MEMORANDUM OF CALL

Previous editions usable

TO: Ros

☒ YOU WERE CALLED BY ☐ YOU WERE VISITED BY

Judith Thoman

OF (Organization)

P6/b(6)

☐ WILL CALL AGAIN ☐ IS WAITING TO SEE YOU

☐ RETURNED YOUR CALL ☐ WISHES AN APPOINTMENT

MESSAGE

Re: apt w/ CR

We asked her to call this week.

RECEIVED BY: B | DATE: 6/21 | TIME: 9:12

63-110 NSN 7540-00-634-4018 STANDARD FORM 63 (Rev. 8-81)
U.S.G.P.O. 1992 312-070-40024 Prescribed by GSA FPMR (41 CFR) 101-11.6

Try July 13, 14 or 15

late morning or early aft.

30 min. max

I

103D CONGRESS
1ST SESSION

H. R. 1627

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 1, 1993

Mr. LEHMAN (for himself, Mr. BLILEY, Mr. ROWLAND, Mr. SMITH of Oregon, Mr. ROBERTS, Mr. PENNY, Mr. ENGLISH of Oklahoma, Mr. HOLDEN, Mr. EMERSON, Mr. KINGSTON, Mr. SARPALIUS, Mr. EWING, Mr. DOOLEY, Mr. JOHNSON of South Dakota, Mr. BARRETT of Nebraska, Mr. BOEHNER, Mr. COMBEST, Mr. DOOLITTLE, Mr. CONDIT, Mr. BISHOP, Mr. GUNDERSON, Mr. POMEROY, Mr. ALLARD, Mr. TOWNS, Mr. COOPER, Mr. HALL of Texas, Mr. MCMILLAN, Mr. HASTERT, Mr. UPTON, Mr. PAXON, Mr. KLUG, Mr. FRANKS of Connecticut, Mr. MANTON, Mr. BOUCHER, Mr. CRAPO, Mr. BARTON of Texas, Mr. GILLMOR, Mr. OXLEY, Mr. TAUZIN, and Mr. MOOREHEAD) introduced the following bill; which was referred jointly to the Committees on Agriculture and Energy and Commerce

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A BILL

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

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food Quality Protection Act of 1993".

TITLE I—CANCELLATION AND SUSPENSION

SEC. 101. REFERENCE.

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

SEC. 102. CANCELLATION.

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

"(b) CANCELLATION AND CHANGE IN CLASSIFICATION OR OTHER TERMS OR CONDITIONS OF REGISTRATION.—

"(1) AUTHORITY.—Notwithstanding any other provision of this Act, the Administrator may, by use of informal rulemaking under this subsection, prescribe requirements regarding the composition, packaging, and labeling of a pesticide (or a group of pesticides containing a common active or inert ingredient), or may classify any such pesticide, or may prohibit the registration or continued registration of any such pesticide for some or all purposes, to the extent necessary to assure that the pesticide, when used in accordance with widespread and commonly

recognized practice, does not generally cause unreasonable adverse effects on the environment.

"(2) BASIS FOR RULE.—

"(A) The Administrator may not initiate a rulemaking under this subsection unless the rulemaking is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse effects to man or to the environment.

"(B)(i) The Administrator shall submit to a scientific peer review committee established by the Administrator the validated test or other significant evidence upon which the Administrator proposes to base a rulemaking under paragraph (1).

"(ii) The scientific peer review committee shall provide written recommendations to the Administrator as to whether the test or evidence reviewed satisfies the criteria under paragraph (1) for initiating a rulemaking under paragraph (1).

"(iii) The scientific peer review committee shall consist of employees of or consultants to the Environmental Protection Agency who have not been involved in any previous analysis of

the validated test or significant evidence presented to the committee and who are expert in the physical or biological disciplines involved in the proposed rulemaking.

"(3) PRENOTICE PROCEDURES.—

"(A) The Administrator may not initiate a rulemaking under paragraph (1) until the Administrator has furnished to the registrant of each affected pesticide a notice that includes a summary of the validated test or other significant evidence upon which the Administrator proposes to base the rulemaking and the basis for a determination that such test or evidence raises prudent concerns that the pesticide causes unreasonable adverse risks to man or to the environment. A registrant shall have 30 days after receipt of a notice provided under this subparagraph to respond to such notice.

"(B) At the same time that the Administrator furnishes notice to registrants of the pesticide under subparagraph (A), the Administrator shall also furnish such notice to the Secretary of Agriculture and the Secretary of Health and Human Services. Upon receipt of such notification, the Secretary of Agriculture,

when an agricultural commodity is affected, shall prepare an analysis of the benefit and use data of the pesticide and provide the analysis to the Administrator.

"(4) ADVANCE NOTICE TO PUBLIC.—

"(A) The Administrator after receiving the recommendation of the peer review committee established under paragraph (2)(B) together with any comments submitted by the Secretary of Agriculture, the Secretary of Health and Human Services, and any registrant shall either—

"(i) issue an advance notice of proposed rulemaking, or

"(ii) issue a notice of a proposed decision not to initiate a rulemaking under paragraph (1).

"(B) The Administrator shall publish such notice in the Federal Register and provide a period of not less than 60 days for comment thereon. The notice shall contain a statement of its basis and purpose, which shall include a summary of—

"(i) the factual data on which the notice is based,

"(ii) the major scientific assumptions underlying the notice, and

"(iii) a summary of the notice under paragraph (3) and any significant comments received from any registrant, the Secretary of Agriculture, and the Secretary of Health and Human Services.

"(C) If the Administrator, after considering any comments received, decides not to issue a notice of proposed rulemaking, the Administrator shall publish in the Federal Register a notice setting forth the decision and its basis.

"(5) DOCKET.—For each rulemaking under paragraph (1), the Administrator shall establish a docket. The docket shall include a copy of the notice under paragraph (3), of any notice issued under paragraph (4), of the notice of proposed rulemaking under paragraph (6), of each timely comment filed with the Administrator, of the report of the Scientific Advisory Panel under paragraph (8), of a record of each hearing held by the Administrator in connection with the rulemaking, and of the final rule or decision to withdraw the rule. Information in the docket shall be made available to the public consistent with the requirements of section 10. No factual

material that has not been entered into the docket in a timely manner may be relied upon by the Administrator in issuing a final rule or in withdrawing a proposed rule or by any person in a judicial review proceeding, except for—

"(A) information of which the Administrator may properly take official notice, or

"(B) information of which a court may properly take judicial notice.

"(6) NOTICE OF PROPOSED RULEMAKING.—

"(A) Not less than 60 days after an advance notice of proposed rulemaking, except as provided in paragraph (14), the Administrator may issue a notice of proposed rulemaking. The notice of proposed rulemaking shall include a statement of its basis and purpose, a request for any additional data needed, and a bibliography of all significant scientific data and studies on which the proposed rule is based. The statement of basis and purpose shall include a summary of—

"(i) the factual data on which the proposed rule is based,

"(ii) the major scientific assumptions, legal interpretations, and policy considerations underlying the proposed rule,

"(iii) a summary of available risk-benefit information, including benefits and use information as provided by the Secretary of Agriculture, and

"(iv) the Administrator's analysis and tentative conclusions regarding the balancing of such risks and benefits.

"(B) Registrants of the pesticide and any person who submits comments on the proposed rule shall make a report to the Administrator of all scientific data and studies in such person's possession concerning the risks and benefits of the pesticide that are the subject of the rulemaking and were not included in the bibliography included in the notice required in subparagraph (A). If such person receives additional scientific data or studies pertinent to the rulemaking that were not included in such bibliography, the person shall make a report of such scientific data and studies to the Administrator promptly after receipt. If the Administrator receives reports containing additional data con-

cerning risks or benefits, the Administrator shall revise the bibliography to reflect such data and make the revised bibliography available to the public.

"(C) The Administrator shall provide a comment period of not less than 90 days after the publication of the notice of proposed rulemaking. During such period any person may submit comments, data, or documentary information on the proposed rule. Promptly upon receipt by the Administrator, all written comments and documentary information on the proposed rule received from any person for inclusion in the docket during the comment period, shall be placed in the docket.

"(D) At the same time that the Administrator publishes notice under subparagraph (A), the Administrator shall provide the Secretary of Agriculture and the Secretary of Health and Human Services with a copy of the proposed rule. Not later than 90 days after the publication of the notice of proposed rulemaking, the Secretary of Agriculture and the Secretary of Health and Human Services may provide comments on such proposed rule. When an agricul-

tural commodity is affected, the Secretary of Agriculture shall provide to the Administrator an analysis of the impact of the proposed action on the domestic and global availability and prices of agricultural commodities and retail food prices and any associated societal impacts (including consumer nutrition and health and low-income consumers).

"(7) INFORMAL HEARING.—

"(A) Any person who has submitted a comment may, not later than 15 days after the close of the comment period, request of the Administrator an informal hearing on questions of fact pertaining to the proposed rule or comments thereon. Upon such request, the Administrator shall schedule an informal hearing not to exceed 20 days duration, and to conduct not later than 60 days after the close of the comment period. The Administrator shall announce the time, place, and purpose of the hearing in the Federal Register. The informal hearing shall be limited to addressing questions of fact raised by materials in the docket. A transcript shall be made of any oral presentation, discussion, or debate and included in the docket.

"(B) The Administrator shall appoint a presiding officer who shall have the authority to administer oaths, regulate the course of the hearing, conduct prehearing conferences, schedule presentations, and exclude irrelevant, immaterial, or unduly repetitious evidence.

"(C) The presiding officer shall conduct the informal hearing in a manner that encourages discussion and debate on questions of fact regarding the docket. The Administrator shall designate one or more employees of the Environmental Protection Agency to participate in the hearing. Any person who submitted a comment on the proposed rule may participate in the hearing and shall be entitled to present evidence and argument to support the participant's position or rebut a contrary position and may choose to present materials in oral or written form.

"(8) REVIEW BY SCIENTIFIC ADVISORY PANEL.—At the time the Administrator issues a notice of proposed rulemaking under paragraph (6), the Administrator shall provide a copy of such notice to the Scientific Advisory Panel established under section 25(d). If any person submits comments

under paragraph (6) in opposition to the proposed rule, the Administrator shall request the comments, evaluations, and recommendations of the Panel as to the impact on health and the environment of the proposed rule and on any disputed issues of fact or scientific policy that appear to be of significance in the rulemaking. The Panel may hold a public hearing to discuss the proposed rule. The Panel shall provide a report to the Administrator not later than 30 days after the close of comment period (or, if a hearing has been requested under paragraph (7), not later than 30 days after the end of such hearing). The Administrator shall allow a reasonable time for written public comment on the Panel's report. A copy of the Panel's report and any comments shall be included in the rulemaking docket.

"(9) FINAL ACTION.—After considering all material in the docket, the Administrator shall publish in the Federal Register either a final rule or a withdrawal of the proposed rule. The Administrator may not prohibit a use of a pesticide if alternative requirements will assure that the pesticide, when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment. In taking any

final action, the Administrator shall take into account the impact of the action on production and prices of agricultural commodities, retail food prices, and otherwise on agricultural economy. The final rule or withdrawal of the proposal shall be accompanied by a statement that—

"(A) explains the reasons for the action;

"(B) responds to any comments made by the Secretary of Agriculture or the Secretary of Health and Human Services, and responds to any report of the Scientific Advisory Panel;

"(C) responds to each significant comment contained in the docket; and

"(D) in the case of a final rule—

"(i) explains the reasons for any major differences between the final rule and the proposed rule;

"(ii) describes the impact of the final rule on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy; and

"(iii) explains any significant disagreements the Administrator may have with the comments, evaluations, or recommendations contained in the report

under paragraph (8) or the benefits and use information described in paragraph (6)(A)(iii) and analysis in paragraph (6)(D) as it bears on the final rule.

A final rule issued under this subsection shall be effective upon the date of its publication in the Federal Register.

"(10) MODIFICATION OR CANCELLATION.—

"(A) A final rule shall state any requirements, classifications, or prohibitions imposed by the rule, and shall state that each affected registrant shall have a 30-day period from the date of publication of the rule in the Federal Register to apply for an amendment to the registration to comply with the rule or to request voluntary cancellation of the registration. However, if the rule unconditionally prohibits all uses of a pesticide, the rule may provide that cancellation of the registration of the pesticide is effective upon publication of the rule. The final rule may prohibit or limit distribution or sale by the registrant of the affected pesticide to any other person in any State during such 30-day period.

"(B) Notwithstanding any other provision of this Act, if an application for an amendment to the registration to make it comply with a rule issued under subparagraph (A) is not submitted within such 30-day period, the Administrator may issue and publish in the Federal Register an order canceling the registration, effective upon the date of publication of the order in the Federal Register.

"(11) DENIAL OF APPLICATIONS.—Notwithstanding any other provision of this Act, no application for initial or amended registration of any pesticide under section 3 or 24(c) may be approved if the registration would be inconsistent with a rule in effect under this subsection.

"(12) AMENDMENT OF RULE.—A registrant, or other interested person with the concurrence of the registrant, may petition for the amendment or revocation of a rule that has been issued under this subsection. The petition shall state the factual material and argument that form the basis for the petition. The Administrator shall publish a notice of the petition in the Federal Register and allow a 60-day comment period thereon. Not later than 180 days after publication of the notice, the Administrator

shall determine whether to deny the petition or to propose to amend or revoke the rule, and publish the determination and its basis in the Federal Register. In making such a determination, the Administrator shall give due regard to the desirability of finality, to the opportunity that the petitioner had to present the factual material and argument in question in the prior rulemaking proceeding, and to any new evidence submitted by the petitioner. If the Administrator proposes to amend or revoke the rule, then the procedures established by paragraph (1) and paragraphs (6) through (9) apply. A denial of a petition shall be judicially reviewable as provided in paragraph (13).

"(13) JUDICIAL REVIEW.—A decision not to initiate a rulemaking published under paragraph (4), a final rule or a withdrawal of a proposed rule published under paragraph (9) or a denial of a petition under paragraph (12) shall be judicially reviewable in the manner specified by section 16(b)(2).

"(14) EXCEPTION TO REQUIREMENTS.—If the Administrator finds it necessary to issue a suspension order under subsection (c), the Administrator may waive the requirements of paragraphs (3) and (4) of this subsection.".

SEC. 103. PESTICIDES IN REVIEW.

If the Administrator, on or before January 1, 1993, has published a document instituting a special review proceeding or public interim administrative review proceeding with respect to a particular pesticide or active ingredient thereof, the Administrator may, in lieu of proceeding under section 6(b) of the Federal Insecticide, Fungicide, and Rodenticide Act as amended by the Food Quality Protection Act of 1993, elect to continue such review proceeding and, upon its completion, take action as warranted in accordance with sections 3(c)(6), 6(b), and 6(d) as those sections were in effect on the day before the date of enactment of the Food Quality Protection Act of 1993.

SEC. 104. SUSPENSION.

(a) SECTION 6(c)(1).—The second sentence of section 6(c)(1) (7 U.S.C. 136d(c)(1)) is revised to read: "Except as provided in paragraph (3), no order of suspension may be issued under this subsection unless the Administrator has issued, or at the same time issues, a proposed rule under subsection (b).".

(b) SECTION 6(c)(3).—Section 6(c)(3) (7 U.S.C. 136d(c)(1)) is amended by inserting after the first sentence the following new sentence: "The Administrator may issue an emergency order under this paragraph before issuing a proposed rule under subsection (b), provided that

the Administrator shall proceed expeditiously to issue a proposed rule.".

SEC. 105. TOLERANCE REEVALUATION AS PART OF REREGISTRATION.

Section 4(g) (7 U.S.C. 136b(g)) is amended in paragraph (2) by adding at the end the following:

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

"(i) reassess each associated tolerance and exemption from the requirement for a tolerance issued under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a),

"(ii) determine whether such tolerance or exemption meets the requirements of that Act,

"(iii) determine whether additional tolerances or exemptions should be issued,

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

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

SEC. 106. SCIENTIFIC ADVISORY PANEL.

The first sentence of section 25(d) (7 U.S.C. 136w(d)) is amended by striking out "The Administrator shall" and inserting in lieu thereof "(1) IN GENERAL.—The Administrator shall" and such section is amended by adding at the end the following:

"(2) SCIENCE REVIEW BOARD.—There is established a Science Review Board to consist of 60 scientists who shall be available to the Scientific Advisory Panel to assist in reviews conducted by the Panel. The Scientific Advisory Panel shall select the scientists from 60 nominations submitted each by the National Science Foundation and the National Institutes of Health. Members of the Board shall be compensated in the same manner as members of the Panel.".

SEC. 107. CONFORMING AMENDMENTS.

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

"(6) DENIAL OF APPLICATION FOR REGISTRATION.—

"(A) Except as provided in subparagraph (B), if the Administrator proposes to deny an application for registration because it does not satisfy the requirements of paragraph (5), the Administrator shall notify the applicant of the proposal and the reasons (including the factual basis thereof). Unless the applicant makes the necessary corrections to the application and notifies the Administrator thereof during the 30-day period beginning with the day after the date the applicant receives the notice, or during that time the applicant submits a request for a hearing, the Administrator may issue an order denying the application. If during that time the Administrator does not receive such corrections to the application or such a request for hearing, the Administrator may issue an order denying the application. Such an order shall be published in the Federal Register and shall not be subject to judicial review. If during that time the Administrator receives a request for a hear-

ing, a hearing shall be conducted under section 6(d) of the Act. If such a hearing is held, a decision after completion of such hearing shall be final and shall be subject to judicial review under section 16(b)(1) of this Act.

"(B) The Administrator may deny an application for registration because it does not comply with the requirements of a rule issued under section 6(b) of this Act. The Administrator shall notify the applicant of such denial. Such notice shall explain why the application does not comply with such requirements and shall state that the applicant may petition to amend or revoke such rule under section 6(b)(12) of this Act.".

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

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

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

(2) in paragraph (2), by striking out all that follows "on the environment," and inserting in lieu

thereof "the Administrator may initiate a proceeding under section 6(b) of the Act.".

(d) SECTION 4(e).—Section 4(e)(3)(B)(iii)(III) (7 U.S.C. 136b(e)(3)(B)(iii)(III)) is amended—

(1) by striking out "section 6(d), except that the" and inserting in lieu thereof "section 6(d). The"; and

(2) by inserting after "guidelines." the following: "If a hearing is held, a decision after completion of such hearing shall be final.";

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

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

(1) by revising the first sentence to read as follows: "If a hearing is requested pursuant to section 3(c)(2)(B)(iv), 3(c)(6), 4(e)(3)(B)(iii)(III), 6(c)(2), or 6(e)(2), such hearing shall be held for the purpose of receiving evidence relevant and material to the issues raised by the request for hearing."; and

(2) by striking all that follows the eighth sentence and inserting the following: "A hearing under this subsection shall be held in accordance with the provisions of sections 554, 556, and 557 of title 5,

United States Code. As soon as practicable after the completion of the hearing, the Administration shall **issue a final order setting forth the Administrator's decision. Such order and decision shall be based only** on substantial evidence of record of such hearing, **shall set forth detailed findings of fact upon which the order is based, and shall be subject to judicial** review under section 16(b)(1).".

(g) SECTION 16(a).—Section 16(a) (7 U.S.C. 136n(a)) is amended by inserting "or a proceeding under section 6(b)" after "a hearing".

(h) SECTION 16(b).—Section 16(b) (17 U.S.C. 136n(b)) is amended—

(1) by striking out "(b) REVIEW BY COURT OF APPEALS.—In the case of" and inserting in lieu thereof the following:

"(b) REVIEW BY COURT OF APPEALS.—

"(1) REVIEW OF CERTAIN ORDERS.—In the case of";

(2) by striking "under this section" in the sixth sentence of paragraph (1) (as so designated) and inserting "under this paragraph"; and

(3) by adding at the end the following new paragraph:

"(2) REVIEW OF CERTAIN RULES.—In the case of actual controversy as to the validity of any rule issued by the Administrator under section 6(b)(9), any decision by the Administrator under section 6(b)(4) or 6(b)(9) not to issue a proposed rule or to withdraw a proposed rule, or any denial of a petition to revoke or amend a final rule under section 6(b)(12), any person who will be adversely affected by such rule or decision and who has filed comments in the proceeding leading to the rule or decision may obtain judicial review by filing a petition in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order. A copy of the petition shall be forthwith transmitted to the Administrator or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in court the record of the proceedings on which the Administrator based such rule or decision, 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 such rule or decision in whole or in part. The standard review shall be that set forth in section 706 of title 5, United States Code. The judg-

ment of the court under this paragraph shall be final, subject to review by the Supreme Court 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.".

(i) SECTION 25(a).—Section 25(a) (7 U.S.C. 136w(a)) is amended by adding a new paragraph (5) at the end, to read as follows:

"(5) EXCEPTION.—The requirements of this subsection shall not apply to any rule or rulemaking proceeding under section 6(b).".

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

(1) in the first sentence by striking out "in notices of intent issued under subsection 6(b) and"; and

(2) in the second sentence by striking out "notices of intent and" and by striking out "section 6(b) or".

(k) SECTION 25(e).—Section 25(e) (7 U.S.C. 136w(e)) is amended by striking out the period at the end of the second sentence and substituting ", except for any action that may be taken under section 6(b).".

TITLE II—DATA COLLECTION

SEC. 201. COLLECTION OF PESTICIDE USE INFORMATION.

The Secretary of Agriculture shall collect data of Statewide or regional significance on the use of pesticides to control pests and diseases of major crops and crops of dietary significance, including fruits and vegetables. Such data shall be collected by surveys of farmers or from other sources offering statistically reliable data. The Secretary shall, as appropriate, coordinate with the Administrator of the Environmental Protection Agency in the design of such surveys and make available to the Administrator the aggregate results of such surveys to assist the Administrator in developing exposure calculations and benefits determinations with respect to pesticide regulatory decisions.

SEC. 202. INTEGRATED PEST MANAGEMENT.

Section 28(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–3(c)) is amended—

(1) by designating the text of such section as paragraph (1) with the margin indented one em, and

(2) by adding at the end the following:

"(2) The Administrator and the Secretary of Agriculture shall research, develop, and disseminate integrated pest management techniques and other pest control methods that enable producers to reduce or eliminate applications of pesticides which pose a greater than negligible die-

tary risk to humans, with a special focus on crops critical to a balanced, healthy diet and which are considered as minor crops in terms of acreage produced.".

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

SEC. 301. REFERENCE.

Whenever in this title an amendment is expressed in terms of an amendment to a section or other provision, or refers to 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. 302. DEFINITIONS.

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

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

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

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

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

"(A) a pesticide chemical, or

"(B) any other added substance that is present 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 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) 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 (21 U.S.C. 321) is amended by adding at the end the following:

"(bb) 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.

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

SEC. 303. PROHIBITED ACTS.

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

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

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

SEC. 304. ADULTERATED FOOD.

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

"(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;

"(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".

SEC. 305. 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.—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. 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 concentration 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.

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

"(B) If an exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered 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, and

"(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 or states 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 consid-

ered to be adulterated within the meaning of section 402(a)(1).

"(b) AUTHORITY AND STANDARD FOR TOLERANCES.—

"(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 initiative under subsection (e).

"(2) STANDARD.—(A) A tolerance may not be established for a pesticide chemical residue in or on a food at a level that is higher than a level that the Administrator determines is adequate to protect the public health.

"(B) The Administrator shall modify or revoke a tolerance if it is at a level higher than the level that the Administrator determines is adequate to protect the public health.

"(C) In making a determination under this paragraph the Administrator shall take into account, among other relevant factors, the validity, completeness, and reliability of the available data from stud-

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

"(D) For purposes of subparagraph (A), a tolerance level for a pesticide chemical residue in or on a food shall be deemed to be adequate to protect the public health if the dietary risk posed to food consumers by such level of the pesticide chemical residue is negligible. The Administrator shall by regulation set forth the factors and methods for determining whether such a risk is negligible.

"(E) Where reliable data are available, the Administrator shall calculate the dietary risk posed to food consumers by a pesticide chemical on the basis of the percent of food actually treated with the pes-

ticide chemical and the actual residue levels of the pesticide chemical that occur in food. In particular, the Administrator shall take into account aggregate pesticide use and residue data collected by the Department of Agriculture.

"(F) For purposes of subparagraph (A), a level of a pesticide chemical residue in or on a food that poses a greater than negligible dietary risk to consumers of the food shall be deemed to be adequate to protect the public health if the Administrator determines that such risk is not unreasonable because—

"(i) use of the pesticide that produces the residue protects humans or the environment from adverse effects on public health or welfare that would, directly or indirectly, result in greater risk to the public or the environment than the dietary risk from the pesticide chemical residue; or

"(ii) use of the pesticide avoids risks to workers, the public, or the environment that would be expected to result from the use of another pesticide or pest control method on the same food and that are greater than the risks

that result from dietary exposure to the pesticide chemical residue; or

"(iii) the unavailability of the pesticide would limit the availability to consumers of an adequate, wholesome, and economical food supply, taking into account regional and domestic effects, and such adverse effects are likely to outweigh the risk posed by the pesticide residue.

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

"(3) LIMITATIONS.—(A) A tolerance may be issued under the authority of paragraph (2)(E) only if the Administrator has assessed the extent to which efforts are being made to develop either an alternative method of pest control or an alternative pesticide chemical for use on such commodity or food that would meet the requirements of paragraph (2)(D).

"(B) A tolerance for a pesticide chemical residue in or on a food shall not be established by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is

a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

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

"(4) INTERNATIONAL STANDARDS.—In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall take into account any maximum residue level for the chemical in or on the food that has been established by the Codex Alimentarius Commission. The Administrator shall determine whether the Codex maximum residue level is adequate to protect the health of United States' consumers and whether the data supporting the maximum residue level are valid, complete, and reliable. If the Administrator determines not to adopt a Codex maximum residue level, the Administrator shall publish a notice in the Federal Register setting forth the reasons.

"(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 a food—

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

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

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

"(B) An exemption from the requirement for a tolerance for a pesticide chemical residue in or on a food shall be revoked if the Administrator, in response to a petition for the revocation of the exemption or at the Administrator's own initiative determines that the exemption does not satisfy the criterion of subparagraph (A).

"(C) In making a determination under this subparagraph, the Administrator shall take into ac-

count, among other relevant factors, the factors set forth in subsection (b)(2)(C).

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

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

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

"(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 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,

"(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 a statement why such a method is not needed,

"(vii) practical methods for removing any amount of the residue that would exceed any proposed tolerance,

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

"(ix) all relevant data bearing on the physical or other technical effect that the

pesticide chemical is intended to have and the quantity of the pesticide chemical that is required to produce the effect,

"(x) 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,

"(xi) such information as the Administrator may require to make the determination under subsection (b)(2)(E), and

"(xii) 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 toler-

ance or to revoke an exemption from the requirement for a tolerance.

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

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

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

"(B) issue a proposed regulation under subsection (e), and thereafter either issue a final regulation under subsection (e) or an order denying the petition; or

"(C) issue an order denying the petition.

"(5) EFFECTIVE DATE.—A regulation issued under paragraph (4) shall take effect upon publication.

"(6) FURTHER PROCEEDINGS.—

"(A) Within 60 days after a regulation or order is issued under paragraph (4), subsection (e)(1), or subsection (f)(1), any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under paragraph (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) 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 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) 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.

"(D) An order issued under this paragraph ruling on an objection shall not take effect before the 90th 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 the Administrator's findings as to such conditions.

"(7) JUDICIAL REVIEW.—(A) In a case of actual controversy as to the validity of any order issued under paragraph (6) or any regulation that is the subject of such an order, any person who will be adversely affected by 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, a petition praying that the order or regulation be set aside in whole or in part.

"(B) A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title 28, United States Code. Upon the filing of 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. 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.

"(C) If a party applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in

the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

"(D) The judgment of the court affirming or setting aside, in whole or in part, any order under paragraph (6) 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 paragraph shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

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

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

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

"(A) establishing, modifying, or revoking a tolerance for a pesticide chemical or a pesticide chemical residue,

"(B) establishing 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.

A regulation issued under this paragraph shall become effective upon its publication.

"(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 contrary to the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking. The Administrator shall provide an opportunity for a public hearing during the rulemaking under procedures provided in subsection (d)(6)(B).

"(f) SPECIAL DATA REQUIREMENTS.—

"(1) REQUIRING SUBMISSION OF ADDITIONAL DATA.—If the Administrator determines that addi-

tional 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 persons 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 90 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 to 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 revise any such order to correct an error.

"(2) NONCOMPLIANCE.—If a submission required by a notice issued in accordance with paragraph (1)(A) or an order issued under paragraph (1)(B) is not made by the time specified in such notice or order, the Administrator may by order pub-

lished in the Federal Register modify or revoke the tolerance or exemption in question.

"(3) REVIEW.—An order issued under this subsection shall be effective upon publication and shall be subject to review in accordance with paragraphs (6) and (7) of subsection (d).

"(g) CONFIDENTIALITY AND USE OF DATA.—

"(1) GENERAL RULE.—Data and information that are submitted to the Administrator under this section in support of 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.—Data that are entitled to confidential treatment under paragraph (1) may nonetheless be disclosed to the Congress of the United States, and may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

"(A) employees of the United States authorized by the Administrator to examine such data in the carrying out of their official duties

under this Act or other Federal statutes intended to protect the public health, or

"(B) contractors with the United States authorized by the Administrator to examine such data in the carrying out of contracts under such statutes.

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

"(h) 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).

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

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

"(i) 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 section 408(a) or 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. An exemption under this subsection may be revoked or modified as if it had been issued under subsection (c).

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

"(1) LIMITATION.—Notwithstanding any other provision of this Act, a final rule under this section that revokes, modifies, or suspends a tolerance or exemption for a pesticide chemical residue in or on a food may be issued only if the Administrator has first taken any necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act with respect to the registration of the pesticide(s) whose use results in such residue to ensure that any authorized use of the pesticide in producing, storing, processing, or transporting food that occurs after the issuance of such final rule under this section will not result in pesticide chemical residues on such

food that are unsafe within the meaning of subsection (a).

"(2) REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS.—If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that 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. The Administrator shall use the procedures set forth in subsection (e) in taking action 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. The Administrator shall use the procedures set forth in subsection (e) in taking action under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

"(B) EFFECT OF SUSPENSION.—The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. 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 a 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 canceled prior to the effective date of this paragraph, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue at a level that permits such unavoidable residue to remain in such food. In estab-

lishing such a tolerance, the Administrator shall take into account the factors set forth in subsection (b)(2)(A)(iii) and shall use the procedures set forth in subsection (e). The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows only that level of the pesticide chemical residue that is unavoidable.

"(5) PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF PESTICIDE.—Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of 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.

"(k) FEES.—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—

"(1) the acceptance for filing of a petition submitted under subsection (d),

"(2) the promulgation of a regulation establishing, modifying, or revoking a tolerance or establishing or revoking an exemption from the requirement of a tolerance under this section,

"(3) the acceptance for filing of objections under subsection (d)(6), or

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

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.

"(l) 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 the Food Quality Protection Act of 1993.

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

"(A) a tolerance or exemption from the requirement for a tolerance for a qualifying pesticide chemical residue that was—

"(i) issued under this section after the date of enactment of the Food Quality Protection Act of 1993;

"(ii) issued (or, pursuant to subsection (h) or (i), deemed to have been issued) under this section, and determined by the Administrator to meet the standard under subsection (b)(2) (in the case of a tolerance) or (c)(2) (in the case of an exemption); and

"(B) any statement, issued by the Secretary, of the residue level below which enforcement action will not be taken under this Act with respect to any qualifying pesticide chemi-

cal residue, if the Secretary finds that such pesticide chemical residue level permitted by such statement during the period to which such statement applies protects human health.

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

"(4) STATE AUTHORITY.—Except as provided in paragraph (5), no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of 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 food if it purports to prohibit or penalize the production, processing, ship-

ping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit), **or if it purports to require that a food containing a pesticide residue be the subject of a warning or other statement relating to the presence of the pesticide residue in the food.**

"(5) PETITION PROCEDURE.—

"(A) 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) 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 with-

in such State to the pesticide chemical residue.

"(C) Subject to paragraph (6), 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;

"(ii) would not unduly burden interstate commerce; and

"(iii) would not cause any food to be in violation of Federal law.

"(D) 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 revoke or modify a tolerance or to revoke 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) 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 (d)(6) and (d)(7).

"(6) RESIDUES FROM LAWFUL APPLICATION.—No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in such residue, the sale of such food with such residue level was lawful under this Act 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.".

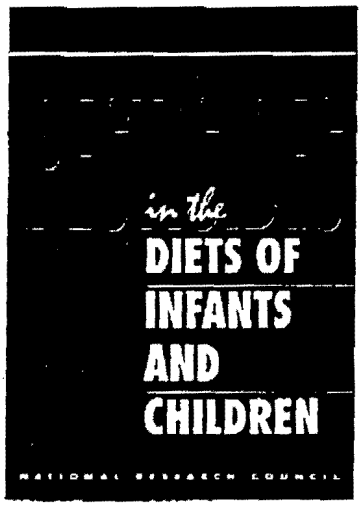
SEC. 306. AUTHORIZATION FOR INCREASE MONITORING.

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

NATIONAL ACADEMY OF SCIENCES
NATIONAL ACADEMY OF ENGINEERING
INSTITUTE OF MEDICINE
NATIONAL RESEARCH COUNCIL

REPORT SUMMARY

The federal government takes a one-size-fits-all approach to the regulation of pesticides, even though infants and children have different growth rates and diets than do adults. Today's regulatory system does not specifically consider variations in pesticide exposure between adults and children or the ways in which children's bodies may react differently to foreign substances. As a result, concern has arisen that some children may be ingesting unsafe amounts of pesticides.



To afford young Americans greater protection from pesticide exposures, a congressionally mandated report from the National Research Council, ***Pesticides in the Diets of Infants and Children,*** recommends that the federal government change some of its scientific and regulatory procedures for pesticides. It also recommends that regulators adopt a new method of risk assessment to gauge more accurately what proportion of the population may be at risk, and it urges that toxicity testing of pesticides be more comprehensive.

The committee that wrote the report did not conclude that parents should change their children's diets to avoid certain foods. But it advocates substantial changes in the current regulatory system to ensure that the foods eaten by infants and children are safe. Also, it urges that tolerance levels regulating permissible levels of pesticides in food be based primarily on considerations of health.

Children are different A fundamental tenet of pediatric medicine is that children are not just "little adults." They are growing and developing, their metabolic rates are higher than those of adults, and their bodies sometimes have different responses to ingested toxins. For example, data on toxic chemicals other than pesticides suggest that children may be more sensitive than adults to some compounds and less sensitive to others. Though these differences in sensitivities are fairly small — usually less than tenfold — the differences need to be systematically studied and, when important, taken into account in regulating pesticides.

Infants and children tend to eat fewer kinds of foods compared with adults and thus consume more of certain foods per unit of body weight, in addition, they drink more water, both alone and mixed with other foods. However, the present regulatory system does not consider these differences in diets. Current food consumption surveys group people into broad categories, such as 1- to 6-year-olds. By focusing on average intakes within these age groups, these methods obscure the full range of children's exposures as well as the rapid changes in diet that occur as a child grows. They also overlook geographic, ethnic, and other factors that can affect exposure to pesticides.

Problems also plague the measurement of pesticide residues that are on or in foods when they are consumed. Available measurements are of variable quality and are often not comparable. They typically reflect average adult consumption patterns and underrepresent foods eaten by infants and children.

Because of the different diets and physical reactions of infants and children to pesticides, their risk may be different from that of adults. To account for special vulnerabilities of infants and children, the current regulatory system needs to be modified.

A new approach In its report, the committee recommends an improved method of assessing the risk to infants and children from pesticides. Infants and children need to be considered separately from adults. Also, rather than using a single number to represent the average exposure of the entire population to pesticides, the committee suggests that data on the kinds and quantities of foods eaten by infants and children be combined with data on the pesticide residues on those foods.

Using this approach, regulators could get a much better idea of how many children might receive exposures above the level thought to be safe. This information could then be used in setting tolerances — the

amounts of pesticides legally allowed on or in foods when they leave the farm.

A major obstacle to the use of this new approach is a lack of data. Without better information on the food consumption patterns, pesticide residues, and toxicity, more accurate risk assessments cannot be widely applied. The committee offers specific recommendations to government regulators, pesticide manufacturers, and the food industry on ways to generate these data.

Better tests and data The federal government should revamp significant aspects of its approach to pesticide regulation, the committee writes. Food consumption surveys need to monitor more specific age groups to determine how children's diets differ from those of adults.

Also, measurements of pesticide residues should be standardized and computerized. These measurements need to reflect the diets of infants and children, the different rates and methods of pesticide application, and the effects of food processing on pesticide concentrations. Regulators also need to take into account children's pesticide exposures from non-dietary sources such as air, soil, lawns, pets, and indoor surfaces, as well as exposure to multiple pesticides with common toxic effects.

In addition, toxicity testing procedures need to be developed that specifically evaluate the vulnerability of infants and children. Particularly important are tests for toxicity to the developing immune, nervous, and reproductive systems.

The committee makes a number of other recommendations that would alter current regulatory procedures. It encourages the Environmental Protection Agency to consider expanding the use of uncertainty factors that are already applied in extrapolating from animal tests to effects in humans. It recommends that estimates of cancer risk from pesticides take into account changes in exposure and susceptibility that occur throughout a person's life.

Children deserve special consideration in this country's approach to pesticide regulation. By taking the steps outlined in this report, the federal government can ensure that their health is not compromised.

The study was sponsored by the Environmental Protection Agency, with additional support from the International Life Sciences Institute, Health and Welfare Canada, and the Kellogg Endowment Fund of the National Academy of Sciences and the Institute of Medicine.

Pesticides in the Diets of Infants and Children,
National Research Council, 1993.

COMMITTEE

PHILIP J. LANDRIGAN *(chair)*
Mount Sinai School of Medicine

DONALD R. MATTISON *(vice chair)*
University of Pittsburgh

HARVEY J. BABICH
Yeshiva University

BARBARA BOARDMAN
Boston University Medical School and Boston City Hospital

JAMES V. BRUCKNER
University of Georgia

MICHAEL A. GALLO
Robert Wood Johnson Medical School

DONALD E. HUTCHINGS
New York State Psychiatric Institute

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California State Department of Health Services

MERYL H. KAROL
University of Pittsburgh

DANIEL KREWSKI
Health and Welfare Canada

GEORGE A. PURVIS
Gerber Products Co.

ROBERT L. RIZEK
U.S. Department of Agriculture

JAMES N. SEIBER
University of Nevada

WILLIAM B. WEIL
Michigan State University

FRANCES M. PETER
Project Manager

RICHARD D. THOMAS
Principal Staff Scientist

CRAIG A. COX
Staff Officer

PESTICIDES in the DIETS OF INFANTS AND CHILDREN

Committee on Pesticides in the Diets of Infants and Children

Board on Agriculture
and
Board on Environmental Studies and Toxicology

Commission on Life Sciences

National Research Council

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Contents

Executive Summary

PESTICIDES ARE USED WIDELY in agriculture in the United States. Their application has improved crop yields and has increased the quantity of fresh fruits and vegetables in the diet, thereby contributing to improvements in public health.

But pesticides may also cause harm. Some can damage the environment and accumulate in ecosystems. And depending on dose, some pesticides can cause a range of adverse effects on human health, including cancer, acute and chronic injury to the nervous system, lung damage, reproductive dysfunction, and possibly dysfunction of the endocrine and immune systems.

Diet is an important source of exposure to pesticides. The trace quantities of pesticides that are present on or in foodstuffs are termed residues. To minimize exposure of the general population to pesticide residues in food, the U.S. Government has instituted regulatory controls on pesticide use. These are intended to limit exposures to residues while ensuring an abundant and nutritious food supply. The legislative framework for these controls was established by the Congress through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Pesticides are defined broadly in this context to include insecticides, herbicides, and fungicides.

Tolerances constitute the single, most important mechanism by which EPA limits levels of pesticide residues in foods. A tolerance is defined as the legal limit of a pesticide residue allowed in or on a raw agricultural commodity and, in appropriate cases, on processed foods. A tolerance must be established for any pesticide used on any food crop.

Tolerance concentrations are based primarily on the results of field trials conducted by pesticide manufacturers and are designed to reflect the highest residue concentrations likely under normal conditions of agricultural use. Their principal purpose is to ensure compliance with good agricultural practice. Tolerances are not based primarily on health considerations.

This report addresses the question of whether current regulatory approaches for controlling pesticide residues in foods adequately protect infants and children. The exposure of infants and children and their susceptibility to harm from ingesting pesticide residues may differ from that of adults. The current regulatory system does not, however, specifically consider infants and children. It does not examine the wide range of pesticide exposure patterns that appear to exist within the U.S. population. It looks only at the average exposure of the entire population. As a consequence, variations in dietary exposure to pesticides and health risks related to age and to such other factors as geographic region and ethnicity are not addressed in current regulatory practice.

Concern about the potential vulnerability of infants and children to dietary pesticides led the U.S. Congress in 1988 to request that the National Academy of Sciences (NAS) appoint a committee to study this issue through its National Research Council (NRC). In response, the NRC appointed a Committee on Pesticide Residues in the Diets of Infants and Children under the joint aegis of the Board on Agriculture and the Board on Environmental Studies and Toxicology.

The committee was charged with responsibility for examining scientific and policy issues faced by government agencies, particularly EPA, in regulating pesticide residues in foods consumed by infants and children. Specifically, the committee was asked to examine the adequacy of current risk assessment policies and methods; to assess information on the dietary intakes of infants and children; to evaluate data on pesticide residues in the food supply; to identify toxicological issues of greatest concern; and to develop relevant research priorities. Expertise represented on the committee included toxicology, epidemiology, biostatistics, food science and nutrition, analytical chemistry, child growth and development, and pediatrics.

The committee was not asked to consider toxicities resulting from exposures to microorganisms (bacteria and viruses) or from other naturally occurring potential toxins. It was not asked to weigh the benefits and risks to be derived from a plentiful and varied food supply against the potential risks resulting from pesticide exposure. It was not asked to assess the overall safety of the food supply.

In this report, the committee considered the development of children from the beginning of the last trimester of pregnancy (26 weeks) through

18 years of age, the point when all biological systems have essentially matured.

CONCLUSIONS

Age-Related Variation in Susceptibility and Toxicity

A fundamental maxim of pediatric medicine is that children are not "little adults." Profound differences exist between children and adults. Infants and children are growing and developing. Their metabolic rates are more rapid than those of adults. There are differences in their ability to activate, detoxify, and excrete xenobiotic compounds. All these differences can affect the toxicity of pesticides in infants and children, and for these reasons the toxicity of pesticides is frequently different in children and adults. Children may be more sensitive or less sensitive than adults, depending on the pesticide to which they are exposed. Moreover, because these processes can change rapidly and can counteract one another, there is no simple way to predict the kinetics and sensitivity to chemical compounds in infants and children from data derived entirely from adult humans or from toxicity testing in adult or adolescent animals.

The committee found both quantitative and occasionally qualitative differences in toxicity of pesticides between children and adults. Qualitative differences in toxicity are the consequence of exposures during special windows of vulnerability—brief periods early in development when exposure to a toxicant can permanently alter the structure or function of an organ system. Classic examples include chloramphenicol exposure of newborns and vascular collapse (gray baby syndrome), tetracycline and dysplasia of the dental enamel, and lead and altered neurologic development.

Quantitative differences in pesticide toxicity between children and adults are due in part to age-related differences in absorption, metabolism, detoxification, and excretion of xenobiotic compounds, that is, to differences in both pharmacokinetic and pharmacodynamic processes. Differences in size, immaturity of biochemical and physiological functions in major body systems, and variation in body composition (water, fat, protein, and mineral content) all can influence the extent of toxicity. Because newborns are the group most different anatomically and physiologically from adults, they may exhibit the most pronounced quantitative differences in sensitivity to pesticides. **The committee found that quantitative differences in toxicity between children and adults are usually less than a factor of approximately 10-fold.**

The committee concluded that the mechanism of action of a toxicant—how it causes harm—is generally similar in most species and across age

and developmental stages within species. For example, if a substance is cytotoxic in adults, it is usually also cytotoxic in immature individuals.

Lack of data on pesticide toxicity in developing organisms was a recurrent problem encountered by the committee. In particular, little work has been done to identify effects that develop after a long latent period or to investigate the effects of pesticide exposure on neurotoxic, immunotoxic, or endocrine responses in infants and children. The committee therefore had to rely mostly on incomplete information derived from studies in mature animals and on chemicals other than pesticides.

The committee reviewed current EPA requirements for toxicity testing by pesticide manufacturers, as well as testing modifications proposed by the agency. In general, the committee found that current and past studies conducted by pesticide manufacturers are designed primarily to assess pesticide toxicity in sexually mature animals. Only a minority of testing protocols have supported extrapolation to infant and adolescent animals. Current testing protocols do not, for the most part, adequately address the toxicity and metabolism of pesticides in neonates and adolescent animals or the effects of exposure during early developmental stages and their sequelae in later life.

Age-Related Differences in Exposure

Estimation of the exposures of infants and children to pesticide residues requires information on (1) dietary composition and (2) residue concentrations in and on the food and water consumed. **The committee found that infants and children differ both qualitatively and quantitatively from adults in their exposure to pesticide residues in foods.** Children consume more calories of food per unit of body weight than do adults. But at the same time, infants and children consume far fewer types of foods than do adults. Thus, infants and young children may consume much more of certain foods, especially processed foods, than do adults. And water consumption, both as drinking water and as a food component, is very different between children and adults.

The committee concluded that differences in diet and thus in dietary exposure to pesticide residues account for most of the differences in pesticide-related health risks that were found to exist between children and adults. Differences in exposure were generally a more important source of differences in risk than were age-related differences in toxicologic vulnerability.

Data from various food consumption surveys were made available to the committee. In analyzing these data, the committee found it necessary to create its own computer programs to convert foods as consumed into their component raw agricultural commodities (RACs). This analytic approach facilitated the use of data from different sources and permitted evaluation of total exposure to pesticides in different food commodities. For processed foods, the committee noted that effects of processing on residue concentrations should be considered, but that information on these effects is quite limited. Processing may decrease or increase pesticide residue concentrations. The limited data available suggest that pesticide residues are generally reduced by processing; however, more research is needed to define the direction and magnitude of the changes for specific pesticide-food combinations. The effect of processing is an important consideration in assessing the dietary exposures of infants and young children, who consume large quantities of processed foods, such as fruit juices, baby food, milk, and infant formula.

Although there are several sources of data on pesticide residues in the United States, the data are of variable quality, and there are wide variations in sample selection, reflecting criteria developed for different sampling purposes, and in analytical procedures, reflecting different laboratory capabilities and different levels of quantification between and within laboratories. These differences reflect variations in precision and in the accuracy of methods used and the different approaches to analytical issues, such as variations in limit of quantification. There also are substantial differences in data reporting. These differences are due in part to different record-keeping requirements, such as whether to identify samples with multiple residues, and differences in statistical treatment of laboratory results below the limit of quantification.

Both government and industry data on residue concentrations in foods reflect the current regulatory emphasis on average adult consumption patterns. The committee found that foods eaten by infants and children are underrepresented in surveys of commodity residues. Many of the available residue data were generated for targeted compliance purposes by the Food and Drug Administration (FDA) to find residue concentrations exceeding the legal tolerances established by the EPA under FFDCA.

Survey data on consumption of particular foods are conventionally grouped by broad age categories. The average consumption of a hypothetical "normal" person is then used to represent the age group. However, in relying solely on the average as a measure of consumption, important information on the distribution of consumption patterns is lost. For example, the high levels of consumption within a particular age group are especially relevant when considering foods that might contain residues capable of causing acute toxic effects. Also, geographic, ethnic, and other differences may be overlooked.

To overcome the problems inherent in the current reliance on "average" exposures, the committee used the technique of statistical convolution (i.e., combining various data bases) to merge distributions of food consumption

with distributions of residue concentrations. This approach permits examination of the full range of pesticide exposures in the U.S. pediatric population. As is described in the next section, this approach provides an improved basis over the approach now used for assessing risks for infants and children.

A New Approach to Risk Assessment for Infants and Children

To properly characterize risk to infants and children from pesticide residues in the diet, information is required on (1) food consumption patterns of infants and children, (2) concentrations of pesticide residues in foods consumed by infants and children, and (3) toxic effects of pesticides, especially effects that may be unique to infants and children. If suitable data on these three items are available, risk assessment methods based on the technique of statistical convolution can be used to estimate the likelihood that infants and children who experience specific exposure patterns may be at risk. To characterize potential risks to infants and children in this fashion, the committee utilized data on distributions of pesticide exposure that, in turn, were based on distributions of food consumption merged with data on the distribution of pesticide residue concentrations. The committee found that age-related differences in exposure patterns for 1- to 5-year-old children were most accurately illuminated by using 1-year age groupings of data on children's food consumption.

Exposure estimates should be constructed differently depending on whether acute or chronic effects are of concern. Average daily ingestion of pesticide residues is an appropriate measure of exposure for assessing the risk of chronic toxicity. However, actual individual daily ingestion is more appropriate for assessing acute toxicity. Because chronic toxicity is often related to long-term average exposure, the average daily dietary exposure to pesticide residues may be used as the basis for risk assessment when the potential for delayed, irreversible chronic toxic effects exists. Because acute toxicity is more often mediated by peak exposures occurring within a short period (e.g., over the course of a day or even during a single eating occasion), individual daily intakes are of interest. Examining the distribution of individual daily intakes within the population of interest reflects day-to-day variation in pesticide ingestion both for specific individuals and among individuals.

Children may be exposed to multiple pesticides with a common toxic effect, and estimates of exposure and of risk could therefore be improved by accounting for these simultaneous exposures. This can be accomplished by assigning toxicity equivalence factors to each of the compounds having a common mechanism of action. Total residue exposure is then estimated by multiplying the actual level of each pesticide residue by its toxicity equivalence factor and summing the results. This information may be combined with data on consumption to construct a distribution of total exposure to all pesticides having a common mechanism of action. To test this multiple-residue methodology, the committee estimated children's acute health risks resulting from combined exposure to five members of the organophosphate insecticide family. This was accomplished by combining actual food consumption data with data on actual pesticide residue levels.

Through this new analytical procedure, the committee estimated that for some children, total organophosphate exposures may exceed the reference dose. Furthermore, although the data were weak, the committee estimated that for some children exposures could be sufficiently high to produce symptoms of acute organophosphate pesticide poisoning.

Compared to late-in-life exposures, exposures to pesticides early in life can lead to a greater risk of chronic effects that are expressed only after long latency periods have elapsed. Such effects include cancer, neurodevelopmental impairment, and immune dysfunction. The committee developed new risk assessment methods to examine this issue.

Although some risk assessment methods take into account changes in exposure with age, these models are not universally applied in practice. The committee explored the use of newer risk assessment methods that allow for changes in exposure and susceptibility with age. However, the committee found that sufficient data are not currently available to permit wide application of these methods.

RECOMMENDATIONS

On the basis of its findings, the committee recommends that certain changes be made in current regulatory practice. Most importantly, estimates of expected total exposure to pesticide residues should reflect the unique characteristics of the diets of infants and children and should account also for all nondietary intake of pesticides. Estimates of exposure should take into account the fact that not all crops are treated with pesticides that can be legally applied to those crops, and they should consider the effects of food processing and storage. Exposure estimates should recognize that pesticide residues may be present on more than one food commodity consumed by infants and children and that more than one pesticide may be present on one food sample. Lastly, determinations of safe levels of exposure should take into consideration the physiological factors that can place infants and children at greater risk of harm than adults.

• *Tolerances.* Tolerances for pesticide residues on commodities are currently established by the EPA under FIFRA and FFDCA. A tolerance concentration is defined under FFDCA as the maximum quantity of a pesticide residue allowable on a raw agricultural commodity (RAC) (FFDCA, Section 408) and in processed food when the pesticide concentrates during processing (FFDCA Section 409). Tolerance concentrations on RACs are based on the results of field trials conducted by pesticide manufacturers and are designed to reflect the highest residue concentrations likely under normal agricultural practice. More than 8,500 food tolerances for pesticides are currently listed in the Code of Federal Regulations (CFR). Approximately 8,350 of these tolerances are for residues on raw commodities (promulgated under section 408) and about 150 are for residues known to concentrate in processed foods (promulgated under section 409).

The determination of what might be a safe level of residue exposure is made by considering the results of toxicological studies of the pesticide's effects on animals and, when data are available, on humans. Both acute and chronic effects, including cancer, are considered, although acute effects are treated separately. These data are used to establish human exposure guidelines (i.e., a reference dose, RfD) against which one can compare the expected exposure. Exposure is a function of the amount and kind of foods consumed and the amount and identity of the residues in the foods (i.e., Theoretical Maximum Residue Contributions, TMRCs). If the TMRCs exceed the RfD, then anticipated residues are calculated for comparison with the proposed tolerance. The percent of crop acreage treated is also considered. If the anticipated residues exceed the RfD, then the proposed tolerance is rejected, and the manufacturer may recommend a new tolerance level.

Although tolerances establish enforceable legal limits for pesticide residues in food, they are not based primarily on health considerations, and they do not provide a good basis for inference about actual exposures of infants and children to pesticide residues in or on foods.

Tolerances constitute the only tool that EPA has under the law for controlling pesticide residues in food. **To ensure that infants and children are not exposed to unsafe levels of pesticide residues, the committee recommends that EPA modify its decision-making process for setting tolerances so that it is based more on health considerations than on agricultural practices. These changes should incorporate the use of improved estimates of exposure and more relevant toxicology, along with continued consideration of the requirements of agricultural production. As a result, human health considerations would be more fully reflected in tolerance levels. Children should be able to eat a healthful diet containing legal residues without encroaching on safety margins. This goal should be kept clear.**

• *Toxicity testing.* The committee believes it is essential to develop toxicity testing procedures that specifically evaluate the vulnerability of infants and children. Testing must be performed during the developmental period in appropriate animal models, and the adverse effects that may become evident must be monitored over a lifetime. Of particular importance are tests for neurotoxicity and toxicity to the developing immune and reproductive systems. Extrapolation of toxicity data from adult and adolescent laboratory animals to young humans may be inaccurate. Careful attention to interspecies differences in pharmacokinetics and metabolism of pesticides and the relative ages at which organ systems mature is essential. It is also important to enhance understanding of developmental toxicity, especially in humans, during critical periods of postnatal development, including infancy and puberty.

• *Uncertainty factors.* For toxic effects other than cancer or heritable mutation, uncertainty factors are widely used to establish guidelines for human exposure on the basis of animal testing results. This is often done by dividing the no-observed-effect level (NOEL) found in animal tests by an uncertainty factor of 100-fold. This factor comprises two separate factors of 10-fold each: one allows for uncertainty in extrapolating data from animals to humans; the other accommodates variation within the human population. Although the committee believes that the latter uncertainty factor generally provides adequate protection for infants and children, this population subgroup may be uniquely susceptible to chemical exposures at particularly sensitive stages of development.

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.

In the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children. To validate this presumption,

the sensitivity of mature and immature individuals should be studied systematically to expand the current limited data base on relative sensitivity.

• *Food consumption data.* The committee recommends that additional data on the food consumption patterns of infants and children be collected within narrow age groups. The available data indicate that infants and children consume much more of certain foods on a body weight basis than do adults. Because higher exposures can lead to higher risks, it is important to have accurate data on food consumption patterns for infants and children. At present, data are derived from relatively small samples and broad age groupings, making it difficult to draw conclusions about the food consumption patterns of infants and children. Because the composition of a child's diet changes dramatically from birth through childhood and adolescence to maturity, "market basket" food consumption surveys should include adequate samples of food consumption by children at 1-year intervals up to age 5, by children between the ages of 5 and 10 years, and by children between 11 and 18 years. Food consumption surveys should be conducted periodically to ascertain changes in consumption patterns over time.

• *Pesticide residue data.* To maximize the utility of pesticide residue data collected by various laboratories, the committee recommends the use of comparable analytical methods and standardized reporting procedures and the establishment of a computerized data base to collate data on pesticide residues generated by different laboratories. Reports on pesticide residue testing should describe the food commodity analyzed (whether processed or raw), the analytical methods used, the compounds for which tests were conducted, quality assurance and control procedures, and the limit of quantification of the tests. All findings should be reported, whether or not the residue sought is found.

–In its surveillance of pesticide residues, FDA should increase the frequency of sampling of the commodities most likely to be consumed by infants and children. The residue testing program should include all toxic forms of the pesticide, for example, its metabolites and degradation products.

–Food residue monitoring should target a special "market basket" survey focused toward the diets of infants and children.

–Pesticide field trials currently conducted by pesticide manufacturers in support of registration provide data on variation in residue concentrations associated with different rates and methods of application. Such data should be consulted to provide a basis for estimating potential maximum residue levels.

–More complete information is needed on the effects of food processing on levels of pesticides—both the parent compound and its metabolites—in specific food-chemical combinations potentially present in the diets of infants and children.

• *Risk assessment.* All exposures to pesticides—dietary and nondietary—need to be considered when evaluating the potential risks to infants and children. Nondietary environmental sources of exposure include air, dirt, indoor surfaces, lawns, and pets.

–Estimates of total dietary exposure should be refined to consider intake of multiple pesticides with a common toxic effect. Converting residues for each pesticide with a common mechanism of action to toxicity equivalence factors for one of the compounds would provide one approach to estimating total residue levels in toxicologically equivalent units.

–Consumption of pesticide residues in water is an important potential route of exposure. Risk assessment should include estimates of exposure to pesticides in drinking water and in water as a component of processed foods.

Given adequate data on food consumption and residues, the committee recommends the use of exposure distributions rather than single point data to characterize the likelihood of exposure to different concentrations of pesticide residues. The distribution of average daily exposure of individuals in the population of interest is most relevant for use in chronic toxicity risk assessment, and the distribution of individual daily intakes is recommended for evaluating acute toxicity. Ultimately, the collection of suitable data on the distribution of exposures to pesticides will permit an assessment of the proportion of the population that may be at risk.

Although the committee considers the use of exposure distributions to be more informative than point estimates of typical exposures, the data available to the committee did not always permit the distribution of exposures to be well characterized. Existing food consumption surveys generally involve relatively small numbers of infants and children, and food consumption data are collected for only a few days for each individual surveyed. Depending on the purpose for which they were originally collected, residue data may not reflect the actual distribution of pesticide residues in the food supply. Since residue data are not developed and reported in a consistent fashion, it is generally not possible to pool data sets derived from different surveys. Consequently, the committee recommends that guidelines be developed for consumption and residue data permitting characterization of distributions of dietary exposure to pesticides.

The committee identified important differences in susceptibility to the toxic effects of pesticides and exposure to pesticides in the diet with age.

For carcinogenic effects, the committee proposed new methods of cancer risk assessment designed to take such differences into account. Preliminary analyses conducted by the committee suggest that consideration of such differences can lead to lifetime estimates of cancer risk that can be higher or lower than estimates derived with methods based on constant exposure. However, underestimation of risk assuming constant exposure was limited to a factor of about 3- to 5-fold in all cases considered by the committee. Because these results are based on limited data and specific assumptions about the mechanisms by which carcinogenic effects are induced, the applicability of these conclusions under other conditions should be established.

Currently, most long-term laboratory studies of carcinogenesis and other chronic end points are based on protocols in which the level of exposure is held constant during the course of the study. To facilitate the application of risk assessment methods that allow for changes in exposure and susceptibility with age, it would be desirable to develop bioassay protocols that provide direct information on the relative contribution of exposures at different ages to lifetime risks. Although the committee does consider it necessary to develop special bioassay protocols for mandatory application in the regulation of pesticides, it would be useful to design special studies to provide information on the relative effects of exposures at different ages on lifetime cancer and other risks with selected chemical carcinogens.

In addition to pharmacodynamic models for cancer risk assessment, the committee recommends the development and application of physiologically based pharmacokinetic models that describe the unique features of infants and children. For example, differences in relative organ weights with age can be easily described in physiologic pharmacokinetic models; special compartments for the developing fetus may also be incorporated. Physiologically based pharmacokinetic models can be used to predict the dose of the proximate toxicant reaching target tissues, and may lead to more accurate estimates of risk.

In summary, better data on dietary exposure to pesticide residues should be combined with improved information on the potentially harmful effects of pesticides on infants and children. Risk assessment methods that enhance the ability to estimate the magnitude of these effects should be developed, along with appropriate toxicological tests for perinatal and childhood toxicity. The committee's recommendations support the need to improve methods for estimating exposure and for setting tolerances to safeguard the health of infants and children.

HOW H.R. 1627 -- THE LEHMAN-BLILEY-ROWLAND BILL -- ADDRESSES ISSUES RAISED BY THE NAS REPORT REGARDING PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN

On June 29, 1993, the National Academy of Sciences (NAS) will release its report on pesticides in the diets of infants and children. The NAS study will examine the adequacy of the current risk assessment methods for pesticides in children's diets by identifying key toxicology concerns, evaluating available data sources on food consumption and pesticide residues, recommending improvements in the risk assessment process, and suggesting research priorities.

The Lehman-Bliley-Rowland bill (H.R. 1627) is comprehensive food safety reform legislation which includes many provisions directly relevant to the reported findings of the NAS study. Specifically, H.R. 1627 provides the following mechanisms to promote the safety of the food supply with respect to the needs of infants and children --

- **Directs EPA to Consider Exposure Levels of Infants and Children in Setting Pesticide Residue Tolerances** -- Although EPA currently addresses exposure of infants and children as a matter of policy, the Agency does so without specific statutory direction. Together EPA, FDA, and USDA consider the unique characteristics and sensitivities of a wide variety of population groups, including infants and children, to determine risk. H.R. 1627 would *mandate* that EPA consider these and other sensitive population groups and would clarify the Agency's obligations in such cases.

- **Provides a Risk Standard to Eliminate the Problems Created by the Delaney Clause** -- H.R. 1627 establishes a unitary negligible risk standard for raw and processed foods that requires protection of public health under a standard reflecting previous recommendations of the NAS.

- **Requires EPA to Consider both Data on Actual Residue Levels on Foods and Consumption Patterns in Setting Pesticide Residue Tolerances** -- H.R. 1627 would require EPA to consider information on food consumption and actual pesticide use and residue levels so that tolerances can be set based on the most accurate, reliable information available. In addition, H.R. 1627 would require USDA to improve its database by collecting information on residue levels and consumption patterns to assist EPA in tolerance-setting.

- **Provides an Expedited Process for Suspension and Cancellation of Pesticides When Warranted** -- H.R. 1627 would remove time-consuming, legalistic paperwork constraints that hinder EPA's ability to cancel pesticide registrations and prohibit pesticide use in emergency situations.

- **Requires Review of Existing Pesticide Tolerances on a Timely Basis** -- H.R. 1627 would require timely review of existing pesticide tolerances (by integrating the review of tolerances with pesticide registration review under FIFRA) to ensure that tolerances meet the law's health standards.

- **Promotes Integrated Pest Management Techniques** -- H.R. 1627 would require EPA and USDA to research, develop, and disseminate integrated pest management techniques and other pest control methods to reduce or eliminate applications of certain pesticides, with a special focus on crops critical to a balanced, healthy diet.

Media backgrounder

Pesticides in the diets of infants and children:

The report from the National Research Council and the National Academy of Sciences

June 1993

G★M★A
GROCERY MANUFACTURERS OF AMERICA

1010 Wisconsin Ave., N.W.
Suite 900
Washington D.C. 20007
(202) 337-9400

• • • Introduction

On June 29, 1993, the National Academy of Sciences will release its study on Pesticides in the Diets of Infants and Children. The study is already the subject of intense speculation by activist groups like the National Resources Defense Council, the organization that initiated the Alar controversy. The probability of misinformation and outright alarmist distortion about the report's conclusions is high.

The Grocery Manufacturers of America, Inc., is a trade association of manufacturers of food and non-food products primarily sold in retail grocery stores throughout America. As the principal voice of the food industry, we believe it is important to inform reporters and editors who cover the industry about these issues.

• • • The Study

The NAS study, Pesticides in the Diets of Infants and Children, does not measure current exposure to pesticides, but rather examines the adequacy of the current risk assessment methods for pesticides in children's diets. The NAS report aims to identify key toxicology concerns, evaluate available data sources on food consumption and pesticide residues, recommend improvements in the risk assessment process and suggest research priorities.

Initiated in 1988 at the request of Congress and funded by the Environmental Protection Agency, the study has cost $1.1 million. Dr. Philip J. Landrigan, M.D, chaired the 14-member panel.

The issue of food safety merits a close look at how risks are evaluated and what regulatory agencies, food producers and manufacturers are doing to safeguard the public, particularly children. In summary, armed with stringent quality assurance procedures and using tools like integrated pest management, our goal is to eliminate detectable residues in finished food products.

A better understanding of the facts will result in sounder food safety decisions and a more informed public.

• • • NAS

The Academy's scientific recommendations.

The Academy is expected to make numerous recommendations centered around four general areas:

- **Testing** — Whenever possible toxicity studies should be done on juvenile animals, not adults, when determining a safety level for children;
- **Dietary information** — Additional and better information on exactly what infants and children eat should be gathered;
- **Residue data** — Additional actual residue (rather than tolerance) information should be collected for foods as consumed by the public; and,
- **Risk Assessment Methodology** — EPA should widely apply new statistical methods in estimating risk for children.

GMA supports this approach to improving the safety of our food supply. These improvements will ensure that the U.S. food supply continues to be the safest in the world.

• • • NAS

Children may or may not be more susceptible to residues.

The Academy's report apparently confirms the knowledge children have different dietary patterns than adults and their bodies handle foods differently. They eat more than adults in relation to their body weight, they eat different foods, they eat a more limited variety of foods and their consumption habits differ. In addition, children have faster metabolisms than adults, with higher rates of breathing, circulation and cell multiplication so substances flow through their bodies at a faster rate. They also have more immature systems than adults.

Children's diets and metabolisms differ from adults. Studies indicate children may or may not necessarily be more susceptible to toxic substances. The NAS has compiled a great deal of information defining these relationships. Children may actually be less susceptible, depending on absorption, distribution, metabolism and excretion characteristics of specific pesticides.

Susceptibility is determined by characteristics of specific pesticides and by the degree of development of exposed individuals and their exposure through diet. Adult systems may be more capable of metabolizing and activating pesticides to more toxic forms, resulting in greater toxicity to adults than children.

Currently, any data that suggest increased toxic susceptibility among children lead to additional safety studies.

• • • NAS

"Estimating Risk": The NAS case studies.

"Estimating Risk," the case study chapter of the report, is reported to contain three food case studies: aldicarb, benomyl and a worst case model of multi-exposure residues.

The three theoretical studies were conducted as examples to demonstrate the capabilities of new statistical methods of calculating exposure estimates for selected pesticide residues. These examples are fabricated hypothetical exercises designed specifically to demonstrate new methods for estimating exposure. The hypothetical examples cannot be equated to real-world situations. They do not reflect actual, day-to-day manufacturing practices and results. There is no evidence to indicate these problems exist in actuality.

Today, regulatory agencies require manufacturers to provide chemistry and toxicity studies of proposed pesticides or food additives that may be found in foods. The resulting data determines safe levels for pesticides and food additives by estimating the amount of a particular substance humans can be exposed to safely every day throughout their lives without adverse effects. Very conservative safety factors are built in.

Risk assessment methods estimate the probability an adverse reaction will occur. Because risk assessments are hypothetical, they do not pretend to measure actual risks. In fact, they greatly overstate risks and build worst-case scenarios to fully safeguard public health.

Risk estimates are usually based on animal studies. Typically, animals consume massive quantities of the chemical under study over their entire lifetimes. Several erroneous assumptions are made when applying animal data to humans — that animals and humans respond the same way to substances, that adverse effects at very high doses indicate similar responses at much lower doses, and that there is no threshold for a level of exposure that generates cancer formation.

Accepted daily intake represents the maximum daily amount of exposure over a lifetime that individuals can have to a chemical without harmful effects. The ADI is calculated by determining the maximum daily exposure that shows no effect in the most sensitive animal species tested, studied throughout the lifetime of the animal. Researchers add an ample safety factor — 100-fold to 1,000-fold — as a safety cushion to account for the application of animal data to humans or for different segments of the population.

• • • The Facts

The food supply is safe.

"America's food supply is safe ... If I thought there was any doubt about the safety of the food our children (and all of us) eat, I would be among the first to act, and act loudly ..."

— **Everett Koop, M.D., Sc.D., U.S. Surgeon General, 1981-89**

"One of the most comprehensive reviews of the epidemiologic literature ever concluded that synthetic chemicals are not a significant cause of human cancer . . . Nothing has appeared in the scientific literature since publication of this review to modify or qualify that conclusion . . .Levels of synthetic pesticide residues in food seem so low as to be of no consequence whatever."

— **Archives of Internal Medicine of the American Medical Association, January 11, 1993.**

The careful use of pesticides is necessary for an abundant, affordable food supply. Nearly half of the world's food crops are lost each year due to pests, causing some $20 billion of damage in the United States alone. Since the 1940s, the appropriate use of pesticides has increased the availability of fruits, vegetables and other crops. When used with adherence to strict guidelines, pesticides do not present a significant health risk.

It is important to remember plants under attack by pests often produce their own natural pesticides. These natural substances can be more harmful to humans than synthetic pesticides. The use of synthetic pesticides inhibits plants' protective formation of natural pesticides.

Advances in food production, manufacturing and distribution have led to the virtual elimination of detectable residues in more than 99 percent of the foods tested in a recent Food and Drug Administration study. *Using integrated pest management techniques, growers and food manufacturers are committed to the goal of eliminating residues in food consumed by the public.*

Indeed, for overall food safety, the FDA and the World Health Organization ranked pesticide residues fifth in priority, following microbiological contamination, nutritional imbalances, environmental contaminants and naturally-occurring toxins.

• • • The Facts

The regulatory system is effective and comprehensive.

"There is no scientific evidence supporting a link between the proper application of pesticides and any ill health effects in humans. Moreover, there is no evidence that the approved use of pesticides contributes in any way to human cancer."

— **Lawrence Garfinkel, Director of Cancer Prevention, American Cancer Society**

An extensive, collaborative regulatory system, comprised of six federal agencies that spend more than $800 million each year, work with international and state organizations to ensure the safety and quality of the U.S. food supply. FDA, EPA and United States Department of Agriculture agencies form an intricate system of checks and balances to establish safety standards and inspect, test and enforce food safety activities. EPA regulates pesticides and establishes tolerance levels; FDA monitors food products; USDA agencies establish and enforce food safety standards. Most agricultural states have supplemental monitoring systems as well.

Chemical manufacturers devote an average of nine years and tens of millions of dollars in research to determine if pesticides will meet EPA approval. If approved, EPA establishes detailed regulations for pesticide application. EPA also sets stringent standards for safe levels of pesticide residues that may remain on a crop after harvest. *Safe residue levels are set 100 to 1,000 times lower than actual safe levels.*

EPA uses food consumption data collected by USDA to estimate potential exposure to pesticide residues. Researchers look at all foods in a typical daily diet and measure the amounts of food components. In conjunction with information on pesticide residues, overall dietary exposure to a pesticide is measured.

Together, EPA, FDA and USDA consider the unique characteristics and sensitivities of a wide variety of populations, including infants and children, to determine risks. Regulators traditionally use data from the most sensitive and relevant animal species or humans. The final determination integrates toxicity evaluations to population groups with information about that group's exposure to the substance through diet.

In addition, EPA has developed a Dietary Risk Evaluation System (DRES). This database allows the agency to pinpoint its exposure estimates for pesticides in the diets of children or other sensitive subgroups. The database provides information on food consumption for more than 300 food types for 22 different segments of the population. When exposure to just one subgroup is too high, then the tolerance level for the entire population is not approved.

• • • The Facts

The food industry takes every precaution to safeguard the public health.

"We believe hysteria over pesticide residues is unwarranted ... In matters of food as well as other aspects of life, risks and benefits must be weighed against one another ... (O)ur conclusion is that, in general, you can feel confident in the safety of what you eat."

— **Mayo Clinic Nutrition Letter**

All segments of the food industry — farmers, manufacturers, distributors and retailers — have a vested interest in the safety of the food supply. Food manufacturers pay scrupulous attention to federal and state guidelines. According to FDA's fifth annual pesticide monitoring report (September 1992), no violative residues were found in 99.2 percent of all foods sampled.

Many grocery manufacturers use a food safety system called Hazard Analysis and Critical Control Point to make sure food products are safe. The process requires strict adherence to safety guidelines at critical points during food production.

Decades of research prove that food producers and distributors understand a great deal about pesticide residues and how they relate to food safety. A safe food supply is in the best interests of everyone. Rigorously enforced risk assessment and regulatory policies can — and do — effectively safeguard the public and the food industry alike.

The Grocery Manufacturers of America • 1010 Wisconsin Ave., NW • Suite 900 • Washington, DC • 202/337-9400

• • • Contacts

For more information about pesticide residues, childhood nutrition, risk assessment, regulatory practices and the food industry, contact the following individuals and organizations.

Jeffrey Nedelman
Vice President, Communications
Grocery Manufacturers of America
Washington, D.C. • 202/337-9400
General background, overview of food industry

Philip S. Guzelian, M.D.
Head of Medical Toxicology/ University of Colorado
Denver, CO • 303/270-3501
Toxicology, risk assessment

Joseph Hotchkiss, Ph.D.
Department of Food Science/ Cornell University
Ithaca, NY • 607/255-7912
Risk assessment, pesticide safety

Marianne Neifert, M.D.
Director of Lactation Program/ Presbyterian-St. Luke's Hospital
Denver, CO • 303/869-1881
Children's health, pediatric nutrition

Ronald Kleinman, M.D.
Chief of Pediatric Gastrointestinal and Nutrition Unit/
Massachusetts General Hospital
Boston, MA • 617/726-2930
Pediatric nutrition

Nancy S. Wellman, Ph.D., R.D.
Professor of Dietetics and Nutrition/ Florida International University
Miami, FL • 305/348-2878
Pediatric nutrition, produce safety

Christine Bruhn, Ph.D., R.D.
Center for Consumer Research/ University of California—Davis
Davis, CA • 916/752-2774
Produce safety, consumer attitudes

Fergus Clydesdale, Ph.D.
Department of Food Science/ University of Massachusetts
Amherst, MA • 413/545-2275
Food science

John D. Graham, Ph.D.
Director of Center for Risk Analysis/ Harvard School of Public Health
Boston, MA • 617/432-1090
Risk assessment

Theodore Labuza, Ph.D.
Department of Food Science, University of Minnesota
St. Paul, MN • 612/624-9701
Food science

Sanford A. Miller, Ph.D.
Dean of Graduate School of Biomedical Sciences/ University of Texas
San Antonio, TX • 512/567-3709
General background

ANALYSIS OF BILLS INTRODUCED IN THE 103D CONGRESS ADDRESSING FOOD SAFETY AND RELEVANT CURRENT LAWS

SIDE-BY-SIDE ANALYSIS OF BILLS INTRODUCED IN THE 103D CONGRESS ADDRESSING FOOD SAFETY AND RELEVANT CURRENT LAWS			
Issue	**Current Law**	**Lehman-Bliley-Rowland (H.R. 1627)**	**Waxman-Kennedy (H.R. 872/S. 331)**
Scope	The Federal Food, Drug & Cosmetic Act (FFDCA) contains standards and procedures for EPA to set pesticide tolerances (*i.e.*, the legal limit) for raw and processed foods. The Federal Insecticide, Fungicide & Rodenticide Act (FIFRA) contains standards for the sale and use of pesticides. Under FIFRA, a pesticide may be registered only if EPA determines that its use will not cause "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits" of using the chemical.	The Lehman-Bliley-Rowland bill takes a comprehensive approach to food safety reform, by amending and harmonizing both FFDCA and FIFRA.	The Waxman-Kennedy bill takes a narrow approach to food safety reform by amending *only* FFDCA and ignoring critical relationships with FIFRA such as the standards and procedures for cancellation and suspension of registrations and coordinating the schedule of tolerance review with FIFRA reregistration.

SIDE-BY-SIDE ANALYSIS OF BILLS INTRODUCED IN THE 103D CONGRESS ADDRESSING FOOD SAFETY AND RELEVANT CURRENT LAWS

Issue		Current Law	Lehman-Bliley-Rowland (H.R. 1627)	Waxman-Kennedy (H.R. 872/S. 331)
Standard for Tolerances	**Risk Standard**	**Bifurcated standard for raw and processed foods.** 1. *FFDCA § 408*: EPA shall set "tolerances with respect to the use in or on *raw* agricultural commodities . . . [and] give appropriate consideration, among other relevant factors (1) to the necessity for the production of an adequate, wholesome, and economical food supply . . . ." 2. *FFDCA § 409*: For residues that concentrate in processed foods, carcinogenic pesticides are prohibited by Delaney clause and non-carcinogens are evaluated as to whether they are "unsafe." EPA has historically interpreted the Delaney clause as allowing for *de minimis* levels of pesticide residues on processed foods. A recent Court decision, however, has invalidated EPA's *de minimis* approach for § 409 processed food tolerances, potentially requiring revocation of a series of such tolerances. Under EPA's coordination policy, not only would pesticides with revoked § 409 tolerances be prohibited, but § 408 tolerances would also be revoked (as well as FIFRA registrations).	**Unitary standard for raw and processed foods requiring protection of public health under a protective narrative standard that reflects the recommendations of the National Academy of Sciences.** *In summary:* EPA may not set a tolerance higher than the level adequate to protect public health. In evaluating whether a tolerance is adequate to protect public health, a two step process is established. EPA would first determine whether dietary risk is negligible and, if it is greater than negligible, undertake careful analysis to ensure that public health is protected. *Specifically:* Tolerances must be adequate to protect public health, and levels that pose a negligible dietary risk automatically qualify. EPA shall by rule identify factors and methods for determining whether a dietary risk is negligible. Where reliable data are available, EPA must calculate dietary risk using the percent of food actually treated with pesticide and the actual residue levels on food. EPA must also consider USDA's aggregate pesticide use and residue data. Tolerances that pose greater than negligible dietary risk are adequate to protect public health if EPA determines that the risk is not unreasonable because: • Use of pesticide protects from adverse effects to the public or the environment that would, directly or indirectly, result in greater risk to the public or environment than the dietary risk from the residue; • Substitute pesticide or pest control method has greater risk to workers, the public, or the environment than the dietary risk of the pesticide residue; *or* • Unavailability of the pesticide would limit availability of an adequate, wholesome, and economical food supply, taking into account regional and domestic effects, and such adverse effects are likely to outweigh the risk posed by the pesticide residue. Under this analysis: EPA *cannot consider* the effects on a registrant, manufacturer, or marketer of the pesticide and *must assess* efforts to develop alternative methods of pest control or pesticide chemicals that pose less than a negligible risk. EPA must consider, among other relevant factors: validity, completeness, and reliability of data; nature of any toxic effects caused by chemical; reasonable assumptions relevant to risk assessment; available information and reasonable assumptions concerning dietary exposure levels of food consumers and major identifiable subgroups of food consumers; and available information and reasonable assumptions concerning variability of the sensitivities of major identifiable groups. (§ 305, p.34-37)	**Complicated combination of narrative and numerical standards, and provides authorization to create three different tolerances for each pesticide.** *In summary:* Depending upon the circumstances various combinations of the following "negligible risk" standards apply: • must be reasonably certain to cause no harm to human health; • must provide for an ample margin of safety for special population groups; • cannot pose greater than a one in a million risk of cancer or other adverse human health effect or one in 70 million for each year of the first five years of life of exposed persons. These standards could be used to set up to three different tolerances for food: (1) at harvest; (2) when purchased at retail; or (3) after processing. *Specifically:* Tolerances may be issued only if risk of dietary exposure is negligible. Existing tolerances *must* be revoked for pesticides posing a greater than negligible dietary risk. The risk to human health from dietary exposure is negligible only if: *Dietary exposure is reasonably certain to cause no harm to human health, and* – *For pesticides which have an identifiable effects threshold,* the tolerance will provide an ample margin of safety (*i.e.*, exposure must be 1/100th of the animal "no observable effects level" (NOEL) or 1/10th of the human NOEL) for each of the following population groups: 0-1 yrs; 1-2 yrs; 2-3 yrs; 3-4 yrs; 4-5 yrs; 6-10 yrs; 11-18 yrs; groups with special food consumption patterns; entire population. EPA must consider the nature of the toxic effects, including the prevalence of the same effects caused by other chemicals; the validity, completeness, and reliability of the data on the pesticide; inter- and intra-species variability; and the possibility that humans may be significantly more susceptible to effects than test animals; *For non-threshold pesticides,* the tolerance must meet the following conditions: (1) the residue level will not cause or contribute, in individuals exposed to the residue, to a lifetime risk of adverse human health effect that occurs at a rate of $1x10^{-6}$ or that occurs at a rate of $1x10^{-6}$ divided by 70 for any single year during the first 5 years of the life of the exposed person, using conservative risk assessment models; (2) the residue level is the lowest effective level; and (3) in the case of processed food, the residue level is the lowest level possible in accordance with good manufacturing practice. (§ 3, p.6-14)
	Benefits Treatment	**Benefit analysis for raw commodities but not for processed foods.**	**Incorporates balanced consideration of important benefits resulting from the use of the pesticide.** (§ 305, p. 36-37)	**Does not provide for the consideration of *any* benefits resulting from use of the pesticide.**

SIDE-BY-SIDE ANALYSIS OF BILLS INTRODUCED IN THE 103D CONGRESS ADDRESSING FOOD SAFETY AND RELEVANT CURRENT LAWS				
Issue		**Current Law**	**Lehman-Bliley-Rowland (H.R. 1627)**	**Waxman-Kennedy (H.R. 872/S. 331)**
Standard for Tolerances (cont.)	**Exposure Analysis**	In practice, EPA considers identifiable subgroups and accounts for sensitivity and unusual food consumption patterns through safety factors.	Incorporates reasonable exposure estimates that use reliable data on actual percentages of food treated with pesticide, actual residue levels on food, and USDA data on aggregate pesticide use and residues. EPA must consider the sensitivities of major identifiable subgroups. {§ 305, p. 34-35}	Uses unrealistic, worst-case exposure analysis. To calculate exposure, EPA must: • Use only reliable, statistically significant data on dietary exposure of people who have consumed food. • Account for all other tolerances for same pesticide. • Account for all other exposure sources for same pesticide, *e.g.*, drinking water if data are available. • Assume all food has residue at proposed or current residue level. • Assume exposure by all other sources for the same pesticide, including drinking water, if data are available. • Assume lifetime exposure. • Evaluate exposure for each of the following population groups: 0-1 yrs; 1-2 yrs; 2-3 yrs; 3-4 yrs; 4-5 yrs; 6-10 yrs; 11-18 yrs; groups with special food consumption patterns; and entire population. *Special Exposure Rule* -- Provides for very limited use of actual exposure data. EPA may calculate dietary exposure based on reliable data that provide a valid statistical basis to identify the percentage of food in which the pesticide actually occurs (but not at the actual residue levels). This percentage shall not be less than the percentage of food consumed in an appropriate locality and shall represent the highest level of exposure to such residue in the country. EPA must reevaluate this calculation every two years. {§ 3, p. 10-14}
Standard for Exemptions		FFDCA § 408 allows EPA to exempt any pesticide from a tolerance requirement where one would not be necessary to protect public health.	Gives EPA the flexibility to exempt a pesticide from the tolerance requirement where a tolerance is not needed to protect public health. Directs EPA to take into account the factors for setting tolerances, in view of reasonably expected dietary exposure. Does not allow exemptions unless there is a practical detection method or EPA has made finding that there is no need for practical detection method. {§ 305, p. 39-40}	Allows EPA to exempt only if the pesticide is not a human or animal carcinogen and presents *no risk* to human health, including any individual in a population subgroup, from dietary exposure (using unrealistic, worst-case exposure estimates). Does not allow tolerances for pesticides that have exemptions. Does not allow exemption unless there is a best available practical detection method. {§ 3, p. 16-19}
Uniformity		No provision.	To eliminate uncertainty and confusion for consumers and producers, bill provides, as a general matter, that States (or political subdivisions) are prohibited from imposing a more restrictive regulatory limit (regarding tolerance levels or warning labels) on recently registered pesticides and pesticides approved for use in reregistration process on or after the enactment of the bill unless: 1. Special local conditions warrant otherwise (as supported by valid data); 2. Restriction would not unduly burden commerce; and 3. Restriction would not cause food to violate any Federal law. To avoid pipeline provision (see discussion of pipeline provision below), State must prove "unreasonable dietary risk" to State's citizens during the period of likely availability. {§ 305, p. 62-67}	No provision to discourage potential ubiquitous and conflicting State and local tolerances and warning labels.

SIDE-BY-SIDE ANALYSIS OF BILLS INTRODUCED IN THE 103D CONGRESS ADDRESSING FOOD SAFETY AND RELEVANT CURRENT LAWS

Issue	Current Law	Lehman-Bliley-Rowland (H.R. 1627)	Waxman-Kennedy (H.R. 872/S. 331)
Evaluation of Existing Tolerances and Exemptions	EPA is not obliged to reevaluate tolerances. In practice, EPA reviews tolerances and exemptions during the FIFRA reregistration process. The 1988 FIFRA amendments require EPA to complete all pre-1984 registrations within 9 years.	Harmonizes FIFRA and FFDCA. Directs EPA to conduct tolerance and exemption reviews whenever it conducts a FIFRA reregistration. As soon as EPA has sufficient information with the respect to dietary risk of a particular active ingredient, but in any event, no later than FIFRA reregistration, EPA must determine whether the pesticide's tolerances or exemptions meet the Act's requirements, determine whether additional tolerances or exemptions should be issued, publish its findings, and promptly commence any proceedings warranted by such determinations. {§ 105, p. 18-19}	Sets up a rigid and rapid schedule that may conflict with the FIFRA reregistration process. In the first year after enactment, EPA must evaluate all data on each chemical that has a tolerance or exemption and determine whether data are sufficient for EPA to determine whether it meets standard or whether data are insufficient to make such determination. • If data are sufficient and EPA finds that the tolerance or exemption meets the standard, EPA will publish a determination to that effect; if it does not meet the standard, EPA has 1 year to modify or revoke it. • If data are insufficient, EPA will establish a data submission schedule. *If a deadline for submitting data is missed, and EPA did not authorize an extension, the tolerance will automatically be revoked 45 days after the missed deadline.* (See discussion of data call-in requirements below.) For chemicals for which data are insufficient, EPA must meet the following schedule for obtaining sufficient data and determining whether the tolerances or exemptions meet the standard: Years after Enactment — Tolerances or Exemptions in Existence at Enactment to Be Reviewed 2 — 30% 4 — 60% 6 — 90% 7 — 100% {§ 4, p. 46-50}
Pipeline	No provision. In practice, EPA has on a case-by-case basis allowed sale of existing inventories of food which has been treated in a lawful manner prior to the time a pesticide a tolerance is revoked.	Avoids unwarranted economic disruptions created by modification or revocation by establishing a presumption for continued sale unless EPA determines otherwise. If EPA revokes or modifies tolerance or revokes exemption, food containing the residue will not be deemed unsafe if residue was present at time of regulation and does not exceed former residue level unless EPA determines that continued consumption of legally treated food would pose unreasonable dietary risk. {§ 305, p. 60-61}	Establishes a mechanism that will likely result in unwarranted and potentially severe economic disruptions following modification or revocation by requiring sales to stop unless EPA affirmatively finds that residues pose a negligible risk, as set out for the tolerance standard. If EPA revokes or modifies tolerance or revokes exemption, EPA may delay effectiveness of regulation for foods that legally contain residue at time of publication of regulation if dietary exposure to residue poses negligible risk. Delay possible for period of time required for food to be sold in course of usual practice. {§ 3, p. 27-29}
Consideration of International Standards	No provision.	To assist EPA in developing effective tolerances efficiently, the bill directs EPA to consider the Codex Alimentarius Commission (Codex) maximum residue levels (MRLs) and to explain any departures from such levels. {§ 305, p. 38}	Contains no provisions directing EPA to consider potentially useful determination made by Codex.

SIDE-BY-SIDE ANALYSIS OF BILLS INTRODUCED IN THE 103D CONGRESS ADDRESSING FOOD SAFETY AND RELEVANT CURRENT LAWS

Issue	Current Law	Lehman-Billey-Rowland (H.R. 1627)	Waxman-Kennedy (H.R. 872/S. 331)
Practical Analytical Method	FFDCA § 408 requires an analytical method for residues of a pesticide *before* a tolerance can be issued.	Adopts a reasonable approach relying on EPA and FDA expertise to consider enforcement needs. A tolerance can only be established if there exists a "practical method for detecting and measuring" the pesticide, and the tolerance is not lower than this detection limit. An exemption can only be established if there exists a "practical method for detecting and measuring" the pesticide *or* EPA determines such a method is not necessary. EPA has discretion to evaluate what is practical. {§ 305, p. 37-38, 40}	EPA must set tolerances above the detection limit of a "practical method," which is defined as a *multi-residue method* that can be performed *routinely* by FDA. EPA is authorized to set a tolerance where only a "non-practical" method exists if the Agency uses the best available method (which must be reevaluated every 2 years). Finally, the bill would place the heavy administrative burden on EPA of *reviewing* all existing methods under the above standard within 180 days of enactment. If an analytical method associated with an existing tolerance is found to not meet requirements, it must be revised within 3 years or the *tolerance will be revoked automatically.* {§ 3, p. 14-16, 19; § 5, p. 50}
Data Call-in Requirements	EPA has no data call-in authority under § 408 but can require data submission under FIFRA to support reregistration of pesticide used on food or to support tolerance or exemption petitions.	Adopts a flexible integrated approach to requiring additional data. If data are necessary to support tolerances, EPA has three options to call it in: 1. FIFRA § 3(c)(2)(b). 2. TSCA § 4. 3. Or, only if options #1 and #2 are not available, after notice and comment, EPA may require submission of specific types of data, designating who must submit the data and when they must be submitted. If data are not submitted under option #1 or #2, EPA may revoke or modify the tolerance. {§ 305, p. 50-53}	Sets the following rigid procedures for requiring additional data: • **Insufficiency Finding:** If EPA determines that data are insufficient to support tolerance or exemption petition or that an existing tolerance or exemption poses a greater than negligible risk to human health, EPA has 30 days to publish order requiring one or more parties to collect, generate, and submit specific data by specific deadlines. • **Automatic Revocation:** *Tolerances or exemptions are automatically revoked 45 days after missed deadline.* • **Extension:** Prior to expiration of deadline, EPA can extend deadline if EPA is notified prior to expiration and extraordinary circumstances beyond the control of the person would prevent the submission. • **Evaluation:** EPA has 90 days to evaluate data. If action by EPA's own initiative is necessary, EPA has 1 year to complete this action from date of determination. {§ 3, p. 30-33; § 4, p. 48}
Metabolites and Degradation Products	No requirement for separate tolerances or exemptions. In practice, EPA allows residues to pass through to processed food if residues no greater than raw food tolerance.	Considers the residues of metabolites or other degradation products to be covered by and tolerance or exemption for the precursor substance if: (1) EPA does not make an adverse finding regarding the likelihood of the residue to pose a greater or different risk than the precursor; (2) the residue level is below the tolerance or exemption for the precursor substance on the food; *and* (3) the tolerance or exemption for the food is not limited so as not to apply to the residue of the degradation product. {§ 305, p. 32-33}	Includes metabolites and degradation products in definition of pesticide chemical and thus requires tolerances or exemptions for them. {§ 2, p. 2-3}
Inert Ingredients	EPA exempts most inerts from tolerance requirements if they are "generally recognized as safe."	Maintains current flexible approach. Chemicals that do not have tolerances because "generally recognized as safe" under § 408 or § 201 or that EPA determines are described by § 201 shall be exempt from the requirement for a tolerance. EPA will identify what substances covered by this. Exemption subject to revocation or modification. {§ 305, p. 55-56}	Provides for rigid mandatory evaluation of inerts. Within 90 days of enactment, EPA must publish list of chemicals "generally recognized as safe" (GRAS) under FFDCA § 408 or § 409. Distributors of chemicals that are not on list but believed to qualify as GRAS must report identity of chemical to EPA with data supporting safeness. Within 270 days, EPA will determine which of these chemicals are GRAS and therefore subject to exemption. This exemption, however, is subject to the new revocation or modification provisions contained in § 3 of the bill. {§ 3, p. 40-42}

SIDE-BY-SIDE ANALYSIS OF BILLS INTRODUCED IN THE 103D CONGRESS ADDRESSING FOOD SAFETY AND RELEVANT CURRENT LAWS

Issue	Current Law	Lehman-Bliley-Rowland (H.R. 1627)	Waxman-Kennedy (H.R. 872/S. 331)
Unavoidable Persistence	No provision.	If tolerance or exemption is revoked and chemical unavoidably persists in the environment, EPA may set a tolerance for the chemical that permits such unavoidable residue to remain in such food. EPA shall periodically review this tolerance and modify it so that it allows only that level of the pesticide that is unavoidable. {§ 305, p. 59-60}	If tolerance or exemption is revoked and chemical unavoidably persists in the environment, EPA *must* set a tolerance that is not greater than the lowest level that permits only such unavoidable level to remain in food. EPA must review the tolerance at least annually. {§ 3, p. 14}
Tolerance (or Exemption) Petition Procedure	1. EPA must file notice of receipt of petition. 2. Referral to independent advisory committee at option of EPA or petitioner. 3. After decision, adversely affected party may request hearing. 4. Decisions after hearings are reviewable by Court of Appeals according to substantial evidence standard.	Changes to current procedures: 1. Any person may file petition. 2. Petition must include data on chemical's safety and residue levels. 3. Public notice of receipt of petition and possible publication of information in petition. 4. No right to referral to advisory committee. {§ 305, p. 40-49}	Changes to current procedures: 1. Any person may file petition. 2. Petition must include data on exposure and safety. 3. Public notice and comment on petition. (Notice must include summary of safety and exposure data.) 4. No right to referral to advisory committee. 5. Requires EPA to prioritize petitions for chemicals that appear to pose a significantly lower risk than tolerances in effect for similar uses. 6. Gives any adversely affected party (not limited to economic adverse effects) the right to challenge tolerance decision. 7. EPA has burden of proof when decision appealed to courts. 8. Court assesses whether data adequate to support tolerance or exemption. 9. Attorneys' fees and costs awarded to prevailing petitioner. {§ 3, p. 19-26}
Tolerance Fees	EPA may collect fees to pay for processing tolerance petitions.	Same as current law. {§ 305, p. 61-62}	Dramatically expands EPA authority to collect funds by authorizing EPA to assess annual fees for tolerances and exemptions. {§ 3, p. 43; § 6, p. 51}
Registration Cancellation Procedure	1. EPA must consult with Secretary of Agriculture and FIFRA Science Advisory Panel, respectively, regarding cancellation's agricultural economic impact and health and environmental impact of cancellation. 2. Notice and comment rulemaking required. 3. Adversely affected party may obtain formal adjudicatory hearing. 4. Judicial review in Court of Appeals; standard of review – substantial evidence when considered on the record as a whole.	Simplifies procedures. 1. EPA must consult with USDA, FDA, EPA Scientific Peer Review Committee, and pesticide registrants. 2. Advance notice of proposed rulemaking or notice not to cancel registration with 60 day comment period. Notice and comment rulemaking with 90 day comment period 3. Opportunity for informal fact-finding hearing after close of comment period. 4. Current judicial review provision retained. {§ 102, p. 2-16}	No provision.
Registration Suspension Procedure	EPA may not issue a suspension order until a cancellation notice is issued.	Removes linkage between suspension and cancellation by allowing EPA to issue an emergency suspension order prior to issuance of a cancellation notice.	No provision.
Integrated Pest Management	No provision.	Requires EPA and USDA to research, develop, and disseminate integrated pest management techniques and other pest control methods to reduce or eliminate applications of pesticides which pose a greater than negligible dietary risk to humans, with a special focus on crops critical to a balanced, healthy diet and which are considered as minor crops in terms of acreage produced.	No provision.
Collection of Pesticide Use Data	No provision.	Requires USDA to collect significant data on the use pesticides to control pests and diseases of major crops and crops of dietary significance to assist in developing information relevant to pesticide regulatory decisions.	No provision.

GMA
GROCERY MANUFACTURERS OF AMERICA

JUDITH M. THORMAN
Director, Federal and State Affairs

Grocery Manufacturers of America, Inc.
1010 Wisconsin Avenue, N.W. Suite 800 Washington, D.C. 20007
202/ 337-9400 FAX: 202/ 337-4508

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REGULATORY AND LEGISLATIVE ISSUES ON FOOD SAFETY REFORM

GMA is the national trade association for more than 130 companies which manufacture 85 percent of the food and grocery products primarily sold in retail outlets in the U.S. and internationally. Member companies employ more than 2.5 million people and have total annual sales exceeding $360 billion. GMA and its members strive to ensure that the Nation enjoys a safe, nutritious, and economic food supply.

EXECUTIVE SUMMARY

The Federal Food Drug & Cosmetic Act contains a provision called the "Delaney Clause" which provides that no "food additive which is found to induce cancer when ingested by man or animal" is allowed in processed foods. Taken literally, the Delaney Clause can be read to create a "zero risk" standard for pesticide residues in processed foods. Historically, however, the U.S. Environmental Protection Agency (EPA) has regulated pesticide residue tolerances in processed foods based on negligible risk -- also referred to as *de minimis* risk. This policy is founded on the premise that applying a "zero risk" standard, in the strictest sense of the term, is inappropriate given the minute levels detectable by modern pesticide residue techniques, which did not exist when the "zero risk" Delaney Clause standard was adopted as Federal law in the 1950s. In short, the Delaney Clause's zero risk approach is inflexible, impractical, and out-of-date with modern technology.

A recent court decision, however, has invalidated EPA's negligible risk approach, threatening the availability of certain pesticides and the continued ability of grocery manufacturers to provide the Nation with an adequate, wholesome, and economic food supply. In response to the case, EPA is seeking suggestions on how to address the fundamental problems posed by the Delaney Clause as well as other related pesticide regulation issues. GMA has submitted comments to the Agency which provide a sound basis for developing a *regulatory* solution that will allow continued use of vital pesticides. GMA is also supporting Federal *legislation* (H.R. 1627, the Lehman-Bliley-Rowland bill), which would establish a clear negligible risk standard, in lieu of the zero risk concept, and would address other important issues, such as nationally uniform food safety laws.

THE PROBLEM -- WHY WE NEED FOOD SAFETY REFORM

- **Impact of the Existing Statutory Scheme and the "Delaney Paradox" --** Although the regulatory and scientific communities agree that the Nation's food supply is safer

May 13, 1993

than it ever has been, conflicting and outdated provisions of long-standing Federal laws regulating food production, processing, and distribution have created uncertainty for consumers, farmers, and food manufacturers. More specifically, the Delaney Clause has created a paradoxical situation in which use of pesticides that clearly *enhance* the safety of the food supply could be prohibited.

- **Congressional Inaction** -- Congress has recognized the problems with the statutory scheme, but over the last 10 years has been unsuccessful in passing legislation to resolve these issues.

- **EPA's Reasonable Regulatory Approach** -- To avoid much of the uncertainty created by the present statutory situation, EPA adopted a negligible risk or *de minimis* approach. With this approach, EPA attempted to balance the need for a strict interpretation of the Delaney Clause standard with the need for reasonable regulations.

- **The Court Decision** -- The problems with the statutory scheme have recently been exacerbated by a Court decision by the U.S. Court of Appeals in the Ninth Circuit. This decision threatens the balance that EPA has struck in its implementation of the Federal laws. The Court decided that EPA had inappropriately established *de minimis* tolerances for four pesticides on processed foods, favoring a literal reading of the zero risk standard in the Delaney Clause.

- **Potential Severe Impact of the Court Decision** -- The Court decision could lead to precipitous and unwarranted revocation of several pesticide tolerances and adversely affect the availability of a varied and safe food supply. The Agency must take a reasoned approach in responding to the Court's decision to avoid harsh and unjustified results for pesticides that have valid *de minimis* tolerances.

RECENT ACTIVITIES TO PROMOTE WORKABLE REGULATORY AND LEGISLATIVE SOLUTIONS

- **Regulatory Activities** -- EPA has the opportunity to settle much of the disruption caused by the recent Court decision with appropriate regulatory action. Indeed, EPA has solicited public input on the appropriate implementation of the Court decision and on EPA's pesticide tolerance policies in general. GMA has given EPA comments that provide a sound basis for a reasonable and appropriate pesticide policy that implements the Court decision. These suggestions include:

  - ***Abandon Unnecessary Coordination Policy*** -- GMA is urging EPA to abandon its current informal policy of prohibiting all tolerances, including raw food tolerances, of pesticides that are ineligible for a processed food tolerance due to the Delaney Clause. This policy was a departure from the Food and Drug

Administration's original interpretation of the statute, and its potential consequences will likely be realized under the Court's strict interpretation of the Delaney Clause standard. Instead, EPA should abandon its ill-conceived coordination policy and not automatically cancel existing raw food tolerances of pesticides whose processed food tolerances are revoked in response to the recent Court decision.

- ***Make Scientifically Valid Decisions*** -- GMA is requesting EPA to improve its risk analyses by using use data on realistic, rather than exaggerated, worst-case, hypothetical, residue level assumptions in evaluating pesticides. Also, GMA urges EPA to scrutinize carefully all relevant toxicological data before concluding that a chemical "induces cancer" and thus is subject to the Delaney Clause.

- ***Give Effect to "Ready-to-Eat"*** -- GMA is urging EPA to give effect to Congress' intention not to require processed food tolerances for pesticide residues on foods that are ready-to-eat which are not higher than the permissible pesticide levels for raw food tolerances.

- ***Apply Court Decision in a Reasonable Manner*** -- GMA urges EPA to adopt a reasonable approach to implementing the Court decision. Specifically, EPA should allow all affected parties to participate in tolerance revocation or cancellation procedures and should phase in the negative impacts of the decision so as to minimize market dislocations.

- **Legislative Activities** -- While the uncertainty created by the Court case may be addressed through future EPA regulatory action, such action will, due to possible statutory constraints, be limited and time-consuming. It will also be uncertain because any EPA action could be challenged in the courts and could eventually be overturned. Accordingly, enacting appropriate legislation would more directly and effectively resolve the problems created by the Court decision and the current statutory scheme.

  If EPA fails to develop a workable, regulatory approach in light of the Court decision, Congress *must* step in to resolve the issues the Delaney Clause raises. The inconsistencies in the statutory scheme and the failure of a nearly 40 year old statute to take into account the capabilities of modern science require Congress to update and harmonize Federal laws governing food regulation.

  Presently, there is a great deal of activity on these issues in the Congress. Two recently introduced bills address pesticide residues -- H.R. 1627 (the Lehman-Bliley-Rowland bill) and H.R. 872/S. 331 (the Waxman-Kennedy bill). While the Lehman-Bliley-Rowland bill takes a realistic, flexible approach to regulating pesticides, the Waxman-Kennedy bill creates just as many problems -- and possibly even more --

than it alleviates. Of the two bills, the Lehman-Bliley-Rowland broad-scoped approach clearly provides the more workable and effective solution to the problems EPA faces in pesticide regulation. GMA therefore supports the Lehman-Bliley-Rowland bill, which would address:

- ***Delaney Reform*** -- The bill establishes a workable negligible risk standard for tolerances for both raw agricultural commodities and processed foods, focusing on health risks, realistic exposures, and other important factors and use of a scientifically sound analysis. The Waxman-Kennedy bill, on the other hand, utilizes unrealistic exposure assumptions and standards that present many of the problems created by the existing Delaney Clause.

- ***National Uniformity*** -- The bill provides for nationally uniform pesticide tolerances and warning labels, while allowing States to establish their own requirements when special local conditions warrant or when important health and safety data are lacking for recently-registered pesticides or those that have not been re-registered.

- ***Harmonization of Federal Food Safety Laws*** -- The bill mandates the review and evaluation of dietary risk during the re-registration program now in place for older pesticides as the top priority; and removes time-consuming, legalistic paperwork constraints that hinder the EPA's ability to cancel pesticide registrations and prohibit pesticide use in emergency situations.

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For further information, please contact Judith Thorman at Grocery Manufacturers of America, Inc. (202) 337-9400.

Roz: Thorman meeting file

July 8, 1993

TO: Carol H. Rasco

FROM: Bill Galston

SUBJ: Judith Thorman meeting

I did indeed meet with Judith Thorman who is something like Director of Government Affairs for the Grocery Manufacturers of America. GMA's principal concern right now is with pesticide legislation. They are strongly in favor of one of the competing bills ("Lehman-Bliley") now before the Congress. Lehman-Bliley represents a pro-producer and pro-industry approach that is unacceptable to the environmental community--and to Rep. Waxman and Sen. Kennedy, who are sponsoring a competing bill.

The pesticide working group I'm chairing is trying to find a reasonable balance between these competing perspectives. Not only is such balance substantively appropriate, it is the only hope for breaking the longstanding legislative logjam in the area.

During the lengthy process of consultation on this issue, I have made no substantive commitments to anyone. I'm not sure why Ms. Thorman wants this meeting with you, but she may want to intensify the pressure on us a bit. If so, that should be resisted, but we should keep the door wide open to continued consultation now that the legislative phase of the working group's efforts are moving into high gear.

I attach a copy of GMA's most recent annual report.

Also, tell Bill G. I've known her for years thru NGA - She used to be in a couple of Gov's DC offices. I assume since she knows me answers why she insisted on meeting w/me.

CHR

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1992
REPORT
TO THE MEMBERSHIP

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