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FOOD QUALITY PROTECTION ACT OF 1996

JULY 11, 1996.—Ordered to be printed

Mr. ROBERTS, from the Committee on Agriculture,

submitted the following

R E P O R T

together with

ADDITIONAL VIEWS

[To accompany H.R. 1627]

[Including cost estimate of the Congressional Budget Office]

The Committee on Agriculture, to whom was referred the bill (H.R. 1627) to amend the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments (stated in terms of the introduced bill) are as follows:

Strike titles I through III and insert in lieu thereof the following:

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 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.".

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) taking into account available information and reasonable assumptions concerning the dietary exposure levels of food consumers (and major identifiable subgroups of food consumers, including infants and children) to residue of the pesticide in food and available information and reasonable assumptions concerning the variability of the sensitivities of major identifiable groups, including infants and children;

"(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. AUTHORITY OF STATES.

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

(1) in subsection (aa), by adding at the end the following new sentence: "The term 'State' does not include a local government, as defined in subsection (ii), and is not intended to grant any authority or to otherwise refer to local governments or political subdivisions of a State."; and

(2) by adding at the end the following:

"(ii) LOCAL GOVERNMENT.—The term 'local government' means any political subdivision of a State including counties, townships, cities, towns, parishes, and boroughs, whether home rule entities or not, or any local agency or body of any type which has an organized existence, governmental character, and substantial autonomy including independent or autonomous school districts, housing authorities, and other special districts.".

(b) RECORDS.—Section 8(b) (7 U.S.C. 136f(b)) is amended by striking "or political subdivision" in the first sentence.

(c) DELEGATION AND COOPERATION.—Section 22(b) (7 U.S.C. 136t(b)) is amended by striking "or any political subdivision thereof".

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

"(d) LOCAL REGULATION.—Subject to subsection (e), a local government shall not impose or continue in effect any requirement or regulation regarding pesticides or devices.

"(e) LOCALLY SPECIFIC STATE REGULATION.—Nothing in this section shall prohibit a State from enforcing laws, enacting laws, or implementing regulations applicable to local governments regarding the sale or use of any federally registered pesticide or device.".

(e) AUTHORITY OF ADMINISTRATOR.—The first sentence of section 25(e) (7 U.S.C. 136w(e)) is amended by striking "or political subdivision thereof".

SEC. 107. 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 control 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 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—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 con-

taining 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 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 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 provisions 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, beginning 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 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 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 extension 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 product 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 107(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 Committee 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 viruses, 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 eco-

nomic 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 determine 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 registration 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 sustain-

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

Add at the end the following:

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 Accounting 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) These Administrator shall complete the processing of the unprocessed expedited review applications within 5 years from the date of enactment of the Food Quality Protection Act of 1996.".

(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.".

TITLE VI—INDIAN TRIBES

SEC. 601. AUTHORITY OF INDIAN TRIBES.

(a) IN GENERAL.—Section 24 (7 U.S.C. 136v) is amended—

(1) in subsection (a), by inserting before the comma the following: "and an Indian tribe may only regulate the sale or use of any federally registered pesticide or device within the boundaries of a Federal Indian reservation for such tribe if at least 50 percent of the lands in such reservation are owned by members of the tribe or the tribe";

(2) in subsections (b) and (c), by inserting "or Indian tribe" after "State" each time it occurs; and

(3) in the section heading, by inserting before the period the following: "**AND INDIAN TRIBES**".

(b) ENFORCEMENT.—Section 26 (7 U.S.C. 136w–1) is amended—

(1) in subsection (a), by inserting "and an Indian tribe with respect to violations which occur within the boundaries of a Federal Indian reservation for such tribe, but only if at least 50 percent of the lands in such reservation are owned by members of the tribe or the tribe" after "violations" and by inserting "or Indian tribe" after "State" each place it occurs;

(2) in subsection (b), by inserting "or Indian tribe" after "State" in the first sentence;

(3) in subsection (c), by inserting "or Indian tribes" after "States"; and

(4) in the section heading, by inserting "**AND INDIAN TRIBE**" after "**STATE**".

BRIEF EXPLANATION

Title I, Subtitle A would amend various FIFRA provisions governing EPA regulation of pesticide distribution and use.

Section 102 would retain the current requirement that EPA issue a notice of its intention to cancel the registration or to change the classification of a pesticide before it issues an order of suspension. However, the bill would amend FIFRA to allow EPA to issue a suspension order in an emergency before issuing a notice of intent to cancel registration, as long as a notice was issued no more than 90 days after the emergency order. If a notice were not issued within 90 days, the emergency order would expire.

Current law requires all pesticides first registered for use prior to 1984 to be reregistered based on current standards. Section 103 of the bill would require EPA, when reregistering these older pesticides for uses on food and animal feed, to reevaluate pesticide residue limits (tolerances) and exemptions issued under the FFDCA Section 408 in light of the requirements of the amended Act. The section directs EPA to consider available information and reasonable assumptions about consumers' exposure to pesticide residue on foods, and specifically the exposures and sensitivities of infants and children.

Section 104 would create a Science Review Board of 60 scientists to assist the EPA Scientific Advisory Panel under FIFRA with reviews.

Section 105 would define "nitrogen stabilizers" for FIFRA purposes.

Section 106 would remove references to political subdivisions of states in sections of FIFRA that authorize state action to enforce FIFRA and that require EPA to coordinate such actions with state governments. Section 106 would prohibit local regulation of pesticides.

Section 107 would eliminate the existing provision of FIFRA that requires a registration to be canceled after 5 years. Instead, Section 107 would require periodic review of registrations with a goal of reviewing each pesticide every 15 years. The existing provision allowing sale and use of existing pesticide stocks after cancellation would be retained.

Title I, Subtitle B would add a new section to FIFRA to authorize states to establish minimum requirements for training of pesticide maintenance applicators, such as janitors and grounds maintenance personnel, and service technicians who use or supervise the use of pesticides for the purpose of providing structural or lawn pest control. Such requirements would not apply to government employees, individuals who use antimicrobial pesticides, private use of pesticides, or any use of ready-to-use consumer products pesticides. EPA's authority would be limited to ensuring that states understood the provisions of this section.

Title II, Subtitle A would address registration and reregistration of pesticides for relatively small-scale uses, such as fruit or nut production; these are known as "minor uses." Section 210(a) would add a definition for "minor use" to FIFRA.

Section 210(b) would extend the period of exclusive use of data supporting a minor use registration by the original registrant. The

current 10-year period of exclusive use would be expanded one additional year for each 3 minor uses registered within 7 years of the first registration. No exclusive use period would be longer than 13 years. Data supporting a new minor use registered after the original exclusive use period has lapsed would be protected for 10 years, as long as the data were not used to support a registration for a non-minor use and the minor use registration remained in effect.

Section 210(c) would require EPA to provide additional time for the submission of residue chemistry data supporting registration or reregistration of minor-use pesticides, if the registrant requests it; commits to provide data for any food use, or if all uses are non-food uses, for any other use; and the Administrator determines that the extension would not significantly delay a reregistration eligibility determination and would not significantly increase the risk of unreasonable adverse effects on the environment.

Section 210(d) would authorize EPA to waive data requirements for a minor-use pesticide registration if it would not adversely affect risk assessment or have an unreasonable adverse effect on the environment.

Section 210(e) would require expeditious review and action on complete applications for registration or reregistration of minor use pesticides. In addition, it would provide a full time period to submit data if a minor use waiver were requested and denied.

Section 210(f) would require EPA to delay action regarding an unsupported minor use reregistration until after the final data submission deadline for supported uses.

Section 210(g) would require the Administrator to defer for 180 days, 90 days longer than required under current law, a decision regarding a request for voluntary cancellation of a registration that might adversely affect the availability of the pesticide for a minor use. This would provide additional time for a registrant to reach an agreement with others to transfer registration of the pesticide. Section 210(g) also facilitates registrations that are transferred.

Section 210(h) would require EPA to process an application for a minor pesticide use without regard to any pending request to voluntarily cancel a substantially similar pesticide use.

Section 210(i) would establish a program in EPA to coordinate activities related to minor use pesticides. The USDA also would be required to coordinate its minor use pesticide activities. A minor-use, matching grant program would be established by USDA to develop data to support registrations. Section 210(i) would authorize appropriations of up to $10 million annually.

Title II, Subtitle B would amend FIFRA to expedite registration procedures for antimicrobial pesticides. The bill directs EPA to identify and evaluate reforms to the registration process for such pesticides in order to reduce review periods to the maximum extent practicable. Maximum time periods for review are specified in Subtitle B for various activities.

Title II, Subtitle C also would modify registration procedures for pesticides used to protect public health, for example, through the control of insect vectors. Subtitle C would mandate increased involvement by the Secretary of the Department of Health and Human Services (DHHS) in decisions about such pesticides. The Administrator would be directed to identify pests of significant pub-

lic health importance and to analyze and compare public health benefits of pesticide use against the risks. Up to $12 million would be authorized to be appropriated for this subtitle in FY1997.

Title II, Subtitle D would establish an expedited review process for applications to register or amend registrations for pesticides that are expected to reduce pesticide risks.

Title III would require the USDA Secretary, in consultation with EPA and DHHS, to coordinate the development and implementation of procedures to ensure collection of adequate data on food consumption patterns and pesticide exposures of infants and children. Title III also would establish a research, demonstration, and education program to support adoption of integrated pest management.

Title IV, as introduced, would amend the FFDCA to restructure the statutory authority for setting pesticide chemical residue tolerances and exemptions for food. It would not amend Section 409 which contains the Delaney Clause, but it would remove pesticide residues in processed food from the definition of a "food additive" and redefine other terms. The effect would be to require tolerances for all pesticide residues on raw and processed food to be based on a single negligible risk criterion, in accordance with new procedures set out in an amended Section 408.

Section 402 would redefine "pesticide chemical," "pesticide chemical residue," and "food additive," and define for the first time "processed food" and "Administrator."

Section 405 would rewrite FIFRA Section 408 so that EPA would be required to set tolerances at a level that the dietary risk to consumers from exposure to the pesticide is negligible. No quantitative standard of negligible risk would be required, but EPA would be directed to take into account the actual levels of residues on foods and USDA pesticide use and residue data. Section 405 would require EPA to consider a tolerance adequate to protect public health when it posed a risk that was not unreasonable, considering the risks avoided through pesticide use as well as the benefits conferred by an adequate, wholesome, and economical food supply. EPA would be prohibited from considering the economic effects of a tolerance level on the pesticide registrant, manufacturer, or marketer of a pesticide. Title IV would allow any person to petition EPA to establish, modify, or revoke a tolerance or an exemption.

Section 405 would codify EPA's "coordination policy" requiring EPA to cancel or suspend tolerances for pesticides when the relevant food-use registration has been canceled or suspended under FIFRA. It also provides for national uniformity of tolerances by prohibiting states and localities from issuing or enforcing different and more stringent tolerance limits on pesticide residues which they can do today; states would be allowed to petition EPA for a different tolerance.

Section 406 would authorize to be appropriated an additional $12 million for FDA monitoring of pesticide residues in imported and domestic food.

Title V Section 501 would extend EPA authorization to collect $14 million annually in registration maintenance fees from pesticide registrants until September 30, 2001. It authorizes collection of up to $2 million in additional fees in the years 1998, 1999, and 2000. EPA would be required to complete processing all pending

applications for expedited review within 5 years of enactment. Section 501 directs EPA to establish and publish annually performance measures and goals, including goals for reregistration, and to ensure that expenditures from fees are used only to accomplish those goals. The bill would require an annual audit of the fees collected and disbursed and of EPA attainment of performance goals.

Title VI would authorize Indian tribes to regulate the sale or use of any federally registered pesticide or device and to enforce violations of FIFRA on lands within the boundaries of a federal Indian reservation if at least 50% of such land is owned by members of the tribe or the tribe.

PURPOSE AND NEED

I

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947 was enacted to regulate the marketing of pesticides and devices, and for other purposes. In the intervening years, the Act was expanded to extend additional authority to the primary federal regulatory agency, the Environmental Protection Agency (EPA), to evaluate and regulate the human health and environmental risks of pesticides. By law, the EPA is authorized to register a pesticide for use in the United States only if a pesticide will not generally cause unreasonable adverse effects on human health or the environment. The FIFRA further specifies that a determination of unreasonable adverse effects requires a finding that the risks associated with the use of a pesticide outweigh the environmental, social and economic benefits associated with the pesticide's use.

Sound, verifiable scientific analysis is critical to ensuring rational regulatory decisions. Many pesticides have been registered, and several have been voluntarily or regulatorily cancelled, since the statute was first enacted. Over the years, the standards for pesticide evaluation and registration have generally evolved in tandem with science and public policy. In particular, test data requirements for pesticides have become increasingly stringent because of analytical advances in toxicology, oncology, residue chemistry, and other scientific disciplines. Under the FIFRA, pesticide registrants are responsible for providing all of the test data necessary to satisfy the EPA's registration requirements.

Titles I, II, and III of the bill are to ensure that the Administrator of EPA is able to make balanced regulatory decisions affecting the registration and use of pesticides. Particular changes to the FIFRA where necessary to preserve and advance the Administrator's ability to accomplish these regulatory decisions and clarify the Act where confusion had emerged. This is accomplished by providing the Administrator of EPA with sufficient authority to adjust pesticide evaluation and registration standards as scientific risk and benefit assessment technologies and methodologies advance, to react expeditiously to threats of imminent hazards as defined in the Act, clarify definitions and the Administrator's role in regulating nitrogen stabilizers, establish continuity among the states regarding the regulation of pesticides, and to ensure the Administrator has sufficient cooperation from the Departments of Agriculture and Health and Human Services in developing and utiliz-

ing dietary and other exposure data that will assist the Administrator in making sound science-based regulatory decisions.

II

The bill requires the Administrator of EPA to periodically review the registration of each pesticide. It has become apparent that the rapid development of science and the subsequent application of that knowledge in how it impacts human health and the environment is not only important but continuing to evolve. The goal of establishing ongoing scientific look-back procedures will enable the important process of registration review to be considered every 15 years during a pesticide product's market life. This creates a continuous reregistration process that both the Agency and the registrant can plan for, rather than creating the need for another complete, resource-intensive reregistration of all pesticide products at one time in the future.

III

A number of pesticides have not been evaluated against the current, more stringent standards that have been developed since the time when the pesticides were first approved. As a result of amendments to FIFRA in 1988, the registrations of pesticides licensed prior to 1984 are currently undergoing review based on the new standards (reregistration). The process of reregistration involves the production of additional data to support the continuation of the registration of a particular pesticide product label. This reregistration process has stimulated the voluntary cancellation of numerous labels important to the smaller acreage agricultural crops also known as "minor use" crops. If the EPA Administrator receives a commitment by a registrant to support a labelled use with the necessary data requirements to reregister that use it is allowed to remain available to farmers. If the labelled use is unsupported then that use is dropped from the label and becomes unavailable to farmers. In other words, reregistration has caused the registrant to withdraw support for minor use labels because of an economic choice between the cost of reregistration testing and future sales of that product. In the final analysis, this acts as a bias against minor uses because they are discontinued while registrants continue to support labels for major uses.

New pesticide registrations require a comprehensive safety testing data package for all labeled uses and few new pesticide product registrations seek labels allowing for use on minor crops. As registrants develop and register new generation pesticides, little economic incentive exists for registrants to pursue the costly safety testing to label them for minor use crops. Similar to the economic dilemma registrants face with reregistration, the potential sales a pesticide product may generate on a minor crop might be insufficient to justify the expense of the required safety data needed to realize a label for that particular crop. The result is fewer pesticide tools being registered for use on minor crops.

The development of regulatory mechanisms that create incentives for registrants to go to the trouble and expense of establishing labels that have uses for minor crops is important. The bill will cre-

ate the following, among other, incentives for a registrant to develop and maintain minor use labels:

(1) Provides to the registrant an additional 3 years of exclusive use of data to support the registration.

(2) Allows a time extension for submission of certain data.

(3) Allows for a waiver of certain data requirements as long as the absence of this data does not prevent a determination of the pesticide's risk.

(4) Allows for the expedited review of new minor use registrations.

IV

Pesticides utilized for the control of microorganisms in restaurants, hospitals, and institutions for sanitation reasons are indispensable. Protection against the presence and growth of microorganisms capable of food borne illness or spread of nosocomial infections need to be addressed through a diverse and efficacious arsenal of antimicrobial sanitizers. The antimicrobial pesticide registration process has been patterned after the process utilized for agricultural pesticides. The registration of antimicrobial pesticides have been plagued with inefficiencies and unnecessary delays. In order to improve upon the registration of antimicrobial pesticides and how those registrations are managed, the bill provides a definition for these important products and improves the registration efficiency by recognizing their unique purpose compared to that of other pesticide products. Furthermore, the bill will streamline label changes for registered antimicrobial products, and require Federal and State coordination where duplicative requirements exist.

V

Pesticides utilized for control of organisms responsible for spread of human illness are important to society. The spread of disease takes many forms and insect carriers or vectors can become a major public health problem. Insect vectors of human disease will continue to persist and new ones continue to emerge. Menacing vectors, such as the Asian Tiger Mosquito, that are capable of transmitting malaria, as well as other diseases, are able to survive under extreme climatic conditions, and therefore pose a grave public health concern and need to be controlled. Pesticides important to the quality of public health qualify as minor uses since they do not always provide sufficient economic incentive to the registrant to maintain existing registrations or support new registrations. The proposed legislation recognizes the distinctive need of these pesticides and that they should be evaluated for approval on a different standard. The bill requires EPA to evaluate a qualifying public health pesticide by comparing the risks from the pesticide to the risks associated with the disease transmitted by the vector.

VI

Many newer generation pesticides have the benefit of being more specific to the indicated target pest and having a shorter environmental life. These newer technologies contain important qualities and should be promoted. Recognizing that some pesticides may

have a reduced risk to human health and the environment, an expedited review by the Administrator of the Environmental Protection Agency would more rapidly advance the registration of these new pesticide tools, and would speed up end-use access to the next generation of pest management tools. The Administrator has already recognized the importance of expediting registrations of reduced risk pesticides. This section of the bill is to compliment and reinforce the processing of the registration applications of those pesticide products that the Administrator reasonably believes will reduce the risks of pesticide use to human health and to nontarget organisms, reduce the potential for contamination of environmental resources, and broaden the adoption of and improve the effectiveness of integrated pest management strategies.

VII

There is an increase in the concerns regarding the effects of pesticide food residues on the young, particularly on infants and children. The medical and risk assessment disciplines have voiced concern about the lack of good data on the dietary consumption patterns of infants and children. These same credible sources have indicated the absence of information on the dietary patterns of the young may be putting our children at risk relative to those pesticide residue tolerances based on generally accepted assumptions by the EPA instead of hard data. The Committee recognizes the need for this information and directs the Secretary of Agriculture (USDA), the Administrator of the EPA, and the Secretary of Health and Human Services (HHS) to coordinate the development and implementation of dietary survey procedures to ensure adequate data on the food consumption patterns of infants and children. It is also the Committee's expectation that USDA, EPA and HHS will extend this cooperative effort to related dietary surveys.

VIII

The 1988 amendments to the FIFRA established a seven-year time frame for the Administrator of EPA to complete the reregistration of the active ingredients and related pesticide products registered for use prior to 1985. Included in the reregistration provisions was the authority for the Administrator to collect fees to augment the Agency resources necessary to conduct reregistration. For several reasons, the Administrator will not be able to finish reregistration by the September 30, 1997 deadline. Therefore it is necessary to extend EPA's authority to annually collect $14 million in maintenance fees under FIFRA Section 4, for a total of $70 million over the five years authorized. In order to assist the Administrator with the so-called "back-log" of reregistration studies the bill authorizes an additional $6 million in fees that can be collected over the five year FIFRA reauthorization.

Due to the various reasons that this reregistration was not successfully completed in the time frame allotted by the 1988 FIFRA amendment, the Committee finds it necessary to establish financial and performance standards and implement an audit procedure for the reregistration process to ensure that the current and future Congresses have adequate information by which to judge the EPA's progress toward completing reregistration.

SECTION-BY-SECTION

Sec. 1. Short title

H.R. 1627 may be cited as the "Food Quality Protection Act of 1996."

TITLE I—SUSPENSION-APPLICATORS

Sec. 101. Reference

Section 101 states that whenever this title provides for amendment to, or repeal of, a section or other provision, the referenced section or provision is of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA; 7 USC 136).

SUBTITLE A—SUSPENSION

Sec. 102. Suspension

Section 102 would amend Section 6(c) of FIFRA (7 USC 136d(c)) pertaining to the necessary suspension of a pesticide registration to prevent an imminent hazard during the time required for cancellation or change in classification proceedings. Existing law requires, as a condition for ordering a suspension, issuance of a notice of intention to cancel the registration or to change the pesticide classification. This provision would be retained. However, under the amended Section 6(c), EPA could issue an emergency order before issuing a notice of its intent to cancel a registration (or to change a pesticide classification). However, if a notice were not issued within 90 days of the issuance of the emergency order, the emergency order would expire.

Sec. 103. Tolerance reevaluation as part of reregistration

Section 103 would amend FIFRA Section 4(g)(2) (7 USC 136a-1(g)(2)), pertaining to reregistration of pesticides, by adding at the end a new subparagraph (E) requiring the Administrator: (i) to reassess each pesticide residue tolerance and exemption from the requirement for a tolerance issued under Section 408 of the FFDCA; (ii) to determine whether it meets requirements of the FFDCA (as it would be amended by the "Food Quality Protection Act of 1995"; (iii) to determine whether additional tolerances or exemptions should be issued; (iv) to publish a notice of these determinations in the Federal Register; and (v) promptly to commence such proceedings as are warranted under FIFRA and the new Section 408 of the FFDCA, as soon as there is sufficient information with respect to the dietary risk of a particular active ingredient and no later than when a determination is made as to whether pesticides containing a particular active ingredient should or should not be reregistered. In reassessing tolerances and exemptions, it directs EPA to consider available information and reasonable assumptions concerning dietary exposure levels of consumers, including major identifiable subgroups such as infants and children, and the variability of sensitivities of such groups.

Sec. 104. Scientific advisory panel

Section 104(1) would amend FIFRA Section 25(d) (7 USC 136w(d)) by making the existing provisions establishing the Scientific Advisory Panel a single subsection (1) and adding the subsection title "IN GENERAL."

Section 104(2) would amend FIFRA Section 25(d) (7 USC 136w(d)) by adding a new subsection (2) creating a Science Review Board consisting of 60 scientists selected and compensated in the same way as members of temporary subpanels created under subparagraph (1). The Board would be available to assist in reviews conducted by the Panel.

Sec. 105. Nitrogen stabilizer

Section 105(a)(1) would amend the definition for "active ingredient" in FIFRA Section 2(a) (7 USC 136(a)) to distinguish the function of active ingredients in nitrogen stabilizers from the functions of other active ingredients. The stated function of an active ingredient in a nitrogen stabilizer would be to "prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria."

Section 105(a)(2) would expand the definition of "pesticide" in Section 2(u) to include nitrogen stabilizers.

Section 105(a)(3) would add a definition at clause (hh) for "nitrogen stabilizer" which excludes from the definition (1) dicyandiamide, (2) ammonium thiosulfate, or (3) any substance or mixture of substances that (A) were not registered prior to January 1, 1992 pursuant to Section 3, and (B) were in commercial agronomic use prior to January 1, 1992; such substances would be excluded from the definition of nitrogen stabilizer if the distributor or seller "has made no specific claim of prevention or hindering of the process of nitrification, denitrification, ammonia volatilization[, or] urease production" after January 1, 1992, "regardless of the actual use or purpose for, or future use or purpose for, the substance or mixture." Statements in materials required to be submitted to a state legislative or regulatory authority or required by such authority to be included in the labelling or other literature for such substance or mixture, would not be considered "a specific claim" for the purpose of this subsection.

Section 105(b) would amend FIFRA Section 3(f) (7 USC 136a(f)), pertaining to miscellaneous matters related to pesticide registration, by adding a new paragraph (4) providing that a mixture of registered nitrogen stabilizers and fertilizer products is not subject to the provisions of Sections 3, 4, 5, 7, 15, or 17(a)(2) if the mixture is labelled as required for the nitrogen stabilizer contained in the mixture, the mixture is in accordance with the label, and the mixture does not contain any other active ingredient.

Sec. 106. Authority of States

Section 106(a)(1) would amend FIFRA Section 2(aa) (7 USC 136(aa)) by adding to the definition of "state" to exclude a local government (as defined in new subsection (ii) below). Section 106(a)(1) also would clarify that the definition is not intended to grant any authority or to otherwise refer to political subdivisions of a state.

Section 106(a)(2) would add a new subsection (ii) to define "local government."

Section 106(b) would amend FIFRA Section 8(b) (7 USC 136f(b)) to eliminate the requirement that pesticide facilities permit political subdivisions of a state access to facility records for the purpose of FIFRA enforcement.

Section 106(c) would amend FIFRA Section 22(b) (7 USC 136t(b)) to eliminate the requirement for EPA to cooperate with political subdivisions of states in implementing FIFRA and in securing uniformity of regulations.

Section 106(d) would amend Section 24 (7 USC 136v), pertaining to the authority of state governments, by adding two new subsections. New Section 24(d) would prohibit local governments from imposing or continuing in effect any regulation or requirement regarding pesticides or devices. New Section 24(e) would declare that Section 24 does not prohibit state enforcement or enactment of laws or implementation of regulations applicable to local governments regarding the sale or use of a federally registered pesticide or device.

Section 106(e) would amend Section 25(e) (7 USC 136w(e)) pertaining to peer review. New Section 25(e) would not require peer review for studies conducted by a political subdivision of a state.

Sec. 107. Periodic registration review

Section 107(a) would rewrite FIFRA Section 6(a) (7 USC 136d(a)) which currently requires EPA to cancel registration of any pesticide at the end of the 5-year period beginning on the date of its registration unless the registrant requests that the registration be continued in effect. The current law permits continued sale and use of existing stocks of a pesticide whose registration is canceled "to such extent, under such conditions, and for such uses as the Administrator may specify, if the Administrator determines that such sale or use is not inconsistent with the purposes of FIFRA and will not have unreasonable adverse effects on the environment." New Section 6(a) would eliminate the requirement for cancellation and permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled "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."

Section 107(b) would amend Section 3, pertaining to registration, by adding a new subsection (g). New Section 3(g)(1)(A) would require registrations of pesticides to be periodically reviewed. It would direct the Administrator to promulgate rules establishing a procedure for such review with a goal of review for each pesticide's registration every 15 years. Cancellation of registration as a result of the review would be permitted only if EPA followed the procedures and substantive requirements of Section 6. New Section 3(g)(1)(B) states that the subsection would not prohibit EPA from undertaking any other review of a pesticide authorized under FIFRA.

New Section 3(g)(2)(A) would direct EPA to use its authority in Section 3(c)(2)(B) to require submission of any data needed for registration review.

New Section 3(g)(2)(B) would extend the application of subsections 3(c)(1), 3(c)(2)(B), and 3(c)(2)(D) to data required for registration renewal under this subsection.

SUBTITLE B—TRAINING FOR MAINTENANCE APPLICATORS AND SERVICE TECHNICIANS

Sec. 120. Maintenance applicators and service technicians definitions

Section 120 would amend FIFRA Section 2 by adding a new definition at clause (jj) for "maintenance applicator." The term would be defined to mean any individual who, in the principal course of employment, uses, or supervises the use of, a pesticide not classified for restricted use (other than a ready-to-use consumer product); for the purpose of providing structural pest control or lawn pest control including janitors, general maintenance personnel, sanitation personnel, and grounds maintenance personnel. The term would not include private applicators as defined in Section 2(e)(2); individuals who use antimicrobial pesticides, sanitizers or disinfectants; individuals employed by federal, state, or 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, green houses, or other non-commercial property.

Section 120 also would add a new definition for "service technician" at clause (kk) of Section 2. The term "service technician" would mean any individual who uses or supervises the use of pesticides (other than ready-to-use consumer products) for the purpose of providing structural pest control or lawn pest control on the property of another for a fee. The term would 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

Section 121 would amend FIFRA by redesignating Sections 30 and 31 as Sections 32 and 33, respectively and by adding a new Section 30. New Section 30 would authorize states to establish minimum requirements for training of maintenance applicators and service technicians, including instruction in the safe and effective handling and use of pesticides in accordance with EPA-approved labels and in integrated pest management techniques. Section 121 would limit EPA authority under this section to ensuring that each state understands the provisions.

The fiscal 1996 appropriations law for the Environmental Protection Agency (P.L. 104-134) provided the Administrator the authority to make grants annually from funds appropriated under the state and Tribal Assistance Grants section. The grants, referred to by the Agency as Performance Partnership Grants, could be made to any State or a federal recognized Indian tribe for multimedia or single media pollution prevention, control and abatement, and related environmental activities at the request of the Governor or other appropriate State official or the tribe. The Committee is seriously concerned about the implementation of these grants; specifi-

cally that the pesticide enforcement programs in the states may not receive the funding necessary to ensure the proper use of pesticides or the safety of the food supply. The Committee is concerned that these important pesticide enforcement funds could, inappropriately, be used to fund other programs. To ensure that safety of the American food supply, the Committee fully expects and intends that in implementing the Performance Partnership Grants, the Agency will ensure that all pesticide enforcement and program monies continue to be provided to the state lead pesticide agency responsible for pesticide enforcement. The Committee further expects and intends that EPA will ensure that pesticide enforcement and programs funds will not be used for other environmental purposes.

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

Sec. 201. Reference

Section 201 establishes that whenever this title provides for amendment to, or repeal of, a section or other provision, the referenced section or provision is of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA; 7 USC 136).

SUBTITLE A—MINOR USE CROP PROTECTION

Sec. 210. Minor crop protection

Section 210(a) would add a definition for "minor use" in a new subsection (ll) of FIFRA Section 2 (7 USC 136). "Minor use" would be defined as the use of a pesticide on an animal, commercial agricultural crop, or site, or for the protection of public health where: (1) total acreage is less than 300,000 acres, as determined by the Secretary of Agriculture, or (2) the use does not provide sufficient economic incentive to support the initial registration or continuing registration for such use, as determined by the Administrator in consultation with the Secretary of Agriculture based on information provided by an applicant for registration or a registrant, and either (A) there are too few effective alternative pesticides registered for the use, (B) alternatives for the use pose greater risks to the environment or human health, (C) the pesticide is important in managing pest resistance, or (D) the pesticide is important in an integrated pest management (IPM) program. Section 210(a) would allow a pesticide to retain its status as a minor use pesticide as long as the pesticide satisfied the definition, and the Administrator had not decided that such use might cause an unreasonable adverse effect on the environment.

Section 210(b) would amend Section 3(c)(1)(F) (7 USC 136a(c)(1)(F)), which establishes requirements for submissions of scientific data in support of pesticide registration. Section 3(c)(1)(F)(i) of existing law provides that data submitted to support the application for the original registration of a pesticide shall not be considered to support an application by another person during a period of ten years following the date the pesticide is first registered. Section 210(b) would redesignate clauses (ii) and (iii) as clauses (iii) and (iv), respectively, and add a new subparagraph (ii). It would extend the period of exclusive use of data submitted to support the application for the original registration of a pesticide

for one additional year for each 3 minor uses registered after the date of enactment of the "Food Quality Protection Act of 1995" and within 7 years of the commencement of the period, up to a total of 3 additional years for all minor uses registered, if: (I) there are too few effective alternative registered pesticides available for the use, (II) alternatives to the minor use pesticide pose greater risks, (III) the pesticide is important in managing pest resistance, or (IV) the pesticide is important to an IPM program. A minor use on a crop grouping established by the Administrator would be considered one minor use for each representative crop for which data are provided in the crop grouping. Additional periods of exclusive use would be modified or terminated if registration for the product or relevant minor use is voluntarily canceled or if the Administrator determines that the product is not actually being marketed for such minor use. Section 210(b) would add a clause (v) to FIFRA Section 3(c)(1)(F) directing that this period of exclusive use provided under clause (ii) may not take effect until one year after enactment of H.R. 1627, except when the application is for registration of a pesticide containing an active ingredient not previously registered.

Section 210(b) also would add a clause (vi) to FIFRA Section 3(c)(1)(F) to provide 10 years of protection for data submitted after enactment in support of an amendment to allow a new minor use of a registered pesticide with no remaining period of data protection. Such exclusive use data would no longer be protected if the minor use registration were canceled voluntarily or if the data were used to support a non-minor use.

Section 210(c)(1) would amend Section 3(c)(2)(B) (7 USC 136a(c)(2)(B)), pertaining to registration, by adding a new clause (vi) to extend (under certain circumstances specified below) the deadline for producing residue chemistry data to support product registration or reregistration for a minor use until the final deadline for submission of data under Section 4 for the other uses of the pesticide that were established before the date of enactment of the "Food Quality Protection Act of 1995." A deadline may be extended if a registrant so requests, and if: (I) data are being provided to support other uses, (II) a schedule to measure progress is provided by the registrant to assure that the data will be complete prior to the end of the extension period, (III) such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination (RED), and (IV) the Administrator has determined based on existing data that such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension, the bill would require monitoring of data development to ensure that the registrant is meeting the schedule. If the registrant does not meet the schedule for data production, the bill would authorize the Administrator to consider the data in support of an application by another applicant or otherwise to proceed in accordance with other provisions of the relevant section regarding continued registration of the affected products. The Administration would be required to inform the public of such action. In addition, the bill would authorize the Administrator to modify or revoke the extension if it may cause an unreasonable adverse effect on the environment. Written notice revoking the extension of time for data sub-

mission must be provided to the registrant. In such cases, data would be due in accordance with the date established by the Administrator prior to granting the extension.

Section 210(c)(2) would amend each of the three FIFRA sections 4(d)(4)(B), 4(e)(2)(B), and 4(f)(2)(B) (7 USC 136a–1(d)(4)(B), (e)(2)(B), and (f)(2)(B)), pertaining to reregistration, in the same manner as Section 210(c)(1) amends Section 3(c)(2)(B).

Section 210(d) would amend Section 3(c)(2) (7 USC 136a(c)(2)) to add headings to existing subparagraphs (A), (B), and (C) and to add a new subparagraph (E) authorizing the Administrator to waive applicable data requirements for registering a pesticide for a minor use if the Administrator determined that the incremental risk posed by the minor use could be assessed without such data and such risk would not be an unreasonable adverse effect on the environment.

Section 210(e) would amend Section 3(c)(3) (7 USC 136a(c)(3)). Paragraph (1) of Section 210(e) would add a heading to existing subparagraph (A). Paragraph (2) would do the same to existing subparagraph (B). Section 210(e)(3) would add two new subparagraphs (C) and (D) pertaining to registration of minor uses. New Section 3(c)(3)(C)(i) would require the Administrator to act as expeditiously as possible to review and act on a complete application: (I) to initially register a new active ingredient solely for minor uses, to amend a registration solely to include minor uses, or (II) to register or amend a registration for significant minor uses. New Section 3(c)(3)(C)(ii)(I) would define "as expeditiously as possible" to mean that review and evaluation of all data should be completed to the greatest extent practicable within 12 months after submission of the application. Failure of the Administrator to complete such a review would not be subject to judicial review. New Section 3(c)(3)(C)(ii)(II) would define "significant minor uses" to mean: 3 or more minor uses proposed for every non-minor use; a minor use that would replace any use that had been canceled during the 5 preceding years; or a minor use that would avoid the reissuance of an emergency exemption under Section 18 for that minor use.

New Section 3(c)(3)(D) would provide a full time period for providing data to EPA if the registrant made a request for a minor use waiver pursuant to new paragraph (2)(E), and the Administrator denied the request in whole or in part. "Full time period" would mean the time period originally established for submission of such data beginning with the date of receipt by the registrant of the notice of denial.

Section 210(f)(1)(A) would amend FIFRA Sections 4(d)(6) and 4(f)(3) (7 USC 136a–1 (d)(6) and (f)(3)), pertaining to the reregistration of pesticides, to require that if a registrant so requests, the Administrator would not take any action regarding an unsupported minor use of a pesticide until after the final data submission deadline for the supported uses, unless the absence of data is significant enough to cause human health or environmental concerns. In the case that absence of data is significant, the Administrator would be authorized to refuse the request for extension of the time period. An unsupported minor use would include any specific minor use of a pesticide which the registrant did not commit to support when the registrant was providing data in a timely and adequate fashion

to support uses of the same pesticide on a food or, when all uses of the pesticide are nonfood uses, on other nonfood uses. The bill would require EPA to publish in the Federal Register a notice of receipt of a request and the effective date upon which the unsupported uses would be voluntarily deleted from the registration pursuant to Section 6(f)(1). If an extension were granted, the Administrator would be required to monitor the development of the data for the supported uses and to ensure that the registrant is meeting the schedule for data production. If the schedule were not being met, the bill would authorize the Administrator to proceed in accordance with the procedure in Section 3(c)(2)(B)(iv) to suspend registration; in such cases, the Administrator would be required to inform the public of such action in accordance with Section 6(f)(2). In addition, Section 210(f) would authorize the Administrator to deny, modify, or revoke a temporary extension under this paragraph if continuation of the minor use may cause an unreasonable adverse effect on the environment. If the temporary extension were to be revoked, the Administrator would be required to provide the registrant written notice and a new effective date when the minor use would be deleted from the registration.

Section 210(f)(1)(B) would amend Section 4(e)(3)(A) (7 USC 136a–1(e)(3)(A)), also pertaining to reregistration, in the same way that Section 210(f)(1)(A) would amend Sections 4(d)(6) and 4(f)(3).

Section 210(f)(2) would amend new Section 3(c)(2)(B) (7 USC 136a(c)(2)(B)), pertaining to data submission to support an initial registration, in the same way as Section 210(f)(1)(A) would amend Sections 4(d)(6) and 4(f)(3).

Section 210(g) would amend FIFRA Section 6(f) (7 USC 136d(f)) which contains general provisions pertaining to changes in classification, cancellation, suspension, and other terms and conditions of registration. New Section 6(f)(1)(C)(ii) would lengthen the normal waiting period from 90 days to 180 days during which time EPA may not respond to a request for voluntary cancellation of a registration when EPA determines that such cancellation or termination of uses would adversely affect the availability of the pesticide for use and the pesticide is registered for a minor use. Section 210(g) amends Section 6(f)(3)(A) to reflect the longer period which is available for registrants to reach an agreement with others to transfer registration of the pesticide in lieu of canceling or amending it to terminate use.

Section 210(h) also would amend Section 6(f) (7 USC 136d(f)) by adding a new paragraph (4). If a registrant requested voluntary cancellation of a pesticide registration for a minor use while an application (by a different applicant) was pending for registration of a substantially similar pesticide for a substantially similar minor use, new Section 6(f)(4) would require the Administrator to process, review, and evaluate the pending application as if the voluntary cancellation had not yet taken place, except if such minor use may cause an unreasonable adverse effect on the environment. The new Section 6(f)(4), however, would require an applicant to certify agreement to satisfy any outstanding data requirements needed to support the registration in accordance with the schedule established by the Administrator.

Section 210(i) would amend FIFRA by redesignating Sections 31 and 32 as Sections 33 and 34, respectively, and adding a new Section 31. New Section 31(a) would require the Administrator to assure coordination of minor use issues by establishing a minor use program within the Office of Pesticide Programs at EPA. The program would be required to coordinate the development of minor use programs and policies and to consult with growers regarding minor use issues and registrations and amendments submitted to the Agency.

New Section 31(b) would direct EPA's Office of Pesticide Programs to prepare a report within 3 years on the progress in registering minor uses, including implementation of the exclusive use as an incentive for registering new minor uses.

Section 210(j) would amend FIFRA by adding a new Section 32. New Section 32(a) would require the Secretary of Agriculture to ensure the coordination of the responsibilities of USDA related to minor uses of pesticides, including: (1) the Inter-Regional Project Number 4 (IR–4), the national pesticide resistance monitoring program, (2) IPM research, (3) consultation with growers to develop data for minor use, and (4) providing assistance for minor use registrations, tolerances, and reregistrations with the EPA.

New Section 32(b)(1)(A) would require the Secretary of Agriculture to establish a minor use grant program to ensure the development of data to support minor use pesticide registrations and reregistrations. The amount of such grants would be limited to no more than one half the cost of each project. New Section 32(b)(1)(B) would authorize any person desiring to develop data to support minor use pesticide registrations to apply for a grant. Priority for grants would be given to applicants who would not directly receive funds from the sale of pesticides registered on minor uses. New Section 32(b)(1)(C) states that any data developed through the program would be jointly owned by the person who received the grant and USDA, and that such person must enter into an agreement with USDA to share any fee paid to such person under Section 3(c)(F). New Section 32(b)(2)(A) would establish in the Treasury a revolving fund to be known as the Minor Use Pesticide Data Revolving Fund. No fiscal year limitation is imposed on the availability of the fund to carry out the authorized purposes of this subsection. New Section 32(b)(2)(B) would require to be deposited in the fund such amounts as may be appropriated to support the purposes of the subsection and any fees collected by the Secretary for any data developed under a grant under paragraph (a)(A). New Section 32(b)(2)(C) would authorize to be appropriated $10,000,000 annually to carry out the purposes of the subsection, to remain available until expended.

SUBTITLE B—ANTIMICROBIAL PESTICIDE REGISTRATION REFORM

Sec. 221. Definitions

Section 221 would amend the definition of "pesticide" at FIFRA Section 2(u) (7 USC 136(u)) to exclude 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 FFDCA Section 201 (21 USC 321) (that is, devices that

come into contact with the human body). Section 221 also would amend Section 2 by adding a new subsection (mm) defining the term "antimicrobial pesticide" to mean a pesticide that: (A) is intended to (i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or (ii) to 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 not subject to, a tolerance under Section 408 or 409 of the FFDCA. Antimicrobial pesticides do not include wood preservatives or antifouling paint products for which a claim is made of pesticidal activity other than an activity described in the definition. The definition also excludes agricultural fungicide products and aquatic herbicide products from the definition of "antimicrobial pesticide." The definition does include any other chemical sterilant product (except liquid chemical sterilant products exempt by Section 2(u)), disinfectant product, industrial microbiocide, and preservative product.

Section 222 would amend Section 3(c)(2)(B) (7 USC 136a(c)(2)(B)), pertaining to data submissions to support pesticide registration applications, by adding at the end new clause (vi). New clause (vi)(I) would direct the Administrator, to the extent practicable, to coordinate data requirements, test protocols, timetables, and standards of review with state and federal authorities that request data described in FIFRA Section 3(c)(2)(A). New subclause (II) authorizes cooperative agreements that achieve the goals of the clause between EPA and the states. New clause (vi)(III) also would require the Administrator to develop a process within one year of enactment to identify and assist in alleviating future federal/state data requirement disparities.

Section 223 of the "Food Quality Protection Act of 1995" would amend Section 3(c) (7 USC 136(a)(c)) by adding a new paragraph (9) pertaining to labels and labeling statements. Subparagraph (A) of new paragraph (9) would permit a registrant of an antimicrobial pesticide to change the label to include information about product efficacy, product composition, container composition or design, or other features not related to a pesticidal claim.

New subparagraph (B) would prohibit false or misleading labels and any changes that conflict with or detract from required statements. Proposed statements on labels must be substantiated at the request of EPA.

New subparagraph (C)(i) would allow registrations to be amended if (I) the registrant notifies EPA in writing at least 60 days prior to distribution or sale of products bearing the amended labels, and (II) EPA does not disapprove the change. New clause (ii) authorizes EPA disapproval; applicants must be notified in writing of EPA disapproval within 30 days of receipt of the registrant's notice. Clause (iii) prohibits sale and distribution of a product with a disapproved label. Clause (iv) would allow a registrant to file an objection in writing within 30 days of receiving a disapproval. Finally, new clause (v) would make the Administrator's decision after consideration of an objection a final agency action.

Subparagraph (D) of new paragraph (9) would allow the label or labeling requirement for an antimicrobial pesticide that is or may

be diluted for use, to contain a different statement of caution or protective measures for use of recommended diluted solutions of the pesticide than for the use of concentrates of the pesticide. However, new clause (i) would compel the registrant to submit adequate data to support the statement, and clause (ii) would require the label to provide adequate protection for exposure to the dilute solution of the pesticide.

Section 224 would amend registration requirements in FIFRA Section 3 (7 USC 136a) by adding a new subsection (g) for antimicrobial pesticides. New Section 3(g)(1) would require the Administrator to identify and evaluate reforms to the antimicrobial registration process to reduce current review periods to the maximum extent practicable, consistent with the degree of risk posed by the pesticide and type of review appropriate, for: (A) new antimicrobial active ingredients, (B) new antimicrobial end-use products, (C) substantially similar or identical antimicrobial pesticides, and (D) amendments to existing antimicrobial pesticide registrations.

New Section 3(g)(2) would mandate that the reforms required by new paragraph (1) be designed to achieve a goal of reducing the review period for each action, after a complete application is submitted and consistent with the degree of risk, to a period of no 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 a current antimicrobial registration that does not require scientific review of data, and (F) 90 to 180 days for an amendment to a current antimicrobial registration that requires scientific review of data.

Within 270 days of the date of enactment, paragraph (3)(A)(i) of new subsection (g) would require the Administrator to publish in the Federal Register proposed rules to accelerate and improve review of antimicrobial pesticide products to the extent practicable to achieve the goals of paragraph (2). Clause (ii) would require that proposed rules: (I) define various classes of antimicrobial use patterns, such as household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, pulp and paper mill additives, and similar products; (II) differentiate types of review for antimicrobial pesticides; (III) conform the degree and type of review to the risks and benefits of the pesticides and the function of the review considering patterns of use of the product, its toxicity, expected exposure, and the product type; (IV) ensure that registration is sufficient to maintain pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each label claim; and (V) implement effective and reliable deadlines for process management. New clause (iii) would require the Administrator to solicit views of registrants and other affected parties in developing the proposed regulations.

New paragraph (3)(B)(i) would provide 240 days from the close of the comment period for EPA to issue the final rules. If final rules would not attain a goal specified in paragraph (2), clause (ii)

would require EPA to identify the goal, explain why it was not attained, describe provisions of the regulation in lieu of the goal, and identify future steps to attain it. New clause (iii) would require the Administrator in issuing regulations: (I) to consider establishing a certification process for regulating risks that could be managed responsibly consistent with their degree in the most cost-efficient manner; (II) to consider establishing a certification process by approved laboratories, as an adjunct to the review process; (III) to utilize 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 and sufficient resources to ensure streamlined management of antimicrobial pesticide registrations; and (IV) clarify criteria for determining the completeness of an application.

New Section 3(g)(3)(C) states that subsection (g) does not affect requirements of subsection (c)(3).

New Section 3(g)(3)(D) would establish review periods specified in new clauses (i) through (vii) for antimicrobial pesticide applications, if the final rules implementing new paragraph (3) were not effective 630 days after the date of enactment of new subsection (g). The specified time periods for review would begin on the date the Agency received a complete application. New clause (i) would limit review for a new active ingredient pesticide registration to 2 years. New clause (ii) would limit review for a new use of a registered active ingredient to 1 year. New clause (iii) would limit review of any other new product to 180 days. New clause (iv) would limit review for a substantially similar or identical product to 90 days. New clause (v) would limit review for an amendment to a current registration that does not require scientific review of data to 90 days. New clause (vi) would limit review for an amendment to a current registration that requires scientific review of data to 240 days.

New subparagraph (E) would require EPA to review an application for registration (or amendment to a registration) of a wood preservative product in the same time period as established for an antimicrobial pesticide product, consistent with the degree of risk posed, if a claim is made for antimicrobial pesticide activity as described in section 2(mm)(A) and the applicant is required to satisfy the data requirements otherwise required for a wood preservative product that is an antimicrobial pesticide.

New Section 3(g)(3)(F) would establish notification requirements related to review periods. Clause (i) of new subparagraph (F) would generally require the Administrator to notify the registrant whether an application has been granted or denied before the end of the appropriate review period specified in new paragraph (3). New clause (ii) would deem EPA failure to notify the registrant as required under new clause (i) a final agency action unlawfully withheld or unreasonably delayed and subject to judicial review under 5 USC 706(1). New clause (iii) states that the subparagraph (F) does not apply to applications filed prior to 90 days after the date of enactment.

New Section 3(g)(4) would require the Administrator to prepare and submit an annual report, due March 1 of each year after the date of enactment until the reform goals specified in new subsection (g) have been achieved, to the House Committee on Agri-

culture and the Senate Committee on Agriculture, Nutrition, and Forestry. As required by subparagraph (B), the report would include (i) measures taken to reduce the backlog of pending registration applications, (ii) progress toward achieving reforms, and (iii) recommendations to improve EPA activities pertaining to antimicrobial registrations.

Section 225 amends FIFRA Section 19(h) (7 USC 136q(h)) by adding at the end a statement that household, industrial, and institutional antimicrobial products that are not subject to regulation under the Solid Waste Disposal Act (42 USC 6901 et. seq.) shall not be subject to regulation under subsections (a), (e), or (f) of FIFRA Section 19, unless necessary to prevent an unreasonable adverse effect on the environment. These subsections authorize EPA to specify requirements for registration applications, containers, and labeling, all pertaining to the storage, disposal, and transportation of pesticides.

SUBTITLE C—PUBLIC HEALTH PESTICIDES

Sec. 230. Definitions

Section 230(a) would amend the existing definition of "unreasonable adverse effects on the environment" in FIFRA Section 2(bb) (7 USC 136(bb)) by adding a statement requiring the Administrator to consider the risks and benefits of public health pesticides separately from the risks and benefits of other pesticides. New Section 2(bb) would require the Administrator to weigh any risks of the pesticide against the health risks posed by the agent that is the target of the pesticide, such as the risks of disease transmitted by a vector to be controlled by the pesticide.

Section 230(b) would add two new definitions to Section 2. New subsection (nn) would define "public health pesticide" as 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 that pose a threat to public health. The definition would exclude "other recognized health protection uses" that prevent or mitigate "viruses, bacteria, or other microorganisms on or in living man or other living animal" that pose a threat to public health.

New Section 2(oo) would define "vector" as any animal 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 231 would amend FIFRA Section 3(c)(2)(A) (7 USC 136a(c)(2)(A)) pertaining to the types of data that registrants may be required to submit in support of an application for pesticide registration. Current law directs the Administrator to set standards for data requirements for registration of pesticides for minor uses commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. New Section 3(c)(2)(A) would direct the Administrator to set such standards commensurate also with—(1)

the public health and agricultural need for such minor use, and (2) the level and degree of potential beneficial or adverse effects on man and the environment, but not with the level and degree of potential exposure of man and the environment to the pesticide.

Sec. 232. Reregistration

Section 232(1) would amend Section 4 (7 USC 136a-1), pertaining to fees, by redesignating subparagraphs (B) and (C) in subsection (i)(4) as subparagraphs (C) and (D), respectively, and adding a new subparagraph (B). New subparagraph B would exempt from fees prescribed in paragraph (3) any public health pesticide if the Administrator, in consultation with the DHHS Secretary, determines that the economic return from sales does not support registration or reregistration. Section 232(2) would amend Section 4(i)(5) by redesignating subparagraphs (F) and (G) as subparagraphs (G) and (H), respectively, and adding a new subparagraph (F) providing that an end-use product registered as a public health pesticide would be exempt from the fees prescribed by paragraph (3), if the Administrator, in consultation with the DHHS Secretary, determines that the economic return from sales does not support registration or reregistration. Section 232(3) would amend subsection (i)(7)(B). The current law authorizes the Administrator to order a registrant to submit necessary reports to allow EPA to determine and apportion fees or to determine the registrant's eligibility for a reduction or waiver of a fee. New Section 4(i)(7)(B) also would authorize such orders for reports to allow EPA to determine the volume usage of public health pesticides. Finally, Section 232(4) would amend subsection (k)(3)(A), pertaining to the reregistration and expedited processing fund, adding a new clause (iii). Currently, Section 4(k)(3)(A) directs the Administrator to use up to $2 million of the fund in each fiscal year to obtain sufficient personnel and resources to assure expedited processing and review of certain applications which are specified in clauses (i) and (ii). New clause (iii) would instruct the Administrator to use some of the authorized expenditures from the fund to obtain sufficient personnel and resources to assure expedited processing and review of applications that propose the initial or amended registration of an end-use pesticide that would be used for a public health pesticide.

Sec. 233. Cancellation

Section 233 would amend FIFRA Section 6(b) pertaining to cancellation of registration and change in classification of a pesticide. A new sentence in section 6(b) would direct that when a public health use is affected, the DHHS Secretary should provide available benefits and use information, or an analysis thereof, in accordance with the procedures and conditions as apply to the Secretary of USDA in the case of agricultural pesticides.

Sec. 234. Views

Section 234 would amend Section 21 (7 USC 136s) pertaining to solicitation of comments and notice of public hearings, to redesignate subsections (b) and (c) as (c) and (d), respectively, and to add a new subsection (b). New subsection (b) would require the Administrator, prior to publishing a regulation for any public health pes-

ticide, to solicit the views of the DHHS Secretary in the same manner as the views of the USDA Secretary are solicited under Section 25(a)(2) of FIFRA.

Sec. 235. Authority of Administrator

Section 235 would amend Section 25(a)(1) (7 USC 136w(a)(1)), which pertains to the authority of the Administrator. Under existing law, when prescribing regulations implementing FIFRA, the Administrator is required to take into account the difference in concept and usage among various classes of pesticides. Section 235(1) would require the Administrator also to take into account public health pesticides. Under current law, the Administrator also must consider differences in environmental risk and the appropriate data for evaluating such risk for agricultural and non-agricultural pesticides. Section 235(2) would direct the Administrator specifically to take into account the risk and relevant data for public health pesticides.

Sec. 236. Identification of pests

Section 236 would amend FIFRA Section 28 (7 USC 136w-3), pertaining to the identification of pests, by adding a new subsection (d). New Section 28(d) would require the Administrator, in coordination with the USDA and DHHS, to identify pests of "significant public health importance." The Administrator also would be required to develop and implement programs, in consultation with the Public Health Service, to improve and facilitate safe and necessary use of chemical, biological, and other methods to combat and control such pests.

Sec. 237. Authorization of appropriations

Section 237 would authorize appropriations of up to $12 million for fiscal year 1995 and such sums as may be necessary thereafter for implementation of Subtitle C.

SUBTITLE D—EXPEDITED REGISTRATION OF REDUCED RISK PESTICIDES

Sec. 250. Expedited registration of pesticides

Section 250(1) would amend FIFRA Section 3(c)(1) (7 USC 136a(c)(1)) by adding a new subparagraph (G). New Section 3(c)(1)(G) would require applicants requesting expedited registration or amendment to registration to explain the basis of such request in accordance with new paragraph (9), which is added by Section 250(2).

New Section 3(c)(9)(A) would direct the Administrator to develop procedures and guidelines and expedite review of applications that satisfy such guidelines. New Section 3(c)(9)(B) states that applications for registration or amendments to registrations would be eligible for expedited reviews if use of the pesticide may: (i) reduce pesticide risks to human health; (ii) reduce pesticide risks to nontarget organisms: (iii) reduce the potential for contamination of valued environment resources; or (iv) broaden adoption of IPM strategies or make them more available or effective.

New Section 3(c)(9)(C) would require the Administrator to notify an applicant for expedited review as to whether or not the applica-

tion is complete within 30 days of receiving it. EPA would be allowed to reject an incomplete request or ask for additional information as indicated by EPA guidelines to be developed under new Section 3(c)(9)(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

Section 301(a) would require the USDA Secretary, in consultation with EPA and DHHS, to coordinate the development and implementation of survey procedures to ensure the collection of adequate data on food consumption patterns of infants and children.

Section 301(b) would require such survey procedures to include collection of data on food consumption patterns of a statistically valid sample of infants and children.

Section 301(c) would require the USDA Secretary to ensure that USDA activities in cooperation with EPA and DHHS improve data collection of pesticide residues in food and provide guidelines for use of comparable analytical methods and standardized reporting methods and increased sampling of foods most likely to be consumed by infants and children.

The Committee is aware of recent scientific reports indicating that some pesticides may imitate, enhance, or block the activity of hormones in humans and wildlife. For example, a linkage has been suggested between human exposure to chemicals that imitate estrogen and breast cancer. Since hormones govern fundamental biological functions such as reproduction, growth, and metabolism in humans and other species, the Committee believes that it is important for EPA to obtain data about the potential hormone-disrupting effects of pesticides in order to make informed regulatory decisions under FIFRA.

The Committee notes that the Agency has commissioned a report from the National Research Council to examine the issue more closely and identify data gaps that exists in current testing requirements. The Committee has reviewed and considered this issue and has determined that the EPA currently has sufficient authority to request information related to such effects. The Committee recognizes there are efforts ongoing to design and implement research to objectively assess and characterize the risk of endocrine disrupters on human health and the environment. Therefore, the Committee expects the Agency, within 4 years of the date of enactment of this Act, to evaluate the need for and, if necessary, to use its existing authorities under sections 3 and 4 of FIFRA to establish standards for data requirements, to determine whether a pesticide can disrupt hormonal activity. Collection and analysis of data specified in EPA standards related to disruption of hormonal activity should not delay reregistration eligibility decisions for pesticides first registered before 1984.

Sec. 302. Collection of pesticide use information

Section 302(a) would require the USDA Secretary to collect data of statewide or regional importance on the use of pesticides to con-

trol pests and diseases of major crops and crops of dietary significance, including fruits and vegetables.

Section 302(b) would require the USDA Secretary to collect such data by surveying farmers or from other sources offering statistically reliable data.

Section 302(c) would require the Secretary to coordinate with the EPA to design surveys and to make the aggregate results of surveys available to EPA to assist the Administrator.

Sec. 303. Integrated pest management

Section 303 would require the USDA Secretary, in cooperation with EPA, to conduct research, demonstration, and education programs to support adoption of IPM. Section 303 would state that IPM is a sustainable approach to pest management that combines biological, cultural, physical, and chemical tools so as to minimize economic, health, and environmental risks. The USDA Secretary and EPA Administrator would be directed to make information on IPM widely available to pesticide users, including federal agencies. Finally, Section 303 would direct federal agencies to use IPM techniques in carrying out pest management activities and to promote IPM through procurement and regulatory policies and other activities.

Sec. 304. Coordination of cancellation

Section 304 would expand FIFRA Section 2(bb), the definition for "unreasonable adverse effects on the environment," to include "human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard the Administrator determines is adequate to protect the public health under Section 408 of the [FFDCA] (21 USC 346a) as amended by the Food Quality Protection Act of 1995."

Sec. 305. Pesticide use information study

Section 305(a) would direct USDA, in consultation with EPA, to prepare a report to Congress evaluating the current status and potential improvements in federal activities to collect pesticide use information. The quality and reliability of the information collected by federal agencies regarding agricultural uses of pesticides and options to increase the effectiveness of national collection of pesticide use information would have to be analyzed in the report. Analysis of options would consider costs, burdens placed on agricultural producers and other pesticide users, and effectiveness in tracking risk reduction. Section 305(b) would require submission of the report within one year of enactment.

TITLE IV—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT [1]

Sec. 401. Reference

Section 401 states that all amendments refer to the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 USC 321 et seq.).

[1] Title IV is summarized as introduced. It was not considered by the House Committee on Agriculture.

Sec. 402. Definitions

Section 402(a) would amend FFDCA Section 201(q) (21 USC 321(q)) to change the definition of "pesticide chemical" to conform to the definition of pesticide in FIFRA and to include (A) any pesticide within the meaning of FIFRA; and (B) any active ingredient of a pesticide within the meaning of FIFRA. Subsection (a) also would expand the definition of a "pesticide chemical residue" to include a residue in or on a raw agricultural commodity or processed food of (A) a pesticide chemical, or (B) any metabolites or degradation products of a pesticide chemical. The EPA Administrator would be allowed to exempt a substance from these definitions if the occurrence of the residue in a food is due to natural causes, or human activities unrelated to "a pesticidal purpose," and the Administrator and Secretary determine that the substance should be regulated under a section of FFDCA other than Sections 402(a)(2)(B) and 408.

Section 402(b) would amend the definition of a "food additive" in FFDCA Section 201(s) to exclude (1) a pesticide chemical residue on raw or processed food, and (2) a pesticide chemical.

Section 302(c) would amend Section 201 by adding definitions for "processed food" and "Administrator." New subsection (bb) would define "processed food" as any food other than a raw agricultural commodity, including any such commodity that has been subject to canning, cooking, freezing, dehydration, or milling. New subsection (cc) would define "Administrator" as the Administrator of the EPA.

Sec. 403. Prohibited acts

Section 403 would amend FFDCA Section 301(j) (21 USC 331(j)) which prohibits disclosure of information about confidential methods or processes, except to employees of USDA or to the courts when relevant to a proceeding. It adds Section 408(g)(2) to the list of sections under which, if confidential information is gained, the prohibition applies.

Sec. 404. Adulterated food

Section 404 would amend FFDCA Section 402(a)(2) (21 USC 342(a)(2)) so that pesticide chemical residues on processed food, as well as raw commodities, that are unsafe within the meaning of Section 408(a) would result in the food being deemed to be adulterated. It also would remove from Section 402 the so-called "pass-through provision" that processed food with a pesticide residue should not be deemed unsafe, if the concentration in the ready-to-eat food is not greater than the raw food tolerance, the residue has been removed to the extent possible, and the pesticide has been used in conformance with a legal exemption or tolerance under Section 408. (However, this provision is retained in new FFDCA Section 408(a)(2)).

Sec. 405. Tolerances and exemptions for pesticide chemical residues

Section 405 would amend FFDCA Section 408 (21 USC 346a), currently pertaining to pesticide residue tolerances for raw food.

The proposed amendments would establish a single regulatory framework for both raw and processed foods.[2]

New Section 408(a) sets out the requirements for setting a tolerance or granting an exemption. Subsection (a)(1) defines "food" to include both raw agricultural commodities and processed food. It retains the current provisions of FFDCA Section 408(a) which deem any pesticide residue on food unsafe (and therefore adulterated under Section 402(a)(2)(B)), unless it has a tolerance and is within the limits of the tolerance, or has an exemption from a tolerance. New subsection (a)(1), however, no longer would exclude from its requirements pesticides "generally recognized . . . as safe" by scientists. However, new subsection (i) would exempt from tolerance requirements pesticides "generally recognized as safe" on the day before enactment of H.R. 1627.

New FFDCA Section 408(a)(2) would contain the "pass-through provision" (removed from FFDCA Section 402) for residues of pesticide chemicals found in processed food at concentrations below the tolerance for such residues in the raw food (or that is exempt from the requirement for a raw food tolerance).

New subsection (a)(3) would require EPA to apply the tolerances and exemptions established for residues of a pesticide chemical to residues of the pesticide's break-down products, except that permitted quantities of degradation product residues could be adjusted to reflect any known differences in toxicity from the parent pesticide. A tolerance for a pesticide would apply to a "stoichiometrically equivalent level"[3] of degradation products as long as it did not exceed the tolerance, the tolerance did not expressly exclude breakdown products, and EPA had not determined that the dietary exposure to the breakdown product posed a different or significantly greater potential health risk than the parent pesticide.

New Section 408(a)(4) would specifically prohibit considering a food adulterated "by reason of bearing or containing any amount" of pesticide residue, if a tolerance or exemption were in effect for that pesticide on that food.[4]

Existing Section 408(b) requires the Administrator to promulgate regulations establishing tolerances for pesticides used on food "to the extent necessary to protect the public health." In setting tolerances, the Administrator is required to consider relevant factors including the necessity for production of an adequate, wholesome, and economical food supply; other ways in which the consumer may be affected by the same pesticide or by other related substances; and to the opinion and certification of usefulness of the pesticide by the Secretary of Agriculture. The Administrator is authorized to

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[2] To facilitate comparison with the proposed amendments, the provisions of the current FFDCA, Section 408 are summarized in the following paragraphs as they pertain to raw and sometimes processed foods. However, current provisions relating to pesticide residues concentrated in processed foods are not summarized, because such residues are treated as food additives and are covered by FFDCA Section 409, which is not amended by S. 1166, as introduced. Instead, S. 1166, Section 302 would redefine "food" and "pesticide chemical residue" so that pesticide residues always would be covered by Section 408, as it would be amended. A key effect of this change is to make the Delaney clause no longer applicable to potentially carcinogenic pesticide residues concentrated in processed foods.

[3] Stoichiometrically equivalent level means the quantity of a chemical substance that is equal with respect to its involvement in chemical reactions.

[4] This provision may contradict new section 408(a)(2)(A) which would deem a food unsafe unless pesticide residues were within the limits of an established tolerance.

establish a tolerance at zero level if the scientific data do not justify establishing a greater tolerance. This provision generally has been applied to certain potentially carcinogenic pesticide residues.

New Section 408(b)(1) would authorize the EPA Administrator to issue regulations establishing, modifying, or revoking tolerances for pesticide chemical residues in response to a petition or on the Administrator's initiative. New Section 408(b)(2)(A), (B), and (C) would prohibit setting, and would require modifying or revoking, a tolerance at a level higher than is adequate to protect the public health.[5] In determining the level that is adequate to protect public health, EPA must take into account relevant factors including: validity, completeness, and reliability of available pesticide chemical residue data; the nature of any demonstrated toxic effects; and available information and reasonable assumptions concerning the relationship of study results to human risk, dietary exposure levels to residues of food consumers (and major identifiable subgroups of food consumers, including infants and children), and variability in sensitivities of major identifiable groups, including infants and children. The Administrator no longer would be authorized to set a tolerance at a zero level; in fact, new subsection (b)(3)(C) would appear to prohibit it.

New Section 408(b)(2)(D) would declare that a tolerance level for a pesticide chemical residue in food is adequate to protect the public health if the dietary risk to consumers from exposure to the pesticide is negligible. The Administrator is authorized to set forth by regulation the factors and methods that are required to determine negligible dietary risk and exposure.[6]

New Section 408(b)(2)(E) would require procedures to ensure that tolerances safeguard the health of infants and children.

New Section 408(b)(2)(F) would require EPA to calculate dietary risk posed to food consumers by residues on the basis of the percent of food actually treated with the chemical and the actual levels of the residues, if reliable data were available. Specifically, the bill would require EPA to take into account USDA pesticide use and residue data.

New Section 408(b)(2)(G) would declare a pesticide residue tolerance level adequate to protect the public health when it poses a risk that is not unreasonable, considering the health and environmental risks avoided through the pesticide use as well as the benefits conferred in terms of an adequate, wholesome, and economical food supply. However, EPA would be prohibited from considering the economic effects on the pesticide registrant, manufacturer, or marketer of a pesticide when setting a tolerance. A tolerance could be established at a residue level posing a more than negligible risk, if the EPA considered the risk reasonable because: (1) the risk to public health or the environment prevented by pesticide use outweighs the dietary pesticide risk; (2) alternative pesticides or pest control methods pose greater risks to the public than the dietary

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[5] It is not clear whether "higher" means more stringent or at a greater concentration.

[6] This definition of negligible risk does not identify a specific numerical expression of a level of risk. It would give EPA the flexibility to decide to ignore de minimis or insignificant risks and to use the evolving science of risk assessment in this process. It implements the 1987 National Academy of Science recommendation for a uniform negligible risk standard for food. This recommendation is found in the report Regulating Pesticides in Food: The Delaney Paradox (Washington, DC, National Academy Press, 1987, 272 p.).

residue; or (3) use of the pesticide maintains the national or regional availability of an adequate, wholesome, and economical food supply for consumers.

New Section 408(b)(3)(A) would limit EPA's authority to set tolerances at residue levels posing more than a negligible risk. It would permit such tolerances only if EPA had assessed the extent to which efforts were being made to develop alternative methods of pesticide control that would meet the negligible risk requirement.

Under new subsection (b)(3)(B), the EPA would be prohibited from setting a tolerance unless a method for detection and measurement of residues were practical, or that a practical method is unavailable or not feasible. New subsection (b)(3)(C) would prohibit tolerance levels from being set at a level lower than the detection limit of the practical residue detection and measurement method identified by EPA.

New subsection (b)(4) would encourage international harmonization of limits to pesticide residues in/on foods. These limits are called tolerances in the United States and Maximum Residue Levels (MRLs) elsewhere. This subsection directs EPA in setting tolerances to determine whether an MRL has been established for the chemical by the Codex Alimentarius Commission (Codex). If it has, and the EPA decides not to adopt the same level, when the EPA publishes the final tolerance, it would also have to publish a determination with supporting data that the Codex level is not supported by adequate and reliable scientific data or would not protect the health of U.S. consumers. It also must state that the effect of the tolerance on the availability to consumers of an adequate, wholesome, and economical food supply does not outweigh the risk posed by the pesticide residue. This new subsection brings our tolerance setting system into compliance with the spirit of the Uruguay Round Agreement of the World Trade Organization (formerly known as the General Agreement on Tariffs and Trade) and other international trade agreements for it tries to avoid unjustified restraints on trade and to make U.S. regulatory decisions consistent with our international trade agreements.

Section 408(c) of current law requires the Administrator to promulgate regulations exempting any pesticide from the necessity of a tolerance when it is not needed to protect public health.

New subsection (c)(1) would authorize the Administrator, in response to a petition or on the Administrator's initiative, to issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue on food. New subsection (c)(2) would limit the Administrator's authority to issue such regulations. An exemption could only be established if a tolerance were not needed to protect the public health, given the dietary levels of exposure to the residue that would reasonably be expected to occur. An existing exemption that did not meet that criterion would have to be revoked. In determining whether a tolerance were needed to protect the public health, the bill would require EPA to consider relevant factors specified in new subsection (b)(2)(C) which include: validity, completeness, and reliability of available pesticide chemical residue data; the nature of any demonstrated toxic effects; and available information and reasonable assumptions concerning the relationship of study results to

human risk, dietary exposure levels to residues of food consumers (and major identifiable subgroups of food consumers, including infants and children), and variability in sensitivities of major identifiable groups, including infants and children.

New subsection (c)(3) would prohibit an exemption, unless there were a practical method for detecting and measuring the levels of the residue, or there were no need for such a method and the reasons were stated in the order issuing the regulation establishing or modifying the regulation.

Existing FFDCA, Section 408(d) authorizes any applicant for a pesticide registration under FIFRA to file a petition for the issuance of a tolerance or an exemption. It requires the petition to contain data showing the name, chemical identity, and composition of the pesticide; the amount, frequency, and time of application of the pesticide; full reports of safety studies conducted; results of tests on pesticide residues on crops and identification of analytical methods used; practicable methods for removing residue that exceeds a proposed tolerance; proposed tolerances, if they are being proposed; and reasonable grounds in support of the petition. The law also requires petitioners to provide samples of the pesticide upon request. The EPA must publish a notice of the petition filing within 30 days, which must include the analytical methods to determine the pesticide residue levels. Within 90 days after a certification of usefulness of the pesticide by the Secretary of Agriculture, the Administrator [of Health and Human Services] [7] is required to either establish a tolerance or exempt the pesticide from a tolerance, unless the petitioner requests or the Administrator decides to refer the petition to an advisory committee. In that case, the Administrator must submit the petition and data to an advisory committee which must report to the Administrator with their recommendation within 60 days. The Administrator is required within 30 days of the committee report to issue a regulation establishing a tolerance or exempting the pesticide; the regulation becomes effective on publication. Section 408 provides 30 days thereafter for any person adversely affected by the regulation to file an objection with the Administrator, who would then be required to hold a public hearing to receive evidence relevant and material to the issues raised by the objection. A member of the National Academy of Sciences is required to designate a member of the advisory committee to testify before the hearing. As soon as practicable after the hearing, the law directs the Administrator to regulate based only on substantial evidence of record at the hearing. The regulation may take effect no sooner than 90 days after the rule is published, unless an emergency condition exists.

New subsection (d) for the most part would be similar to current law, but the amended subsection would authorize any person to file a tolerance petition rather than only an applicant for a pesticide registration. New subsection (d)(1) also would authorize petitions for modifying or revoking a tolerance or for revoking an exemption. New subsection (d)(2) would authorize the Administrator to require additional information accompanying a petition. In addition to the

[7] The words "Health and Human Services" probably are inadvertent, but appear in several places in the codified FFDCA, for example, at 21 USC 346a(d).

information required to be submitted under current law, new subsection (d)(2) would require a petitioner to provide: a summary of the petition, data, information, and arguments; a statement that the petitioner agrees to have the summary contents published with the notice of petition filing and as part of any proposed or final regulation; and information about practical methods for detecting and measuring levels of residue (or a statement that it is not needed), the methods used in safety and residue testing, the effect that the pesticide is intended to have and the quantity of chemical required to produce it, and, if the petition relates to a tolerance for a processed food, the processing methods used to produce the food.

New subsection (d)(3) would direct the Administrator to publish the notice of petition filing, including an announcement of the availability of a description of the analytical methods for detecting and measuring residues (or a statement that such methods are not needed) and the summary of the petition. H.R. 1627 does not provide for referral of the petition to an advisory committee. Nor would the bill impose time limits on the Administrator to act.

New subsection (d)(4) would authorize the Administrator to issue a final regulation, to issue a proposed regulation followed by a final regulation or an order denying the petition, or to issue an order denying the petition. New subsection (d)(5) states that any regulation would take effect upon publication. New subsection (d)(6) would double the time allowed for a person adversely affected by the regulation to file an objection from 30 days to 60 days. An objector could request a public evidentiary hearing. New Section 408(d)(6) would allow the Administrator to decide whether a hearing were necessary to receive factual evidence relevant to material issues of fact raised by the objections. The bill would provide the hearing officer with various authorities, for example to issue a subpoena to compel testimony, but would also impose limitations.

New subsection (d)(7) would retain most of the existing provisions of FFDCA Section 408(i). The existing section authorizes any person adversely affected by an order within 60 days of its publication to obtain judicial review in the U.S. Court of Appeals for the circuit wherein that person resides or has a business or with the U.S. Court of Appeals for the District of Columbia Circuit. The Administrator must file with the court the record of the rulemaking. The court has exclusive jurisdiction to affirm or set aside the order in whole or in part. The findings of the Administrator are required to be sustained only if supported by substantial evidence when considered on the record as a whole. FFDCA Section 408(i) allows for additional evidence to be introduced if it appears proper to do so. The EPA can then modify its order or regulation to take into account that evidence. The judgment of the court is final, subject to review by the U.S. Supreme Court, but this appeal may not operate as a stay of the order. Currently, the rulemaking record, which becomes part of the court record, includes certification by the Secretary of Agriculture as to the usefulness of the pesticide. New subsection (d)(7) omits references to certification of usefulness and to the Secretary. New Section 408(d)(7)(E) would prohibit review under any other section of law of issues that are subject to review under new paragraph (6).

New Section 408(e) authorizes the Administrator to propose a tolerance or an exemption at any time. Thirty days after the proposal is published, the Administrator may publish the final regulation, which becomes effective upon publication, unless a registrant or applicant for a registration of the pesticide chemical named in the proposal requests referral of the proposal to an advisory committee. If requested, the Administrator must submit the proposal and the advisory committee must report back certified recommendations within 60 days. Within 30 days of such certification, the Administrator may publish a regulation establishing a tolerance for a pesticide or exempting it. A regulation is effective upon publication, but any person adversely affected by it may file an objection, as described with reference to Section 408(d) above.

New subsection (e)(1) also authorizes rulemaking by the EPA Administrator to establish a tolerance or an exemption. In addition, it authorizes the Administrator to modify or to revoke a tolerance and to revoke an exemption, as well as to establish general implementation procedures and requirements. New subsection (e)(2) would require EPA to issue a notice of proposed rulemaking and to provide a 60-day public-comment period, unless there were good cause to modify this requirement. EPA must provide an opportunity for a public hearing during the rulemaking procedures. However, the new procedure provides no role for an advisory committee.

New subsection (f)(1) would authorize EPA to collect additional data to support an existing pesticide tolerance or exemption. The Administrator would be allowed to collect data under FIFRA, Section 3(c)(2)(B) or the Toxic Substances Control Act (TSCA), Section 4, or by publishing an order in the *Federal Register*. In the last case, the order would be required to identify the persons required to submit the data, the type of data and information and why it could not be obtained under FIFRA or TSCA, the reports that would be prepared from this data, and the dates that the information is due. A 90-day notice-and-comment period would be required. Subsection (f)(2) would authorize the Administrator to modify or revoke the tolerance or exemption in question if this required data were not submitted in the time specified. Subsection (f)(3) would make an order subject to review in accordance with new subsection (d), paragraphs (6) and (7).

Existing FFDCA Section 408(f) requires that all data submitted in support of a petition be considered confidential until publication of a regulation. New subsection (g)(1) would require EPA to treat all data and information submitted in support of a tolerance confidentially. In addition, such information would be entitled to exclusive use and data compensation to the same extent as provided under FIFRA, Sections 3 and 10. Subsection (g)(2) would allow disclosure of the information to the Congress of the United States and, at the Administrator's discretion, to authorized federal employees and contractors. Subsection (g)(3) would permit publication of an informative summary of the data.

FFDCA Section 408(g) sets forth requirements related to the appointment and functioning of advisory committees. Section 408(h) provides a petitioner and representatives of the Department of Health and Human Services the right to consult with the advisory committee. These provisions are not included in H.R. 1627.

New subsection (h)(1) retains the provisions of FFDCA, Section 408(k), which concerns regulations promulgated based on hearings held before 1953, but would subject modifications and revocations of such regulations to new Section 408, subsections (d) and (e). New paragraphs (2) and (3) in subsection (h) are technical amendments which continue in effect all current regulations affecting pesticide residues that have been promulgated under FFDCA Sections 408 or 409 and subject modifications and revocations of such rules to new subsections (d) and (e). Under current law, the Administrator is required by subsection 408(m) to amend or repeal regulations according to a procedure that conforms to that for establishing tolerances. Subsection 408(m) would be eliminated by H.R. 1627.

New subsection (i) would exempt from tolerance regulations those pesticide residues and food or color additives that on the day before enactment the Administrator or Secretary regard as generally-recognized-as-safe (GRAS) within the meaning of the existing provisions of FFDCA Section 408(a) or 201(s). The new subsection also would exempt from regulation substances described in FFDCA 201(s)(4). EPA would be required to publish regulations listing which substances are covered by this exemption.

Under current law, FFDCA Section 408(j) authorizes the Administrator to grant temporary tolerances for experimental pesticide uses. H.R. 1627 omits this provision.

New subsection (j)(1) would codify part of EPA's coordination policy by linking the tolerance or exemption, to any action revoking, modifying, or suspending a pesticide registration under FIFRA. Subsection (j)(2) states that if the Administrator acting under FIFRA cancels or modifies the registration of a pesticide for a food use because of dietary risks to human health posed by the residues, the Administrator also must revoke any tolerance or exemption that would allow the presence of the pesticide chemical in or on that food. A revocation under this paragraph would become effective not later than 180 days after the date on which the use of the canceled pesticide becomes unlawful. Subsection (j)(3) similarly would require the suspension of tolerances for food use pesticides, if the registration were suspended under FIFRA. A tolerance suspension would become effective not later than 60 days after the registration was suspended. Tolerances or exemptions would be restored if the Administrator rescinded any suspension of the pesticide registration.

New subsection (j)(4) would authorize the Administrator to establish tolerances for unavoidable residues of canceled or suspended pesticides on food. The required tolerance level would be set taking into account the potential risk from exposure to the pesticide residue. These tolerances would have to be revisited periodically and modified as necessary to allow only that level of residue that is unavoidable due to its environmental persistence.

New subsection (j)(5) would be known as the "pipeline" provision. It would allow pesticide residues on foods that were the result of lawful application of a pesticide. In a case where a tolerance or exemption for a pesticide residue is revoked, suspended, or modified, a food that was legally treated with the pesticide would not be deemed unsafe, if the pesticide residue did not exceed the previously authorized tolerance level. EPA would retain the power to

declare legally treated food unlawful, but only after determining that consumption of the legally treated food during the period of its likely availability in commerce poses an unreasonable dietary risk. This provision would allow the use of existing food stocks that were treated with a lawful pesticide, thus protecting against unnecessary destruction of legally treated food, disruption in the marketplace, and economic loss. It also would ensure that food producers were not unfairly penalized for use of legal pesticides that were subject to regulatory action at a subsequent date.

New subsection (k) would require EPA to assess or waive fees to the same extent as required by current law (FFDCA, Section 408(o); 21 USC 346a(o)).

Currently, FFDCA Section 408(n) makes the provisions of Section 303(c), furnishing guaranties, applicable to raw agricultural commodities. This provision is not included in H.R. 1627.

New Section 408(l) would preempt state and local regulation of food with pesticide residues under certain conditions. Under current law, states and local governments can set tolerances for pesticide residues in foods that are lower (more stringent) than those established by EPA. They also may require warnings for food products that contain legal pesticide residues (that is, below federal tolerance levels). Subsection (l)(1) would define "qualifying pesticide chemical residue" as a residue from a pesticide use first registered after April 25, 1985 (and therefore not subject to FIFRA Section 4(g), reregistration requirements) or older pesticides reregistered in the future after H.R. 1627 is enacted.[8] Subsection (l)(2) would define "qualifying [f]ederal determination" as (A) a tolerance or exemption issued after enactment of H.R. 1627 or determined by the Administrator (by rule as required under new subsection (d) or (e)) to adequately protect public health as defined under new Section 408(b)(2) or (c)(2); and (B) any statement by the Secretary of a level permitted that protects human health during the period to which the statement applies. New subsection (l)(4) would prohibit state and local regulation of any "qualifying pesticide chemical residue" to which any "qualifying federal determination" applied. This appears to mean that state and local governments would not be permitted to regulate foods with residues of pesticides registered after 1985 or reregistered after enactment, if: an exemption or tolerance for the residue was issued under new subsection (b)(2) or (c)(2), an exemption or tolerance was determined by an EPA rulemaking to meet the requirements of new subsection (b)(2) or (c)(2), or the Secretary (of Health and Human Services, by definition at FFDCA Section 201(d)) stated that the residue level would protect human health and would be permitted during some specified period. The only exception allowed would be for state or local regulation of food with "qualifying pesticide chemical residue" at the level of the "qualifying federal determination." Specifically, state and local governments would be precluded from prohibiting or penalizing the production, processing, shipping, or handling of a food containing qualifying residue levels deemed protective of public health by fed-

[8] This provision does not affect pesticides that were reregistered before enactment of H.R. 1627.

eral officials. "Warning requirements" and other statements relating to the presence of such residues in food would not be permitted.

New subsection (l)(5) would set up petition procedures for states. Subsection (l)(5)(A) would allow states to petition for a regulatory limit on a qualifying residue different than the federal limit, if the state's petition established adequate justification to EPA. Subsection (l)(5)(B) would require that this justification include scientific data about the pesticide, consumption data, and exposure data of people residing in the state. Subsection (l)(5)(C) would give the states exemptions from uniform federal limits if justified by evidence of compelling local conditions, and it would not unduly burden interstate commerce nor cause any food to be in violation of federal law. Subsection (l)(5)(D) would allow the Administrator to treat a state petition as if it were a new petition for a tolerance and would require it to meet requirements set out in Sec. 408(d).

New subsection (l)(6) assures that no state or political subdivision can declare a food unlawful which contains a residue that was the result of the application of a pesticide that, at the time of its use, complied with all federal and state laws. However, the only exception would be if the state or locality could show that a certain residue level in a food would pose an unreasonable dietary risk to the health of persons within that state.

Sec. 406. Authorization for increase monitoring.[9]

Section 306 would authorize appropriations of an additional $12 million for increased monitoring by FDA of pesticide residues in imported and domestic food.

TITLE V—FEES

Sec. 501. Fees

Section 501(a)(1) would extend EPA authorization to collect $14 million annually in registration maintenance fees from pesticide registrants until September 30, 2001. Section 501(a)(2) would authorize collection of up to $6 million in additional fees, $2 million in each of the years 1998, 1999, and 2000.

Section 501(b) would amend FIFRA Section 4(k)(1) to name the fund established the Reregistration and Expedited Processing Fund.

Section 501(c) would amend FIFRA Section 4(k)(2) to direct EPA to deposit in the fund all money derived from maintenance fees. H.R. 1627 would make this money available to offset the costs of reregistration and expedited processing of applications specified in FIFRA Section 3(c)(3)(B) (7 USC 136a(c)(3)(B)), which refers to applications to register or amend the registration of an end-use pesticide that would be identical or substantially similar to a currently registered pesticide, or to amend the registration of a pesticide that does not require scientific review of data. The bill would prohibit expenditures in the fiscal year in excess of the amount appropriated and expended for reregistration and expedited processing of applications. Prior to expending any money derived from fees, EPA would have to adopt specific and cost accounting rules and procedures approved by the General Accounting Office and the EPA In-

[9] "Increase" in the title probably should be "Increased."

spector General. Such rules and procedures are required to ensure that funds are allocated only to costs of reregistration and expedited processing of applications and in the same portion as appropriated funds. New FIFRA Section 4(k)(2) would require EPA to prohibit use of fees to pay any costs other than those necessary to achieve reregistration and expedited processing of the applications specified in paragraph (3). It would direct EPA to ensure that personnel and facility costs of the program did not exceed agency averages for comparable personnel and facility costs. In addition, the bill would require EPA to complete review of unreviewed reregistration studies required to support the reregistration eligibility decisions scheduled for completion according to subsection (l)(2) and to contract (after selecting vendors through a competitive process) for outside assistance as necessary to conduct the reviews.

H.R. 1627, Section 501(d) would amend FIFRA Section 4(k)(3) which allocates a portion of the collected maintenance fees to obtain sufficient personnel and resources to ensure expedited processing of applications. The bill would direct EPA to use no more than 1/7th of the maintenance fees collected in each fiscal year 1997 through 2001 for that purpose. It also would mandate completion of processing of unprocessed expedited review applications within 5 years of enactment.

Section 501(e) would amend FIFRA Section 4(k)(5) (7 USC 136a-1(k)(5)) pertaining to accounting. It would require EPA to ensure that expenditures from fees are used only to carry out the goals of subsection (l). The bill would designate the Federal Insecticide and Rodenticide Fund as an EPA component in financial statements under 31 USC 3515(c) which must be audited annually under 31 USC 3521. The bill would require the EPA Inspector General to conduct (or to contract with a nationally recognized accounting firm to conduct) an audit of the maintenance fees collected and disbursed, the amount appropriated to match the fees, and EPA attainment of performance measures and goals, and to review the basis for and accuracy of all costs, overhead allocation, and disclosures of direct and indirect costs of reregistration and expedited processing of applications. Findings of the audit and review and recommendations are to be reported to EPA and to the House Committee on Agriculture and the Senate Committee on Agriculture, Nutrition, and Forestry. The bill mandates payment for the audit from the maintenance fees collected.

Section 501(f) redesignates FIFRA Section 4(l) as Section 4(m) and inserts a new subsection (l) on performance measures and goals. It directs EPA to establish and publish in the *Federal Register* each year performance measures and goals which must include number of products reregistered, canceled, or amended; status of reregistration; number and type of EPA data requests issued to support reregistration, by active ingredient; the progress in reducing the number of unreviewed, required reregistration studies; status of tolerances reassessed; number of approvals and disapprovals of applications for registration; projected schedule for reregistration in the current and succeeding fiscal year, including reregistration of antimicrobial pesticides; and projected year of completion of the reregistrations under FIFRA Section 4.

The 1988 amendments to the FIFRA established a 9-year timetable for the EPA to complete the review and reregistration of approximately 600 groups—or "cases"—of related pesticide active ingredients representing 1,150 active ingredients used in approximately 45,000 pesticide products that were registered for use prior to 1985. The 1988 cost estimated was $260 million to complete the reregistration program by September 30, 1997. The cost of reregistration was to be split between industry and appropriated tax payer dollars. The estimated industry share was $150 million over the nine years.

According to EPA the Agency has collected a cumulative (projected) total of $147 in industry fees through FY–1997. The Committee recognizes the importance of keeping the reregistration program moving forward with sufficient resources to accomplish reregistration and ensure the older pesticides are safe to use as intended. However, the Committee is not satisfied with the Agency's performance and the estimate that it will need at least eight additional years—nearly twice the original estimate of nine years—to complete the reregistration program.

To address this concern, the Committee took two specific actions. First, the Committee extends the EPA's current authority to annually collect up to $14 million in maintenance fees from pesticide registrants from September 30, 1997, to September 30, 2001. To address backlogged case studies and related reregistration reviews, the Committee also authorizes collection of an additional $6 million in maintenance fees. In addition to the $14 million currently authorized for FY–1997, this legislation authorizes the EPA to collect an additional $62 million in industry contributions to continue the reregistration process beyond FY–1997, for a total of $76 million over the five-year authorization of this legislation.

Second, to ensure that this Committee is able to conduct meaningful oversight in the future as to how the FIFRA reregistration fees and related appropriated monies are spent by the Agency, this legislation includes requirements mandating that:

—The EPA Inspector General (EPA IG) and the General Accounting Office (GAO) are to work cooperatively with the EPA Administrator to develop financial and performance standards consistent with the goals of the reregistration program.

—The EPA IG is to conduct an annual comprehensive financial audit of the EPA pesticide program and a performance audit of the reregistration program. The results and recommendations of this audit are to be reported to the EPA Administrator and to the House and Senate Committees on Agriculture.

—To ensure the audit is performed as stipulated and free of undue influence as is possible, the Administrator shall reimburse the EPA IG for the cost of the audit out of the reregistration maintenance fees, rather than from appropriated monies.

The Committee expects the EPA IG to exercise thrift in conducting the audit and to take steps to ensure that expenditures are made for the exclusive purpose of completing the annual audit as outlined in the legislation be included in the cost of the audit. Furthermore, in order to protect the registrant, who is paying for the audit, and the EPA Administrator, who needs the maintenance fees

to help finance Agency activities associated with the registration program, it is the expectation of the Committee that the EPA IG will attempt to limit spending to $100,000 for each yearly audit.

The Committee does recognize that the EPA has made progress in issuing final reregistration eligibility determinations, and in reviewing and acting upon expedited review applications, including "me-too" applications and amendments. For example, the Committee notes that in FY–95, the EPA Office of Prevention, Pesticides and Toxic Substances completed 40 registration eligibility determinations (REDs) and 4,113 expedited review applications, including 570 "me-too" applications and 3,543 amendments. The Committee expects the EPA to work expeditiously to maintain, if not increase, its level of activity to achieve the goal of completing the reregistration program as soon as possible.

The Committee expects that the information provided to the Committee, the EPA Administrator, and the GAO through the annual EPA IG audits will provide much-needed benchmarks by which the efficiency and progress of the program can be judged, as well as provide recommendations on how to improve the program in the coming years. The Committee notes that Subcommittee Chairman Bill Emerson provided valuable information to the Committee via his investigation of reregistration fees and related activities which was instrumental in creating a system of accountability that would track the increased costs for reregistration.

The Committee expects EPA and industry to work cooperatively to avoid future regulatory logjams such as is illustrated by the reregistration program. The Committee provides the foundation for this cooperation is provided in Title I, Sections 103 and 107, which require the EPA to review the FIFRA registration of a pesticide at least once every 15 years to ensure the data supporting the pesticide's safe use meet currently accepted registration standards, and at the same time, to review any tolerance or exemption from a tolerance established under the appropriated Section of the Federal Food, Drug, and Cosmetic Act.

TITLE VI—INDIAN TRIBES

Sec. 601. Authority of Indian tribes

Section 601(a)(1) would amend Section 24 (7 USC 136v) to authorize Indian tribes to regulate the sale or use of any federally registered pesticide or device only within the boundaries of a federal Indian reservation for such tribe, if at least 50 percent of the lands in such reservation are owned by members of the tribe or the tribe. Section 601(b) would amend Section 26 (7 USC 136w–1) to provide similar limited authority to tribes to enforce FIFRA on federal Indian reservation land if at least 50 percent of it is owned by members of the tribe or the tribe.

COMMITTEE CONSIDERATION

I—HEARINGS

On May 16, 1995, the Subcommittee on Department Operations, Nutrition and Foreign Agriculture conducted a hearing for the pur-

poses of reviewing H.R. 1627, the "Food Quality Protection Act of 1995". (Serial #104–15).

The Subcommittee received testimony from the following witnesses: Mr. Daniel Botts, Chairman, Minor Crop Alliance Technical Committee; Ms. Rebecca Doyle, Director, Illinois Department of Agriculture; Ms. Juanita Duggan, National Food Processors Association; Mr. Ralph Engel, Chemical Specialties Manufacturers Association; Mr. Jay Feldman, National Coalition Against the Misuse of Pesticides; Mr. Alan Goldhammer, Biotechnology Industry Organization; Ms. Lynn Goldman, Assistant Administrator, EPA; Mr. Gerald Pflug, President, The Soap and Detergent Association; Mr. Ray Ratto, Ratto Brothers, Inc. Mr. Warren Stickle, Chemical Producers and Distributors Association; Mr. Dennis Stolte, American Farm Bureau Federation; Mr. Jay Vroom, President, American Crop Protection Association; and Mr. Paul Wright, Senior Attorney, the Dow Chemical Company.

Additional material submitted was provided by the Agricultural Retailers Association, by EPA in response to questions by Mr. Emerson, and by the International Sanitary Supply Association.

II—SUBCOMMITTEE CONSIDERATION

On May 23, 1995, the Subcommittee on Department Operations, Nutrition, and Foreign Agriculture met, pursuant to notice to consider H.R. 1627, the "Food Quality Protection Act of 1995".

Chairman Emerson called the meeting to order and stated that the Subcommittee had received permission to sit while the House was under the five-minute rule. The Chairman then offered an Amendment in the Nature of a Substitute to H.R. 1627 and without objection it was considered as original text for purposes of amendment.

Chairman Emerson made a brief opening statement and recognized Messrs. Condit and Canady for opening statements. Chairman Emerson also noted that Members could offer amendments for discussion purposes with the understanding that the amendments could be withdrawn for further consideration by representatives of the EPA and staff for consideration at the Full Committee. The Chairman further noted that representatives of EPA and the pest control industry were to work on an issue involving termiticides before full Committee consideration of the bill.

Mr. Allard was then recognized to discuss an amendment regarding additional exclusive use of data and minor use reregistration which he did not offer, but which he reserved the right to offer at Full Committee.

Mr. Brown was then recognized to offer and explain an amendment regarding registration renewal. Discussion occurred and without objection, the amendment was withdrawn.

Mr. Brown then offered and explained an amendment restricting a pesticide to use only by prescription. Discussion occurred and without objection, the amendment was withdrawn.

Mr. Brown also expressed concern about a provision in the bill that exempts nitrogen stabilizers. Chairman Emerson noted that Mr. Canady had discussed this provision in his opening statement and indicated a desire to seek a solution to the problem before full Committee consideration.

Mr. Bishop was recognized and advised the Committee that he was working on an amendment that would provide for adequate staff and funds from the EPA budget to expedite processing applications for minor use pesticides. Mr. Allard expressed some concern about earmarking EPA funds. Mr. Emerson encouraged the Members to continue discussions on the amendment and to work for a solution.

Mr. Farr was then recognized to offer and explain an amendment to retain current roles of USDA and the Science Advisory Panel in cancellation procedures. Discussion occurred and by a voice vote the amendment was adopted.

Mr. Farr was recognized to offer and explain an amendment regarding recordkeeping and reporting requirements. Discussion occurred and without objection the amendment was withdrawn.

Mr. Farr was recognized to offer and explain an amendment to waive fees for biological pesticides. Discussion occurred and Chairman Emerson noted that he had requested specific information from EPA regarding fees and that their forthcoming response would be helpful in consideration of the amendment. Discussion occurred and without objection the amendment was withdrawn.

Mr. Farr offered an amendment concerning risk assumptions with respect to infants and children. Discussion occurred and without objection, the amendment was withdrawn.

Mr. Farr offered an amendment that would make certain changes to section 102 entitled, cancellation. Discussion occurred and without objection the amendment was withdrawn.

Mr. Condit then moved that H.R. 1627, as amended, be ordered favorably reported to the full Committee. By a voice vote, H.R. 1627 as amended, was adopted and favorably reported to the full Committee in the presence of a quorum.

III—FULL COMMITTEE

The Committee on Agriculture met, pursuant to notice on June 20, 1995, a quorum being present, to consider the bill H.R. 1627, as reported by the Subcommittee on Department Operations, Nutrition, and Foreign Agriculture.

Chairman Roberts called the meeting to order and noted the procedures, which had been cleared with the Minority, under which the bill would be considered. He stated that title IV of H.R. 1627 was under the jurisdiction of the Committee on Commerce and there was a place holder for new title VI, Fees, in the Roberts Substitute to H.R. 1627, as reported by the Subcommittee. The Chairman further noted that it was his intention to defer consideration of title VI until such time as the Commerce Committee completed mark up of title IV. Chairman Roberts also indicated that there may be further consideration of section 110 relating to the administrative hearing process and the relationship to the Administrative Procedures Act at that later date

Thereafter, Messrs. de la Garza, Emerson, and Condit made brief opening statements.

Chairman Roberts then offered an amendment in the nature of a substitute to the bill, H.R. 1627, as reported by the Subcommittee. Without objection the substitute amendment was laid before

the Committee and considered as original text for purposes of amendment. Counsel then explained the substitute amendment.

Mr. Farr was recognized to offer and explain an amendment regarding pesticide use data gathering. Discussion occurred and by a voice vote the amendment was adopted.

Mr. de la Garza advised the Committee that some Members were not present and that he wished to have it noted in the record that he wanted to preserve their right to continue working with the Committee staff on an amendment. Mr. de la Garza then moved for the adoption of the substitute amendment, as amended by the Farr amendment. By a voice vote and in presence of a quorum, the substitute amendment, as amended, was adopted.

Without objection, staff was given permission to make technical, clarifying or conforming changes to the substitute adopted. The Chairman then adjourned, to reconvene subject to the call of the Chair.

On June 19, 1996, the Committee on Agriculture met, pursuant to notice to consider H.R. 1627, the Food Quality Protection Act and other pending business. Chairman Roberts advised the Committee that H.R. 1627 had been considered by the Subcommittee on Department Operations, Nutrition, and Foreign Agriculture on May 23, 1995, and it had been ordered reported to the full Committee. The full Committee had considered the bill on June 20, 1995. Furthermore, Chairman Roberts explained that the Committee on Agriculture did not report the bill on June 20, 1995, because it was the Chair's intention to reconvene the Committee after final consideration by the Commerce Committee on title IV.

Chairman Roberts at that point stated that the fees language had been worked out and would provide the Environmental Protection Agency authority to collect $76 million in reregistration fees through the year 2001 and would require a thorough annual financial and performance audit of the fees collected and appropriated monies used for reregistration. It was further noted that the outstanding issue of new product registration fees was still being discussed with the registrant community.

Chairman Roberts indicated that the cancellation provisions of H.R. 1627 were being dropped at the request of EPA and the chemical industry which negated the need for such amendments, including section 110. The Chairman also wanted the record to reflect that it had never been the intent of section 110 to shift the burden of proof, but rather to ensure that hearings conducted under the reform cancellation procedures would conform to the Administrative Procedures Act.

The Chairman also noted the many years of effort that had been put forth by many Members of the Committee to try and address the concerns of the current Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food Drug and Cosmetic Act (FFDCA) pesticide regulatory policies. He specifically commended Messrs. Emerson and Condit for their leadership in the Subcommittee and Mr. de la Garza, the former Secretary of Agriculture Ed Madigan, Mr. Brown, Mr. Stenholm, and others who had worked on the FIFRA issues over a period of years.

Mr. de la Garza was then recognized for a statement and he pointed out that Mr. Berkley Bedell from Iowa had also worked on

the issue and had come very close to getting a bill passed. Mr. Condit was also recognized and wished to state for the record that if there were no action taken by the Commerce Committee that it was his intention to go forward with a discharge petition.

Discussion occurred with Mr. Smith questioning staff about the issue of the disposal of pesticide containers.

Mr. Brown was also recognized by Chairman Roberts for his hard work over the years on FIFRA, and Mr. Brown made an opening statement.

Chairman Roberts then offered a substitute amendment to H.R. 1627 which contained all that was considered by the Committee on June 20, 1995, with certain exceptions, such as replacing the antimicrobial language in the text and inserting the text of H.R. 3338, which is identical to S. 1491, and substitutes for earlier antimicrobial pesticide registration reform language that appeared in the June 1995 version of H.R. 1627. The substitute amendment also contained a provision on fees not previously in the bill, H.R. 1627, and a provision relating to Indian nations' pesticide authority that appeared earlier in H.R. 1627 but that had been changed by compromise language which it was believed would address the concerns of all parties to that issue. The Chairman stated that he would work with all those interested to resolve the issue. Without objection, the substitute amendment to H.R. 1627 was considered as original text for purposes of amendment.

Mr. Volkmer was then recognized to ask Administration witnesses for their views on the fee provisions in the bill. The Administration expressed concern about the cost of the audit required by the bill. Chairman Roberts indicated that he would work with Mr. Volkmer on report language which would address the concerns of the Administration. The advice of the Inspector General and the General Accounting Office had also been requested on that issue.

Mr. Brown was then recognized to offer and explain an amendment regarding reregistration labeling of those pesticides that have not been reregistered. It would have required that each pesticide which is not reregistered by September 30, 1997, bear a label stating that the pesticide is subject to reregistration requirements and may not meet current health and safety standards of the EPA. Mr. Brown expressed his frustration with the reregistration process that began in 1988 and was to have been completed by now. Chairman Roberts indicated his disagreement with the Brown amendment and said that EPA had recently estimated they could not finish reregistration before 2005 and that he did not think that the companies should be punished for the lack of speed and efficiency of EPA. Discussion occurred and without objection, the amendment was withdrawn.

Mr. Brown was further recognized to offer and explain an amendment for himself and on the behalf of Mr. Farr that would require a standard for the submission of data for hormonally active pesticide chemicals. Mr. Brown also noted that the Commerce Committee has some language regarding this issue in legislation that would reauthorize the Safe Drinking Water Act.

Discussion occurred and Chairman Roberts indicated that he would resist putting this in legislation as he thought that EPA had the authority to consider the matter and suggested that Mr. Brown

and staff work together on report language to address Mr. Brown's concerns. Without objection, the amendment was withdrawn.

Mr. Baker was recognized to offer report language regarding Performance Partnership Grants appropriated under the State and Tribal Assistance Grants section and the use of those funds. Discussion occurred and without objection, the report language was adopted.

Mr. Baldacci was recognized to ask staff a question concerning the preemption of local government regulations in section 106 and indicated that he would be offering dissenting views to the report accompanying H.R. 1627 to assure that his concerns about this issue are noted.

Chairman Roberts stated that Messrs. Pombo and Dooley had written to the Chair in relation to a food safety issue involving a potential problem that would be created by a regulation being developed by EPA and the U.S. Fish and Wildlife Service to restrict the use of pesticides within a critical habitat of endangered and threatened species where commercial facilities are located. The Chairman indicated his readiness to work with Messrs. Pombo and Dooley and any other Member on this issue as the bill proceeds to the Floor.

Mr. Gunderson then moved that the amendment to H.R. 1627, as amended, be reported favorably to the House. By a voice vote, H.R. 1627, as amended, was ordered favorably to the House.

Mr. Gunderson also moved that the Committee authorize the Chairman to offer such motions as may be necessary to go to conference with the Senate on the bill H.R. 1627 and other pending business or similar Senate bills. By a voice vote the motion was agreed to.

Without objection, staff was given permission to make such technical, clarifying, or conforming changes as are appropriate without changing the substance of the legislation.

The Chairman then thanked the Members and adjourned the meeting subject to the call of the chair.

REPORTING THE BILL—ROLLCALL VOTES

In compliance with clause 2(l)(2) of rule XI of the House of Representatives, H.R. 1627, was reported, as amended, with a quorum actually present. There was no motion or request for a recorded vote.

BUDGET ACT COMPLIANCE (SECTION 308 AND SECTION 403)

The provisions of clause 2(l)(3)(B) of Rule XI of the Rules of the House of Representatives and section 308(a) of the Congressional Budget Act of 1974 (relating to estimates of new budget authority, new spending authority, or new credit authority, or increased or decreased revenues or tax expenditures) are not considered applicable. The estimate and comparison required to be prepared by the Director of the Congressional Budget Office under clause 2(l)(C)(3) of Rule XI of the Rules of the House of Representatives and section 403 of the Congressional Budget Act of 1974 submitted to the Committee prior to the filing of this report are as follows:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 10, 1996.

Hon. PAT ROBERTS,
Chairman, Committee on Agriculture,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1627, the Food Quality Protection Act of 1996.

Enactment of H.R. 1627 would affect direct spending. Therefore, pay-as-you-go procedures would apply to the bill.

If you wish further details on their estimate, we will be pleased to provide them.

Sincerely,

JAMES L. BLUM
(For June E. O'Neill, Director).

Enclosure.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: H.R. 1627.

2. Bill title: Food Quality Protection Act of 1996.

3. Bill status: As ordered reported by the House Committee on Agriculture on June 19, 1996.

4. Bill purpose: The bill would amend the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, and would provide additional fund to the Environmental Protection Agency (EPA) and the Department of Agriculture (USDA) to continue their responsibilities under these acts. Title I would establish a goal for EPA to review pesticide registrations every 15 years. Title II would direct EPA and USDA to establish programs to facilitate the registration of minor-use pesticides. Minor use of a pesticide is defined as use on a crop grown on less than 300,000 acres nationwide, or where the use is insufficient to provide an economic incentive to the manufacturer to register the pesticide. The bill would authorize the appropriation of $10 million annually for grants to develop the necessary data to support the registration of minor-use pesticides. The bill also would authorize the appropriation of $12 million to the Department of Health and Human Services (HHS) in 1997 for grants to develop data to register pesticides used predominantly in public health programs.

Title III would direct USDA to develop survey data on food consumption patters of infants and children and to improve the data collected by the department on pesticide residues in food. Title IV would change the standards EPA is directed to use when setting tolerances for pesticide residues in raw and processed food. Title V would authorize EPA to continue collecting up to $14 million annually for pesticide reregistration maintenance fees over the 1998–2001 period. In addition, EPA would be authorized to collect an additional $2 million annually in such fees over the 1998–2000 period.

5. Estimated cost to the Federal Government: Assuming appropriation of the amounts either estimated or specifically authorized for discretionary programs conducted by EPA, USDA, and HHS,

enacting H.R. 1627 would lead to fiscal year 1997 funding for pesticide programs of $289 million. CBO estimates that the bill would authorize appropriations totaling about $1.9 billion over the 1997–2002 period.

EPA's authority to collect and spend pesticide reregistration fees from the pesticide industry expires at the end of 1997. The bill would extend the agency's authority to collect $14 million annually for reregistration maintenance fees until 2001, and would authorize the collection of an additional $2 million annually over the 1998–2000 period. Under current law, EPA is authorized to spend reregistration maintenance fees without further appropriation. If H.R. 1627 were enacted, however, the agency would be authorized to spend the fees to pay the costs of reregistration and expedited processing of such applications only to the extent that a matching amount is appropriated for those purposes from general funds. In 1996, approximately $26 million was appropriated for reregistration activities. Over the 1997–2001 period, we assume sufficient amounts would be appropriated for reregistration work to allow the agency to spend all of the fees collected. Hence, the income from the fees and the spending of that income would offset each other in each year, and there would be no net impact on direct spending for each fiscal year.

[By fiscal year, in millions of dollars]

	1996	1997	1998	1999	2000	2001	2002
SPENDING SUBJECT TO APPROPRIATION							
Spending under current law:							
Estimated budget authority	253	—	—	—	—	—	—
Estimated outlays	247	56	15	—	—	—	—
Proposed changes:							
Estimated authorization level	—	289	297	306	315	324	334
Estimated outlays	—	215	276	303	312	321	330
Spending under H.R. 1627:							
Estimated authorization level	253	289	297	306	315	324	334
Estimated outlays	247	271	291	303	312	321	330

The costs of this bill fall within budget functions 300, 350, and 550.

6. Basis of estimate: Spending Subject to Appropriations. For purposes of this estimate, CBO assumes that the bill will be enacted before 1997 appropriations for EPA, USDA, and HHS are provided and that all funds authorized by H.R. 1627 will be appropriated for each fiscal year. The bill would specify authorizations totaling $72 million over the 1997–2002 period for grants to support the registration of minor-use pesticides and public health pesticides. In addition, CBO estimates the bill would authorize the appropriation of $1.8 billion for pesticide programs to be conducted by USDA, EPA, and HHS over the next six years.

CBO estimates that, if H.R. 1627 is enacted, EPA would need to maintain the level of funding provided in 1996 (about $47 million in appropriated funds, plus direct spending of $14 million of pesticide fees) for registering or reregistering pesticides, and establishing food tolerances for pesticide residues over the 1997–2002 period. Estimated appropriations over the six-year period would total $313 million.

CBO estimates that, if H.R. 1627 is enacted, USDA would be required to continue to perform a variety of tasks currently undertaken, such as surveys of pesticide use, collection of data on pesticide residues, research and extension activities related to integrated pest management (IMP) programs, and data management and reporting on pesticide use. These activities at USDA received $206 million in funding for 1996. Section 210 would authorize the appropriation of $10 million annually to USDA to establish a grant program for developing data to support minor-use pesticide registrations. In addition, Title III would require USDA to conduct surveys on food consumption patterns of infants and children. CBO estimates that about $7 million would be required annually to provide such data. In total, CBO estimates the bill would authorize appropriations of $1,475 million over the 1997–2002 period for pesticide and IPM activities at USDA.

Section 237 would direct the Secretary of HHS to establish a grant program for the development of data to support registration or reregistration of pesticides used in the control of public health pests. Based on the bill's specified authorization for fiscal year 1997 and information from HHS, CBO estimates this program would initially cost $12 million a year, increasing to about $14 million by 2002.

Direct Spending. CBO estimates that enacting H.R. 1627 would result in additional offsetting receipts and direct spending of $16 million annually over the 1998–2000 period and $14 million in 2001 from pesticide reregistration fees paid by industry. Thus, this provision would result in no net budgetary impact.

In addition, section 210 would direct the Secretary of Agriculture to collect fees from industry for the use of data developed with federal funds to support minor-use pesticide registrations. The bill also would authorize the Secretary to spend, without further appropriation, any fees collected to conduct additional minor-use pesticide research. CBO estimates that the amount of any fees collected by USDA for this purpose would be spent as authorized, and that over time this provision would result in no net budgetary impact.

7. Pay-as-you-go considerations: Section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985 sets up pay-as-you-go procedures for legislation affecting direct spending or receipts through 1998. CBO estimates that enacting H.R. 1627 would affect direct spending. Therefore, pay-as-you-go procedures would apply to the bill. We estimate the pesticide reregistration fee authorized by this bill would result in new offsetting receipts of $16 million in 1998, and new direct spending of the same amount, thus resulting in no net impact. (The affected fees are already authorized under current law for fiscal years 1996 and 1997.)

[By fiscal year, in millions of dollars]

	1996	1997	1998
Change in outlays	0	0	0
Change in receipts	.....	[1]	.....

[1] Not applicable.

8. Estimated impact on State, local, and tribal governments: H.R. 1627 contains intergovernmental mandates as defined in Public

Law 104–4, but these mandates would impose no costs on state, local, or tribal governments.

This bill would prohibit local governments from regulating pesticides. It also would limit the authority of Indian tribes to regulate pesticides within the boundaries of a reservation. The later provision would limit such authority to reservations in which at least 50 percent of the lands are owned by the tribe or members of the tribe. While these provisions would limit the regulatory authority of these governments and tribes, they would not impose any costs.

9. Estimated impact on the private sector: CBO estimates that annual direct costs imposed by private-sector mandates in the bill would not exceed the $100 million threshold established in Public Law 104–4. Moreover, the direct costs of the new mandates on the private sector could be at least partially offset by savings from changes the bill would make in the registration and reregistration processes and in other aspects of federal pesticide regulation.

Section 105 of the bill would expand the definition of "pesticide" to include nitrogen stabilizers for which manufacturers make pesticidal claims. However, the bill would provide exemptions from regulations for several uses of nitrogen stabilizers that would make the incremental cost to the industry zero.

Further, H.R. 1627 would impose a mandate by extending EPA's authorization to collect certain fees. Under current law EPA requires pesticide manufacturers and developers to submit data on a pesticide's toxicity and behavior in the environment when they apply to register a pesticide for new use or to reregister an existing pesticide. Registrants must pay annual registration maintenance fees in an amount that would total $14 million annually. EPA's authority to collect maintenance fees from registrants expires at the end of 1997. H.R. 1627 would extend EPA's authority to collect registration maintenance fees until 2001 and would authorize an increase in the total level to $16 million, from 1998 to 2000. Thus, the fees required by the bill for fiscal years 1998–2000 would be $16 million more than required for that year under current law, and $2 million more than is currently being paid.

These additional costs to registrants could be at least partially offset by a number of other changes in pesticide programs that could lower the costs of complying with requirements. Savings could result from reforms in the registration and review of agricultural minor-use, antimicrobial, and public health pesticides that would enable EPA to expedite the regulatory process. Moreover, provisions in Title IV would change standards EPA is directed to use when setting tolerances for pesticide residues in raw and processed food and could potentially provide savings to the private sector.

In addition to the potential savings in the bill, H.R. 1627 would authorize an appropriation of $10 million annually for grants to develop necessary data to support the registration of minor-use pesticides. The bill also would authorize an appropriation of $12 million in 1997 for grants to develop data to register pesticides used predominantly in public health programs.

10. Previous CBO estimate: None.

11. Estimate prepared by: Federal cost estimate—Kim Cawley, David Hull, and Jennifer Jenson; State and local government impact—Majorie Miller; private-sector impact—Patrice Gordon.

12. Estimate approved by: Robert A. Sunshine for Paul N. Van de Water, Assistant Director for Budget Analysis.

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of Rule XI of the Rules of the House of Representatives, the Committee estimates that enactment of H.R. 1627, as amended, will have no inflationary impact on the national economy.

OVERSIGHT STATEMENT

No summary of oversight findings and recommendations made by the Committee on Government Reform and Oversight under clause 2(l)(3)(D) of Rule XI of the Rules of the House of Representatives was available to the Committee with reference to the subject matter specifically addressed by H.R. 1627, as amended.

No specific oversight activities other than the hearings detailed in this report were conducted by the Committee within the definition of clause 2(b)(1) of Rule X of the Rules of the House of Representatives.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by titles I–III and V of the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

* * * * * * *

SEC. 2. DEFINITIONS.

For purposes of this Act—

(a) ACTIVE INGREDIENT.—The term "active ingredient" means—

(1) in the case of a pesticide other than a plant regulator, defoliant, [or] desiccant*, or nitrogen stabilizer*, an ingredient which will prevent, destroy, repel, or mitigate any pest;

(2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

(3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant; [and]

(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue[.]*; and*

(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.

* * * * * * *

(u) PESTICIDE.—The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, [and] (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, *and (3) any nitrogen stabilizer,* except that the term "pesticide" shall not include any article that is a "new animal drug" within the meaning of section 201(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(w)), that has been determined by the Secretary of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 201(x) of such Act (21 U.S.C. 321(x)) bearing or containing a new animal drug. *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.*

* * * * * * *

(aa) STATE.—The term "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa. *The term "State" does not include a local government, as defined in subsection (ii), and is not intended to grant any authority or to otherwise refer to local governments or political subdivisions of a State.*

(bb) UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT.—The term "unreasonable adverse effects on the environment" means *(1)* any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide[.]*, 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 the Administrator determines is adequate to protect the public health under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a). 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.*

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(hh) NITROGEN STABILIZER.—The term "nitrogen stabilizer" means any substance or mixture of substances intended for prevent-

ing 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.

(ii) LOCAL GOVERNMENT.—The term "local government" means any political subdivision of a State including counties, townships, cities, towns, parishes, and boroughs, whether home rule entities or not, or any local agency or body of any type which has an organized existence, governmental character, and substantial autonomy including independent or autonomous school districts, housing authorities, and other special districts.

(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 control 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.

(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.

(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).

(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 viruses, 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. 3. REGISTRATION OF PESTICIDES.

(a) * * *

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(c) PROCEDURE FOR REGISTRATION.—

(1) STATEMENT REQUIRED.—Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) * * *

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(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) * * *

(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.

[(ii)] *(iii)* Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an

agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

[(iii)**]** *(iv)* After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i) **[**and (ii)**]**, *(ii), and (iii)*, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

(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 pro-

visions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

(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.

(2) DATA IN SUPPORT OF REGISTRATION.—

(A) *IN GENERAL*.—The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, *the public health and agricultural need for such minor use,* and the level and degree of **[**potential exposure of man and the environment to the pesticide**]** *potential beneficial or adverse effects on man and the environment*. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this Act, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 10, within 30 days after the Administrator registers a pesticide under this Act the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

(B) *ADDITIONAL DATA*.—(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

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(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 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 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 provisions 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.

(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 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 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 extension 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.

(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.

(C) *SIMPLIFIED PROCEDURES*.—Within nine months after the date of enactment of this subparagraph, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) EXEMPTION.—No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

(i) submit or cite data pertaining to such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(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 Adminis-

trator 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.

(3) TIME FOR ACTING WITH RESPECT TO APPLICATION.—

(A) *IN GENERAL.*—The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of the Administrator's determination that it does not comply with the provisions of the Act in accordance with paragraph (6).

(B) *IDENTICAL OR SUBSTANTIALLY SIMILAR.*—(i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that—

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(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, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

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(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 product 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.

(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).

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(f) MISCELLANEOUS.—

(1) * * *

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(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.

(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.

(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 pes-

ticide 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 Committee 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. 4. REREGISTRATION OF REGISTERED PESTICIDES.

(a) * * *

* * * * * * *

(d) PHASE TWO.—

(1) * * *

* * * * * * *

(4) TIME PERIODS.—

(A) * * *

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. *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.

* * * * * * *

(6) SUSPENSIONS AND PENALTIES.—The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if the Administrator determines that (A) progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under paragraph (3)(B) within the time period prescribed by paragraph (4)(B) or (B) the registrant has not submitted such data to the Administrator within such time period. *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 enact-*

ment 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.

* * * * * * *

(e) PHASE THREE.—

(1) * * *

(2) TIME PERIODS.—

(A) * * *

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such paragraph. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. *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.

(3) CANCELLATION.—

(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide. *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.

* * * * * * *

(f) PHASE FOUR.—

(1) * * *

(2) TIME PERIODS.—

(A) * * *

(B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of additional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. *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.

(3) SUSPENSIONS AND PENALTIES.—The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if the Administrator determines that (A) tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under paragraph (1)(B), or (B) progress is insufficient to ensure submission of the data referred to in clause (A) within the time period prescribed by paragraph (2)(B) or the required data have not been submitted to the Administrator within such time period. *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.

(g) PHASE FIVE.—

(1) * * *

(2) REREGISTRATION AND OTHER ACTIONS.—

(A) * * *

* * * * * * *

(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) taking into account available information and reasonable assumptions concerning the dietary exposure levels of food consumers (and major identifiable subgroups of food consumers, including infants and children) to residue of the pesticide in food and available information and reasonable assumptions concerning the variability of the sensitivities of major identifiable groups, including infants and children;

(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.

* * * * * * *

(i) FEES.—

(1) * * *

* * * * * * *

(4) REDUCTION OR WAIVER OF FEES FOR MINOR USE AND OTHER PESTICIDES.—

(A) An active ingredient that is contained only in pesticides that are registered solely for agricultural or nonagricultural minor uses, or a pesticide the value or volume of use of which is small, shall be exempt from the fees prescribed by paragraph (3).

(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.

[(B)**]** *(C)* An antimicrobial active ingredient, the production level of which does not exceed 1,000,000 pounds per year, shall be exempt from the fees prescribed by paragraph (3). For purposes of this subparagraph, the term "antimicrobial active ingredient" means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are—

(i) * * *

* * * * * * *

[(C)**]** *(D)*(i) Notwithstanding any other provision of this subsection, in the case of a small business registrant of a pesticide, the registrant shall pay a fee for the reregistration of each active ingredient of the pesticide that does not exceed an amount determined in accordance with this subparagraph.

* * * * * * *

(5) MAINTENANCE FEE.—

(A) * * *

* * * * * * *

(C)*(i)* The amount of each fee prescribed under subparagraph (A) shall be adjusted by the Administrator to a level that will result in the collection under this paragraph of, to the extent practicable, an aggregate amount of $14,000,000 each fiscal year.

(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.

* * * * * * *

(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.

[(F)**]** *(G)* If any fee prescribed by this paragraph with respect to the registration of a pesticide is not paid by a registrant by the time prescribed, the Administrator, by order and without hearing, may cancel the registration.

[(G)**]** *(H)* The authority provided under this paragraph shall terminate on September 30, **[**1997**]** *2001*.

(6) OTHER FEES.—During the period beginning on the date of enactment of this section and ending on September 30, **[**1997**]** *2001*, the Administrator may not levy any other fees for the registration of a pesticide under this Act except as provided in paragraphs (1) through (5).

(7) APPORTIONMENT.—

(A) * * *

(B) The Administrator, by order, may require any registrant to submit such reports as the Administrator determines to be necessary to allow the Administrator to determine and apportion fees under this subsection **[**or to determine**]***, to determine* the registrant's eligibility for a reduction or waiver of a fee*, or to determine the volume usage for public health pesticides*.

* * * * * * *

(k) REREGISTRATION AND EXPEDITED PROCESSING FUND.—

(1) ESTABLISHMENT.—There shall be established in the Treasury of the United States a reregistration and expedited processing fund *which shall be known as the Reregistration and Expedited Processing Fund*.

[(2) SOURCE AND USE.—All fees collected by the Administrator under subsection (i) shall be deposited into the fund and shall be available to the Administrator, without fiscal year limitation, to carry out reregistration and expedited processing of similar applications.**]**

(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 Accounting 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.

(3) EXPEDITED PROCESSING OF SIMILAR APPLICATIONS.—

(A) The Administrator shall use **[**for each of the fiscal years 1992, 1993, and 1994, 1/7th of the maintenance fees collected, up to $2 million each year**]** *for each of the fiscal years 1997 through 2001, not more than 1/7 of the maintenance fees collected in such fiscal year* to obtain sufficient personnel and resources to assure the expedited processing and review of any application that—

(i) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from any such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; **[**or**]**

(ii) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data**[**.**]***; or*

(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.

(B) Any amounts made available under subparagraph (A) shall be used to obtain sufficient personnel and resources to carry out the activities described in such subparagraph that are in addition to the personnel and resources available to carry out such activities on the date of enactment of this section.

(C) The Administrator shall complete the processing of the unprocessed expedited review applications within 5 years from the date of enactment of the Food Quality Protection Act of 1996.

* * * * * * *

[(5) ACCOUNTING.—The Administrator shall—

[(A) provide an annual accounting of the fees collected and disbursed from the fund; and

[(B) take all steps necessary to ensure that expenditures from such fund are used only to carry out this section.]

(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).

(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.

[(l)**]** *(m)* JUDICIAL REVIEW.—Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 16(b).

* * * * * * *

(n) 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 registration 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.

SEC. 6. ADMINISTRATIVE REVIEW; SUSPENSION.

[(a) CANCELLATION AFTER FIVE YEARS—

[(1) PROCEDURE.—The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five-year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect.]

(a) EXISTING STOCKS AND INFORMATION.—

(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) CANCELLATION AND CHANGE IN CLASSIFICATION.—If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either—

(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or

(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the

Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection (b) and section 25(d), in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to subsection (b) and of submission to the Scientific Advisory Panel pursuant to section 25(d) and proceed in accordance with subsection (c). *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.* The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact.

(c) SUSPENSION.—

(1) ORDER.—If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, the Administrator may, by order, suspend the registration of the pesticide immediately. **[**No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of the Administrator's intention to cancel the registration or change the classification of the pesticide.**]** *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). Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of "imminent hazard". The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the Administrator on the question of whether an imminent hazard exists.

* * * * * * *

(3) EMERGENCY ORDER.—Whenever the Administrator determines that an emergency exists that does not permit the Administrator to hold a hearing before suspending, the Administrator may issue a suspension order in advance of notification to the registrant. *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.* In that case, paragraph (2) shall apply except that (A) the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and (B) no party other than the registrant and the Administrator shall participate except that any person adversely affected may file briefs within the time allotted by the Administrator's rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 16(b).

* * * * * * *

(f) GENERAL PROVISIONS.—

(1) VOLUNTARY CANCELLATION.—

(A) * * *

* * * * * * *

(i) shall publish in the Federal Register a notice of the receipt of the request and make reasonable efforts to inform persons who so use the pesticide of the request; and

(ii) may not approve or reject the request until the termination of the **[**90-day**]** *180-day* period beginning on the date of publication of the notice in the Federal Register, except that the Administrator may waive the **[**90-day**]** *180-day* period upon the request of the registrant or if the Administrator determines that the continued use of the pesticide would pose an unreasonable adverse effect on the environment.

* * * * * * *

(3) TRANSFER OF REGISTRATION OF PESTICIDES REGISTERED FOR MINOR AGRICULTURAL USES.—In the case of a pesticide that is registered for a minor agricultural use:

(A) During the **[**90-day**]** *180-day* period referred to in paragraph (1)(C)(ii), the registrant of the pesticide may no-

tify the Administrator of an agreement between the registrant and a person or persons (including persons who so use the pesticide) to transfer the registration of the pesticide, in lieu of canceling or amending the registration to terminate the use.

* * * * * * *

(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.

* * * * * * *

SEC. 8. BOOKS AND RECORDS.

(a) * * *

(b) INSPECTION.—For the purposes of enforcing the provisions of this Act, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this Act, shall, upon request of any officer or employee of the Environmental Protection Agency or of any State **[**or political subdivision**]**, duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to, and to copy: (1) all records showing the delivery, movement, or holding of such pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee; or (2) in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device. Any inspection with respect to any records and information referred to in this subsection shall not extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed). Before undertaking an inspection under this subsection, the officer or employee must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such in-

spection shall be commenced and completed with reasonable promptness.

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SEC. 19. STORAGE, DISPOSAL, TRANSPORTATION, AND RECALL.

(a) * * *

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(h) RELATIONSHIP TO SOLID WASTE DISPOSAL ACT.—**[**Nothing in**]** *(1) IN GENERAL.—Nothing in* this section shall diminish the authorities or requirements of the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).

(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.

* * * * * * *

SEC. 21. SOLICITATION OF COMMENTS; NOTICE OF PUBLIC HEARINGS.

(a) SECRETARY OF AGRICULTURE.—The Administrator, before publishing regulations under this Act, shall solicit the views of the Secretary of Agriculture in accordance with the procedure described in section 25(a).

(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).

[(b)**]** *(c)* VIEWS.—In addition to any other authority relating to public hearings and solicitation of views, in connection with the suspension or cancellation of a pesticide registration or any other actions authorized under this Act, the Administrator may, at the Administrator's discretion, solicit the views of all interested persons, either orally or in writing, and seek such advice from scientists, farmers, farm organizations, and other qualified persons as the Administrator deems proper.

[(c)**]** *(d)* NOTICE.—In connection with all public hearings under this Act the Administrator shall publish timely notice of such hearings in the Federal Register.

SEC. 22. DELEGATION AND COOPERATION.

(a) DELEGATION.—All authority vested in the Administrator by virtue of the provisions of this Act may with like force and effect be executed by such employees of the Environmental Protection Agency as the Administrator may designate for the purpose.

(b) COOPERATION.—The Administrator shall cooperate with the Department of Agriculture, any other Federal agency, and any appropriate agency of any State **[**or any political subdivision thereof**]**, in carrying out the provisions of this Act, and in securing uniformity of regulations.

* * * * * * *

SEC. 24. AUTHORITY OF STATES *AND INDIAN TRIBES*.

(a) IN GENERAL.—A State may regulate the sale or use of any federally registered pesticide or device in the State *and an Indian tribe may only regulate the sale or use of any federally registered pesticide or device within the boundaries of a Federal Indian reservation for such tribe if at least 50 percent of the lands in such reservation are owned by members of the tribe or the tribe*, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.

(b) UNIFORMITY.—Such State *or Indian tribe* shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act.

(c) ADDITIONAL USES.—

(1) A State *or Indian tribe* may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State *or Indian tribe* to meet special local needs in accord with the purposes of this Act and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 3 for all purposes of this Act, but shall authorize distribution and use only within such State *or Indian tribe*.

(2) A registration issued by a State *or Indian tribe* under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State *or Indian tribe* of the Administrator's intention to disapprove and the reasons therefor, and provide the State *or Indian tribe* time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State *or Indian tribe* under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide.

(3) In no instance may a State *or Indian tribe* issue a registration for a food or feed use unless there exists a tolerance or exemption under the Federal Food, Drug, and Cosmetic Act that permits the residues of the pesticide on the food or feed. If the Administrator determines that a registration issued by a State *or Indian tribe* is inconsistent with the Federal Food, Drug, and Cosmetic Act, or the use of, a pesticide under a registration issued by a State *or Indian tribe* constitutes an imminent hazard, the Administrator may immediately disapprove the registration.

(4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 25 of this Act, that a State *or Indian tribe* is not capable of exercising adequate controls to assure that State *or Indian tribe* registration under this section will be in accord with the purposes of this Act or has failed to exercise adequate controls, the Administrator may suspend the authority of the State *or Indian tribe* to register pesticides until such time as the Administrator is satisfied that the State *or Indian tribe* can and will exercise

adequate controls. Prior to any such suspension, the Administrator shall advise the State *or Indian tribe* of the Administrator's intention to suspend and the reasons therefor and provide the State *or Indian tribe* time to respond.

(d) LOCAL REGULATION.—Subject to subsection (e), a local government shall not impose or continue in effect any requirement or regulation regarding pesticides or devices.

(e) LOCALLY SPECIFIC STATE REGULATION.—Nothing in this section shall prohibit a State from enforcing laws, enacting laws, or implementing regulations applicable to local governments regarding the sale or use of any federally registered pesticide or device.

SEC. 25. AUTHORITY OF ADMINISTRATOR.

(a) IN GENERAL.—

(1) REGULATIONS.—The Administrator is authorized in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this Act. Such regulations shall take into account the difference in concept and usage between various classes of pesticides*, including public health pesticides,* and differences in environmental risk and the appropriate data for evaluating such risk between agricultural [and nonagricultural pesticides]*, nonagricultural, and public health pesticides*.

* * * * * * *

(d) SCIENTIFIC ADVISORY PANEL.—[The Administrator shall]

(1) IN GENERAL.—The Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 6(b) and of the proposed and final form of regulations issued under section 25(a) within the same time periods as provided for the comments of the Secretary of Agriculture under such sections. The time requirements for notices of intent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the requirements of section 6(b) or 25(a), as applicable, the advisory panel has failed to comment on the proposed action within the prescribed time period or has agreed to the modification or waiver. The Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this Act. The comments, evaluations, and recommendations of the advisory panel submitted under this subsection and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections. The chairman of the advisory panel, after consultation with the Administrator, may create temporary subpanels on specific projects to assist the full advisory panel in expediting and preparing its evaluations, comments, and recommendations. The subpanels may be composed of scientists other than members of the advisory panel, as deemed necessary for the purpose of evaluating scientific studies relied

upon by the Administrator with respect to proposed action. Such additional scientists shall be selected by the advisory panel. The panel referred to in this subsection shall consist of 7 members appointed by the Administrator from a list of 12 nominees, 6 nominated by the National Institutes of Health and 6 by the National Science Foundation, utilizing a system of staggered terms of appointment. Members of the panel shall be selected on the basis of their professional qualifications to assess the effects of the impact of pesticides on health and the environment. To the extent feasible to insure multidisciplinary representation, the panel membership shall include representation from the disciplines of toxicology, pathology, environmental biology, and related sciences. If a vacancy occurs on the panel due to expiration of a term, resignation, or any other reason, each replacement shall be selected by the Administrator from a group of 4 nominees, 2 submitted by each of the nominating entities named in this subsection. The Administrator may extend the term of a panel member until the new member is appointed to fill the vacancy. If a vacancy occurs due to resignation, or reason other than expiration of a term, the Administrator shall appoint a member to serve during the unexpired term utilizing the nomination process set forth in this subsection. Should the list of nominees provided under this subsection be unsatisfactory, the Administrator may request an additional set of nominees from the nominating entities. The Administrator may require such information from the nominees to the advisory panel as the Administrator deems necessary, and the Administrator shall publish in the Federal Register the name, address, and professional affiliations of each nominee. Each member of the panel shall receive per diem compensation at a rate not in excess of that fixed for GS–18 of the General Schedule as may be determined by the Administrator, except that any such member who holds another office or position under the Federal Government the compensation for which exceeds such rate may elect to receive compensation at the rate provided for such other office or position in lieu of the compensation provided by this subsection. In order to assure the objectivity of the advisory panel, the Administrator shall promulgate regulations regarding conflicts of interest with respect to the members of the panel. The advisory panel established under this section shall be permanent. In performing the functions assigned by this Act, the panel shall consult and coordinate its activities with the Science Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978. Whenever the Administrator exercises authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly submit to the advisory panel for comment, as to the impact on health and the environment, the action taken to suspend the registration of such pesticide.

(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.

(e) PEER REVIEW.—The Administrator shall, by written procedures, provide for peer review with respect to the design, protocols, and conduct of major scientific studies conducted under this Act by the Environmental Protection Agency or by any other Federal agency, any State [or political subdivision thereof], or any institution or individual under grant, contract, or cooperative agreement from or with the Environmental Protection Agency. In such procedures, the Administrator shall also provide for peer review, using the advisory panel established under subsection (d) of this section or appropriate experts appointed by the Administrator from a current list of nominees maintained by such panel, with respect to the results of any such scientific studies relied upon by the Administrator with respect to actions the Administrator may take relating to the change in classification, suspension, or cancellation of a pesticide. Whenever the Administrator determines that circumstances do not permit the peer review of the results of any such scientific study prior to the Administrator's exercising authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly thereafter provide for the conduct of peer review as provided in this sentence. The evaluations and relevant documentation constituting the peer review that relate to the proposed scientific studies and the results of the completed scientific studies shall be included in the submission for comment forwarded by the Administrator to the advisory panel as provided in subsection (d). As used in this subsection, the term "peer review" shall mean an independent evaluation by scientific experts, either within or outside the Environmental Protection Agency, in the appropriate disciplines.

SEC. 26. STATE *AND INDIAN TRIBE* PRIMARY ENFORCEMENT RESPONSIBILITY.

(a) IN GENERAL.—For the purposes of this Act, a State *or Indian tribe* shall have primary enforcement responsibility for pesticide use violations *and an Indian tribe with respect to violations which occur within the boundaries of a Federal Indian reservation for such tribe, but only if at least 50 percent of the lands in such reservation are owned by members of the tribe or the tribe* during any period for which the Administrator determines that such State *or Indian tribe*—

(1) has adopted adequate pesticide use laws and regulations, except that the Administrator may not require a State *or Indian tribe* to have pesticide use laws that are more stringent than this Act;

(2) has adopted and is implementing adequate procedures for the enforcement of such State *or Indian tribe* laws and regulations; and

(3) will keep such records and make such reports showing compliance with paragraphs (1) and (2) of this subsection as the Administrator may require by regulation.

(b) SPECIAL RULES.—Notwithstanding the provisions of subsection (a) of this section, any State *or Indian tribe* that enters into

a cooperative agreement with the Administrator under section 23 of this Act for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of section 11 of this Act that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under section 11 of this Act in effect on the date of enactment of the Federal Pesticide Act of 1978 not later than six months after that date.

(c) ADMINISTRATOR.—The Administrator shall have primary enforcement responsibility for those States *or Indian tribes* that do not have primary enforcement responsibility under this Act. Notwithstanding the provisions of section 2(e)(1) of this Act, during any period when the Administrator has such enforcement responsibility, section 8(b) of this Act shall apply to the books and records of commercial applicators and to any applicator who holds or applies pesticides, or uses dilutions of pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and section 9(a) of this Act shall apply to the establishment or other place where pesticides or devices are held for application by such persons with respect to pesticides or devices held for such application.

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SEC. 28. IDENTIFICATION OF PESTS; COOPERATION WITH DEPARTMENT OF AGRICULTURE'S PROGRAM.

(a) * * *

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(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.

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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.

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.

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.

SEC. [30.] *33.* SEVERABILITY.

If any provision of this Act or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this Act which can be given effect without regard to the invalid provision or application, and to this end the provisions of this Act are severable.

SEC. [31.] *34.* AUTHORIZATION FOR APPROPRIATIONS.

There is authorized to be appropriated to carry out this Act (other than section 23(a))—

(1) $83,000,000 for fiscal year 1989, of which not more than $13,735,500 shall be available for research under this Act;

(2) $95,000,000 for fiscal year 1990, of which not more than $14,343,600 shall be available for research under this Act; and

(3) $95,000,000 for fiscal year 1991, of which not more than $14,978,200 shall be available for research under this Act.

ADDITIONAL VIEWS OF HON. JOHN BALDACCI

The Food Quality Protection Act of 1995 ensures that the system of pesticide regulation will undergo needed reforms. The Titles reported by the House Agriculture Committee not only continue to protect human health and safety, they create sensible laws for America's farmers.

I am especially pleased with reforms contained in Title II, Subtitle A—Minor Use Crop Protection. The streamlined procedures contained in the legislation will benefit the thousands of farmers engaged in the production of fruits and vegetables. The benefits of a diet rich in these foods are undeniable.

However, I remain troubled by Title I, Section 106, Authority of States. This Section would create a federal preemption of the rights of local governments to impose or continue in effect any pesticide regulations.

The thrust of many of the reforms considered by the 104th Congress has been to give authority to states and local units of governments. The change embodied in this legislation runs counter to those efforts. This change would impede the ability of communities to craft local solutions to local problems.

With Section 106, Congress imposes itself into decisions that are best left to state and local governments. While many states already have passed laws preempting local authority over pesticides, 10 have not. The local preemption contained in H.R. 1627 seems to be little more than a solution in search of a problem.

JOHN BALDACCI.

ADDITIONAL VIEWS OF HON. GEORGE E. BROWN, JR.

Consideration of H.R. 1627, the Food Quality Protection Act, has become a tradition of this Committee. I have wrestled with many of the issues addressed by this legislation since I first became a member of the House Agriculture Committee 24 years ago. The portions of the bill amending FIFRA, as reported, represent an improvement over the original bill. However, I continue to have a number of reservations about this legislation.

One of these reservations pertains to the issue of pesticide reregistration and the authorization of fees to support this activity. First, a bit of history. In 1972, Congress passed the first comprehensive FIFRA law and mandated that all of the pesticides registered at that time be brought up to the new registration standards for health and safety by 1976. In 1976, the deadline was moved to 1978. In 1978, the deadline was done away with and the EPA was told to review all of the pesticides, giving top priority to food and agriculture chemicals, as soon as they could.

During the 1980's there were a series of pesticides crises due to the discovery of adverse health effects from pesticides undergoing the EPA process of review. Ethylene dibromide and alar are two memorable "surprises" caused by this ad hoc review process.

In 1988, this Committee made a promise to the American people that we would accelerate the review of pesticides on the market at the time. The Committee felt that since most of the "surprises" had been coming from chemicals grandfathered in under increasingly stringent requirements, the best use of limited resources would be to work on the backlog of chemicals to insure that they met current health and safety standards.

Back in 1988, the General Accounting Office estimated that EPA would take until 2005 to finish the job. The Committee wanted the job done faster and was willing to allow EPA to impose fees on the chemical industry to pay for the additional financial burden that an accelerated reregistration would entail.

Yet here we are today, having broken another promise with the American people. In 1997 when the latest reregistration deadline lapses, on the 25th anniversary of the passage of the 1972 FIFRA law when we first promised to bring all registered pesticides up to current standards, we will have failed again.

Who are the losers? Farmers and ranchers lose because they cannot defend themselves against critics who claim adverse health and safety effects from the pesticides they use. Consumers lose because they cannot be confident that EPA is protecting them against health risks. Processors lose as they await another pesticide scare, perhaps blown out of proportion in the absence of definitive health and safety data.

I am pleased that we have included a reauthorization for the collection of reregistration fees in this bill. However, I am concerned

that the level of the authorization is too low and that the duration of the authorization is too short to enable EPA to complete the reregistration. As time goes on, recommendations made by the scientific community are increasing the number and complexity of the health and safety tests for pesticides. The 1993 National Academy of Sciences report, "Pesticides in the Diets of Infants and Children" is a recent example of increased complexity. These additional evaluations require more time and more money to complete, not less. The current fee reauthorization does not sufficiently take these factors into account.

There are several other issues within the FIFRA portion of the bill which should be addressed when the bill comes before the House. Section 106: Authority of States was included in response to the 1991 Supreme Court decision in Wisconsin Public Intervenor v. Mortier which stated that local governments are not pre-empted by FIFRA from regulating the sale and use of pesticides.

In my view, this provision of the bill is unnecessary and attempts to address a problem that does not exist. Forty states have already enacted their own statutes to clarify the role of State and local government in regard to the regulation of pesticides. The remaining ten States where local governments maintain the authority to regulate in this area have the ability to enact a law to deal with any problems that might arise from over-regulation of pesticides by local communities.

Furthermore, there is some ambiguity about exactly which laws would be affected by this section. I asked the American Law Division of the Congressional Research Service to examine Section 106 of the bill and to provide me with an analysis. I have also seen an analysis of the same Section requested from the State of Wisconsin's Attorney General's office. The analyses are somewhat different, but raise similar questions and illustrate the lack of clarity in the language of this section.

According to the American Law Division's analysis there are two possible interpretations of the addition to FIFRA; new section 24(e). This section could be interpreted to allow States to grant their local jurisdictions authority to regulate pesticides independently of any State scheme, or it could be interpreted to mean that only states can initiate pesticide requirements. Under the latter interpretation, local governments would never be permitted to enact pesticide requirements that differed from those of the state even if a state decided they could do so.

It is also unclear whether only laws explicitly dealing with pesticide sale and use will be subject to Section 106 or whether laws involving regulation of pesticide use by local governments in the context of water quality protection, such as the Safe Drinking Water Act groundwater protection provisions, would be affected. Enactment of Section 106 may result in state-local water quality plans in a number of states falling victim to the law of unintended consequences. The American Law Division's analysis indicated this might be a problem if the language were interpreted broadly by judicial review, but not if it were interpreted narrowly. While the American Law Division felt the narrow interpretation would be more likely, the Wisconsin Attorney General's office suggested the broader interpretation was more likely, and their analysis indi-

cated that water quality protection laws might be jeopardized by this provision.

In either case, it appears this Section may introduce a number of problems while solving nothing. There has never been any evidence presented to show that local communities have run amok enacting excessive pesticide laws. In the case of Section 106 of H.R. 1627, it would be best if we followed the old adage: if it isn't broken, don't fix it.

During the Committee markup I offered, and subsequently withdrew, an amendment to require EPA to develop a data standard for hormonally active pesticides under existing authorities in Sections 3 and 4 of FIFRA. These substances, commonly referred to as endocrine disrupters, are believed to interfere with fundamental biological functions such as reproduction and development in humans and other organisms. A link to some types of breast cancer has also been suggested. The Chairman was gracious enough to offer me the opportunity to include language addressing this subject in the report accompanying the bill. However, I continue to believe we need statutory language to move this process along. As I indicated during the markup, I plan to offer my amendment again when the bill comes before the House.

My greatest reservations about H.R. 1627 concern Title IV: the amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA).

Of particular concern to me as a Californian is the provision in this Title that would override California's state law: Proposition 65. California has exercised its option to adopt a law that is more stringent than Federal law in some areas of food safety. Under the right-to-know provisions of Proposition 65 food products containing chemical residues known to cause cancer or adverse reproductive effects are required to bear a label informing the consumer about the presence of these residues.

Although aspects of this law are not popular with some in the agribusiness industry, there is no evidence that it has had any negative impact an agricultural production in California. Our state produces a wide variety of the finest agricultural products in the world. Our strong food safety laws facilitate, not hinder, the export of our agricultural products—products which we can confidently claim are the safest, highest quality agricultural products in the world. If reforming FIFRA and FFDCA comes at the expense of California's state law, the price is too high. Inclusion of this provision to override California's law is likely to draw vigorous opposition from other members of the California delegation. This is another provision of H.R. 1627 that is a solution in search of a problem.

The FFDCA amendments of H.R. 1627 also attempt to elevate the international standards set by the Codex Alimentarius Commission to a position of preeminence over our own national standards. The U.S. EPA should not have to provide an elaborate explanation in order to establish a standard stricter than one set by an international organization. The U.S. has many environmental and public health standards that exceed international ones. We should be looking for ways to encourage the international community to adopt stricter standards. Our citizens have nothing to gain if our

government is encouraged to participate in a race to the bottom where health and safety standards are concerned.

We face a difficult task in reforming the tolerance-setting provisions of FFDCA if we are to follow the recommendations in the 1987 National Academy of Sciences Report on the Delaney clause because we will be moving from zero risk to some risk with respect to carcinogens. In the process of developing this reform package we should not lose sight of the primary purpose of this law: to ensure the safety of the food supply.

Neither the 1987 NAS Report or the 1993 NAS Report on Pesticides in the Diets of Infants and Children declared our pesticide laws to be excessive in the area of public health protection. The scientific shortcomings of the Delaney clause relate as much to health effects as they do to the problem of detecting infinitesimal, and perhaps insignificant quantities of pesticide residues. The Delaney clause has also resulted in too great an emphasis on carcinogenic effects of pesticides, while other toxic effects may have received less attention than were warranted. The NAS recommendations regarding infants and children should be incorporated with the same enthusiasm we have for correcting flaws related to the Delaney clause.

If we are to succeed in our efforts, we are going to have to develop a standard-setting process the public believes will protect them from potential health hazards resulting from pesticides residues in food. A scheme which includes broadly defined considerations of the benefits of pesticide use will not accomplish this. Whether it is right or wrong, scientific or unscientific, consumers are interested in one thing only: the safety of the food they are eating. If the public feels that we are replacing current law with one designed primarily to maintain pesticide sales and current agricultural practices rather than to protect public health, we will be unsuccessful in our efforts to achieve reform. The proposed revisions to Section 408 of FFDCA in H.R. 1627 now suffer from this appearance.

I have worked for many years to reasonably reform our pesticide laws so they would reflect an appropriate balance between the need for farmers and ranchers to utilize cost-effective tools to produce the food and fiber we all depend on, and the need for comprehensive, scientifically-based laws to ensure the safety of our food supply and the health of the public and our environment. I hope we will be able to work together to realize this goal during the 104th Congress. This bill needs to garner the type of broad-based support that was achieved with the Amendments to the Safe Drinking Water Act. While H.R. 1627 has considerable support with the agribusiness community, it appears we still have a way to go before it will also have the support of consumer and environmental advocates.

GEORGE E. BROWN, Jr.

ADDITIONAL VIEWS ON H.R. 1627

(TITLE VI—INDIAN RESERVATIONS)

There are concerns that have been expressed by a number of groups in regard to the constitutionality of the provisions in Title VI dealing with the ability of Indian tribes to regulate the sale and use of pesticides utilizing Federal statutes. This includes the Environmental Protection Agency, the Department of Agriculture and a number of tribes and organizations representing Native Americans. We have included several letters along with our views which articulate the concerns surrounding these provisions.

The restrictions on the authority of tribes to regulate the use of pesticides on their own reservations could result in the Federal Government being required to enforce pesticide use violations on a significant number of Indian tribes. It appears to us that this compromise language would be even more unworkable than the provision previously adopted by the full Committee.

In addition to the potential for a dramatically increased workload on the agency, the provision provides for an arbitrary cut-off for trying to determine which reservations will be able to carry out their own pesticide programs. This would treat a portion of Indian reservations in this country differently from another portion only because of the application of allotment policy and other policies which have resulted in a combination of trust and fee lands within reservations in certain parts of the country. By targeting only those reservations which were subject to these policies, we are reversing long-standing policies within the Federal Government, upheld by the Supreme Court, which recognize the sovereignty of tribal governments and their treatment as States for the administration of Federal policy.

It is our hope that the Members who have an interest in this issue will continue to discuss the provisions in Title VI as H.R. 1627 proceeds to the floor. We have supported this legislation and hope that the inclusion of these provisions do not jeopardize the future progress of the legislation.

TIM JOHNSON.
CHARLIE ROSE.
EVA M. CLAYTON.
COLLIN C. PETERSON.
EARL POMEROY.
BENNIE G. THOMPSON.

JUNE 28, 1996.

Hon. PAT ROBERTS,
Chairman, Committee on Agriculture,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: In response to the June 19, 1996, mark-up of H.R. 1627, the Administration reiterates its opposition to the Title VI language which would limit Tribal regulatory authority. Title VI would amend sections 24 and 26 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to limit explicitly Indian tribal authority to regulate and enforce pesticide usage on Federal Indian Reservations to those instances in which the Tribe or Tribal members own at least fifty percent of the lands within the Reservation.

The Administration continues to strongly support Tribal authority to regulate pesticide use on lands within Tribal jurisdiction. These amendments would limit the authority of Indian Tribes to protect their economic security, health and welfare. The amendment is inconsistent with policies supported by every President of the United States for the past 30 years.

The Clinton Administration maintains a government-to-government relationship between Indian Tribes and the Federal Government and encourages Tribal self-governance. The U.S. Environmental Protection Agency (EPA), the U.S. Department of Agriculture (USDA), and the Department of the Interior recognize the sovereign status of Tribal governments and recognize the rights of the Tribes to govern themselves and manage their resources. The provisions in H.R. 1627 undermine the government-to-government relationship with Tribes by diminishing Tribal authority without prior consultation. The changes to this amendment made at full Committee could result in the Federal Government being required to enforce pesticide use violations on a significant number of Federal Indian Reservations. This level of direct Federal activity is inconsistent with the general trend to allow more local control to strengthen environmental protection. Since Federal resources generally are not available to implement pesticides programs at the local level, significant gaps may be created in environmental protection on reservations. This could leave reservations and their populace (both Indian and non-Indian) less protected than the rest of the Nation and, in certain situations, might abrogate Federal obligations to Tribes.

The Administration is opposed to the Title VI Indian-specific language. Since 1984, the EPA has recognized Tribal governments as the appropriate parties to regulate Tribal environments, wherever Tribes can demonstrate the ability to do so. The USDA Native American policy also recognizes the sovereign status of Tribal governments as well as the rights of Tribes to manage Tribal resources. For years, a number of Tribes have regulated pesticide use on reservation lands through cooperative agreements with EPA. The record is one of sensible environmental protection, respect, cooperation, and a few, well-justified enforcement actions. We look forward to working with you to strengthen our pesticide and food safety laws.

The Office of Management and Budget advises that there is no objection to the presentation of these views from the standpoint of the President's Program.

Sincerely,

CAROL M. BROWNER,
Administrator, Environmental Protection Agency.
DAN GLICKMAN,
Secretary, Department of Agriculture.
BRUCE BABBITT,
Secretary, Department of the Interior.

INTERTRIBAL AGRICULTURE COUNCIL,
Billings, MT, June 20, 1996.

Hon. PAT ROBERTS,
House Agriculture Committee,
Longworth House Office Building, Washington, DC.

DEAR CONGRESSMAN ROBERTS: Please accept this correspondence as comment on H.R. 1627 which amends the Federal Insecticide, Fungicide, and Rodenticide Act and the Food and Drug Act. The added Bereuter Amendment restricts administration of FIFRA to only those Indian Reservations in which the Tribe or members of that Tribe own greater than 50 percent of the land within the external boundaries of that respective Reservation.

This amendment will unfairly affect those Indian Reservations which were subject to the Allotment Acts. Beyond focusing on allotted Reservations, this amendment is a complete reversal of long established application of federal law, not state law, on Indian Reservations. The Bereuter Amendment flies in the face of the government-to-government relationship by stating that this relationship is only recognized if you own land.

The Bereuter Amendment puts FIFRA regulatory authority in the hands of state governments which is in direct conflict with present U.S. and Environmental Protection Agency policy. EPA policy states "EPA recognizes Tribal Governments as sovereign entities with primary authority and responsibility for the reservation populace. Accordingly, EPA will work directly with Tribal Governments as the independent authority for reservation affairs and not as political subdivisions of States or other governmental units."

Please assist this organization in preventing this amendment to H.R. 1627 from abrogating 150 years of federal Indian policy and assist us in assuring that Tribal Governments, working with EPA, can continue their stewardship of the earth.

Sincerely,

GREG SMITMAN, *Executive Director.*

NATIONAL CONGRESS OF AMERICAN INDIANS,
Washington, DC, July 10, 1995.

Re H.R. 1627—FIFRA Amendment and Indian Tribes.

Hon. PAT ROBERTS,
Chairman, Agriculture Committee,
House of Representatives, Washington, DC.

DEAR CHAIRMAN ROBERTS: On behalf of the National Congress of American Indians (NCAI), the oldest, largest, and most representative advocacy organization in the nation, I am writing on behalf of our Tribes in opposition to language concerning Indian Tribes that has been added to H.R. 1627, amendments to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). This language, offered by Rep. Bereuter, provides that "an Indian Tribe could regulate the sale or use of any federally registered pesticide or device within the boundaries of a Federal Indian reservation for such tribe, *except lands in such reservation owned in whole or in part by a non-member of the tribe*" (emphasis added), and goes on to say that Tribal governments would not have enforcement authority for FIFRA violations occurring on reservation lands owned in whole or in part by a non-member of the tribe.

Such as amendment flies in the face of well-established Supreme Court precedent holding that the authority of Tribal governments is *not* limited to authority over Tribal citizens on lands that are held in trust by the U.S., but may be exercised to control the conduct of non-members and non-Indians within reservation boundaries when that conduct may affect the Tribe's political integrity, economic security, or health and welfare, See *Montana* v *United States,* 450 U.S. 544, 656–66 (1981).

If inappropriately regulated the chemicals FIFRA regulates obviously "may affect" the health and welfare of those residing on reservation, and if left unregulated could threaten the long-term political integrity and economic viability of the reservation. There are many Indian Tribes that are now managing EPA-approved FIFRA programs, and the Bereuter amendment would create inconsistent application of FIFRA and result in a regulatory and jurisdictional void within the boundaries of Indian reservations. We therefore urge you, as Chairman of the Agriculture Committee, to delete the language contained in the Bereuter amendment before reporting HR 1627 to the full House of Representatives. If you have any questions, or need additional information, please contact me or Paul Moorehead of our staff at (202) 466–7767.

Sincerely.

JOANN K. CHASE, *Executive Director.*

DUCHENEAUX, TAYLOR & ASSOCIATES,
Washington, DC, June 18, 1996.

Re H.R. 1627—Bereuter amendments to FIFRA.

Hon. PAT ROBERTS,
Chairman, Committee on Agriculture,
House of Representatives, Washington, DC.

DEAR CHAIRMAN ROBERTS: As currently written, H.R. 1627 contains a provision to amend two sections of Title 7, U.S.C., the Fed-

eral Insecticide, Fungicide and Rodenticide Act (FIFRA) in a way which is highly objectionable to Indian tribes. This provision was incorporated in the bill at the request of Rep. Bereuter of Nebraska when the House Agriculture Committee acted on the bill last year.

This amendment would limit the authority of tribes to administer this program to lands that are wholly owned by the tribe or tribal members. Because of the land ownership on most Indian reservations, this will effectively strip tribes of the authority EPA has recognized that tribes possess under the existing law.

About 54 million acres of land are held for Indians by the United States in trust or restricted status in the contiguous 48 states. Approximately 15 million of these acres are located on the Navajo Reservation in Arizona, New Mexico and Utah. The remaining 39 million acres of trust or restricted lands are located in 29 states—mostly in the west. Most of these reservations have highly "checker-board" land ownership patterns with intermingling of Indian and non-Indian ownership of individual tracts. Many thousands of acres of allotted lands are held in multiple-ownership with fractional interests in individual parcels owned by non-member Indians or non-Indians.

We understand that over 30 tribes throughout the country currently operate FIFRA programs. A list of 20 such tribes is attached to this memorandum. If the Bereuter amendment remains in the bill most if not all of these programs will close. We urge that the Bereuter amendments be deleted from this bill.

Sincerely,

PETER S. TAYLOR.

LIST OF TRIBES OPERATING FIFRA PROGRAMS

Region 5

White Earth Band of Chippewa

Region 6

Jicarilla Apache Tribe

Region 7

Santee Sioux Tribe
Omaha Tribe
Winnebago

Region 8

Standing Rock Sioux Tribe
Three Affiliated Tribes of Fort Berthold
Cheyenne River Sioux Tribe
Rosebud Sioux Tribe
Oglala Sioux Tribe

Region 9

Ak Chin Tribe
Coccopath Tribe
Colorado River Indian Tribes
Fort Mohave Tribe
Gila River Indian Community

Navajo Tribe
Quechan Tribe
Salt River Pima Maricopa Indian Community

Region 10

Couer d'Alene Tribe
Shoshone-Bannock Tribes of Fort Hall.

MNI-SOSE INTERTRIBAL WATER RIGHTS
COALITION, INC.,
Rapid City, SD, June 21, 1996.

Re H.R. 1627.

Hon. TIM JOHNSON,
Committee on Agriculture,
House of Representatives, Washington, DC.

DEAR CONGRESSMAN JOHNSON: Please find enclosed a Mni Sose Intertribal Water Rights Coalition Resolution 96–14, An intertribal resolution in opposition to H.R. 1627, an amendment to the Federal Insecticide, Fungicide, and Rodenticide Act.

The Twenty-four (24) member Tribes of the Coalition, representing over 100,000 tribal people, strongly oppose the limitations imposed on the Tribal ability to protect and preserve safe, sanitary environments for Indian families and communities. The Bereuter Amendment as proposed would limit and restrict tribal leadership's ability to manage and control toxic substances on their lands. Although the amendment cites certain conditions that would be necessary to evoke the effects of the Bureuter Amendment, the tribal leaders perceive that an limitation within federal laws and regulations that ignores or reduces the tribe's sovereignty and ability to protect their tribal member from harm is unacceptable.

The effects of the Bereuter Amendment will result an increase in pollution in Indian communities and unregulated use of toxic substances on tribal lands.

On behalf of the Board of Directors, I request your support and assistance in the deletion of the Bereuter Amendment from future action on the Federal Insecticide, Fungicide, and Rodenticide Act.

Thank you for your consideration of this request.

Sincerely,

RICHARD BAD MOCCASIN, *Executive Director.*

A RESOLUTION OF THE MNI SOSE INTERTRIBAL WATER RIGHTS COALITION TO OPPOSE H.R. 1627, A BILL TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT, TO LIMIT TRIBAL AUTHORITY TO LANDS WHOLLY OWNED BY A TRIBE OR ITS MEMBERS

Whereas, Mni Sose Intertribal Water Rights Coalition, Inc., (herein after called Mni Sose) is a non-profit corporation dedicated to the preservation, enhancement, and protection of water rights of Indian Tribes in the Missouri River Basin; and

Whereas, the Missouri River Basin Tribes, by virtue of inherent Tribal sovereignty and the acknowledgment by Congress of Tribal authority in the area of environmental protection, are the appropriate sovereigns to protect the environment on or near Indian Reservations; and

Whereas, Mni Sose is composed of twenty-four Indian Tribes located in the Missouri River Basin with vested interests in water rights; and

Whereas, Mni Sose Coalition Member Tribes have collectively identified its' long range goals as: strengthening Tribal capabilities so member Tribes can appropriately manage control, and to protect water resources pursuant to individual Tribal goals and values as defined by Tribal laws; and

Whereas, the House Agriculture Committee has provided action on the Federal Insecticide, Fungicide, and Rodenticide Act, identified at H.R. 1627, and

Whereas, H.R. 1627 is amended to limit tribal authority to operate FIFRA programs on specific lands, and

Whereas, H.R. 1627 contains an amendment, commonly known as the Bereuter Amendment, to limit tribal authority to operate FIFRA programs on lands only if at least 50 percent of such lands on such reservations are owned by members of the tribe or the tribe; and

Whereas, the proposed amendment to H.R. 1627, would severely impact the tribal authority to develop environmental protection strategies on traditional homelands; and

Whereas, the proposed amendment to H.R. 1627, ignores or aborigates sovereignty of the tribes and ignores Executive Orders and other appropriate laws; now

Therefore be it resolved, the House Agriculture Committee and the United States House of Representatives recognize the sovereignty of the Tribes and limit H.R. 1627 amendments to respect tribal sovereignty.

Be it further resolved, that the Bereuter Amendment be removed from the language of the amendments to H.R. 1627.

KICKAPOO TRIBE IN KANSAS,
Horton, KS, June 19, 1996.

Hon. PAT ROBERTS,
Chairman, Committee on Agriculture,
House of Representatives, Washington, DC.

DEAR HONORABLE ROBERTS: The Kickapoo Tribe in Kansas opposes the Bereuter Bill (H.R. 1627) which proposes to amend the federal Insecticide, Fungicide and Rodenticide Act (FIFRA) of 1947, and the Food, Drug and Cosmetic Act of 1958. The bill will change 24 U.S.C. 136v, subsection (a) to read as follows:

> Section 136v, Authority of States.
>
> (a) IN GENERAL.—A State may regulate the sale or use of any federally registered pesticide or device in the State and an Indian tribe may regulate the sale or use of any federal registered pesticide or device within the boundaries of a Federal Indian reservations for such tribe, except lands in such reservation owned in whole or in part by a nonmember of the tribe, but only if and to the extent the regulation does not permit any sale or use prohibited by the subchapter.

This amendment effectively limits the authority of Indian Tribe to administer the FIFRA program to lands wholly owned by tribes or tribal members. Because land ownership on most reservations is fractionated, this language strips tribes of authority that EPA has recognized, they possess under existing law.

Your support in defeating H.R. 1627 will be greatly appreciated.

Sincerely,

FRED THOMAS, *Chairman.*

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