
4	(iii); and
5	"(v) establishing dates by which the
6	submissions described in clauses (i) and
7	(iv) must be made.
8	The Administrator may revise any such order to cor-
9	rect an error.
10	"(2) Noncompliance.—If a submission re-
11	quired by a notice issued in accordance with para-
12	graph (1)(A) or a rule issued under paragraph
13	(1)(B) is not made by the time specified in the no-
14	tice or the rule, the Administrator may by order
15	published in the Federal Register modify or revoke
16	the tolerance or exemption in question.
17	"(3) REVIEW.—An order issued under this sub-
18	section shall be effective upon publication and shall
19	be subject to review in accordance with paragraphs
20	(6) and (7) of subsection (d).
21	"(g) Confidentiality and Use of Data.—
22	"(1) GENERAL RULE.—Data and information
23	that are submitted to the Administrator under this
24	section in support of a tolerance shall be entitled to
25	confidential treatment for reasons of business con-

- fidentiality and to exclusive use and data compensation, to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136a and 136h).
 - "(2) EXCEPTIONS.—Data that are entitled to confidential treatment under paragraph (1) may nonetheless be disclosed to the Congress, and may be disclosed, under such security requirements as the Administrator may provide by regulation, to—
 - "(A) employees of the United States who are authorized by the Administrator to examine the data in the carrying out of their official duties under this Act or other Federal statutes intended to protect the public health; or
 - "(B) contractors with the United States authorized by the Administrator to examine the 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.

- 1 "(h) Status of Previously Issued Regula-2 tions.—
- "(1) REGULATIONS UNDER SECTION 406.—Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in ac-cordance with section 701(e), under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under sub-sections (d) and (e).
 - "(2) Regulations under section 409.—Regulations that established tolerances for substances that are pesticide chemical residues on or in processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely 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).
 - "(3) REGULATIONS UNDER SECTION 408.—Regulations that established tolerances or exemptions under this section that were issued on or before the date of the enactment of this paragraph shall remain

1	in effect unless modified or revoked under subsection
2	(d) or (e).
3	"(i) Transitional Provision.—If, on the day be-
4	fore the date of the enactment of this subsection, a sub-
5	stance that is a pesticide chemical was, with respect to
6	a particular pesticidal use of the substance and any result-
7	ing pesticide chemical residue in or on a particular food—
8	"(1) regarded by the Administrator or the Sec-
9	retary as generally recognized as safe for use within
10	the meaning of the provisions of section 408(a) or
11	201(s) as then in effect; or
12	"(2) regarded by the Secretary as a substance
13	described by section 201(s)(4),
14	such a pesticide chemical residue shall be regarded as ex-
15	empt from the requirement for a tolerance, as of the date
16	of enactment of this subsection. The Administrator shall
17	by regulation indicate which substances are described by
18	this subsection. An exemption under this subsection may
19	be revoked or modified as if the exemption had been issued
20	under subsection (c).
21	"(j) Harmonization With Action Under Other
22	Laws.—
23	"(1) Limitation.—Notwithstanding any other
24	provision of this Act, a final rule under this section
25	that revokes, modifies, or suspends a tolerance or

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

"(2) REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS.—

"(A) IN GENERAL.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit the use of the pesticide in connection with the production, storage, or transportation of the food, due in whole

1	or in part to dietary risks to humans posed by
2	residues of the pesticide chemical on that food
3	the Administrator shall revoke any tolerance or
4	exemption that allows the presence of the pes-
5	ticide chemical, or any pesticide chemical resi-
6	due that results from the use of the pesticide
7	chemical, in or on the food. The Administrator
8	shall use the procedures set forth in subsection
9	(e) in taking action under this paragraph.
10	"(B) Effective date.—A revocation
11	under this paragraph shall become effective not
12	later than 180 days after—
13	"(i) the date by which each such can-
14	cellation of a registration has become effec-
15	tive; or
16	"(ii) the date on which the use of the
17	canceled pesticide becomes unlawful under
18	the terms of the cancellation,
19	whichever is later.
20	"(3) Suspension of Tolerance or exemp-
21	TION FOLLOWING SUSPENSION OF ASSOCIATED REG-
22	ISTRATIONS.—
23	"(A) Suspension.—If the Administrator
24	acting under the Federal Insecticide, Fungicide
25	and Rodenticide Act (7 U.S.C. 136 et seq.)

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suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of the pesticide chemical on the food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from the use of the pesticide chemical, in or on that food. The Administrator shall use the procedures set forth in subsection (e) in taking action under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension 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 (7 U.S.C. 136 et seq.). While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If

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the suspension of use of the pesticide under such Act is terminated, leaving the registration of the pesticide for the use in effect under such Act, the Administrator shall rescind any associated suspension of a tolerance or exemption.

TOLERANCES FOR UNAVOIDABLE RESI-DUES.—In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were canceled prior to the effective date of this paragraph, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue at a level that permits such unavoidable residue to remain in or on the food. In establishing such a tolerance, the Administrator shall take into account the factors set forth in subsection (b)(2)(C) and shall use the procedures set forth in subsection (e). The Administrator shall review a tolerance established under this paragraph periodically and modify the tolerance as necessary so that the tolerance allows only that level of the pesticide chemical residue that is unavoidable.

"(5) Pesticide residues resulting from Lawful application of pesticide.—Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of the food shall not be considered unsafe solely because of the presence of the pesticide chemical residue in or on the food if it is shown to the satisfaction of the Secretary 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 (7 U.S.C. 136 et seq.); and

that was authorized at the time of the application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act, unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of the likely availabil-

- ity of the food in commerce will pose an unreasonable dietary risk.
- 3 "(k) FEES.—The Administrator shall by regulation
- 4 require the payment of such fees as will in the aggregate,
- 5 in the judgment of the Administrator, be sufficient over
- 6 a reasonable term to provide, equip, and maintain an ade-
- 7 quate service for the performance of the functions of the
- 8 Administrator under this section. Under the regulations,
- 9 the performance of the services or other functions of the
- 10 Administrator under this section, including—
- "(1) the acceptance for filing of a petition submitted under subsection (d);
- 13 "(2) the promulgation of a regulation establish-
- ing, modifying, or revoking a tolerance or establish-
- ing or revoking an exemption from the requirement
- of a tolerance under this section;
- 17 "(3) the acceptance for filing of objections
- under subsection (d)(6); or
- 19 "(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 the fees. The
- 23 regulations may further provide for waiver or refund of
- 24 fees in whole or in part when in the judgment of the Ad-

ministrator the waiver or refund is equitable and not contrary to the purposes of this subsection. 3 "(I) NATIONAL UNIFORMITY OF TOLERANCES.— "(1) QUALIFYING PESTICIDE CHEMICAL RESI-4 DUE.—For purposes of this subsection, the term 5 'qualifying pesticide chemical residue' means a pes-6 7 ticide chemical residue resulting from the use, in production, processing, or storage of a food, of a 8 pesticide chemical that is an active ingredient and 9 10 that— "(A) was first approved for such use in a 11 registration of a pesticide issued under section 12 13 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)(5)) on 14 15 or after April 25, 1985, on the basis of data determined by the Administrator to meet all ap-16 17 plicable requirements for data prescribed by 18 regulations in effect under such Act on April 19 25, 1985; or "(B) was approved for such use in a rereg-20 istration eligibility determination issued under 21 22 section 4(g) of such Act on or after the date of 23 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 prior to the date
13	of enactment of the Food Quality Protec-
14	tion Act of 1995, and determined by the
15	Administrator to meet the standard under
16	subsection (b)(2) (in the case of a toler-
17	ance) or $(c)(2)$ (in the case of an exemp-
18	tion); and
19	"(B) any statement, issued by the Sec-
20	retary, of the residue level below which enforce-
21	ment action will not be taken under this Act
22	with respect to any qualifying pesticide chemi-
23	cal residue, if the Secretary finds that the pes-
24	ticide chemical residue level permitted by the

statement during the period to which the statement applies protects human health.

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

"(4) STATE AUTHORITY.—Except as provided in paragraph (5), no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of the pesticide chemical residue in or on the food, unless the State regulatory limit is identical to the qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on food if the State or political subdivision purports to prohibit or penalize the production, processing, shipping, or other handling of a food because the food contains a pesticide resi-

due (in excess of a prescribed limit), or if the State or political subdivision purports to require that a food containing a pesticide residue be the subject of a warning or other statement relating to the presence of the pesticide residue in the food.

"(5) PETITION PROCEDURE.—

- "(A) IN GENERAL.—Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to the qualifying pesticide chemical residue.
- "(B) PETITION REQUIREMENTS.—Any petition made by a State under subparagraph (A) shall—
 - "(i) satisfy any requirements prescribed, by rule, by the Administrator; and
 - "(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within the State of food bearing the pesticide chemical residue, and data on exposure of humans with-

1	in the State to the pesticide chemical resi-
2	due.
3	"(C) Order.—Subject to paragraph (6),
4	the Administrator may, by order, grant the au-
5	thorization described in subparagraph (A) if the
6	Administrator determines that the proposed
7	State regulatory limit—
8	"(i) is justified by compelling local
9	conditions;
10	"(ii) would not unduly burden inter-
11	state commerce; and
12	"(iii) would not cause any food to be
13	in violation of Federal law.
14	"(D) Consideration of Petition as Pe-
15	TITION FOR TOLERANCE OR EXEMPTIONS.—In
16	lieu of any action authorized under subpara-
17	graph (C), the Administrator may treat a peti-
18	tion under this paragraph as a petition under
19	subsection (d) to revoke or modify a tolerance
20	or to revoke an exemption. If the Administrator
21	determines to treat a petition under this para-
22	graph as a petition under subsection (d), the
23	Administrator shall thereafter act on the peti-
24	tion pursuant to subsection (d).

"(E) REVIEW OF ORDER.—Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in paragraphs (6) and (7) of subsection (d).

"(6) Residues from lawful application.—
No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in the residue, the sale of the food with the residue level was lawful under this Act and under the law of the State, unless the State demonstrates that consumption of the food containing the pesticide residue level during the period of the likely availability of the food in the State will pose an unreasonable dietary risk to the health of persons within the State."

18 SEC. 306. AUTHORIZATION FOR INCREASE MONITORING.

There are 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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