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FOOD QUALITY PROTECTION ACT OF 1996

JULY 23, 1996.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. BLILEY, from the Committee on Commerce, submitted the following

R E P O R T

[To accompany H.R. 1627]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, 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 an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:

Page 50, strike line 5 and all that follows through page 91, line 16, and insert the following:

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

SEC. 401. SHORT TITLE AND REFERENCE.

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

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

SEC. 402. DEFINITIONS.

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

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

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

"(A) a pesticide chemical; or

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

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

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

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

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

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

"(2) a pesticide chemical; or".

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

"(gg) The term 'processed food' means any food other than a raw agricultural commodity and includes any raw

agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

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

SEC. 403. PROHIBITED ACTS.

Section 301(j) (21 U.S.C. 331(j)) is amended in the first sentence by inserting before the period the following: "; or the violating of section 408(i)(2) or any regulation issued under that section.".

SEC. 404. ADULTERATED FOOD.

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

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

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

"TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

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

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

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

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

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

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

"(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue

that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

"(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B).

"(3) RESIDUES OF DEGRADATION PRODUCTS.—If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

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

"(B) either—

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

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

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

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

"(b) AUTHORITY AND STANDARD FOR TOLERANCE.—

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

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

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

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

"(2) STANDARD.—

"(A) GENERAL RULE.—

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

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

"(iii) RULE OF CONSTRUCTION.—With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

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

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

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

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

"(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a 'threshold effect'), the Administrator determines that the level of aggregate exposure is safe.

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

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

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

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

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

"(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

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

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

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

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

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

"(C) EXPOSURE OF INFANTS AND CHILDREN.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

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

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

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

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

"(ii) shall—

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

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

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

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

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

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

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

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

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

"(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances

in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

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

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

"(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

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

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

"(ii) REQUIREMENT.—If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

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

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

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

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

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

"(3) DETECTION METHODS.—

"(A) GENERAL RULE.—A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

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

"(4) INTERNATIONAL STANDARDS.—In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

"(c) AUTHORITY AND STANDARD FOR EXEMPTIONS.—

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

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

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

"(2) STANDARD.—

"(A) GENERAL RULE.—

"(i) STANDARD.—The Administrator may establish or leave in effect an exemption from

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

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

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

"(3) LIMITATION.—An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

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

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

"(d) PETITION FOR TOLERANCE OR EXEMPTION.—

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

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

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

"(2) PETITION CONTENTS.—

"(A) ESTABLISHMENT.—A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

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

"(II) a statement that the petitioner agrees that such summary or any information it con-

tains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

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

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

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

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

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

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

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

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

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

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

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

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

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator may require a petition to be

accompanied by samples of the pesticide chemical with respect to which the petition is filed.

"(B) MODIFICATION OR REVOCATION.—The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

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

"(4) ACTIONS BY THE ADMINISTRATOR.—

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

"(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

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

"(iii) issue an order denying the petition.

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

"(C) EXPEDITED REVIEW OF CERTAIN PETITIONS.—

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

been left in effect or modified under subsection (b)(2)(B), the Administrator shall complete action on such petition under this paragraph within 1 year.

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

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

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

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

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

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

"(2) NOTICE.—Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

"(f) SPECIAL DATA REQUIREMENTS.—

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

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

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

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

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

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

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

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

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

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

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

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

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

spect to such regulation or order pursuant to paragraph (2).

"(2) FURTHER PROCEEDINGS.—

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

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

"(C) FINAL DECISION.—As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

"(h) JUDICIAL REVIEW.—

"(1) PETITION.—In a case of actual controversy as to the validity of any regulation issued under subsection

(e)(1)(C), or any order issued under subsection (f)(1)(C) or (g)(2)(C), or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

"(2) RECORD AND JURISDICTION.—A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28, United States Code. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

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

"(4) FINAL JUDGMENT; SUPREME COURT REVIEW.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

"(5) APPLICATION.—Any issue as to which review is or was obtainable under this subsection shall not be

the subject of judicial review under any other provision of law.

"(i) CONFIDENTIALITY AND USE OF DATA.—

"(1) GENERAL RULE.—Data and information that are or have been submitted to the Administrator under this section or section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act.

"(2) EXCEPTIONS.—

"(A) IN GENERAL.—Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

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

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

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

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

"(j) STATUS OF PREVIOUSLY ISSUED REGULATIONS.—

"(1) REGULATIONS UNDER SECTION 406.—Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 701(e), under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e), and shall be subject to review under subsection (q).

"(2) REGULATIONS UNDER SECTION 409.—Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or

that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 409 on or before the date of the enactment of this paragraph, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e), and shall be subject to review under subsection (q).

"(3) REGULATIONS UNDER SECTION 408.—Regulations that established tolerances or exemptions under this section that were issued on or before the date of the enactment of this paragraph shall remain in effect unless modified or revoked under subsection (d) or (e), and shall be subject to review under subsection (q).

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

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

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

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of the date of enactment of this subsection. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c).

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

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

"(2) REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall

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

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

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

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

"(A) SUSPENSION.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

"(B) EFFECT OF SUSPENSION.—The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

"(4) TOLERANCES FOR UNAVOIDABLE RESIDUES.—In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to the date of the enactment of this paragraph under the Federal Insecticide, Fungicide, and Rodenticide Act, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a

tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) and the unavoidability of the residue. Subsection (e) shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

"(5) PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF PESTICIDE.—Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

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

"(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

"(6) TOLERANCE FOR USE OF PESTICIDES UNDER AN EMERGENCY EXEMPTION.—If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after the date of the enactment of this paragraph governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

"(m) FEES.—

"(1) AMOUNT.—The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be suf-

ficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

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

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

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

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

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

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

"(n) NATIONAL UNIFORMITY OF TOLERANCES.—

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

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

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

"(2) QUALIFYING FEDERAL DETERMINATION.—For purposes of this subsection, the term 'qualifying Federal determination' means a tolerance or exemption from

the requirement for a tolerance for a qualifying pesticide chemical residue that—

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

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

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

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

"(4) STATE AUTHORITY.—Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

"(5) PETITION PROCEDURE.—

"(A) IN GENERAL.—Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

"(B) PETITION REQUIREMENTS.—Any petition under subparagraph (A) shall—

"(i) satisfy any requirements prescribed, by rule, by the Administrator; and

"(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing

the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

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

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

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

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

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

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

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

"(8) SAVINGS.—Nothing in this Act preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue

bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

"(o) CONSUMER RIGHT TO KNOW.—Not later than 2 years after the date of the enactment of the Food Quality Protection Act of 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

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

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

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

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

"(p) ESTROGENIC SUBSTANCES SCREENING PROGRAM.—

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

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

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

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

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

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

"(5) COLLECTION OF INFORMATION.—

"(A) IN GENERAL.—The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

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

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

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

"(ii) HEARING.—If a person requests a hearing under clause (i), the hearing shall be conducted in accordance with section 554 of title 5, United States Code. The only matter for

resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

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

"(D) NONCOMPLIANCE BY OTHER PERSONS.—Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act (15 U.S.C. 2601 and following) in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

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

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

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

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

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

"(q) SCHEDULE FOR REVIEW.—

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

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

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

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

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections (b)(2) or (c)(2) and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

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

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

"(r) TEMPORARY TOLERANCE OR EXEMPTION.—The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) shall apply to actions taken under this subsection.

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

SEC. 406. AUTHORIZATION FOR INCREASED MONITORING.

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

SEC. 407. ALTERNATIVE ENFORCEMENT.

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

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

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

"(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) shall be subject to a civil money penalty of not more than $50,000 in the case of an individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

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

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

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

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

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

PURPOSE AND SUMMARY

The purpose of H.R. 1627, Title IV, is to amend the Federal Food, Drug, and Cosmetic Act to modernize the regulation of pesticides. This measure replaces the outdated Delaney Clause with a unified safety standard, institutes workable protections for infants and children, establishes parameters for comprehensive risk assessment, ensures uniformity of safety standards, and improves consumer access to dietary information, among other provisions.

BACKGROUND AND NEED FOR LEGISLATION

Pesticides are chemicals used to control pests (such as weeds, rodents, and insects) that hinder the production of an abundant, affordable, and varied food supply. Pesticide residues are small amounts of pesticide that remain in or on food after the crop has been harvested and processed. Over the years, a complex regulatory scheme has emerged to balance the agricultural and

consumer benefits that pesticides can provide against potential risks to human health and the environment.

This regulatory scheme is administered by three agencies: the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA). It is also based on two statutes: the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In the House of Representatives, the regulation of pesticides for agricultural use under FIFRA historically has been within the jurisdiction of the Committee on Agriculture, with the Committee on Commerce exercising jurisdiction over FFDCA provisions relating to health effects of pesticide residues in or on food, as well as certain monitoring and enforcement activities.

THE REGULATORY FRAMEWORK FOR PESTICIDE RESIDUES IN FOOD

Pesticide residues in food are regulated under the FFDCA. Current law contains two standards: one for raw products and the other for processed food. This standard, known as the Delaney Clause, bars the establishment of tolerances for pesticide residues in processed foods if the pesticide is a carcinogen.

EPA is responsible, under FIFRA, for regulating pesticide use and, under FFDCA, for setting residue tolerances for pesticides used on food crops. A tolerance establishes the maximum level of residue that can remain on the food products. Any food containing excess residues is considered adulterated and can be withheld from the market by the FDA, which is responsible for enforcing the tolerances.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

FIFRA governs pesticide registration and licensing, including labeling that prescribes conditions under which pesticides may be used legally. Manufacturers must register pesticides and be granted a license before a pesticide can be sold. FIFRA requires the registration or pre-market approval (in essence, a license) of any pesticide distributed in the United States for each intended use. The sale or use of a pesticide in a manner inconsistent with the terms of its registration is unlawful.

The legal requirements for registration recognize that pesticides are both necessary and potentially harmful. EPA must register a pesticide if it will perform its intended function without posing "any unreasonable risk to man or the environment taking into account the economic, social, environmental costs and benefits" of the pesticide use. In sum, to register a pesticide, EPA must conclude that the benefits of such a product exceed its risks. EPA bases its decision on risk assessment which measures the probability and severity of adverse effects or harm to human and/or animal health. Assessments of dietary risks from pesticide residues depend on data from many sources: field studies that show what pesticides are used and the levels of residues that can be expected to occur; the estimates of food people eat; and toxicological data which assess the potential for adverse health effects from specific pesticides.

The burden of showing that a pesticide meets FIFRA standards rests with the registrant. Developing this health and environ-

mental data is costly and time-consuming. Currently, this process typically takes $8 million and 5 years to complete, excluding the time and expense of the basic research that leads to the discovery of a new pesticide or the cost of building new manufacturing facilities.

As a result of amendments to FIFRA, EPA is in the process of reregistering pesticides originally registered many years ago when tests for the safety of residues were less sophisticated. New data required for reregistration may lead to the conclusion that some existing uses should be canceled or changed because of risks to public health.

FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA)

FFDCA governs "tolerances" for the maximum residue level legally allowed for a specific pesticide on a specific food. FFDCA prohibits the distribution of raw agricultural commodities and processed foods that contain levels of pesticide residues that are greater than permitted under Federally-approved "tolerances." FFDCA currently contains two different legal standards for tolerances, one for raw agricultural commodities and one for certain processed foods, which are described below.

In general, tolerances are calculated by measuring the amount of a pesticide that remains in or on a crop after it is treated with a pesticide at its proposed maximum allowable rate. Actual residues can vary as a result of weather and other factors. A tolerance is set at a level calculated to give 95 percent certainty that the remaining residue will not exceed the tolerance when the pesticide is applied at the maximum level and frequency.

Once EPA establishes the tolerances, FDA enforces these them by inspecting foods at various stages from the farm gate to the port of entry to retail stores. FDA and USDA also do studies that simulate the typical dietary intake of American consumers.

Products with residues exceeding tolerances are considered to be "adulterated" and subject to seizure. It is important to note that EPA will not register the use of a pesticide on a food crop under FIFRA until the Agency has established all necessary tolerances under FFDCA.

RAW AGRICULTURAL COMMODITIES

Under Section 408 of FFDCA, EPA sets tolerances that are "safe for use, to the extent necessary to protect the public health" for pesticide residues on raw agricultural commodities. In doing this, EPA must give appropriate consideration to "the necessity for the production of an adequate, wholesome, and economical food supply." Thus, Section 408 is similar to registration under FIFRA in that it allows both the risks and benefits of a pesticide to be considered in setting tolerances for residues on raw agricultural commodities.

PROCESSED FOODS

Section 409 of FFDCA controls the regulation of pesticide residues that concentrate in processed foods. In this instance, consideration of benefits is not permitted. Under Section 409, pesticide resi-

dues are subject to the zero-risk standard of the Delaney Clause which states that "no additive shall be deemed safe (and therefore no tolerance may be set), if it is found * * * to induce cancer in man or animal. * * *" The Delaney Clause sets a zero-risk standard for pesticides that induce cancer in test animals, even if the risk to humans is inconsequential.

A major problem with the existing statutory framework derives from the current law's emphasis on whether a pesticide residue concentrates in processed food. If a raw agricultural product has a processed form but its pesticide residues do not concentrate (i.e., the residue on the processed food is less than the residue on the raw product), the residue in the processed food is covered by the raw food tolerance under Section 402 (a), which is known as the "pass-through" provision of the statute. The pass-through provision allows pesticides that do not concentrate in processed foods to bypass the zero-risk standard of the Delaney Clause. However, if the pesticide residue concentrates in the processed food (i.e., the processed food residue is greater than the raw product tolerance), it will be denied a 409 tolerance because it falls under the standard of the Delaney Clause. This policy has been the subject of litigation, and EPA is required under a consent agreement to meet deadlines for making decisions on a number of pending residue matters.

CURRENT EPA POLICY

At the request of the EPA, the National Academy of Sciences (NAS) studied existing Delaney policy and issued a report entitled "Regulating Pesticides in Food: The Delaney Paradox." The NAS report recommends that pesticide residues in both raw and processed food be regulated on the basis of a unified safety standard. In response to the NAS study, EPA issued a new policy interpretation of the Delaney Clause in October 1988. Instead of applying the zero-risk standard of the Delaney Clause, EPA tried to set one standard of de minimis or negligible risk, which was defined as a hypothetical cancer risk of less than one in a million over a 70-year lifetime for food tolerances under Section 409 of FFDCA. However, EPA's de minimis interpretation of the Delaney Clause was subsequently challenged in court and ruled invalid.

Under the current court-imposed consent degree, EPA has agreed to a schedule for making tolerance revocation decisions on a number of section 408 and 409 tolerances, many of which EPA has acknowledged only pose a negligible risk. If the tolerances under which use of these pesticides is permitted are revoked, an estimated 100 crops—including numerous fruits and vegetables—will be affected. Disruption in the production of these crops could have serious dietary and cost consequences for consumers and serious adverse impacts on the economies of the nation's major agricultural States.

HEARINGS

The Subcommittee on Health and Environment held two days of hearings on H.R. 1627, the Food Quality Protection Act, on June 7, 1995, and June 29, 1995. (The June 29, 1995 hearing also considered H.R. 1771.)

Testifying before the Subcommittee on June 7, 1995 were: Dr. Lynn R. Goldman, Assistant Administrator, Office of Prevention, Pesticides, and Toxic Substances, Environmental Protection Agency; Mr. William B. Schultz, Deputy Commissioner for Policy, Food and Drug Administration; Mr. Lawrence Elworth, Special Assistant for Pesticide Policy, Department of Agriculture; Dr. Carl K. Winter, Director, FoodSafe Program, University of California; Mr. Leonard P. Gianessi, Senior Research Associate, National Center for Food and Agricultural Policy; Dr. George M. Gray, Deputy Director, Harvard Center for Risk Analysis, Harvard School of Public Health; Ms. Juanita Duggan, Executive Vice President, Government Affairs and Public Communications, National Food Processors Association; Mr. Dennis Stolte, American Farm Bureau Federation; Dr. Steven Ziller, Vice President for Science and Technical Affairs, Grocery Manufacturers Association of America; Mr. Jay J. Vroom, President, American Crop Protection Association; Mr. Erik Olson, Natural Resources Defense Council; Mr. Jay Feldman, Executive Director, National Coalition Against the Misuse of Pesticides; and Ms. Carolyn Brickey, Executive Director, National Campaign for Pesticide Policy Reform.

Testifying before the Subcommittee on June 29, 1995 were: Ms. Nancy Gould Chuda, Chair, The Colette Chuda Environmental Fund and Children's Health Environmental Coalition, accompanied by Mr. James Chuda, Vice-Chair; Mr. Robert Eichler; Dr. Philip J. Landrigan, Professor and Chair, Department of Community Medicine, Mount Sinai Medical Center; Dr. J. Routt Reigart, representing the American Academy of Pediatrics; Dr. Mary S. Wolff, Professor of Community Medicine, Environmental and Occupational Medicine, Mt. Sinai School of Medicine; Mr. Edward Hopkins, Environmental Policy Director, Citizen Action; and Ms. Caroline Smith-DeWaal, Director, Food Safety Program, Center for Science in the Public Interest.

COMMITTEE CONSIDERATION

On July 17, 1996, the Subcommittee on Health and Environment met in open markup session and approved H.R. 1627, the Food Quality Protection Act of 1996, for Full Committee consideration, as amended, by a voice vote. On July 17, 1996, the Full Committee met in open markup session and ordered H.R. 1627 reported to the House, as amended, by a roll call vote of 45 yeas to 0 nays, a quorum being present.

ROLLCALL VOTES

Clause 2(l)(2)(B) of rule XI of the Rules of the House requires the Committee to list the recorded votes on the motion to report legislation and amendments thereto. The following is the recorded vote on the motion to report H.R. 1627, as amended by the Subcommittee on Health and Environment, including the names of those Members voting for and against.

COMMITTEE ON COMMERCE—104TH CONGRESS, ROLLCALL VOTE NO. 150

Bill: H.R. 1627, Food Quality Protection Act of 1996.

Motion: Motion by Mr. Bliley to order H.R. 1627 reported to the House, as amended.

Disposition: Agreed to, by a rollcall vote of 45 yeas to 0 nays.

Representative	Aye	Nay	Present	Representative	Aye	Nay	Present
Mr. Bliley	X			Mr. Dingell	X		
Mr. Moorhead	X			Mr. Waxman	X		
Mr. Tauzin	X			Mr. Markey	X		
Mr. Fields	X			Mr. Collins			
Mr. Oxley	X			Mr. Hall	X		
Mr. Bilirakis	X			Mr. Richardson	X		
Mr. Schaefer	X			Mr. Bryant	X		
Mr. Barton	X			Mr. Boucher	X		
Mr. Hastert	X			Mr. Manton	X		
Mr. Upton	X			Mr. Towns	X		
Mr. Stearns	X			Mr. Studds			
Mr. Paxon	X			Mr. Pallone	X		
Mr. Gillmor	X			Mr. Brown	X		
Mr. Klug	X			Mrs. Lincoln			
Mr. Franks	X			Mr. Gordon	X		
Mr. Greenwood	X			Ms. Furse	X		
Mr. Crapo	X			Mr. Deutsch	X		
Mr. Cox	X			Mr. Rush			
Mr. Deal	X			Ms. Eshoo	X		
Mr. Burr	X			Mr. Klink	X		
Mr. Bilbray	X			Mr. Stupak	X		
Mr. Whitfield	X			Mr. Engel	X		
Mr. Ganske	X						
Mr. Frisa	X						
Mr. Norwood	X						
Mr. White	X						
Mr. Coburn	X						

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee held legislative hearings and made findings that are reflected in this report.

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform and Oversight.

NEW BUDGET AUTHORITY AND TAX EXPENDITURES

In compliance with clause 2(l)(3)(B) of rule XI of the Rules of the House of Representatives, the Committee states that H.R. 1627 would result in no new or increased budget authority or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 403 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 2(l)(3)(C) of rule XI of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 403 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 23, 1996.

Hon. THOMAS J. BLILEY, Jr.,
Chairman, Committee on Commerce,
House of Representatives, Washington, DC.

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

Enactment of Title IV 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 this estimate, we will be pleased to provide them.

Sincerely,

JUNE E. O'NEILL, *Director.*

Enclosure.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: Title IV of H.R. 1627.

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

3. Bill status: Title IV, as ordered reported by the House Committee on Commerce on July 17, 1996.

4. Bill purpose: Title IV of the bill would amend the Federal Food, Drug, and Cosmetic Act, and would authorize the appropriation of $12 million over the 1997–1999 period to the Department of Health and Human Services (HHS) to increase monitoring of pesticide residues in imported and domestic food. Title IV would change the standards EPA is directed to use when setting tolerances for pesticide residues in raw and processed food.

5. Estimated cost to the Federal Government: Assuming appropriation of estimated amounts authorized for discretionary programs conducted by EPA and HHS, enacting Title IV of H.R. 1627 would lead to fiscal year 1997 funding for food tolerance programs of about $26 million. CBO estimates that the bill would authorize appropriations totaling about $154 million over the 1997–2002 period.

In 1996, about $2 million in fees was collected and spent by EPA for establishing pesticide tolerances in food. Under Title IV of H.R. 1627, we assume sufficient fees would continue to be collected for food tolerance work, and that the agency would spend all of the fees collected. Hence, the income from the fees and the spending of that income would offset each other, and there would be no net impact on direct spending for each fiscal year.

SPENDING SUBJECT TO APPROPRIATION

[By fiscal year, in millions of dollars]

	1996	1997	1998	1999	2000	2001	2002
Spending under current law:							
Budget authority	22	.....	.....	.....	.....	.....	.....
Estimated outlays	22	7	.....	.....	.....	.....	.....
Proposed changes:							
Estimated authorization level	.....	26	27	27	24	25	26
Estimated outlays	.....	18	27	27	25	25	25
Spending under H.R. 1627, title IV	22	26	27	27	24	25	26
Estimated outlays	22	25	27	27	25	25	25

Note.—The 1996 level is the amount appropriated for that year.

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

6. Basis of estimate: For the purpose of this estimate, CBO assumes that the bill will be enacted before 1997 appropriations for EPA and HHS are provided and that all funds authorized by Title IV of H.R. 1627 will be appropriated.

The bill would specify an authorization of $12 million over the 1997–1999 period to HHS for increased monitoring of pesticide residues on imported and domestic food. For this estimate, we split the $12 million authorization into equal components of $4 million a year for fiscal years 1997 through 1999. In addition, CBO estimates the bill would authorize the appropriation of $45 million to continue food safety programs conducted by EPA and about $97 million to continue pesticide residue monitoring conducted by HHS over the next six years.

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 Title IV of H.R. 1627 could affect direct spending. Therefore, pay-as-you-go procedures would apply to the bill. We estimate the pesticide tolerance fee collected under current law could increase if EPA's resource needs grow as a result of enactment of this title. If the fees are increased, we estimate that direct spending would increase by the same amount, thus resulting in no net impact.

[By fiscal year, in millions of dollars]

	1996	1997	1998
Change in outlays	0	0	0
Change in receipts	(1)	(1)	(1)

[1] Not applicable.

8. Estimated impact on State, local, and tribal governments: Title IV of H.R. 1627 contains an intergovernmental mandate as defined in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) but this mandate would impose no significant costs on state, local, or tribal governments.

This title would prohibit state and local governments from establishing or enforcing regulatory limits on pesticide residues that differ from limits established by the federal government. The bill would establish a process under which states could petition EPA for an exception to this prohibition. We estimate that state and local governments would incur no significant costs as a result of this provision.

9. Estimated impact on the private sector: CBO has identified several private-sector mandates in the bill. Among these are provisions that would require large retail grocers to display information provided by EPA about pesticides, and that would require businesses that register, manufacture, or import certain products to screen for substances that may have an effect on humans that is similar to an effect produced by naturally occurring estrogen, or other endocrine effects as directed by EPA.

Although the mandates become effective at different dates, CBO, estimates that the aggregate direct costs of mandates in this bill would not likely exceed the $100 million threshold established in Public Law 104–4 in the first five years that the mandates become effective. Costs for estrogenic testing could exceed the threshold in subsequent years, if more expensive tests become required. 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 to the standards EPA is directed to use when setting tolerances for pesticide residues in raw and processed food.

10. Previous CBO estimate: On July 10, 1996, CBO prepared a cost estimate for H.R. 1627 (Titles I–V) as ordered reported by the House Committee on Agriculture, on June 19, 1996. The Commerce Committee version of Title IV is different from the Agriculture Committee version, and has a different budgetary impact.

11. Estimate prepared by: Federal Cost Estimate: Kim Cawley and Anne Hunt. Impact on State, Local, and Tribal Governments: Marjorie Miller. Impact on the Private Sector: 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 finds that the bill would have no inflationary impact.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

SEC. 401. SHORT TITLE AND REFERENCE

Section 401(a) authorizes citations to refer to this title as the Food Quality Protection Act of 1996; all amendments refer to the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 USC 321 et seq.), according to Section 401(b).

SEC. 402. DEFINITIONS

Section 402(a) amends Section 201(q)(1) of the FFDCA (21 USC 321(q)(1)) to change the existing definition of "pesticide chemical" to include: any pesticide as defined in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); any active ingredient of a pesticide; and any inert ingredient of a pesticide. (FIFRA definitions of these terms are at Section 2(a) (7 USC 136(a)), Section 2(u) (7

USC 136(u)), and Section 2(m) (7 USC 136(m)), respectively.) Section 402(a) also adds a new paragraph (2) at the end of Section 201(q) to define "pesticide chemical residue" as a residue, in or on either raw or processed food, of a pesticide chemical (as defined at (1)) or of any other added substance that is present primarily due to metabolism or degradation of a pesticide chemical. It allows the Administrator of the U.S. Environmental Protection Agency (EPA) 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 if the Administrator, after consulting with the Secretary of Health and Human Services (DHHS), determined that the substance should be regulated under a section of FFDCA other than Sections 402(a)(2)(B) and 408.

Section 402(b) amends the current 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 402(c) amends FFDCA Section 201 by adding definitions for "processed food" and "Administrator." New subsection (gg) defines "processed food" as any food other than a raw agricultural commodity, including any such commodity that has been subject to canning, freezing, cooking, dehydration, milling, or other processing. New subsection (hh) defines "Administrator" as the Administrator of the EPA.

SEC. 403. PROHIBITED ACTS

Section 403 amends FFDCA Section 301(j) (21 USC 331(j)), which prohibits disclosure of information about confidential methods or processes, except to employees of the DHHS, U.S. Department of Agriculture (USDA), certain committees of Congress, or to the courts when relevant to a proceeding. It adds FFDCA Section 408(i)(2) to the list of sections under which, if confidential information is gained, the prohibition applies.

SEC. 404. ADULTERATED FOOD

Section 404 amends FFDCA section 402(a)(2) (21 USC 342(a)(2)) so that all pesticide residues in all foods are regulated under Sections 408 and 402(a)(2), but not Section 406 or 409. Existing Section 402(a)(2) states that all food shall be deemed adulterated (A) if it "contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of Section 406," (B) "if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a)", or (C) "if it is, or if it bears or contains, any food additive which is unsafe within the meaning of Section 409." Under current law, therefore, pesticide residues on raw food are governed by Section 408, but pesticide residues on processed food are regulated under Section 409 if they concentrate during processing. Section 406 states that food containing added poisonous or deleterious substances is unsafe unless the substance cannot be avoided and does not exceed limits set by EPA to protect public health (i.e., tolerances). Section 404 of H.R. 1627 also removes the clause following "*Provided*" in FFDCA Section 402 (a)(2). The effect is to

retain the principle that food is considered adulterated or "unsafe" if a raw agricultural commodity contains a pesticide residue that is "unsafe" within the meaning of the new section 408, if a food contains any food additive that is unsafe within Section 409, if a food contains a new animal drug that is unsafe within the meaning of Section 512, or if a food contains any other added poisonous or deleterious substance that is unsafe within the meaning of Section 406. However, pesticide residues in processed food also would be excluded from coverage of Section 406 (and Section 409) and would fall instead under Section 408.

SEC. 405. TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

Section 405 amends 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.[1]

Sec. 408(a). Requirement for Tolerance or Exemption

New Section 408(a)(1)—General Rule retains the current provisions of Section 408(a) which deem any pesticide residue on food unsafe (and therefore the food is 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. For purposes of new Section 408, both raw agricultural commodities and processed food products are considered "food." A provision of the current law is moved by the bill; new subsection (k) exempts from tolerance requirements pesticides "generally recognized as safe" before enactment of H.R. 1627 (see below).

New Section 408(a)(2)—Processed Food writes into law the "pass-through" provision used currently by EPA. Presently, if a tolerance or exemption is in effect for a pesticide chemical in a raw food, the residue of that pesticide in that food, after it is processed, is not unsafe as long as the residue is below the raw food tolerance or is exempt from the requirement for a raw food tolerance. The new subsection permits all foods to be considered safe, and not adulterated under Section 402(a)(2)(B), if they contain pesticide residues that are within a tolerance, or are exempt from the requirement for a tolerance, and the residues have been removed to the extent possible.

New subsection 408(a)(3)—Residues of Degradation Products discusses products of precursor or parent pesticides. It requires EPA to apply the tolerances and exemptions established for residues of the parent pesticide to residues of the pesticide's breakdown products, as long as 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. The Committee understands that in making such a determination today, EPA does not include, in calculating the combined levels, degradation prod-

[1] FFDCA Section 409 is not amended by H.R. 1627. Instead, H.R. 1627, Section 402 redefines "food additive" and "pesticide chemical residue" so that pesticide residues always are 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 pesticide residues concentrated in processed foods.

ucts that pose no health risk (such as GRAS substances). It is the Committee's intention that such degradation products not be included in any determination as to whether the combined residues of a pesticide and its degradation products meet the tolerance levels.

New Section 408(a)(4)—Effect of a Tolerance Or Exemption specifically prohibits considering a food adulterated within the meaning of Section 402(a)(1) because it contains a pesticide residue, if a tolerance or exemption were in effect for that pesticide on that food. This clarifies the principle that pesticide residues are regulated under Section 402(a)(2) only.

Sec. 408(b). Authority and Standard for Tolerance

Existing FFDCA Section 408(b) requires the EPA 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 the opinion and certification of usefulness of the pesticide by the Secretary of Agriculture. The Administrator is authorized to establish a tolerance at zero level if the scientific data do not justify establishing a greater tolerance.

New Section 408(b)(1)—Authority authorizes the Administrator to issue regulations establishing, modifying, or revoking tolerances for pesticide chemical residues in or on a food in response to a petition or on the Administrator's initiative.

New Section 408(b)(2)—Standard lays out the criterion by which tolerances would be set. New subsection 408(b)(2)(A)—General Rule would set the general rule for the standard. Under new subsection 408(b)(2)(A)(i)—Standard the Administrator may establish or leave in effect a tolerance for a pesticide residue in or on food only if the Administrator determines that the tolerance is safe. EPA must revoke or modify a tolerance if it is not safe.

New Section 408(b)(2)(A)—Determination of Safety defines "safe" as a determination that there is a reasonable certainty that no harm will result from aggregate exposure to the residue, including all dietary exposures and all other exposures for which there is reliable information.

In new Section 408(b)(2)(A)(iii) a rule of construction clarifies that if a determination is made under subsection 408(b)(2)(A) the provisions of subsection of 408(b)(2)(B) do not apply.

Subsection (b)(2)(A) establishes the standard of "safe" for tolerances for pesticide chemical residues in or on food. For the purposes of this section, "safe" means there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. The Committee understands "aggregate exposure" to the pesticide chemical residue to include dietary exposures under all tolerances for the pesticide chemical residue, and exposure from other non-occupational sources as well.

The Committee has adopted the standard of "reasonable certainty of no harm" based on EPA's current application of the standard. The Committee understands that the Administrator currently

applies this standard differently to threshold and nonthreshold effects. A threshold effect is an effect for which the Administrator is able to identify a level at which the pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health. A nonthreshold effect is an effect for which the Administrator is not able to identify such a level.

In the case of a threshold effect for a pesticide chemical residue, the Committee expects that a tolerance will provide a "reasonably certainty of no harm" if the Administrator determines that the aggregate exposure to the pesticide chemical residue will be lower by an ample margin of safety than the level at which the pesticide chemical residue will not cause or contribute to any known or anticipated harm to human health. The Committee further expects, based on discussions with the Environmental Protection Agency, that the Administrator will interpret an ample margin of safety to be a 100-fold safety factor applied to the scientifically determined "no observable effect" level when data are extrapolated from animal studies.

In the case of a nonthreshold effect which can be assessed through quantitative risk assessment, such as a cancer effect, the Committee expects, based on its understanding of current EPA practice, that a tolerance will be considered to provide a "reasonable certainty of no harm" if any increase in lifetime risk, based on quantitative risk assessment using conservative assumptions, will be no greater than "negligible." It is the Committee's understanding that, under current EPA practice, utilizing quantitative risk assessment to calculate Potency Factors called "Q star", EPA interprets a negligible risk to be a one-in-a-million lifetime risk. The Committee expects the Administrator to continue to follow this interpretation.

The statutory language does not preclude EPA from changing its risk assessment methodology as the science of risk assessment evolves. If the Administrator in the future chooses to adopt a different interpretation of "reasonable certainty of no harm," however, the new interpretation should be adopted by regulation and should be at least equally protective of public health. Any new interpretation must be scientifically based and the Administrator should bear the burden to demonstrate that the revised interpretation is equally protective of the public.

New Section 408(b)(2)(B)—Tolerances for Eligible Pesticide Chemical Residues allows EPA to maintain or modify a tolerance for an eligible pesticide residue which does not fall under subsection (A) if: (1) EPA is not able to identify a level of exposure that will not cause or contribute to known or anticipated harm to human health (that is, there is a nonthreshold effect); (2) the lifetime risk of the nonthreshold effect is assessed by means of quantitative risk assessment; and (3) aggregate exposure to the residue is safe with respect to other effects for which EPA can identify a safe level of exposure (that is, threshold effects). The EPA Administrator may leave a tolerance in effect or modify it if: (1) the use of the pesticide that produces the residue protects consumers from adverse effects to health that pose a greater risk than the dietary risk from the residue, or the pesticide use avoids significant disruption in domestic production of an adequate, wholesome, and economical

food supply; and (2) the annual risk from the nonthreshold effect (from aggregate exposure to the residue) does not exceed 10 times the annual risk allowed under a safe tolerance level, and the lifetime risk of the nonthreshold effect is not greater than twice the safe lifetime risk for such effect. In addition, all such tolerances must be safe for children. New Section 408(b)(2)(B)(v) directs EPA to review the need for the pesticide use and the risks of such use within 5 years of determining to leave in effect or modify such a tolerance, and as necessary thereafter. If it has not been demonstrated that the tolerance continues to meet the requirements of this subparagraph, EPA must issue a regulation to modify or revoke the tolerance within 180 days, in accordance with procedures under subsection (e).

Clause (b)(2)(B)(iii) establishes the conditions regarding use that must be present before a tolerance may be modified or left in effect under subsection (b)(2)(B). Subclause (iii)(I) provides that the authority of subsection (b)(2)(B) may be used when use of the pesticide that produces the residue protects consumers from adverse effects on health that pose a greater risk than the dietary risk from the pesticide chemical residue. In this situation, eating food treated with the pesticide chemical is safer for consumers than eating the same food that is not treated with the pesticide. The Committee intends to address a situation in which, for example, a pesticide is the only effective way to prevent or minimize a dietary risk from a fungus or other crop condition. The fungus aflatoxin, a dangerous fungus which can be present on peanuts and corn, is one such representative example. Although there is currently no pesticide chemical which can protect these crops from aflatoxin, if such a pesticide were to be developed, the Committee believes it would be a candidate for a tolerance under this subparagraph if its dietary risks were lower than the dietary risks of aflatoxin.

Subclause (iii)(II) provides that the authority of subsection (b)(2)(B) may be used when use of the pesticide that produces the residue is necessary to avoid a significant disruption in domestic production of a safe, economical, and wholesome food supply. This standard is a more precise version of the current provision in section 408(b). By adding reference to a "significant disruption," the Committee intends to clarify the general understanding of the type of effect on farmers and consumers that is covered by this language. In determining whether the loss of a pesticide would cause a significant disruption in the production of an adequate, wholesome, and economical food supply, EPA is expected at take into account the availability and effectiveness of alternative pest control methods, the impact of loss of the pesticide on crops, the impact on the national availability and cost of food combined with the dietary impact of such loss, and the impact on the ability of consumers to access a nutritious food supply.

The Committee expects this type of analysis to apply in exceptional situations such as the one illustrated here: In the 1980s, unusual weather conditions caused a substantial increase in aflatoxin on corn used for animal feed across the Southeast. The FDA determined that it was necessary to raise the action level for aflatoxin on corn to avoid widespread shortages of animal feed. Although FDA's action in this illustrative case occurred under other provi-

sions of this Act, the potential significant disruption that triggered the action is of the type the Committee envisions as representative.

New Section 408(b)(2)(C)—Exposure to Infants and Children mandates criteria relating to safety of infants and children to be considered when establishing, modifying, leaving in effect, or revoking tolerances or exemptions for pesticide residues. In making such decisions, the Administrator shall (i) assess the risk of the pesticide residue based on: (I) data on consumption patterns among infants and children, if these patterns are likely to result in a disproportionately high consumption of foods bearing the residue as compared with the consumption by the general population; (II) data on the special susceptibility of infants and children to pesticide residues, including data on the neurological differences between infants, children, and adults and effects of in-utero exposure to chemicals; and (III) data on the cumulative effects on infants and children of such residues that have common mechanisms of toxicity. In the decision, the Administrator shall also (ii): (I) ensure that there is a reasonable certainty of no harm to infants and children from aggregate exposure to the pesticide chemical residue; and (II) publish a determination regarding the safety of the residue for infants and children.

When data relating to infants and children are incomplete, and also to account for potential pre- and post-natal toxicity, the Administrator is to apply, under new Section 408(b)(2)(C), an additional tenfold margin of safety for infants and children. However, EPA may apply a different margin of safety if reliable data indicate that it will be safe for infants and children. The Secretary of Health and Human Services (DHHS) and the Secretary of Agriculture (USDA), in consultation with EPA, will document, through surveys, dietary exposure to pesticides among infants and children.

It is the intention of the Committee that EPA interpret the language of this section in furtherance of the following recommendation of the National Research Council's Study, "Pesticides in the Diets of Infants and Children":

> At present, to provide added protection during early development, a third uncertainty factor of 10 is applied to the NOEL, to develop the RfD. This third 10-fold factor has been applied by the EPA and FDA whenever toxicity studies and metabolic/disposition studies have shown fetal developmental effects.
>
> Because there exist specific periods of vulnerability during postnatal development, the committee recommends that an uncertainty factor up to the 10-fold factor traditionally used by EPA and FDA for fetal developmental toxicity should also be considered when there is evidence of postnatal developmental toxicity and when data from toxicity testing relative to children are incomplete. The committee wishes to emphasize that this is not a new, additional uncertainty factor but, rather, an extended application of a uncertainty factor now routinely used by the agencies for a narrower purpose. (page 9)

New Section 408(b)(2)(D)—Factors lists nine factors that EPA should consider in establishing, modifying, leaving in effect, or re-

voking a pesticide chemical residue tolerance or exemption. These include: (i) the validity, completeness, and reliability of the data from studies of the pesticide and its residue; (ii) the nature of any toxic effect shown to be caused by the pesticide or its residue; (iii) available information concerning the relationships of such studies to human risk; (iv) available information on dietary consumption patterns of consumers and major subgroups; (v) available information concerning cumulative effects of residues and other substances with a common toxicity mechanism; (vi) available information about the aggregate exposure levels of consumers and major subgroups to the residues and related substances, including dietary exposure under the tolerance and all other tolerances in effect for that pesticide, and exposure from other non-occupational sources; (vii) information about the variability of the sensitivities of major identifiable subgroups of consumers; (viii) information as EPA may require on whether the pesticide may have similar health effects as naturally occurring estrogen, or other endocrine effects; and (ix) safety factors which experts believe are generally recognized as appropriate for use of animal experimentation data.

New Section 408(b)(2)(E)—Data and Information Regarding Anticipated and Actual Residue Levels authorizes EPA to consider data on the anticipated residue levels on or in food and the actual residue levels that have been measured in food, including residue data collected by FDA, when the agency establishes, modifies, leaves in effect, or revokes a tolerance. However, within 5 years of a tolerance decision and thereafter as needed, clause (ii) requires EPA to require the submission of residue data demonstrating that residue levels have not increased above levels relied upon for a decision to establish, modify, or retain a tolerance. If data are not submitted or do not demonstrate this, Section 408(b)(2)(E) directs EPA to issue an order or regulation to modify or revoke the tolerance.

New Section 408(b)(2)(F)—Percent of Food Actually Treated authorizes considering information on the percent of food actually treated with the pesticide, including aggregate pesticide use data collected by USDA, when EPA assesses chronic dietary risk and establishes a tolerance. The section limits use of such information to situations in which EPA finds: (i) the data are reliable and valid indicators of the percentage of food likely to contain the residue derived from the crop; (ii) the exposure is not underestimated for any significant subpopulation; and (iii) available data for a particular area do not indicate higher levels of dietary exposure. In addition, clause (iv) requires that EPA provide for the periodic reevaluation of the estimate of anticipated dietary exposure.

New Section 408(b)(3)—Detection Methods concerns methods for detecting and measuring residue levels at the level of the tolerance. As a general rule, the EPA is prohibited from setting a tolerance unless there is a practical method for detecting and measuring residues. Subparagraph (B)-Detection Limit prohibits setting tolerance levels below the limit of detection of the method for measuring residues identified by EPA.

New Section 408(b)(4)—International Standards requires EPA to consider any maximum residue level (MRL) established for a chemical by the international Codex Alimentarius Commission (Codex),

when the Agency determines tolerance levels.[2] If a Codex MRL exists, and the EPA decides not to adopt the same level, the bill requires EPA to publish for public comment a notice explaining the departure. This new subsection is intended to avoid unnecessary restraints on international food trade by requiring EPA explicitly to consider international standards when setting U.S. tolerances and encouraging EPA to support international harmonization efforts.

Sec. 408(c). Authority and standard for exemptions

Section 408(c) of current law requires the Administrator to promulgate regulations exempting any pesticide from the necessity of a tolerance if such an exemption is safe.

New subsection (c)(1)—Authority authorizes 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 pesticide residue tolerance on food. The Committee expects EPA to continue to issue exemptions for GRAS substances under this authority.

New subsection (c)(2)—Standard limits the Administrator's authority to issue exemptions. Subsection (c)(2)(A)—General Rule provides that an exemption only can be established if it is safe, and that EPA must modify or revoke an exemption that is not safe. Clause (ii) defines "safe" as a determination that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue," including all dietary and other exposures for which reliable data exist. Subsection (c)(2)(B)—Factors requires the Administrator, in deciding on an exemption, to consider relevant factors, including those related to infants and children that are specified in subparagraph (C) and the nine factors specified in subparagraph (D)[3] of the new subsection (b)(2). The Committee understands that EPA currently issues exemptions only for the pesticide chemical residues that do not pose a dietary risk under reasonably foreseeable circumstances. The Committee intends that EPA retain its current practice.

New subsection (c)(3)—Limitation prohibits an exemption, unless there is (A) a practical method for detecting and measuring the levels of the residue, or (B) there is no need for such a method, and the reasons are stated in the regulation establishing or modifying the exemption.

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[2] The Codex is sponsored by the United Nations Food and Agriculture Organization and the World Health Organization. Its purpose is to negotiate international standards for food. The United States is represented on various standing committees of the Codex by officials from FDA, EPA, and USDA.

[3] These 9 factors include: (i) the validity, completeness, and reliability of the data from studies of the pesticide and its residue; (ii) the nature of any toxic effect shown to be caused by the pesticide or its residue; (iii) available information concerning the relationships of such studies to human risk; (iv) available information on dietary consumption patterns of consumers and major subgroups; (v) available information concerning cumulative effects of residues and other substances with a common toxicity mechanism; (vi) available information about the aggregate exposure levels of consumers and major subgroups to the residues and related substances, including dietary exposure under the tolerance and all other tolerances in effect for that pesticide, and exposure from other non-occupational sources; (vii) information about the variability of the sensitivities of major identifiable subgroups of consumers; (viii) information as EPA may require on whether the pesticide may have similar health effects as naturally occurring estrogen or other endocrine effects; and (ix) safety factors which experts believe are generally recognized as appropriate for use of animal experimentation data.

Sec. 408(d). Petition for tolerance or exemption

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; practical 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 discussion of 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 is required either to establish a tolerance or to 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.

New subsection (d) is similar, for the most part, to current law, but the amended subsection authorizes any person to file a tolerance petition rather than only an applicant for a pesticide registration. New subsection (d)(1)—Petitions and Petitioners also authorizes petitions for establishing, modifying, or revoking a tolerance or an exemption.

New subsection (d)(2)—Petition Contents identifies the information required in the petition. Subparagraph (d)(2)(A)—Establishment authorizes the Administrator to require through regulations certain data and information to support a petition for a tolerance or an exemption. A petitioner must provide: (i)(I) a summary of the petition, data, information, and arguments; (II) 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; (ii) the name, chemical identity, and composition of the parent pesticide and its residue; (iii) data showing the recommended amount, frequency, method, and time of application of that pesticide; (iv) full reports on the results and methods used in safety testing; (v) full reports on the results and analytical methods used to decide on the nature and amount of residue likely to remain in or on the food; (vi) a practical method for detecting and measuring levels of residue (or for exemptions a statement of why it is not needed); (vii) a proposed tolerance for the residue if one is proposed; (viii) if the petition relates to a tolerance for a processed food, studies of the processing methods used to produce the food; (ix) any information that the Administrator requires to assess risk to infants and children; (x) any information that the Administrator requires related to whether the pesticide chemical may have a similar effect in humans as a naturally occurring estrogen or

other endocrine effects; (xi) exposure information due to any tolerance or exemption already granted; (xii) practical methods for removing any residue amount that could exceed a proposed tolerance; and (xiii) other information that EPA requires to support the petition. If the information is already available to the Administrator, the petition may reference it in lieu of submitting it. Samples of the pesticide may be required.

New subsection (d)(2)(B)—Modification or Revocation gives the Administrator authority to establish by regulation information and data requirements to support a petition to modify or revoke a tolerance or an exemption from a tolerance.

New subsection (d)(3)—Notice directs the Administrator to publish the notice of petition filing within 30 days after determining that the petition has met the requirements in paragraph (2). The notice will include 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.

New subsection (d)(4)—Actions by the Administrator describes how EPA shall respond to a petition. Subparagraph (A)—In General directs EPA to (i) issue a final regulation; (ii) issue a proposed regulation followed by a final regulation; or (iii) issue an order denying the petition. New subparagraph (B) requires EPA to give priority to petitions for establishing or modifying a tolerance or exemption for the residue of a pesticide that is expected to pose less dietary risk to human health than other pesticide residues for which tolerances are in effect for the same or similar purposes. Subparagraph (C) provides for expedited EPA review of complete petitions for a tolerance or exemption for a pesticide residue posing less risk than a tolerance left in effect or modified for "an eligible pesticide chemical residue" under subsection (b)(2)(B). EPA must act on such a petition within 1 year. Clause (ii) directs EPA to review the need for the tolerance for the eligible pesticide chemical residue within 180 days of the date EPA issues a regulation establishing a tolerance or exemption for the safer pesticide residues. If EPA finds the need for such higher risk pesticide use no longer exists, new Section 408 requires EPA to revoke or modify the tolerance within 180 days of such a finding under the procedures of subsection (e).

Sec. 408(e). Action on administrator's own initiative

The current FFDCA, 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.

New subsection 408(e)(1)—General Rule authorizes rule making by the EPA Administrator to establish a tolerance or an exemption. In addition, it authorizes the Administrator to modify or to revoke a tolerance or an exemption, as well as to establish general implementation procedures and requirements. New subsection (e)(2)—Notice requires EPA to issue a notice of proposed rule making and to provide a 60 day public comment period before issuing the final regulation, unless there is good cause and it is in the public interest to shorten this requirement. An opportunity for a public hearing is provided by Section 408(g) below.

Sec. 408(f). Special data requirements

New subsection (f)(1)—Requiring Submission of Additional Data requires EPA to collect additional data when reasonably required to support an existing pesticide tolerance or exemption. The Administrator is 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, a 60-day notice-and-comment period is required before the order could be issued. The order (i) directs persons who are required to submit data to identify which of them will provide data to EPA, (ii) describes the type of data and information required and why it could not be obtained under FIFRA or TSCA, (iii) describes the reports that would be prepared from this data, (iv) requires submissions of data and reports, and (v) sets the dates that the information is due. The Administrator may revise the order to make corrections. Subsection (f)(2)—Noncompliance authorizes the Administrator to modify or revoke the tolerance or exemption in question if the required data or reports are not submitted by the due date. The only issue that could be decided if the order were reviewed under subsection (g)(2) is whether a required submission had been made by the time specified. This provision does not prevent the Administrator from acting to modify or revoke a tolerance or exemption which does not meet the safety standard in subsection (b)(2) or (c)(2).

Sec. 408(g). Effective date, objections, hearings, and administrative review

The current FFDCA, Section 408(d)(5), provides 30 days after a regulation is issued for any person adversely affected by the regulation to file an objection with the Administrator and to request 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 (g)(1)—Effective Date states that any regulation or order will take effect upon publication unless the regulation or order specifies otherwise. The Administrator may adjust this effective date if objections are filed with respect to such a regulation or order.

New subsection (g)(2)—Further Proceedings lists criteria for raising objections. New subparagraph (A) authorizes any person, not just a person adversely affected, to file an objection to a regulation or order issued under subsections (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C) and doubles the time allowed for filing from 30 days to 60 days. It also requires the Administrator to give the petitioner a copy of the objections, if the regulation or order was issued in response to a petition filed under subsection (d)(1).

New subparagraph (g)(2)(B) allows an objector to request a public evidentiary hearing. The Administrator would decide whether a hearing were necessary to receive factual evidence relevant to material issues of fact raised by the objections. The Committee expects EPA to use this discretion fairly and to grant hearings to responsible parties on all sides. The bill provides the hearing officer with various authorities, for example, to issue a subpoena to compel testimony, but requires the presiding officer to follow the Federal Rules of Civil Procedure in ordering protection of witnesses or documents and payment of expenses for witnesses. A subpoena may be enforced by a Federal district court.

New subparagraph (g)(2)(C) requires the Administrator to issue an order as soon as practicable after the hearing, stating action to be taken. But, as under current law, any action taken must be based on substantial evidence in the hearing record and, if a hearing is held, explained in detail.

Sec. 408(h). Judicial review

New Section 408(h) retains most of the existing provisions of FFDCA, Section 408(i). New subsection 408(h)(1)—Petition allows any person adversely affected by a regulation under subsection (c)(1)(a) or an order, issued under subsection (e)(1)(C), (f)(1)(C), or (g)(2)(C) or any regulation that is the subject of such an order within 60 days of its publication, to petition to have the regulation or order set aside and 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. New subsection (h)(2)—Record and Jurisdiction requires the Administrator to file with the court the administrative record. The court has exclusive jurisdiction to affirm or set aside the order or regulation 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. New subsection 408(h)(3)—Additional Evidence allows for additional evidence to be presented to EPA if it appears proper to do so. The EPA can then modify its order or regulation to take into account that evidence. New subsection 408(h)(4)—Final Judgment; Supreme Court Review makes the judgment of the court final, subject to review by the U.S. Supreme Court (as provided in section 1254 of Title 28 U.S.C.). Any petition or this appeal may not operate as a stay of the order or regulation, unless specifically ordered by the court. New subsection 408(h)(5)—Application prohibits review under any other section of law of issues subject to review under this subsection.

Sec. 408(i). Confidentiality and use of data

Existing FFDCA, Section 408(f), requires that all data submitted under Section 408 or Section 409 be considered confidential by EPA or an advisory committee until publication of a regulation. New subsection 408(i)(1)—General Rule requires EPA to treat all submitted data and information confidentially and to provide for exclusive use and data compensation to the same extent as provided under FIFRA, Sections 3 and 10. New subsection 408(i)(2)—Exceptions allows disclosure of the information at the Administrator's discretion, to authorized Federal employees and contractors in carrying out official duties under this Act or other Federal statutes intended to protect the public health. Subparagraph (B) notes that information may not be withheld from either House of Congress or from any Committee, Subcommittee, or Joint Committee or Subcommittee to the extent that the matter lies within its jurisdiction. New subsection 408(i)(3)—Summaries permits publication of an informative summary of the data. The Committee intends that this section apply to data submitted to EPA prior to enactment, under old section 408 or 409, including data submitted under EPA guidelines by manufacturers of inert ingredients of pesticides. This provision is not intended to bring political forces to bear on EPA decision-making. The Committee expects EPA to issue regulations adequate to ensure appropriate protection of trade secret or confidential business information.

Sec. 408(j). Status of previously issued regulations

New subsection 408(j)(1)—Regulations Under Section 406 retains the provisions of FFDCA, Section 408(k), which concern regulations promulgated based on hearings held before 1953, but subjects modifications and revocations of such regulations to new Section 408, subsections (d) and (e), as well as to review under subsection (q). New subsections 408(j)(2)—Regulations under Section 409 and new subsection 408(j)(3)—Regulations under Section 408 are technical amendments which continue in effect all current regulations affecting pesticide residues that have been promulgated under current FFDCA Sections 408 or 409 and subjects modifications and revocations of such rules to new subsections (d) and (e) and to review under subsection (q).

Sec. 408(k). Transitional provision

New section 408(k) exempts from tolerance regulations those pesticide residues that before enactment (1) the Administrator or Secretary of Health and Human Services regarded as generally-recognized-as-safe (GRAS) within the meaning of subsection 408(a) or section 201(s). The new subsection (k)(2) also exempts from regulation any particular pesticide chemical on a particular food that was regarded as described in FFDCA section 201(s)(4). EPA is required to publish regulations listing which substances are covered by this exemption. Any exemption could be modified or revoked as if it had been issued under new subsection (c).

If a new pesticide chemical residue would be generally regarded as safe, the Committee expects the Administrator to use the authority of subsection (c) to exempt the residue from the requirement for a tolerance. Under subsection (c), the Administrator has

the authority to grant the residue a broad exemption covering multiple types of food in a single proceeding. Any petition to establish such an exemption should generally be given priority by the Administrator under subparagraph (d)(4)(B).

Sec. 408(l). Harmonization with action under other laws

New subsection (l)(1)—Limitation directs EPA, to the extent practicable and consistent with deadlines for review in subsection (q), to coordinate any final action to suspend or revoke a tolerance or exemption with related action that might be necessary under FIFRA. The Committee expects EPA to coordinate and harmonize its actions under FIFRA and the FFDCA in a careful, consistent manner which is fair to all interested parties.

New subsection (l)(2)—Revocation of Tolerance or Exemption Following Cancellation of Associated Registrations states that if EPA cancels or modifies the FIFRA registration of a pesticide for a food use because of dietary risks to human health posed by the residues, EPA also must revoke any tolerance or exemption that would allow the presence of the pesticide chemical in or on that food, using procedures set forth in subsection (e). A revocation under this paragraph becomes effective not later than 180 days after the date on which the use of the canceled pesticide becomes unlawful.

New subsection 408(l)(3)—Suspension of Tolerance or Exemption Following Suspension of Associated Registrations—(A) Suspension requires the suspension of tolerances for food use pesticides, if the pesticide registration is suspended under FIFRA. A tolerance suspension becomes effective not later than 60 days after the registration is suspended. Subparagraph (B)—Effect of Suspension restores tolerances or exemptions if the Administrator rescinds a suspension of the registration for use of the pesticide.

New subsection 408(l)(4)—Tolerances For Unavoidable Residues authorizes the Administrator to establish tolerances for unavoidably persistent residues of canceled or suspended pesticides on food. The required tolerance level is set taking into account the potential risk from exposure to the pesticide residue. These tolerances will be revisited periodically and modified as necessary to allow only that level of residue that is unavoidable due to its environmental persistence.

New subsection 408(l)(5)—Pesticide Residues Resulting From Lawful Application of Pesticide allows 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 treated legally with the pesticide cannot be deemed unsafe, if: (A) the residue is present because of a lawful use under FIFRA, and (B) the pesticide residue did not exceed the previously authorized tolerance, exemption, food additive regulation, or other sanction level. EPA retains 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 allows continued 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 ensures that food producers are

not unfairly penalized for legal use of pesticides that were subject to regulatory action at a subsequent date.

New subsection 408(l)(6)—Tolerance for Use of Pesticides under an Emergency Exemption requires EPA to establish a tolerance or exemption for a pesticide residue if the agency grants a local or State exemption in the case of an emergency under FIFRA Section 18. Such a tolerance or exemption must terminate on a given date. EPA is not required to provide notice or a comment period on such a tolerance or exemption. The bill requires EPA, within 365 days of enactment of H.R. 1627, to promulgate regulations concerning tolerances and exemptions under this paragraph. These regulations must be consistent with the safety standard established in Section 408 (b)(2) and (c)(2) and with FIFRA Section 18.

The Committee intends this requirement for Section 18 tolerances or exemptions to resolve a long-standing dilemma regarding legal pesticide residues that, because there were no tolerances or exemptions, could have been considered technically in violation of law. However, the Committee also intends for the extremely important Section 18 process to continue in place, and for EPA to issue emergency exemption tolerances or exemptions expeditiously.

Sec. 408(m). Fees

New subsection 408(m)(1)—Amount requires EPA to assess fees to cover, for example, the Agency's costs for accepting petitions, writing regulations, accepting objections, and certifying and filing court transcripts. Waivers or refunds of fees may be given by the Administrator, if it is equitable and not contrary to the purposes of this subsection. New subsection 408(m)(2)—Deposit requires all collected fees to be deposited in the FIFRA 4(k) Reregistration and Expedited Processing Fund, and made available without fiscal year constraints for EPA's tolerance-related activities which are specified in Section 408(m)(1).

Sec. 408(n). National uniformity of tolerances.

New section 408(n) preempts 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). New subsection 408(n)(1)—Qualifying Pesticide Chemical Residues defines "qualifying pesticide chemical residue" as (A) a residue from a pesticide use (A) first registered under section 3(c)(5) of FIFRA on or after April 25, 1985 (the pesticides not subject to reregistration requirements of FIFRA Section 4(g)) or (B) residues of "older" pesticides (subject to reregistration requirements) that EPA has evaluated and approved for reregistration for that use.

New subsection 408(n)(2)—Qualifying Federal Determination defines "qualifying Federal determination" as a tolerance or exemption (A) issued after enactment of this Act, and determined by the Administrator to meet the safety standard of new Section 408(b)(2)(A) (tolerances) or (c)(2) (exemptions); or (B) left in effect or deemed to have been issued under Section 408 pursuant to sub-

section (j), or regarded as exempt under subsection (k), and determined by EPA to meet the relevant safety standard. A determination to modify or leave in effect a tolerance under subsection (b)(2)(B) is not a qualifying Federal determination.

New subsection 408(n)(3)—Limitation requires the Administrator to establish the safety of a "qualifying Federal determination" that was deemed to have been issued under Section 408, rather than actually issued after enactment, by issuing a rule in accord with Section 408(d) or (e), after first proposing the rule and allowing at least 30 days for public comment. The rule is reviewable in accordance with subsections (g) and (h).

New subsection 408(n)(4)—State Authority prohibits State and local regulation of any "qualifying pesticide chemical residue" to which any "qualifying Federal determination" applies except as provided in paragraphs (5), (6), and (8). State and local governments are not authorized to regulate qualifying pesticide chemical residues covered by a qualifying Federal determination unless the State or local regulation is identical to the qualifying Federal determination.

New subsection (n)(5)—Petition Procedures establishes petition procedures for States to request exceptions to the prohibition on State regulations. Subsection (n)(5)(A)—In General allows States to petition for a regulatory limit on a qualifying residue different than the Federal limit, if the State's petition establishes adequate justification to EPA. Subsection (n)(5)(B)—Petition Requirement requires that this justification include supporting scientific data about the pesticide, consumption data, and exposure data of people residing in the State, and any other EPA requirements. Subsection (n)(5)(C)—Authorization authorizes State exemptions from uniform Federal limits if (i) they are justified by compelling local conditions and (ii) they would not cause any food to be in violation of Federal law. Subsection (n)(5)(D)—Treatment of Petition allows the Administrator to treat a State petition as if it were a petition to modify or revoke a tolerance or exemption under Section 408(d). Subsection (n)(5)(E)—Review subjects to review under subsections (g) and (h) (pertaining to administrative and judicial review, respectively) any EPA order granting or denying State authority in response to a petition.

New subsection (n)(6)—Urgent Petition Procedure provides for temporary State regulations if EPA does not act within 30 days of receiving an urgent petition for State authorization. If a State petition demonstrates that a significant public health threat exists from acute exposure to a pesticide residue on food during the period that such food is available in that State, the petition will be considered urgent. If EPA does not issue an order to grant or deny State authority that is requested in an urgent petition within 30 days of its receipt, the State is authorized to establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The final EPA order will validate or terminate the temporary regulatory limit.

New subsection (n)(7)—Residues from Lawful Application assures that no State or political subdivision can declare a food unlawful because it contains a residue that resulted from the application of a pesticide at a time when such residue level complied with

all Federal and State laws. An exception is allowed if the State can demonstrate that the residue level will pose an unreasonable dietary risk to the health of persons within that State due to consumption of that food during the period in which it is likely to be available.

New subsection (n)(8)—Savings excludes from the preemption provisions of subsection (n) "warning requirements" and other statements relating to the presence of such residues in food.

Sec. 408(o). Consumer right to know

This section requires EPA within 2 years of enactment and annually thereafter, in consultation with USDA and DHHS, to publish and distribute to large retail grocers for public display (in a manner determined by each grocer) certain information relevant to pesticide residues. The information, which must be conveyed in a format understandable to a lay person, includes: (1) a discussion of the risks and benefits of pesticide chemical residues in or on food; (2) a list of actions taken under subsection (b)(2)(B) relating to eligible pesticide residues that may result in risks greater than allowed for under subparagraph (A), and of the food on which the pesticides producing such residues are used; and (3) recommendations on how consumers might reduce dietary exposures to pesticide residues while maintaining a healthy diet. The Committee expects the EPA recommendations to be consistent with established nutritional guidelines. Retail grocers may provide additional information.

Sec. 408(p). Estrogenic substances screening program

New *Section 408(p)(1)* directs EPA, in consultation with DHHS, to develop a screening program within 2 years to gather information scientifically to evaluate whether certain substances may have effects in humans that are similar to effects produced by naturally occurring estrogen or other endocrine effects. Paragraph (2) requires EPA to solicit public comments on and review of the screening program by the scientific advisory panel for pesticide policy or the EPA science advisory board, which evaluates a broader range of EPA programs. The program must be implemented within 3 years of enactment of H.R. 1627. Paragraph (3) mandates testing of all pesticide chemicals and authorizes EPA to test any other substance that may have an effect cumulative to that of a pesticide chemical residue, if a substantial population may be exposed to it. Paragraph (4) authorizes EPA to issue orders exempting substances from the testing requirements if they are not expected to produce an estrogenic effect in humans. EPA must issue an order to conduct testing of covered substances and to submit reports to pesticide registrants and to persons who manufacture or import covered substances. The bill requires such orders to establish a reasonable time period for generating the information and reporting to EPA. EPA implementing regulations and orders should minimize duplicative testing requirements, provide equitable arrangements for sharing testing costs, and develop procedures to handle confidential business information. The other substances that may be tested under this paragraph are intended by the Committee to be other environmental contaminants. Paragraph (5)(C) requires issu-

ance of a notice of intent to suspend the sale or distribution of a substance if a registrant fails to comply with a test order. Such suspension will become final after 30 days unless a hearing is requested or the EPA decides that the registrant has complied fully with paragraph (5). However, EPA must terminate a suspension if the registrant has fully complied with paragraph (5). Any hearing held will be conducted in accordance with section 554 of title 4 U.S.C. (that is, the formal adjudicatory hearing process). The only matter to be resolved at the hearing is whether the registrant failed to comply with an EPA order. An EPA decision after the hearing is a final agency action and thus may be judicially reviewed under the Administrative Procedure Act (5 U.S.C. 701). If a manufacturer or an importer who is not a registrant fails to comply with a test order, that person is liable for the penalties and sanctions provided under TSCA Section 16, which may include up to $25,000 per day in fines and, if the person knowingly or willfully violates an order, imprisonment for up to one year. A person assessed a fine may request a hearing and, if ordered to pay the fine after the hearing, may file a petition for judicial review of EPA's order. The bill mandates EPA action "as is necessary to ensure the protection of public health" if the screening program finds a substance to have an endocrine effect on humans. Any action is to be taken under EPA's existing statutory authority. EPA must report to Congress within 4 years on its findings from the screening program and any recommendations for further testing and actions.

Sec. 408(q). Schedule for review

New Section 408(q) directs EPA to review tolerances and exemptions for pesticide residues in effect before enactment of H.R. 1627. Review should take place as expeditiously as practicable and assure that (A) 33 percent of the tolerances and exemptions are reviewed within 3 years, (B) 66 percent are reviewed within 6 years, and (C) all tolerances and exemptions are reviewed within 10 years. In reviewing the tolerances and exemptions, EPA is required to determine whether they meet the requirements of subsections (b)(2) or (c)(2). Before the deadline for review, the bill directs EPA to issue regulations under subsection (d)(4) or (e)(1) to modify or revoke tolerances and exemptions that do not meet the requirements of subsections (b)(2) or (c)(2).

Paragraph (2) orders the Administrator to give priority to the review of tolerances or exemptions that appear to pose the greatest risk to public health. New paragraph (3) requires that EPA publish within 12 months a schedule for review of tolerances and exemptions established prior to enactment of H.R. 1627. Priority setting for the review of tolerances and exemptions under this subsection is not to be considered a rulemaking and is not subject to judicial review. However, if EPA fails to take final action pursuant to the schedule, this failure shall be subject to judicial review.

In establishing an orderly review of existing tolerances and providing EPA with discretion in setting priorities, the Committee intends for the Agency to align such priorities responsibly with other important business, such as reviewing and responding to petitions. The Committee does not intend the petition process to be used in

a way that is disruptive of EPA's priorities, except in cases where an action is needed urgently to protect the public health.

Sec. 408(r). Temporary tolerance or exemption

New Section 408(r) provides, as in current FFDCA, section 408(j), that EPA may issue temporary tolerances or exemptions for the use of pesticides under a FIFRA experimental use permit.

Sec. 408(s). Savings clause

New Section 408(s) clarifies that the section does not modify or amend TSCA or FIFRA.

SEC. 406. AUTHORIZATION FOR INCREASED MONITORING

Section 6 authorizes to be appropriated an additional $12 million for increased monitoring by FDA of pesticide residues in imported and domestic food.

SEC. 407. ALTERNATIVE ENFORCEMENT

Section 407 amends FFDCA Section 303(g) (21 U.S.C. 333(f)) to insert a new paragraph (2). It subjects any person who introduces into interstate commerce or delivers for introduction into interstate commerce any food that is adulterated by a pesticide chemical residue to a civil money penalty of not more than $50,000 for an individual or $250,000 for a corporation for such introduction or delivery. An aggregate limit of $500,000 is set for all individuals and corporations subject to adjudication in a single proceeding. This paragraph does not apply to growers. Persons assessed a civil penalty may not be sanctioned under the criminal authorities for the introduction or delivery for introduction into interstate commerce of the adulterated food. Nor may seizure authorities of Section 304 or the injunction authorities of Section 302 be used against a person who is assessed a civil penalty. Subparagraph (C) provides the presiding officer in a hearing to assess a civil penalty with the same authority to compel testimony or production of documents as a presiding officer has under Section 408(g)(2)(B). The third sentence of paragraph (3)(A) (of Section 303(g), as amended by this section, which authorizes the Secretary to issue subpoenas) does not apply to any investigation under Section 303(g)(2).

The Committee intends for FDA to use this new civil penalty authority judiciously and to impose penalties that are commensurate with the level of violation and with other factors such as the history of past violations and ability of the individual or company to pay a fine. The Committee intends that one important factor to be considered in determining whether to levy a civil monetary penalty, and the amount of such penalty, is whether the individual or company has acted promptly and responsibly to remove a violative product from the market and to correct the cause of the violation. Finally, the Committee intends that all civil penalties collected under this authority shall be deposited in the general fund.

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 title IV 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 italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) * * *

* * * * * * *

[(q) The term "pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances, is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C., secs. 135–135k) as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities.]

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

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

(A) a pesticide chemical; or

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

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

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

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

* * * * * * *

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as hav-

ing been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

[(1) a pesticide chemical in or on a raw agricultural commodity; or

[(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or]

* * * * * * *

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

(2) a pesticide chemical; or

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

* * * * * * *

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 412, 505, 506, 507, 510, 512, 513, 514, 515, 516, 518, 519, 520, 704, 708, or 721 concerning any method or process which as a trade secret is entitled to protection*; or the violating of section 408(i)(2) or any regulation issued under that section.* This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

* * * * * * *

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

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

* * * * * * *

PENALTIES

SEC. 303. (a) * * *

* * * * * * *

(g)(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this Act which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed

$1,000,000 for all such violations adjudicated in a single proceeding.

* * * * * * *

(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) shall be subject to a civil money penalty of not more than $50,000 in the case of an individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

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

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

[(2)**]** *(3)*(A) A civil penalty under paragraph (1) *or (2)* shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1) *or (2)*. The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

[(3)**]** *(4)* Any person who requested, in accordance with paragraph **[**(2)(A)**]** *(3)(A)*, a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for

any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued.

[(4)] *(5)* If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph [(3)] *(4)*, or

(B) after a court in an action brought under paragraph [(3)] *(4)* has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph [(3)] *(4)* or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

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CHAPTER IV—FOOD

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ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or [(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided,* That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 512; (3) if it consists] *(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide*

chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a); or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 409; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.

* * * * * * *

[TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

[SEC. 408. (a) Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, added to a raw agricultural commodity, shall be deemed unsafe for the purposes of the application of clause (2) of section 402(a) unless—

[(1) a tolerance for such pesticide chemical in or on the raw agricultural commodity has been prescribed by the Administrator of the Environmental Protection Agency (hereinafter in this section referred to as the "Administrator") under this section and the quantity of such pesticide chemical in or on the raw agricultural commodity is within the limits of the tolerance so prescribed; or

[(2) with respect to use in or on such raw agricultural commodity, the pesticide chemical has been exempted from the requirement of a tolerance by the Administrator under this section.

While a tolerance or exemption from tolerance is in effect for a pesticide chemical with respect to any raw agricultural commodity, such raw agricultural commodity shall not, by reason of bearing or containing any added amount of such pesticide chemical, be considered to be adulterated within the meaning of clause (1) of section 402(a).

[(b) The Administrator shall promulgate regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary

to protect the public health. In establishing any such regulation, the Administrator shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion of the Secretary of Agriculture as submitted with a certification of usefulness under subsection (l) of this section. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section. In carrying out the provisions of this section relating to the establishment of tolerances, the Administrator may establish the tolerance applicable with respect to the use of any pesticide chemical in or on any raw agricultural commodity at zero level if the scientific data before the Administrator does not justify the establishment of a greater tolerance.

[(c) The Administrator shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance with respect to use in or on any or all raw agricultural commodities when such a tolerance is not necessary to protect the public health. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section.

[(d)(1) Any person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act may file with the Administrator, a petition proposing the issuance of a regulation establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of such pesticide, or exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain data showing—

[(A) the name, chemical identity, and composition of the pesticide chemical;

[(B) the amount, frequency, and time of application of the pesticide chemical;

[(C) full reports of investigations made with respect to the safety of the pesticide chemical;

[(D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;

[(E) practicable methods for removing residue which exceeds any proposed tolerance;

[(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

[(G) reasonable grounds in support of the petition.

Samples of the pesticide chemical shall be furnished to the Administrator upon request. Notice of the filing of such petition shall be published in general terms by the Administrator within thirty days after filing. Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed.

[(2) Within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (l) with respect to the pesticide chemical named in the petition, the Administrator shall, after giving due consideration to the data submitted in the petition or otherwise before him, by order make public a regulation—

[(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful, or

[(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes,

unless within such ninety-day period the person filing the petition requests that the petition be referred to an advisory committee or the Administrator within such period otherwise deems such referral necessary, in either of which events the provisions of paragraph (3) of this subsection shall apply in lieu hereof.

[(3) In the event that the person filing the petition requests, within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (l), with respect to the pesticide chemical named in the petition, that the petition be referred to an advisory committee, or in the event the Administrator within such period otherwise deems such referral necessary, the Administrator shall forthwith submit the petition and other data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Administrator and other data before it, certify to the Administrator a report and recommendations on the proposal in the petition to the Administrator, together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Administrator shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, by order make public a regulation—

[(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful; or

[(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes.

[(4) The regulations published under paragraph (2) or (3) of this subsection will be effective upon publication.

[(5) Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (2) or (3) of this subsection [1], or pursuant to subsection (e), may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. A copy of the objections filed by a person other than the petitioner shall be served on the petitioner, if the regulation was issued pursuant to a petition. The petitioner shall have two weeks to make a written reply to the objections. The Administrator shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Administrator by an advisory committee shall be made a part of the record of the hearing,

if relevant and material, subject to the provisions of section 556(c) of title 5, United States Code. The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Administrator, the petitioner, or the officer conducting the hearing: *Provided,* That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Administrator shall act upon such objections and by order make public a regulation. Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Administrator by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Administrator finds that emergency conditions exist necessitating an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

[(e) The Administrator may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Thirty days after publication of such a proposal, the Administrator may by order publish a regulation based upon the proposal which shall become effective upon publication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act containing the pesticide chemical named in the proposal, requests that the proposal be referred to an advisory committee. In the event of such a request, the Administrator shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Administrator and other data before it, certify to the Administrator a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Administrator may, after giving due consideration to all data before him, including such report, recommendations, underlying data and statement, by order publish a regulation establishing a tolerance for the pesticide chemical named in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publication. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d).

[(f) All data submitted to the Administrator or to an advisory committee in support of a petition under this section shall be considered confidential by the Administrator and by such advisory

committee until publication of a regulation under paragraph (2) or (3) of subsection (d) of this section. Until such publication, such data shall not be revealed to any person other than those authorized by the Administrator or by an advisory committee in the carrying out of their official duties under this section.

[(g) Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Administrator otherwise deems such referral necessary, the Administrator shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Administrator. Members of an advisory committee shall receive compensation and travel expenses in accordance with subsection (b)(5)(D) of section 721. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Administrator shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedures to be followed by the committee.

[(h) A person who has filed a petition or who has requested the referral of a proposal to an advisory committee in accordance with the provision of this section, as well as representatives of the Department of Health and Human Services, shall have the right to consult with any advisory committee provided for in subsection (g) in connection with the petition or proposal.

[(i)(1) In a case of actual controversy as to the validity of any order under subsection (d)(5), (e), or (l) any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after entry of such order, a petition praying that the order be set aside in whole or in part.

[(2) In the case of a petition with respect to an order under subsection (d)(5) or (e), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

[(3) In the case of a petition with respect to an order under subsection (l), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary of Agriculture, or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which

he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

[(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Administrator or the Secretary of Agriculture, as the case may be, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Administrator or the Secretary of Agriculture, as the case may be, may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

[(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

[(j) The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon his own initiative, establish a temporary tolerance for the pesticide chemical for the uses covered by the permit whenever in his judgment such action is deemed necessary to protect the public health, or may temporarily exempt such pesticide chemical from a tolerance. In establishing such a tolerance, the Administrator shall give due regard to the necessity for experimental work in developing an adequate, wholesome, and economical food supply and to the limited hazard to the public health involved in such work when conducted in accordance with applicable regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

[(k) Regulations affecting pesticide chemicals in or on raw agricultural commodities which are promulgated under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, in accordance with section 701(e), shall be deemed to be regulations under this section and shall be subject to amendment or repeal as provided in subsection (m).

[(l) The Secretary of Agriculture, upon request of any person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act, and whose request is accompanied by a copy of a petition filed by such person under subsection (d)(1) with respect to a pesticide chemical which constitutes, or is an ingredient of, such [a pesticide], shall, within thirty days or within sixty days if upon notice prior to the termination of such thirty days the Administrator deems it necessary to postpone action for such period, on the basis of data before him, either—

[(1) certify to the Administrator that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or

[(2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Secretary of Agriculture takes the action described in clause (2) of the preceding sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Secretary of Agriculture to certify to the Administrator [1] on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and such hearing. If no such action is taken, the Administrator may by order make the certification as proposed. In the event that the action described in clause (A) or (C) taken, the Administrator shall by order make the certification as proposed with respect to such parts thereof as are requested. In the event a hearing is requested, the Secretary of Agriculture shall provide opportunity for a prompt hearing. The certification of the Secretary of Agriculture as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Secretary of Agriculture exceed one hundred and sixty days. The Administrator shall submit to the Administrator with any certification of usefulness under this subsection an opinion, based on the data before him, whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Secretary of Agriculture, after due notice and opportunity for public hearing, is authorized to promulgate rules and regulations for carrying out the provisions of this subsection.

[(m) The Administrator shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations establishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

[(n) The provisions of section 303(c) with respect to the furnishing of guaranties shall be applicable to raw agricultural commodities covered by this section.

[(o) The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Secretary's functions under this section. Under such regulations, the performance of the Secretary's services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) the acceptance of fil-

ing of a petition submitted under subsection (d); (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d)(5); or (5) the certification and filing in court of a transcript of the proceedings and the record under subsection (i)(2). Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such waiver or refund is equitable and not contrary to the purposes of this subsection.]

TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES

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

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

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

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

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

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

(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B) despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 402(a)(2)(B).

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

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

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

(B) either—

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

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

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

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

(b) AUTHORITY AND STANDARD FOR TOLERANCE.—

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

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

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

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

(2) STANDARD.—

(A) GENERAL RULE.—

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

(ii) DETERMINATION OF SAFETY.—As used in this section, the term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all an-

ticipated dietary exposures and all other exposures for which there is reliable information.

(iii) RULE OF CONSTRUCTION.—With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B) TOLERANCES FOR ELIGIBLE PESTICIDE CHEMICAL RESIDUES.—

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

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

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

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a "threshold effect"), the Administrator determines that the level of aggregate exposure is safe.

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

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

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

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

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

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

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

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that

would be allowed under subparagraph (A) for such effect.

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

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

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

(C) EXPOSURE OF INFANTS AND CHILDREN.—In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

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

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

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

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

(ii) shall—

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

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

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

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

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

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

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

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

(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

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

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

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

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

as appropriate for the use of animal experimentation data.

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

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

(ii) REQUIREMENT.—If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

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

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

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

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

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

(3) DETECTION METHODS.—

(A) GENERAL RULE.—A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

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

(4) INTERNATIONAL STANDARDS.—In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

(c) AUTHORITY AND STANDARD FOR EXEMPTIONS.—

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

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

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

(2) STANDARD.—

(A) GENERAL RULE.—

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

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

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

(3) LIMITATION.—An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

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

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

(d) PETITION FOR TOLERANCE OR EXEMPTION.—

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

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

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

(2) PETITION CONTENTS.—

(A) ESTABLISHMENT.—A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

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

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

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

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

(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

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

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

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

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

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

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

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

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

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

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

(B) MODIFICATION OR REVOCATION.—The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

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

(4) ACTIONS BY THE ADMINISTRATOR.—

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

(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

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

(iii) issue an order denying the petition.

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

(C) EXPEDITED REVIEW OF CERTAIN PETITIONS.—

(i) DATE CERTAIN FOR REVIEW.—If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or ex-

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

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

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

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

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

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

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

(2) NOTICE.—Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(f) SPECIAL DATA REQUIREMENTS.—

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

(A) issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act;

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

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

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

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

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

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

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

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

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

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

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

(2) FURTHER PROCEEDINGS.—

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

other than the petitioner shall be served by the Administrator on the petitioner.

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

(C) FINAL DECISION.—As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

(h) JUDICIAL REVIEW.—

(1) PETITION.—In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C), or any order issued under subsection (f)(1)(C) or (g)(2)(C), or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

(2) RECORD AND JURISDICTION.—A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28, United States Code. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole

or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

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

(4) FINAL JUDGMENT; SUPREME COURT REVIEW.—The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

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

(i) CONFIDENTIALITY AND USE OF DATA.—

(1) GENERAL RULE.—Data and information that are or have been submitted to the Administrator under this section or section 409 in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(2) EXCEPTIONS.—

(A) IN GENERAL.—Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

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

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

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

any joint committee of Congress or any subcommittee of such joint committee.

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

(j) STATUS OF PREVIOUSLY ISSUED REGULATIONS.—

(1) REGULATIONS UNDER SECTION 406.—Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 701(e), under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e), and shall be subject to review under subsection (q).

(2) REGULATIONS UNDER SECTION 409.—Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 409 on or before the date of the enactment of this paragraph, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e), and shall be subject to review under subsection (q).

(3) REGULATIONS UNDER SECTION 408.—Regulations that established tolerances or exemptions under this section that were issued on or before the date of the enactment of this paragraph shall remain in effect unless modified or revoked under subsection (d) or (e), and shall be subject to review under subsection (q).

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

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

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

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of the date of enactment of this subsection. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c).

(l) HARMONIZATION WITH ACTION UNDER OTHER LAWS.—

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

related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act.

(2) REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

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

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

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

(A) SUSPENSION.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

(B) EFFECT OF SUSPENSION.—The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

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

Federal Insecticide, Fungicide, and Rodenticide Act, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) and the unavoidability of the residue. Subsection (e) shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

(5) PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF PESTICIDE.—Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

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

(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

(6) TOLERANCE FOR USE OF PESTICIDES UNDER AN EMERGENCY EXEMPTION.—If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after the date of the enactment of this paragraph governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(m) FEES.—

(1) AMOUNT.—The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term

to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

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

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

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

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

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

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

(n) NATIONAL UNIFORMITY OF TOLERANCES.—

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

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

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

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

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

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

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

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

(4) STATE AUTHORITY.—Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

(5) PETITION PROCEDURE.—

(A) IN GENERAL.—Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

(B) PETITION REQUIREMENTS.—Any petition under subparagraph (A) shall—

(i) satisfy any requirements prescribed, by rule, by the Administrator; and

(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

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

(i) is justified by compelling local conditions; and

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

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

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

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

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

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

(o) CONSUMER RIGHT TO KNOW.—Not later than 2 years after the date of the enactment of the Food Quality Protection Act of 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

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

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

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

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

(p) ESTROGENIC SUBSTANCES SCREENING PROGRAM.—

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

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

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

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

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

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

"(5) COLLECTION OF INFORMATION.—

"(A) IN GENERAL.—The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

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

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

"(i) SUSPENSION.—If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an

order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph.

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

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

"(D) NONCOMPLIANCE BY OTHER PERSONS.—Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act (15 U.S.C. 2601 and following) in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

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

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

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

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

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

(q) SCHEDULE FOR REVIEW.—

(1) IN GENERAL.—The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before the date of the enactment of the Food Quality Protec-

tion Act of 1996, as expeditiously as practicable, assuring that—

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

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

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

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections (b)(2) or (c)(2) and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

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

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

(r) TEMPORARY TOLERANCE OR EXEMPTION.—The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) shall apply to actions taken under this subsection.

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

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