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106TH CONGRESS
1ST SESSION

H. R. 1592

To establish certain requirements regarding the Food Quality Protection Act of 1996, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 28, 1999

Mr. POMBO (for himself, Mr. TOWNS, Mr. CONDIT, Mr. BOYD, Mr. KOLBE, Mr. JOHN, Mr. ISTOOK, Mr. STRICKLAND, Mr. SHOWS, Mrs. BONO, Mr. BOUCHER, Mr. ETHERIDGE, Mr. DOOLITTLE, Mr. SANDLIN, Mr. GOODE, Mr. HUNTER, Mr. SALMON, Mr. HILL of Montana, Mr. RADANOVICH, Mr. CANADY of Florida, Mr. NETHERCUTT, and Mr. BISHOP) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To establish certain requirements regarding the Food Quality Protection Act of 1996, 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 ''Regulatory Fairness and Openness Act of 1999''.

SEC. 2. DEFINITIONS.

As used in this Act:

(1) ADMINISTRATOR.—The term ''Administrator'' means the Administrator of the Environmental Protection Agency.

(2) AGENCY.—The term ''Agency'' means the Environmental Protection Agency.

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Agriculture.

(4) TOLERANCE.—The term ''tolerance'' means a regulation establishing a tolerance, including an exemption from the requirement for a tolerance, under section 408 of the Federal Food, Drug, and Cosmetic Act.

SEC. 3. FINDINGS.

The Congress finds as follows:

(1) The Food Quality Protection Act of 1996 (Public Law 104–170), enacted on August 3, 1996, made many major modifications to section 408 of the Federal Food, Drug, and Cosmetic Act (''FFDCA''), requiring the Administrator to consider new kinds of information and use additional criteria in regulating pesticide residues and in reviewing existing tolerances that had previously been found to be adequate to protect the public health.

(2) The Food Quality Protection Act of 1996 (''FQPA'') prescribes the use of a number of new

risk assessment criteria that require the development of major modifications to existing regulatory policies and procedures used by the Administrator to regulate pesticide tolerances. Since the enactment of the FQPA it has become clear that several of the new concepts embodied in it involve a high degree of complexity. Practical implementation of them demands new scientific tools in addition to those that were available when the FQPA was enacted.

(3) To reach sound, suitably protective decisions on tolerance reviews under the new criteria, the Administrator also will need a great deal of new data, not only on the newly considered non-food routes of exposure, but also, in some cases, on dietary exposure and toxicity, so that it can be determined whether pesticides that were found safe under the former criteria satisfy the new criteria as well. Some data collection efforts are underway, but will not yield results for one or more years. In some areas, the need for new data depends on decisions not yet made by the Administrator about what kinds of tests should be conducted and which compounds should be tested.

(4) The Administrator has instituted public proceedings on such topics as what new interpreta-

tions and policies are needed, what new kinds of data are needed, how the new data would be used, and how the needed regulatory transition can be achieved. These proceedings are not yet finished, and on some issues public notice-and-comment proceedings have been scheduled but have not yet begun.

(5) The FQPA added to the FFDCA several provisions that provide flexibility to the Administrator in making the transition to the new approach. The FFDCA anticipates a continuing process of refinement and improvement in tolerance decision-making, as additional information is collected and as new policies and methods are developed and adopted for the practical implementation of the new requirements. The FFDCA provides that the data requirements for tolerances must be set out clearly in regulations and guidelines, so that the regulated community will know what types of information the Agency requires and what testing procedures should be used to develop the information. The FQPA only allows the use of ''reliable'' information on the non-dietary exposure routes that were not previously considered in risk assessments affecting tolerances. The Congress did not anticipate that a tolerance would be

revoked because of Agency reliance on estimates or assumptions stemming from absence of such data, without first providing notice of what data are needed and a reasonable opportunity to collect the data. Thus, when an existing tolerance is under review and the Administrator determines that additional information is needed to support the continuation of the tolerance, the FFDCA now authorizes the Administrator to postpone the effective date of any tolerance rule resulting from a review, and this authority can be utilized as appropriate where additional information is pertinent to a tolerance review. Finally, the current FFDCA permits the Agency to conduct a review in stages, as allowed by the available, reliable information.

(6) Although these authorities already are provided by law, it appears that further congressional guidance is needed to ensure that Agency decisions are reasonable, well supported, and balanced, and to avoid disruptions in agriculture, other sectors of the economy, and international trade. During the transition to revised standards, procedures, and requirements, the Administrator must ensure that decisions are balanced, reasonable, understandable, and based on and supported by sound information, in order to

avoid unnecessary disruptions in agriculture, the economy, and world trade, and to maintain the public trust in the food supply.

(7) Unless the Administrator implements section 408 of the FFDCA carefully and wisely, decisions made under it could cause great harm to the presently safe and affordable food supply, to American agriculture (including food, fiber, nursery, and forestry production, and food storage and transportation), to related industries, and to other private and public sector activities such as public health protection against bacteria and other microorganisms, control of insects and other disease vectors, and residential and business pest control.

SEC. 4. REQUIREMENTS FOR TRANSITION ANALYSIS AND DESCRIPTION OF BASIS FOR DECISIONS.

(a) IN GENERAL.—This section applies to any proposed or final rule, order, notice, report, guidance document, or risk assessment issued by the Administrator that is based on or results from a review or reassessment of an existing tolerance or of the uses of a pesticide having an existing tolerance. However, this section does not apply to any document that concludes or recommends that no revocation or denial of a tolerance, or other adverse action against a tolerance, is required.

(b) PERIOD OF APPLICABILITY.—This section applies to any document described by subsection (a) that the Administrator issues or otherwise discloses to any member of the public during the period beginning on January 1, 1999, and ending on the date of completion of the process of tolerance review under section 408(q) of the Federal Food, Drug, and Cosmetic Act.

(c) REQUIREMENT FOR TRANSITION ANALYSIS REPORT.—Before issuing any document to which this section applies, the Administrator shall conduct a transition analysis of the findings and regulatory steps recommended by or set forth in the document. The document shall include a report describing the results of the analysis and the extent to which the conclusions in the document are tentative, preliminary, or subject to possible modification because of policy reevaluation, correction of data deficiencies, or use of new data to replace assumptions. A transition analysis statement under this section shall describe the extent to which any finding or regulatory step recommended by or set forth in the analyzed document is based in whole or in part on—

(1) any assumption, if the Administrator is in possession of data that would make use of the assumption unnecessary;

(2) any information about possible exposure from drinking water or other non-occupational, non-dietary exposure routes that is derived from use of—

(A) worst-case assumptions;

(B) computations or modeling results that are based on high-end or upper-bound inputs or are designed to be worst-case, high-end, or bounding estimates; or

(C) information that otherwise is not reasonably representative of risks to consumers or to major identifiable subgroups of consumers, on a national or regional basis;

(3) any assumption about exposure from drinking water or other non-occupational, non-dietary exposure routes, if data that would make use of the assumption unnecessary, and would likely demonstrate a lower level of exposure than that used in the assumption or model—

(A) are being developed and will be submitted within a reasonable period, in accordance with a request by the Administrator under section 408(f) of the Federal Food, Drug, and Cosmetic Act or any of the authorities referred to in such section or at the initiative of an interested person; or

(B) could be obtained by the Administrator by an action taken in accordance with section 408(f) of such Act;

(4) any assumption regarding the method for determining the aggregate exposure to a pesticide chemical or the cumulative effect of exposure to two or more pesticides having a common mechanism of toxicity, if the use of such assumption is based in whole or in part on the absence of data that could be obtained by the Administrator by an action taken in accordance with section 408(f) of the Federal Food, Drug, and Cosmetic Act, unless the data that would eliminate the need for use of the assumption have been identified and made known by the Administrator to interested persons and sufficient time has been provided to allow the data to be developed, submitted, and subsequently evaluated by the Agency;

(5) any calculation developed by use of the additional safety factor described by section 408(b)(2)(C) of the Federal Food, Drug, and Cosmetic Act, if the use of such additional safety factor is based in whole or in part on the absence of data that could be obtained by the Administrator by an action taken in accordance with section 408(f) of such Act, unless the data that would eliminate the

need for use of the assumption have been identified and made known by the Administrator to interested persons and sufficient time has been provided to allow the data to be developed, submitted, and subsequently evaluated by the Agency; or

(6) any information about an alleged adverse effect if the information is anecdotal, unverified, or scientifically implausible, or comes from any study whose design and conduct has not been found by the Administrator to be scientifically sound with regard to design, conduct, reporting, and data availability.

(d) ADDITIONAL CONTENTS OF REPORT.—A transition analysis report under this section shall:

(1) Summarize and respond briefly to comments received by the Administrator from any other persons regarding the applicability of any provision of subsection (c) to the document analyzed under this section.

(2) Discuss briefly the availability and suitability of pesticidal and nonpesticidal alternatives to the pesticide uses being reviewed or reassessed. At a minimum, the Administrator, in consultation with the Secretary of Agriculture, shall include in the analysis a determination on the extent to which an effective and economical alternative to the pesticidal

tolerance under review has been approved and whether revocation or modification of the tolerance will result in—

(A) a significant regional shift of production within the United States;

(B) an increase in imports of corresponding commodities;

(C) an increase in pest control costs;

(D) pest crop damage and yield loss, including quality degradation, due to the lack of an effective alternative; or

(E) a disruption of domestic production of an adequate, wholesome and economical food supply.

(3) Identify the data that, if available, would make unnecessary any reliance on any information, calculation, or assumption described in paragraph (2), (3), (4), or (5) of subsection (c) that is identified in the report.

(4) Describe the extent to which any finding or regulatory step recommended by or set forth in the analyzed document is based in whole or in part on—

(A) any assumption about toxicity, dietary exposure, or risk from dietary exposure, if data

that would make use of the assumption unnecessary—

(i) are being developed and will be submitted within a reasonable period, in accordance with a request by the Administrator under section 408(f) of the Federal Food, Drug, and Cosmetic Act or any of the authorities referred to in that section or at the initiative of an interested person; or

(ii) could be obtained by the Administrator by an action taken in accordance with section 408(f) of such Act;

(B) any use of data on the presence or absence of non-adverse effects, rather than data on the presence or absence of adverse effects, as the basis for calculation of allowable exposure levels; or

(C) any policy that the Administrator may revise after completion of any reevaluation of such policy that is being conducted or is scheduled to be conducted.

SEC. 5. INTERIM PROCEDURES FOR REVIEWS OR REASSESSMENTS.

(a) DOCUMENTS AND ACTIONS TO WHICH THIS SECTION APPLIES.—To the extent provided by subsection (b), this section applies to—

(1) any review or reassessment by the Administrator of any existing tolerance for a pesticide chemical, whether initiated by the Administrator or by petition by another person; and

(2) any review or reassessment by the Administrator of any pesticide registration under the Federal Insecticide, Fungicide, and Rodenticide Act that is associated with or results from such a tolerance review or reassessment.

(b) PERIOD OF APPLICABILITY.—This section applies to any review or reassessment described by subsection (a) that the Administrator issues during the period beginning on January 1, 1999, and ending on the date of completion of the process of tolerance review under section 408(q) of the Federal Food, Drug, and Cosmetic Act.

(c) LIMITATION.—Notwithstanding any provision of section 408 of the Federal Food, Drug, and Cosmetic Act:

(1) In any tolerance review or reassessment to which this section applies, the Administrator may not base the revocation of or other adverse action

against an existing tolerance on any information, calculation, or assumption described in section 4(c).

(2) In any review or reassessment of the registration of a pesticide product to which this section applies, the Administrator may not base any adverse action against the registration under the Federal Insecticide, Fungicide, and Rodenticide Act on any information, calculation, or assumption described in section 4(c).

SEC. 6. IMPLEMENTATION RULES.

(a) IN GENERAL.—The Administrator shall issue rules in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act establishing general procedures and requirements to implement section 408 of such Act, including guidance regarding the provisions of such Act regarding aggregate exposure to residues of a single pesticide and cumulative effects of exposure to pesticides having a common mechanism of toxicity. The Administrator shall include in such rules general procedures and requirements to implement this Act.

(b) RULES.—The rules described by subsection (a) shall be issued in proposed form not later than 6 months after the date of enactment of this Act and in final form not later than one year after the date of enactment of this

Act, and shall be revised thereafter as necessary and appropriate.

SEC. 7. DATA IN SUPPORT OF TOLERANCES AND REGISTRATIONS.

(a) GUIDELINES.—Section 408(f) of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:

"(3) ISSUANCE OF GUIDELINES.—The Administrator shall issue guidelines specifying the kinds of information that will be required to support the issuance or continuation of a tolerance or exemption from the requirement for a tolerance and shall revise such guidelines from time to time. Such guidelines shall specify the conditions under which data requirements will apply to particular types of pesticide chemicals. Notice and comment procedures shall be used in the issuance of such guidelines, except for those guidelines that already have been issued after notice and comment under section 3(c)(2)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act.".

(b) FIFRA.—Section 3(c)(2)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act is amended by striking the period at the end and inserting ", after first

providing notice and opportunity for comment by interested parties.''.

SEC. 8. EXPEDITING CERTAIN MATTERS.

(a) IN GENERAL.—

(1) FIFRA.—Section 3(c)(3) of the Federal Insecticide, Fungicide, and Rodenticide Act is amended by adding at the end the following:

''(E) EXPEDITED ACTION TO PROVIDE EFFECTIVE, ECONOMIC ALTERNATIVES.—The Administrator shall expedite the review of any complete application for registration or amended registration of a product under section 3, for an experimental use permit under section 5, or for an emergency exemption under section 18, if such application seeks approval for the registration or use of a product that, in the opinion of the Administrator, is likely to provide an effective, economic alternative to the use of a pesticide that has been or is likely to be removed from the market as a result of a review conducted under section 408 of the Federal Food, Drug, and Cosmetic Act and for which there is no currently registered effective and economical alternative or for which the number of

such alternatives is insufficient to avoid problems such as pest resistance.''.

(2) COORDINATION WITH PRIORITIES UNDER FFDCA.—Section 408(d)(4)(B) of the Federal Food, Drug, and Cosmetic Act is amended—

(A) by striking ''for a pesticide chemical residue that appears to pose'' and inserting the following: ''for a pesticide chemical residue that—

''(i) appears to pose'';

(B) by striking ''same or similar uses.'' and inserting ''same or similar uses; or''; and

(C) by adding at the end the following:

''(ii) is needed in connection with a request under section 3(c)(3)(E) of the Federal Insecticide, Fungicide, and Rodenticide Act for approval of an effective, economic alternative.''.

(b) AMENDMENT.—Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act is amended by striking the period at the end and inserting '', except that the Administrator may issue a tolerance associated with an emergency exemption without regard to other tolerances for the pesticide and before reassessing those other tolerances, if the Administrator determines that any incremental exposure

that may result from the tolerance associated with the emergency exemption will not pose any significant risk to food consumers.''.

SEC. 9. PRIORITIES AND RESOURCES.

The Administrator and the Secretary shall prepare a report that shall be delivered to the Congress not later than 6 months after the date of enactment of this Act. The report shall include a proposal for revising the priorities of and resources available to the Administrator that will allow the Administrator to process promptly all registration applications and petitions for tolerances or exemptions, requests for experimental use permits, requests for approval of new inert ingredients, and requests for emergency exemptions and for decisions on the merits of such applications, petitions, and requests, in addition to performing tolerance reviews and reassessments and other duties required by the Federal Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act. The report shall also include a proposal for revising the priorities of and resources available to the Secretary that will allow the Secretary to obtain and provide to the Administrator adequate and timely information on food consumption, pesticide residues in or on food and drinking water, and pesticide use and usage, to review actions proposed by the Administrator under the Federal

Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act, and to perform other duties related to the regulation of pesticides and pesticide chemical residues.

SEC. 10. INTERNATIONAL TRADE EFFECTS.

(a) STUDY.—

(1) PROGRAM.—The Secretary shall establish and administer a program to continuously monitor the competitive strength of major United States agricultural commodity sectors in the international marketplace. Such commodity sectors include fruits and vegetables, corn, wheat, cotton, rice, soybeans, and nursery and forest products.

(2) EXAMINATION.—In carrying out the requirements of paragraph (1) of this section, the Secretary shall examine factors pertinent to assessing, by sector, the sustainability and competitive strength in the international marketplace and the relationship of such factors to regulatory decisions issued under the Federal Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act. Such factors include sector changes, regional changes, prices, quality, input costs and availability, and ratio of imports to exports.

(b) REPORT.—The Secretary shall prepare periodic reports describing the findings from the program conducted under subsection (a). The first such report shall be submitted to the House Committee on Agriculture and the Senate Committee on Agriculture, Nutrition, and Forestry not later than October 1, 2000, with subsequent reports submitted by October 1 of every second year thereafter until 2010.

SEC. 11. ADVISORY COMMITTEE.

(a) ESTABLISHMENT AND PURPOSE.—There is established a Federal advisory committee to be known as the Pesticide Advisory Committee (in this section referred to as the ''Advisory Commitee''). The purpose of the Advisory Committee shall be to provide advice to the Administrator and the Secretary on matters related to implementation of section 408 of the Federal Food, Drug, and Cosmetic Act and this Act, including proposed and final rules, policies, procedures, and testing guidelines used to regulate pesticide tolerances and registrations, and to foster communication between the Administrator, the Secretary, and the various stakeholder organizations who represent persons having particular interest in the regulation of pesticides under Federal Food, Drug, and Cosmetic Act. The Advisory Committee shall be permanent, and shall among other things assume the functions formerly performed by

the Tolerance Reassessment Advisory Committee. The Secretary shall provide staff to serve as a secretariat for the Advisory Committee.

(b) MEMBERSHIP.—The Advisory Committee shall be composed of representatives of organizations interested in the regulation of pesticides, and shall consist of 20 members appointed by the Administrator and Secretary utilizing a system of staggered terms of appointment. The membership of the Advisory Committee shall be chosen to represent a wide variety of interests and viewpoints, and shall include representatives of organizations that represent the following groups: Food consumers, persons with a special interest in environmental protection, farm workers, agricultural producers (including crop production, livestock and poultry production, and nursery and forestry), non-agricultural pesticide users, food manufacturers and processors, food distributors and marketers, manufacturers of agricultural and nonagricultural pesticides, and Federal and State agencies. The Administrator may extend the term of a member of the Advisory Committee until the new member is appointed to fill the vacancy. The Administrator shall publish in the Federal Register the name, address, and professional affiliations of each nominee. Each member of the Advisory Committee shall be entitled to be reimbursed by the Administrator for reason-

able costs of lodging, meals, and travel associated with attendance at meetings of the advisory committee, as determined by the Administrator.

(c) MEETINGS.—The Advisory Committee shall conduct its principal business in meetings that are open to the public in facilities that can accommodate the reasonably foreseeable number of attendees, or by teleconferences with open access. Written communications between the Secretary or Administrator and the Committee shall be docketed and available to any person upon request. The Secretary shall be responsible for providing or making arrangements for the meeting facilities. Meetings of the full committee shall be held at least two times per year at times determined jointly by the Administrator and the Secretary. All meetings of the Advisory Committee shall be the subject of notices published in the Federal Register by the Administrator not less than two weeks before the date of the meeting.

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