104TH CONGRESS
2D SESSION

H. R. 1627

AN ACT

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

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

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Food Quality Protection Act of 1996''.

TITLE I—SUSPENSION-APPLICATORS

SEC. 101. REFERENCE.

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

Subtitle A—Suspension

SEC. 102. 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 suspension may be issued under this subsection unless the Administrator has issued, or at the same time issues, a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b).''.

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

(1) by inserting after the first sentence the following new sentence: ''The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration

or change the classification of the pesticide under subsection (b) and the Administrator shall proceed to issue the notice under subsection (b) within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) within 90 days of issuing an emergency order, the emergency order shall expire.''; and

(2) by striking ''In that case'' and inserting ''In the case of an emergency order''.

SEC. 103. TOLERANCE REEVALUATION AS PART OF REREGISTRATION.

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 sufficient information with respect to the dietary risk of a particular active ingredient, but in any event no later than the time the Administrator makes a determination under subparagraph (C) or (D) with respect to pesticides containing a particular active ingredient, the Administrator shall—

''(i) reassess each associated tolerance and exemption from the requirement for a tolerance issued under section 408 of the

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

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

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

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

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

SEC. 104. SCIENTIFIC ADVISORY PANEL.

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

(1) in the first sentence, by striking ''The Administrator shall'' and inserting:

''(1) IN GENERAL.—The Administrator shall''; and

(2) by adding at the end the following:

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

Panel. Members of the Board shall be selected in the same manner as members of temporary subpanels created under paragraph (1). Members of the Board shall be compensated in the same manner as members of the Panel.''.

SEC. 105. NITROGEN STABILIZER.

(a) SECTION 2.—Section 2 (7 U.S.C. 136) is amended—

(1) in subsection (a)—

(A) in paragraph (1) by striking ''or'' after ''defoliant,'' and inserting '', or nitrogen stabilizer'' after ''desiccant'';

(B) at the end of paragraph (3) by striking ''and'';

(C) at the end of paragraph (4) by striking the period and inserting ''; and''; and

(D) at the end by adding the following:

''(5) in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria.'';

(2) in subsection (u), by striking ''and'' before ''(2)'' and by inserting ''and (3) any nitrogen stabilizer,'' after ''desiccant,''; and

(3) at the end by adding the following:

''(hh) NITROGEN STABILIZER.—The term 'nitrogen stabilizer' means any substance or mixture of substances intended for preventing or hindering the process of nitrification, denitrification, ammonia volatilization, or urease production through action upon soil bacteria. Such term shall not include—

''(1) dicyandiamide;

''(2) ammonium thiosulfate; or

''(3) any substance or mixture of substances.—

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

''(B) that was in commercial agronomic use prior to January 1, 1992, with respect to which after January 1, 1992, the distributor or seller of the substance or mixture has made no specific claim of prevention or hindering of the process of nitrification, denitrification, ammonia volatilization urease production regardless of the actual use or purpose for, or future use or purpose for, the substance or mixture.

Statements made in materials required to be submitted to any State legislative or regulatory authority, or required by such authority to be included in the labeling or other literature accompanying any such substance or mixture

shall not be deemed a specific claim within the meaning of this subsection.''.

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

''(4) MIXTURES OF NITROGEN STABILIZERS AND FERTILIZER PRODUCTS.—Any mixture or other combination of—

''(A) 1 or more nitrogen stabilizers registered under this Act; and

''(B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections 4, 5, 7, 15, and 17(a)(2) if the mixture or other combination is accompanied by the labeling required under this Act for the nitrogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer.''.

SEC. 106. PERIODIC REGISTRATION REVIEW.

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

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

''(a) EXISTING STOCKS AND INFORMATION.—''; and

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

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

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

''(g) REGISTRATION REVIEW.—

''(1)(A) GENERAL RULE.—The registrations of pesticides are to be periodically reviewed. The Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations. The goal of these regulations shall be a review of a pesticide's registration every 15 years. No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 6.

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

''(2)(A) DATA.—The Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review.

''(B) DATA SUBMISSION, COMPENSATION, AND EXEMPTION.—For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) shall be utilized for and be applicable to any data required for registration review.''.

Subtitle B—Training for Maintenance Applicators and Service Technicians

SEC. 120. MAINTENANCE APPLICATORS AND SERVICE TECHNICIANS DEFINITIONS.

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

''(jj) MAINTENANCE APPLICATOR.—The term 'maintenance applicator' means any individual who, in the principal course of such individual's employment, uses, or supervises the use of, a pesticide not classified for restricted use (other than a ready to use consumer products pesticides); for the purpose of providing structural pest con-

trol or lawn pest control including janitors, general maintenance personnel, sanitation personnel, and grounds maintenance personnel. The term 'maintenance applicator' does not include private applicators as defined in section 2(e)(2); individuals who use antimicrobial pesticides, sanitizers or disinfectants; individuals employed by Federal, State, and local governments or any political subdivisions thereof, or individuals who use pesticides not classified for restricted use in or around their homes, boats, sod farms, nurseries, greenhouses, or other noncommercial property.

''(kk) SERVICE TECHNICIAN.—The term 'service technician' means any individual who uses or supervises the use of pesticides (other than a ready to use consumer products pesticide) for the purpose of providing structural pest control or lawn pest control on the property of another for a fee. The term 'service technician' does not include individuals who use antimicrobial pesticides, sanitizers or disinfectants; or who otherwise apply ready to use consumer products pesticides.''.

SEC. 121. MINIMUM REQUIREMENTS FOR TRAINING OF MAINTENANCE APPLICATORS AND SERVICE TECHNICIANS.

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

(1) by redesignating sections 30 and 31 as sections 33 and 34, respectively; and

(2) by adding after section 29 the following:

"SEC. 30. MINIMUM REQUIREMENTS FOR TRAINING OF MAINTENANCE APPLICATORS AND SERVICE TECHNICIANS.

''Each State may establish minimum requirements for training of maintenance applicators and service technicians. Such training may include instruction in the safe and effective handling and use of pesticides in accordance with the Environmental Protection Agency approved labeling, and instruction in integrated pest management techniques. The authority of the Administrator with respect to minimum requirements for training of maintenance applicators and service technicians shall be limited to ensuring that each State understands the provisions of this section.''.

TITLE II—MINOR USE CROP PROTECTION, ANTIMICROBIAL PESTICIDE REGISTRATION REFORM, AND PUBLIC HEALTH PESTICIDES

SEC. 201. REFERENCE.

Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a sec-

tion or other provision, the reference shall be considered to be made to a section or other provision of the Federal Insecticide, Fungicide, and Rodenticide Act.

Subtitle A—Minor Use Crop Protection

SEC. 210. MINOR CROP PROTECTION.

(a) DEFINITION.—Section 2 (7 U.S.C. 136), as amended by section 120, is further amended by adding at the end the following:

''(ll) MINOR USE.—The term 'minor use' means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—

''(1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or

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

''(A) there are insufficient efficacious alternative registered pesticides available for the use;

''(B) the alternatives to the pesticide use pose greater risks to the environment or human health;

''(C) the minor use pesticide plays or will play a significant part in managing pest resistance; or

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

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.''.

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

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

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

''(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses

registered after the date of enactment of this clause and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that—

''(I) there are insufficient efficacious alternative registered pesticides available for the use;

''(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

''(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

''(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the

Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.'';

(3) in clause (iv), as amended by paragraph (1), by striking ''and (ii)'' and inserting '', (ii), and (iii)''; and

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

''(v) The period of exclusive use provided under clause (ii) shall not take into effect until 1 year after enactment of this clause, except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.

"(vi) With respect to data submitted after the date of enactment of this clause by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such 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 such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall

no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.''.

(c) TIME EXTENSIONS FOR DEVELOPMENT OF MINOR USE DATA.—

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

''(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under section 4 for the other uses of the pesticide established as of the date of enactment of the Food Quality Protection Act of 1996, if—

''(I) the data to support other uses of the pesticide on a food are being provided;

''(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data pro-

duction will be completed before the expiration of the extension period;

''(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 4; and

''(IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provi-

sions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.''.

(2) REREGISTRATION.—Sections 4(d)(4)(B), 4(e)(2)(B), and 4(f)(2)(B) (7 U.S.C. 136a–1(d)(4)(B), (e)(2)(B), and (f)(2)(B)) are each amended by adding at the end the following: ''Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of the date of enactment of the Food Quality Protection Act of 1996 if—

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

''(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

''(iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and

''(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule

for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 3(c)(2)(B) or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse affect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.''.

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

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

(2) by inserting ''ADDITIONAL DATA.—'' after ''(B)'';

(3) by inserting ''SIMPLIFIED PROCEDURES.—'' after ''(C)''; and

(4) by adding at the end the following:

''(E) MINOR USE WAIVER.—In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining—

''(i) the incremental risk presented by the minor use of the pesticide; and

''(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.''.

(e) EXPEDITING MINOR USE REGISTRATIONS.—Section 3(c)(3) (7 U.S.C. 136a(c)(3)) is amended —

(1) by inserting after ''(A)'' the following: ''IN GENERAL.—'';

(2) by inserting after ''(B)'' the following: ''IDENTICAL OR SUBSTANTIALLY SIMILAR.—''; and

(3) by adding at the end the following:

''(C) MINOR USE REGISTRATION.—

''(i) The Administrator shall, as expeditiously as possible, review and act on any complete application—

''(I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or

''(II) for a registration or a registration amendment that proposes significant minor uses.

''(ii) For the purposes of clause (i)—

''(I) the term 'as expeditiously as possible' means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause

(i) shall not be subject to judicial review; and

''(II) the term 'significant minor uses' means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Administrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 18 for that minor use.

''(D) ADEQUATE TIME FOR SUBMISSION OF MINOR USE DATA.—If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term 'full-time period' means the time period originally established by the Administrator for submission of such data, begin-

ning with the date of receipt by the registrant of the Administrator's notice of denial.''.

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

(1) REREGISTRATION.—

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

paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 3(c)(2)(B)(iv) regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2).

Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.''.

(B) Section 4(e)(3)(A) (7 U.S.C. 136a–1(e)(3)(A)) is amended by adding at the end the following: ''If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant

to this subparagraph in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Food Quality Protection Act of 1996, for the submission of data under this section for the supported uses identified pursuant to this subparagraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the

production of such data, the Administrator may proceed in accordance with section 3(c)(2)(B)(iv) regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.''.

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

''(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pes-

ticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Food Quality Protection Act of 1996, for the submission of data under section 4 for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 6(f)(1). If the Administrator grants an ex-

tension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.''.

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

(1) in paragraph (1)(C)(ii) by striking ''90-day'' each place it appears and inserting ''180-day''; and

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

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

''(4) UTILIZATION OF DATA FOR VOLUNTARILY CANCELED PESTICIDE.—When an application is filed with the Administrator for the registration of a pesticide for a minor use and another registrant subsequently voluntarily cancels its registration for an identical or substantially similar pesticide for an identical or substantially similar use, the Administrator shall process, review, and evaluate the pending application as if the voluntary cancellation had not yet taken place except that the Administrator shall not take such action if the Administrator determines that such minor use may cause an unreasonable adverse effect on the environment. In order to rely on this subsection, the applicant must certify that it agrees to satisfy any outstanding data requirements necessary to support the reregistration of

the pesticide in accordance with the data submission schedule established by the Administrator.''.

(i) ENVIRONMENTAL PROTECTION AGENCY MINOR USE PROGRAM.—The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), as amended by section 121, is amended by adding after section 30 the following:

''SEC. 31. ENVIRONMENTAL PROTECTION AGENCY MINOR USE PROGRAM.

''(a) The Administrator shall assure coordination of minor use issues through the establishment of a minor use program within the Office of Pesticide Programs. Such office shall be responsible for coordinating the development of minor use programs and policies and consulting with growers regarding minor use issues and registrations and amendments which are submitted to the Environmental Protection Agency.

''(b) The Office of Pesticide Programs shall prepare a public report concerning the progress made on the registration of minor uses, including implementation of the exclusive use as an incentive for registering new minor uses, within 3 years of the passage of the Food Quality Protection Act of 1996.''.

(j) DEPARTMENT OF AGRICULTURE MINOR USE PROGRAM.—The Federal Insecticide, Fungicide, and

Rodenticide Act (7 U.S.C. 136 et seq.), as amended by subsection (i), is amended by adding after section 31 the following:

"SEC. 32. DEPARTMENT OF AGRICULTURE MINOR USE PROGRAM.

''(a) IN GENERAL.—The Secretary of Agriculture (hereinafter in this section referred to as the 'Secretary') shall assure the coordination of the responsibilities of the Department of Agriculture related to minor uses of pesticides, including—

''(1) carrying out the Inter-Regional Project Number 4 (IR–4) as described in section 2 of Public Law 89–106 (7 U.S.C. 450i(e)) and the national pesticide resistance monitoring program established under section 1651 of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5882);

''(2) supporting integrated pest management research;

''(3) consulting with growers to develop data for minor uses; and

''(4) providing assistance for minor use registrations, tolerances, and reregistrations with the Environmental Protection Agency.

''(b)(1) MINOR USE PESTICIDE DATA.—

''(A) GRANT AUTHORITY.—The Secretary, in consultation with the Administrator, shall establish a program to make grants for the development of data to support minor use pesticide registrations and reregistrations. The amount of any such grant shall not exceed ½ of the cost of the project for which the grant is made.

''(B) APPLICANTS.—Any person who wants to develop data to support minor use pesticide registrations and reregistrations may apply for a grant under subparagraph (A). Priority shall be given to an applicant for such a grant who does not directly receive funds from the sale of pesticides registered for minor uses.

''(C) DATA OWNERSHIP.—Any data that is developed under a grant under subparagraph (A) shall be jointly owned by the Department of Agriculture and the person who received the grant. Such a person shall enter into an agreement with the Secretary under which such person shall share any fee paid to such person under section 3(c)(1)(F).

''(2) MINOR USE PESTICIDE DATA REVOLVING FUND.—

''(A) ESTABLISHMENT.—There is established in the Treasury of the United States a revolving fund

to be known as the Minor Use Pesticide Data Revolving Fund. The Fund shall be available without fiscal year limitation to carry out the authorized purposes of this subsection.

''(B) CONTENTS OF THE FUND.—There shall be deposited in the Fund—

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

''(ii) fees collected by the Secretary for any data developed under a grant under paragraph (1)(A).

''(C) AUTHORIZATIONS OF APPROPRIATIONS.—There are authorized to be appropriated for each fiscal year to carry out the purposes of this subsection $10,000,000 to remain available until expended.''.

Subtitle B—Antimicrobial Pesticide Registration Reform

SEC. 221. DEFINITIONS.

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

(1) in subsection (u), by adding at the end the following: ''The term 'pesticide' does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device,

as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321). For purposes of the preceding sentence, the term 'critical device' includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term 'semi-critical device' includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.''; and

(2) by adding at the end the following:

''(mm) ANTIMICROBIAL PESTICIDE.—

''(1) IN GENERAL.—The term 'antimicrobial pesticide' means a pesticide that—

''(A) is intended to—

''(i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or

''(ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

''(B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a and 348) or a food additive regulation under section 409 of such Act.

''(2) EXCLUDED PRODUCTS.—The term 'antimicrobial pesticide' does not include —

''(A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addition to an activity described in paragraph (1) is made;

''(B) an agricultural fungicide product; or

''(C) an aquatic herbicide product.

''(3) INCLUDED PRODUCTS.—The term 'antimicrobial pesticide' does include any other chemical sterilant product (other than liquid chemical sterilant products exempt under subsection (u)), any other disinfectant product, any other industrial microbiocide product, and any other preservative product that is not excluded by paragraph (2).''.

SEC. 222. FEDERAL AND STATE DATA COORDINATION.

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

''(viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

''(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

''(III) Not later than 1 year after the date of enactment of this clause, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.''.

SEC. 223. LABEL AND LABELING.

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

''(9) LABELING.—

''(A) ADDITIONAL STATEMENTS.—Subject to subparagraphs (B) and (C), it shall not be a violation of this Act for a registrant to modify the labeling of an antimicrobial pesticide prod-

uct to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

''(B) REQUIREMENTS.—Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

''(C) NOTIFICATION AND DISAPPROVAL.—

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

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

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

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

''(iii) RESTRICTION ON SALE.—A registrant may not sell or distribute a product bearing a disapproved modification.

''(iv) OBJECTION.—A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

''(v) FINAL ACTION.—A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

''(D) USE DILUTION.—The label or labeling required under this Act for an antimicrobial pesticide that is or may be diluted for use may

have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that —

''(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

''(ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.''.

SEC. 224. REGISTRATION REQUIREMENTS FOR ANTIMICROBIAL PESTICIDES.

Section 3 (7 U.S.C. 136a), as amended by section 106(b), is further amended by adding at the end the following:

''(h) REGISTRATION REQUIREMENTS FOR ANTIMICROBIAL PESTICIDES.—

''(1) EVALUATION OF PROCESS.—To the maximum extent practicable consistent with the degrees of risk presented by a antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of the date

of enactment of this subsection for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including—

"(A) new antimicrobial active ingredients;

"(B) new antimicrobial end-use products;

"(C) substantially similar or identical antimicrobial pesticides; and

"(D) amendments to antimicrobial pesticide registrations.

"(2) REVIEW TIME PERIOD REDUCTION GOAL.—Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than —

"(A) 540 days for a new antimicrobial active ingredient pesticide registration;

"(B) 270 days for a new antimicrobial use of a registered active ingredient;

"(C) 120 days for any other new antimicrobial product;

"(D) 90 days for a substantially similar or identical antimicrobial product;

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

''(F) 90 to 180 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

''(3) IMPLEMENTATION.—

''(A) PROPOSED RULEMAKING.—

''(i) ISSUANCE.—Not later than 270 days after the date of enactment of this subsection, the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

''(ii) REQUIREMENTS.—Proposed regulations issued under clause (i) shall —

''(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and

pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

''(II) differentiate the types of review undertaken for antimicrobial pesticides;

''(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this Act, considering the use patterns of the product, toxicity, expected exposure, and product type;

''(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products

continue to meet product performance standards and effectiveness levels for each type of label claim made; and

''(V) implement effective and reliable deadlines for process management.

''(iii) COMMENTS.—In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

''(B) FINAL REGULATIONS.—

''(i) ISSUANCE.—The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

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

''(iii) REQUIREMENTS.—In issuing final regulations, the Administrator shall—

''(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

''(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

''(III) use all appropriate and cost-effective review mechanisms, including—

''(aa) expanded use of notification and non-notification procedures;

''(bb) revised procedures for application review; and

''(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

"(IV) clarify criteria for determination of the completeness of an application.

"(C) EXPEDITED REVIEW.—This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3).

"(D) ALTERNATIVE REVIEW PERIODS.—If the final regulations to carry out this paragraph are not effective 630 days after the date of enactment of this subsection, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be —

"(i) 2 years for a new antimicrobial active ingredient pesticide registration;

"(ii) 1 year for a new antimicrobial use of a registered active ingredient;

"(iii) 180 days for any other new antimicrobial product;

"(iv) 90 days for a substantially similar or identical antimicrobial product;

"(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

"(vi) 240 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

"(E) WOOD PRESERVATIVES.—An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 2(mm) is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

"(F) NOTIFICATION.—

"(i) IN GENERAL.—Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final

day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

''(ii) FINAL DECISION.—If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of title 5, United States Code.

''(iii) EXEMPTION.—This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) prior to 90 days after the date of enactment of this subsection.

''(4) ANNUAL REPORT.—

''(A) SUBMISSION.—Beginning on the date of enactment of this subsection and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Com-

mittee on Agriculture, Nutrition, and Forestry of the Senate.

''(B) REQUIREMENTS.—A report submitted under subparagraph (A) shall include a description of—

''(i) measures taken to reduce the backlog of pending registration applications;

''(ii) progress toward achieving reforms under this subsection; and

''(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.''.

SEC. 225. DISPOSAL OF HOUSEHOLD, INDUSTRIAL, OR INSTITUTIONAL ANTIMICROBIAL PRODUCTS.

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

(1) by striking ''Nothing in'' and inserting the following:

''(1) IN GENERAL.—Nothing in''; and

(2) by adding at the end the following:

''(2) ANTIMICROBIAL PRODUCTS.—A household, industrial, or institutional antimicrobial product that is not subject to regulation under the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.) shall not be subject to the provisions of subsections (a), (e), and

(f), unless the Administrator determines that such product must be subject to such provisions to prevent an unreasonable adverse effect on the environment.''.

Subtitle C—Public Health Pesticides

SEC. 230. DEFINITIONS.

(a) ADVERSE EFFECTS.—Section 2(bb) (7 U.S.C. 136(bb)) is amended by adding at the end the following: ''The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this Act, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.''.

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

''(nn) PUBLIC HEALTH PESTICIDE.—The term 'public health pesticide' means any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria, or other microorganisms (other than vi-

ruses, bacteria, or other microorganisms on or in living man or other living animal) that pose a threat to public health.

''(oo) VECTOR.—The term 'vector' means any organism capable of transmitting the causative agent of human disease or capable of producing human discomfort or injury, including mosquitoes, flies, fleas, cockroaches, or other insects and ticks, mites, or rats.''.

SEC. 231. REGISTRATION.

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

(1) by inserting after ''pattern of use,'' the following: ''the public health and agricultural need for such minor use,''; and

(2) by striking ''potential exposure of man and the environment to the pesticide'' and inserting ''potential beneficial or adverse effects on man and the environment''.

SEC. 232. REREGISTRATION.

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

(1) in subsection (i)(4), by redesignating subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively, and by adding after subparagraph (A) the following:

''(B) The Administrator shall exempt any public health pesticide from the payment of the fee prescribed under paragraph (3) if, in consultation with the Secretary of Health and Human Services, the Administrator determines, based on information supplied by the registrant, that the economic return to the registrant from sales of the pesticide does not support the registration or reregistration of the pesticide.'';

(2) in subsection (i)(5), by redesignating subparagraphs (F) and (G) as subparagraphs (G) and (H), respectively, and by adding after subparagraph (E) the following:

''(F) The Administrator shall exempt any public health pesticide from the payment of the fee prescribed under paragraph (3) if, in consultation with the Secretary of Health and Humans Services, the Administrator determines, based on information supplied by the registrant, that the economic return to the registrant from sales of the pesticide does not support the registration or reregistration of the pesticide.'';

(3) in subsection (i)(7)(B), by striking ''or to determine'' and inserting '', to determine'' and by inserting before the period the following: '', or to de-

termine the volume usage for public health pesticides''; and

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

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

SEC. 233. CANCELLATION.

Section 6(b) (7 U.S.C. 136d(b)) is amended by adding after the eighth sentence the following: ''When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides.''.

SEC. 234. VIEWS OF THE SECRETARY OF HEALTH AND HUMAN SERVICES.

Section 21 (7 U.S.C. 136s) is amended by redesignating subsections (b) and (c) as subsections (c) and (d), respectively, and by adding after subsection (a) the following:

''(b) SECRETARY OF HEALTH AND HUMAN SERVICES.—The Administrator, before publishing regulations under this Act for any public health pesticide, shall solicit the views of the Secretary of Health and Human Services in the same manner as the views of the Secretary of Agriculture are solicited under section 25(a)(2).''.

SEC. 235. AUTHORITY OF ADMINISTRATOR.

Section 25(a)(1) (7 U.S.C. 136w(a)(1)) is amended—

(1) by inserting after ''various classes of pesticides'' the following: '', including public health pesticides,''; and

(2) by striking ''and nonagricultural pesticides'' and inserting '', nonagricultural, and public health pesticides''.

SEC. 236. IDENTIFICATION OF PESTS.

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

''(d) PUBLIC HEALTH PESTS.—The Administrator, in coordination with the Secretary of Agriculture and the Secretary of Health and Human Services, shall identify pests of significant public health importance and, in coordination with the Public Health Service, develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological, and other methods

to combat and control such pests of public health importance.''.

SEC. 237. PUBLIC HEALTH DATA.

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

''(m) AUTHORIZATION OF FUNDS TO DEVELOP PUBLIC HEALTH DATA.—

''(1) DEFINITION.—For the purposes of this section, 'Secretary' means the Secretary of Health and Human Services, acting through the Public Health Service.

''(2) CONSULTATION.—In the case of a pesticide registered for use in public health programs for vector control or for other uses the Administrator determines to be human health protection uses, the Administrator shall, upon timely request by the registrant or any other interested person, or on the Administrator's own initiative may, consult with the Secretary prior to taking final action to suspend registration under section 3(c)(2)(B)(iv), or cancel a registration under section 4, 6(e), or 6(f). In consultation with the Secretary, the Administrator shall prescribe the form and content of requests under this section.

''(3) BENEFITS TO SUPPORT FAMILY.—The Administrator, after consulting with the Secretary, shall make a determination whether the potential benefits of continued use of the pesticide for public health or health protection purposes are of such significance as to warrant a commitment by the Secretary to conduct or to arrange for the conduct of the studies required by the Administrator to support continued registration under section 3 or reregistration under section 4.

''(4) ADDITIONAL TIME.—If the Administrator determines that such a commitment is warranted and in the public interest, the Administrator shall notify the Secretary and shall, to the extent necessary, amend a notice issued under section 3(c)(2)(B) to specify additional reasonable time periods for submission of the data.

''(5) ARRANGEMENTS.—The Secretary shall make such arrangements for the conduct of required studies as the Secretary finds necessary and appropriate to permit submission of data in accordance with the time periods prescribed by the Administrator. Such arrangements may include Public Health Service intramural research activities, grants, contracts, or cooperative agreements with academic,

public health, or other organizations qualified by experience and training to conduct such studies.

''(6) SUPPORT.—The Secretary may provide for support of the required studies using funds authorized to be appropriated under this section, the Public Health Service Act, or other appropriate authorities. After a determination is made under subsection (d), the Secretary shall notify the Committees on Appropriations of the House Representatives and the Senate of the sums required to conduct the necessary studies.

''(7) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out the purposes of this section $12,000,000 for fiscal year 1997, and such sums as may be necessary for succeeding fiscal years.''.

Subtitle D—Expedited Registration of Reduced Risk Pesticides

SEC. 250. EXPEDITED REGISTRATION OF PESTICIDES .

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

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

''(G) If the applicant is requesting that the registration or amendment to the registration of

a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.''; and

(2) by adding at the end the following:

''(10) EXPEDITED REGISTRATION OF PESTICIDES.—

''(A) Not later than 1 year after the date of enactment of this paragraph, the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.

''(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

''(i) Reduce the risks of pesticides to human health.

''(ii) Reduce the risks of pesticides to nontarget organisms.

''(iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.

''(iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

''(C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).''.

TITLE III—DATA COLLECTION ACTIVITIES TO ASSURE THE HEALTH OF INFANTS AND CHILDREN AND OTHER MEASURES

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

(a) IN GENERAL.—The Secretary of Agriculture, in consultation with the Administrator of the Environmental Protection Agency and the Secretary of Health and Human Services, shall coordinate the development and implementation of survey procedures to ensure that adequate data on food consumption patterns of infants and children 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.

(c) RESIDUE DATA COLLECTION.—The Secretary of Agriculture shall ensure that the residue data collection activities conducted by the Department of Agriculture in cooperation with the Environmental Protection Agency and the Department of Health and Human Services, provide for the improved data collection of pesticide residues, including guidelines for the use of comparable analytical

and standardized reporting methods, and the increased sampling of foods most likely consumed by infants and children.

SEC. 302. COLLECTION OF PESTICIDE USE INFORMATION.

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

(b) COLLECTION.—The data shall be collected by surveys of farmers or from other sources offering statistically reliable data.

(c) COORDINATION.—The Secretary of Agriculture shall, as appropriate, coordinate with the Administrator of the Environmental Protection Agency in the design of the surveys and make available to the Administrator the aggregate results of the surveys to assist the Administrator.

SEC. 303. INTEGRATED PEST MANAGEMENT.

The Secretary of Agriculture, in cooperation with the Administrator, shall implement research, demonstration, and education programs to support adoption of Integrated Pest Management. Integrated Pest Management is a sustainable approach to managing pests by combining biological, cultural, physical, and chemical tools in a way that

minimizes economic, health, and environmental risks. The Secretary of Agriculture and the Administrator shall make information on Integrated Pest Management widely available to pesticide users, including Federal agencies. Federal agencies shall use Integrated Pest Management techniques in carrying out pest management activities and shall promote Integrated Pest Management through procurement and regulatory policies, and other activities.

SEC. 304. COORDINATION OF CANCELLATION.

Section 2(bb) (7 U.S.C. 136(bb)) is amended—

(1) by inserting ''(1)'' after ''means''; and

(2) by striking the period at the end of the first sentence and inserting '', or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a).''.

SEC. 305. PESTICIDE USE INFORMATION STUDY.

(a) The Secretary of Agriculture shall, in consultation with the Administrator of the Environmental Protection Agency, prepare a report to Congress evaluating the current status and potential improvements in Federal pesticide use information gathering activities. This report shall at least include—

(1) an analysis of the quality and reliability of the information collected by the Department of Agriculture, the Environmental Protection Agency, and other Federal agencies regarding the agricultural use of pesticides; and

(2) an analysis of options to increase the effectiveness of national pesticide use information collection, including an analysis of costs, burdens placed on agricultural producers and other pesticide users, and effectiveness in tracking risk reduction by those options.

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

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

SEC 401. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This title may be cited as the ''Food Quality Protection Act of 1996 ''.

(b) REFERENCE.—Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 402. DEFINITIONS.

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

''(q)(1) The term 'pesticide chemical' means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide.

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

''(A) a pesticide chemical; or

''(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

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

''(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

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

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

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

''(2) a pesticide chemical; or''.

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

''(gg) The term 'processed food' means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

''(hh) The term 'Administrator' means the Administrator of the United States Environmental Protection Agency.''.

SEC. 403. PROHIBITED ACTS.

Section 301(j) (21 U.S.C. 331(j)) is amended in the first sentence by inserting before the period the following:

''; or the violating of section 408(i)(2) or any regulation issued under that section.''.

SEC. 404. ADULTERATED FOOD.

Section 402(a) (21 U.S.C. 342(a)) is amended by striking ''(2)(A) if it bears'' and all that follows through ''(3) if it consists'' and inserting the following: ''(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a); or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 409; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512; or (3) if it consists''.

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

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

''TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

''SEC. 408. (a) REQUIREMENT FOR TOLERANCE OR EXEMPTION.—

''(1) GENERAL RULE.—Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 402(a)(2)(B) unless—

''(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

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

For the purposes of this section, the term 'food', when used as a noun without modification, shall mean a raw agricultural commodity or processed food.

''(2) PROCESSED FOOD.—Notwithstanding paragraph (1)—

''(A) 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 pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

''(B) if an exemption for 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 unsafe within the meaning of section 402(a)(2)(B).

''(3) RESIDUES OF DEGRADATION PRODUCTS.—If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within

the meaning of section 402(a)(2)(B) despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

"(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

"(B) either—

"(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

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

"(C) the tolerance or exemption for residues of the precursor substance does not state that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

"(4) EFFECT OF TOLERANCE OR EXEMPTION.—While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 402(a)(1).

"(b) AUTHORITY AND STANDARD FOR TOLERANCE.—

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

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

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

As used in this section, the term 'modify' shall not mean expanding the tolerance to cover additional foods.

''(2) STANDARD.—

''(A) GENERAL RULE.—

''(i) STANDARD.—The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

''(ii) DETERMINATION OF SAFETY.—As used in this section, the term 'safe', with respect to a tolerance for a pesticide chemical residue', means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

''(iii) RULE OF CONSTRUCTION.—With respect to a tolerance, a pesticide chemical residue meeting the standard

under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

''(B) TOLERANCES FOR ELIGIBLE PESTICIDE CHEMICAL RESIDUES.—

''(i) DEFINITION.—As used in this subparagraph, the term 'eligible pesticide chemical residue' means a pesticide chemical residue as to which—

''(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a 'nonthreshold effect');

''(II) the lifetime risk of experiencing the nonthreshold effect is appropriately assessed by quantitative risk assessment; and

''(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to

in this section as a 'threshold effect'), the Administrator determines that the level of aggregate exposure is safe.

"(ii) DETERMINATION OF TOLERANCE.—Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

"(I) at least one of the conditions described in clause (iii) is met; and

"(II) both of the conditions described in clause (iv) are met.

"(iii) CONDITIONS REGARDING USE.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

"(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

"(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disrup-

tion in domestic production of an adequate, wholesome, and economical food supply.

''(iv) CONDITIONS REGARDING RISK.—For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

''(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

''(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

''(v) REVIEW.—Five years after the date on which the Administrator makes a determination to leave in effect or modify

a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

''(vi) INFANTS AND CHILDREN.—Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

''(C) EXPOSURE OF INFANTS AND CHILDREN.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for

a pesticide chemical residue, the Administrator—

"(i) shall assess the risk of the pesticide chemical residue based on—

"(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

"(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

"(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

"(ii) shall—

"(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

"(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of

safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

''(D) FACTORS.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

''(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

''(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

''(iii) available information concerning the relationship of the results of such studies to human risk;

''(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

''(v) available information concerning the cumulative effects of such residues and

other substances that have a common mechanism of toxicity;

''(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

''(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

''(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

''(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as

appropriate for the use of animal experimentation data.

"(E) DATA AND INFORMATION REGARDING ANTICIPATED AND ACTUAL RESIDUE LEVELS.—

"(i) AUTHORITY.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

"(ii) REQUIREMENT.—If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not

above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

''(F) PERCENT OF FOOD ACTUALLY TREATED.—In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

''(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

''(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

"(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

"(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

"(3) DETECTION METHODS.—

"(A) GENERAL RULE.—A tolerance for a pesticide chemical residue in or on a food shall not be established or modified 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.

"(B) DETECTION LIMIT.—A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

''(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 pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

''(c) AUTHORITY AND STANDARD FOR EXEMPTIONS.—

''(1) AUTHORITY.—The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

''(A) in response to a petition filed under subsection (d); or

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

''(2) STANDARD.—

''(A) GENERAL RULE.—

''(i) STANDARD.—The Administrator may establish or leave in effect an exemp-

tion from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

''(ii) DETERMINATION OF SAFETY.—The term 'safe', with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

''(B) FACTORS.—In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2).

''(3) LIMITATION.—An exemption from the requirement for a tolerance for a pesticide chemical

residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

''(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

''(B) that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

''(d) PETITION FOR TOLERANCE OR EXEMPTION.—

''(1) PETITIONS AND PETITIONERS.—Any person may file with the Administrator a petition proposing the issuance of a regulation—

''(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

''(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

''(2) PETITION CONTENTS.—

''(A) ESTABLISHMENT.—A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall

be supported by such data and information as are specified in regulations issued by the Administrator, including—

"(i)(I) an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

"(II) a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

"(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

"(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

"(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls

used in conducting those tests and investigations;

''(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

''(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

''(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

''(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

''(ix) such information as the Administrator may require to make the determination under subsection (b)(2)(C);

''(x) such information as the Administrator may require on whether the pes-

ticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

''(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

''(xii) practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

''(xiii) such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

''(B) MODIFICATION OR REVOCATION.—The Administrator may by regulation establish the requirements for information and data to

support a petition to modify or revoke a tolerance or to modify or 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 petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

''(4) ACTIONS BY THE ADMINISTRATOR.—

''(A) IN GENERAL.—The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

''(i) 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 res-

idue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

"(ii) issue a proposed regulation under subsection (e), and thereafter issue a final regulation under such subsection; or

"(iii) issue an order denying the petition.

"(B) PRIORITIES.—The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

"(C) EXPEDITED REVIEW OF CERTAIN PETITIONS.—

"(i) DATE CERTAIN FOR REVIEW.—If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health

than a pesticide chemical residue for which a tolerance has been left in effect or modified under subsection (b)(2)(B), the Administrator shall complete action on such petition under this paragraph within 1 year.

''(ii) REQUIRED DETERMINATIONS.—If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B). If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

''(e) ACTION ON ADMINISTRATOR'S OWN INITIATIVE.—

''(1) GENERAL RULE.—The Administrator may issue a regulation—

''(A) establishing, modifying, suspending under subsection (l)(3), or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

''(B) establishing, modifying, suspending under subsection (l)(3), or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

''(C) establishing general procedures and requirements to implement this section.

''(2) NOTICE.—Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period 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.

''(f) SPECIAL DATA REQUIREMENTS.—

"(1) REQUIRING SUBMISSION OF ADDITIONAL DATA.—If the Administrator determines that additional data or information are 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 person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act;

"(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act; or

"(C) publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days' duration, an order—

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

''(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act or section 4 of the Toxic Substances Control Act;

''(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

''(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

''(v) establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect pro-

duced by a naturally occurring estrogen or other endocrine effects.

''(2) NONCOMPLIANCE.—If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in question. In any review of such an order under subsection (g)(2), the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

''(g) EFFECTIVE DATE, OBJECTIONS, HEARINGS, AND ADMINISTRATIVE REVIEW.—

''(1) EFFECTIVE DATE.—A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with respect to such regulation or order pursuant to paragraph (2).

''(2) FURTHER PROCEEDINGS.—

"(A) OBJECTIONS.—Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1), a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

"(B) HEARING.—An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator 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 such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a 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 a reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

''(C) FINAL DECISION.—As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such 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 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.

''(h) JUDICIAL REVIEW.—

''(1) PETITION.—In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C), or any order issued under subsection (f)(1)(C) or (g)(2)(C), or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the 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, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

''(2) RECORD AND JURISDICTION.—A copy of the petition under paragraph (1) 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 such a petition, the court shall have exclusive jurisdiction to af-

firm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, 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.

''(3) 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.

''(4) FINAL JUDGMENT; SUPREME COURT REVIEW.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or any

order and any regulation which is the subject of such an 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 subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

''(5) APPLICATION.—Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

''(i) CONFIDENTIALITY AND USE OF DATA.—

''(1) GENERAL RULE.—Data and information that are or have been submitted to the Administrator under this section or section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality 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.

''(2) EXCEPTIONS.—

''(A) IN GENERAL.—Data and information that are entitled to confidential treatment

under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

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

"(ii) contractors with the United States authorized by the Administrator to examine such data and information in the carrying out of contracts under this Act or such statutes.

"(B) CONGRESS.—This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

"(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 issu-

ing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

''(j) STATUS OF PREVIOUSLY ISSUED REGULATIONS.—

''(1) REGULATIONS UNDER SECTION 406.—Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance 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 subsections (d) and (e), and shall be subject to review under subsection (q).

''(2) REGULATIONS UNDER SECTION 409.—Regulations that established tolerances for substances that are pesticide chemical residues in or on 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 rev-

ocation under subsection (d) or (e), and shall be subject to review under subsection (q).

''(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 in effect unless modified or revoked under subsection (d) or (e), and shall be subject to review under subsection (q).

''(k) TRANSITIONAL PROVISION.—If, on the day before the date of the enactment of this subsection, a substance that is a pesticide chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

''(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) or section 201(s) as then in effect; or

''(2) regarded by the Secretary as a substance described by section 201(s)(4);

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of the date of enactment of this subsection. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may

be modified or revoked as if it had been issued under subsection (c).

''(l) HARMONIZATION WITH ACTION UNDER OTHER LAWS.—

''(1) COORDINATION WITH FIFRA.—To the extent practicable and consistent with the review deadlines in subsection (q), in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act.

''(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 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 its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption

that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

''(A) the date by which each such cancellation of a registration has become effective; or

''(B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

''(3) SUSPENSION OF TOLERANCE OR EXEMPTION FOLLOWING SUSPENSION OF ASSOCIATED REGISTRATIONS.—

''(A) SUSPENSION.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, 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 that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that re-

sults from its use, in or on that food. Subsection (e) shall apply to actions taken 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. 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.

''(4) TOLERANCES FOR UNAVOIDABLE RESIDUES.—In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to the date of the enactment of this paragraph under the

Federal Insecticide, Fungicide, and Rodenticide Act, 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. In establishing such a tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) and the unavoidability of the residue. Subsection (e) shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than 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 that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such 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; and

"(B) the residue does not exceed a level that was authorized at the time of that 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 its likely availability in commerce will pose an unreasonable dietary risk.

"(6) TOLERANCE FOR USE OF PESTICIDES UNDER AN EMERGENCY EXEMPTION.—If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption

from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after the date of the enactment of this paragraph governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

''(m) FEES.—

''(1) AMOUNT.—The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

''(A) the acceptance for filing of a petition submitted under subsection (d);

''(B) establishing, modifying, leaving in effect, or revoking a tolerance or establishing, modifying, leaving in effect, or revoking an exemption from the requirement for a tolerance under this section;

''(C) the acceptance for filing of objections under subsection (g); or

''(D) the certification and filing in court of a transcript of the proceedings and the record under subsection (h);

may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection.

''(2) DEPOSIT.—All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act. Such fees shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator's services or functions as specified in paragraph (1).

''(n) NATIONAL UNIFORMITY OF TOLERANCES.—

''(1) QUALIFYING PESTICIDE CHEMICAL RESIDUE.—For purposes of this subsection, the term 'qualifying pesticide chemical residue' means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

''(A) was first approved for such use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, Rodenticide Act on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations in effect under 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 this subsection.

''(2) QUALIFYING FEDERAL DETERMINATION.—For purposes of this subsection, the term 'qualifying Federal determination' means a tolerance or exemption from the requirement for a tolerance for a qualifying pesticide chemical residue that—

"(A) is issued under this section after the date of the enactment of this subsection and determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption); or

"(B)(i) pursuant to subsection (j) is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (k) as exempt from the requirement for a tolerance; and

"(ii) is determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption).

"(3) LIMITATION.—The Administrator may make the determination described in paragraph (2)(B)(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 subsections (g) and (h).

''(4) STATE AUTHORITY.—Except as provided in paragraphs (5), (6), and (8) 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 such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such 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 a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

''(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 such qualifying pesticide chemical residue.

''(B) PETITION REQUIREMENTS.—Any petition 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 such State of food bearing the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

"(C) AUTHORIZATION.—The Administrator may, by order, grant the authorization described in subparagraph (A) if the Administrator determines that the proposed State regulatory limit—

"(i) is justified by compelling local conditions; and

"(ii) would not cause any food to be a violation of Federal law.

"(D) TREATMENT.—In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (d) to modify or revoke a tolerance or an exemption.

If the Administrator determines to treat a petition under this paragraph as a petition under subsection (d), the Administrator shall thereafter act on the petition pursuant to subsection (d).

''(E) REVIEW.—Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in subsections (g) and (h).

''(6) URGENT PETITION PROCEDURE.—Any State petition to the Administrator pursuant to paragraph (5) that demonstrates that consumption of a food containing such pesticide residue level during the period of the food's likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent petition. If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The temporary regulatory limit shall be validated or ter-

minated by the Administrator's final order on the petition.

"(7) 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 such residue, the sale of such food with such residue level was lawful under this section and under the law of such State, unless the State demonstrates that consumption of the food containing such pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within such State.

"(8) SAVINGS.—Nothing in this Act preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

"(o) CONSUMER RIGHT TO KNOW.—Not later than 2 years after the date of the enactment of the Food Quality Protection Act of 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of

Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

''(1) A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

''(2) A listing of actions taken under subparagraph (B) of subsection (b)(2) that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subparagraph (A) of such subsection, and the food on which the pesticide chemicals producing the residues are used.

''(3) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under paragraph (2).

Nothing in this subsection shall prevent retail grocers from providing additional information.

''(p) ESTROGENIC SUBSTANCES SCREENING PROGRAM.—

''(1) DEVELOPMENT.—Not later than 2 years after the date of enactment of this section, the Administrator shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

''(2) IMPLEMENTATION.—Not later than 3 years after the date of enactment of this section, after obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act or the science advisory board established by section 8 of the Environmental Research, Development, and Demonstration Act of 1978 (42 U.S.C. 4365), the Administrator shall implement the program.

''(3) SUBSTANCES.—In carrying out the screening program described in paragraph (1), the Administrator—

''(A) shall provide for the testing of all pesticide chemicals; and

''(B) may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance.

''(4) EXEMPTION.—Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

''(5) COLLECTION OF INFORMATION.—

''(A) IN GENERAL.—The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Adminis-

trator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

"(B) PROCEDURES.—To the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.

"(C) FAILURE OF REGISTRANTS TO SUBMIT INFORMATION.—

"(i) SUSPENSION.—If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a

hearing or the Administrator determines that the registrant has complied fully with this paragraph.

"(ii) HEARING.—If a person requests a hearing under clause (i), the hearing shall be conducted in accordance with section 554 of title 5, United States Code. The only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

"(iii) TERMINATION OF SUSPENSIONS.—The Administrator shall terminate a suspension under this subparagraph issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

"(D) NONCOMPLIANCE BY OTHER PERSONS.—Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under sec-

tion 16 of the Toxic Substances Control Act (15 U.S.C. 2601 and following) in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

''(6) AGENCY ACTION.—In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this Act, as is necessary to ensure the protection of public health.

''(7) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of this section, the Administrator shall prepare and submit to Congress a report containing—

''(A) the findings of the Administrator resulting from the screening program described in paragraph (1);

''(B) recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program; and

"(C) recommendations for any further actions (including any action described in paragraph (6)) that the Administrator determines are appropriate based on the findings.

"(q) SCHEDULE FOR REVIEW.—

"(1) IN GENERAL.—The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before the date of the enactment of the Food Quality Protection Act of 1996, as expeditiously as practicable, assuring that—

"(A) 33 percent of such tolerances and exemptions are reviewed within 3 years of the date of enactment of such Act;

"(B) 66 percent of such tolerances and exemptions are reviewed within 6 years of the date of enactment of such Act; and

"(C) 100 percent of such tolerances and exemptions are reviewed within 10 years of the date of enactment of such Act.

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections (b)(2) or (c)(2) and shall, by the deadline for the review of the tolerance or exemption, issue

a regulation under subsection (d)(4) or (e)(1) to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

''(2) PRIORITIES.—In determining priorities for reviewing tolerances and exemptions under paragraph (1), the Administrator shall give priority to the review of the tolerances or exemptions that appear to pose the greatest risk to public health.

''(3) PUBLICATION OF SCHEDULE.—Not later than 12 months after the date of the enactment of the Food Quality Protection Act of 1996, the Administrator shall publish a schedule for review of tolerances and exemptions established prior to the date of the enactment of the Food Quality Protection Act of 1996. The determination of priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking and shall not be subject to judicial review, except that failure to take final action pursuant to the schedule established by this paragraph shall be subject to judicial review.

''(r) TEMPORARY TOLERANCE OR EXEMPTION.—The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and

Rodenticide Act or upon the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) shall apply to actions taken under this subsection.

''(s) SAVINGS CLAUSE.—Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act or the Federal Insecticide, Fungicide, and Rodenticide Act.''.

SEC. 406. AUTHORIZATION FOR INCREASED MONITORING.

For the fiscal years 1997 through 1999, there is authorized to be appropriated in the aggregate an additional $12,000,000 for increased monitoring by the Secretary of Health and Human Services of pesticide residues in imported and domestic food.

SEC. 407. ALTERNATIVE ENFORCEMENT.

Section 303(g) (21 U.S.C. 333(f)) is amended—

(1) by redesignating paragraphs (2), (3), and (4) as paragraphs (3), (4), and (5), respectively,

(2) by inserting after paragraph (1) the following:

''(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) shall be subject to a civil

money penalty of not more than $50,000 in the case of an individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

''(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 304 or the injunction authorities of section 302 with respect to the article of food that is adulterated.

''(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 408(g)(2)(B). The third sentence of paragraph (3)(A) shall not apply to any investigation under this paragraph.'';

(3) in paragraph (3), as so redesignated, by striking ''paragraph (1)'' each place it occurs and inserting ''paragraph (1) or (2)'';

(4) in paragraph (4), as so redesignated, by striking ''(2)(A)'' and inserting ''(3)(A)''; and

(5) in paragraph (5), as so redesignated, by striking ''(3)'' each place it occurs and inserting ''(4)''.

TITLE V—FEES

SEC. 501. REREGISTRATION FEES.

(a) SECTION 4(i).—Section 4(i) (7 U.S.C. 136a–1(i)), as amended by section 232(2), is amended—

(1) in paragraphs (5)(H) and (6), by striking ''1997'' and inserting ''2001''; and

(2) in paragraph (5)(C), by inserting ''(i)'' after ''(C)'' and by adding at the end the following:

''(ii) in each of the fiscal years 1998, 1999, and 2000, the Administrator is authorized to collect up to an additional $2,000,000 in a manner consistent with subsection (k)(5) and the recommendations of the Inspector General of the Environmental Protection Agency. The total fees that may be collected under this clause shall not exceed $6,000,000.''.

(b) SECTION 4(k)(1).—Section 4(k)(1) (7 U.S.C. 136a–1(k)(1) is amended by inserting before the period the following: ''which shall be known as the Reregistration and Expedited Processing Fund''.

(c) SECTION 4(k)(2).—Section 4(k)(2) (7 136a–1(k)(2)) is amended to read as follows:

''(2) SOURCE AND USE.—

''(A) All moneys derived from fees collected by the Administrator under subsection (i) shall be deposited in the fund and shall be available to the Administrator, without fiscal year limitation, specifically to offset the costs of reregistration and expedited processing of the applications specified in paragraph (3). Such moneys derived from fees may not be expended in any fiscal year to the extent such moneys derived from fees would exceed money appropriated for use by the Administrator and expended in such year for such costs of reregistration and expedited processing of such applications. The Administrator shall, prior to expending any such moneys derived from fees—

''(i) effective October 1, 1997, adopt specific and cost accounting rules and procedures as approved by the General Ac-

counting Office and the Inspector General of the Environmental Protection Agency to ensure that moneys derived from fees are allocated solely to the costs of reregistration and expedited processing of the applications specified in paragraph (3) in the same portion as appropriated funds;

''(ii) prohibit the use of such moneys derived from fees to pay for any costs other than those necessary to achieve reregistration and expedited processing of the applications specified in paragraph (3); and

''(iii) ensure that personnel and facility costs associated with the functions to be carried out under this paragraph do not exceed agency averages for comparable personnel and facility costs.

''(B) The Administrator shall also—

''(i) complete the review of unreviewed reregistration studies required to support the reregistration eligibility decisions scheduled for completion in accordance with subsection (l)(2); and

''(ii) contract for such outside assistance as may be necessary for review of required studies, using a generally accepted competitive process for the selection of vendors of such assistance.''.

(d) SECTION 4(k)(3).—Section 4(k)(3) (7 U.S.C. 136a–1(k)(3)) is amended—

(1) in subparagraph (A), by striking out ''for each of the fiscal years 1992, 1993, and 1994, 1/7th of the maintenance fees collected, up to 2 million each year'' and inserting in lieu thereof ''for each of the fiscal years 1997 through 2001, not more than 1/7 of the maintenance fees collected in such fiscal year''; and

(2) by adding a new subparagraph (C) to read as follows:

''(C) So long as the Administrator has not met the time frames specified in clause (ii) of section 3(c)(3)(B) with respect to any application subject to section 3(c)(3)(B) that was received prior to the date of enactment of the Food Quality Protection Act of 1996, the Administrator shall use the full amount of the fees specified in subparagraph (A) for the purposes specified therein. Once all applications subject

to section 3(c)(3)(B) that were received prior to such date of enactment have been acted upon, no limitation shall be imposed by the preceding sentence of this subparagraph so long as the Administrator meets the time frames specified in clause (ii) of section 3(c)(3)(B) on 90 percent of affected applications in a fiscal year. Should the Administrator not meet such time frames in a fiscal year, the limitations imposed by the first sentence of this subparagraph shall apply until all overdue applications subject to section 3(c)(3)(B) have been acted upon.''.

(e) SECTION 4(k)(5).—Section 4(k)(5) (7 U.S.C. 136a–1(k)(5)) is amended to read as follows:

''(5) ACCOUNTING AND PERFORMANCE.—The Administrator shall take all steps necessary to ensure that expenditures from fees authorized by subsection (i)(5)(C)(ii) are used only to carry out the goals established under subsection (l). The Reregistration and Expedited Processing Fund shall be designated as an Environmental Protection Agency component for purposes of section 3515(c) of title 31, United States Code. The annual audit required under section 3521 of such title of the financial statements of activities under this Act under section

3515(b) of such title shall include an audit of the fees collected under subsection (i)(5)(C) and disbursed, of the amount appropriated to match such fees, and of the Administrator's attainment of performance measure and goals established under subsection (l). Such an audit shall also include a review of the reasonableness of the overhead allocation and adequacy of disclosures of direct and indirect costs associated with carrying out the reregistration and expedited processing of the applications specified in paragraph (3), and the basis for and accuracy of all costs paid with moneys derived from such fees. The Inspector General shall conduct the annual audit and report the findings and recommendations of such audit to the Administrator and to the Committees on Agriculture of the House of Representatives and the Senate. The cost of such audit shall be paid for out of the fees collected under subsection (i)(5)(C).''.

(f) GOALS.—Subsections (l) and (m) of section 4 (7 U.S.C. 136a–1), as amended by section 237, are redesignated as subsections (m) and (n) respectively and the following is inserted after subsection (k):

''(l) PERFORMANCE MEASURES AND GOAL.—The Administrator shall establish and publish annually in the

Federal Register performance measures and goals. Such measures and goals shall include—

''(1) the number of products reregistered, canceled, or amended, the status of reregistration, the number and type of data requests under section 3(c)(2)(B) issued to support product reregistration by active ingredient, the progress in reducing the number of unreviewed, required reregistration studies, the aggregate status of tolerances reassessed, and the number of applications for registration submitted under subsection (k)(3) that were approved or disapproved;

''(2) the future schedule for reregistrations, including the projection for such schedules that will be issued under subsection (g)(2)(A) and (B) in the current fiscal year and the succeeding fiscal year; and

''(3) the projected year of completion of the reregistrations under this section.''.

Passed the House of Representatives July 23, 1996.

Attest:

Clerk.