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106TH CONGRESS
1ST SESSION

H. R. 1334

To provide for the enhanced implementation of the amendments made to the Federal Food, Drug, and Cosmetic Act by the Food Quality Protection Act of 1996, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 25, 1999

Mr. LAHOOD (for himself, Mr. BLUNT, and Mr. HASTINGS of Washington) 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 provide for the enhanced implementation of the amendments made to the Federal Food, Drug, and Cosmetic Act by 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 ''FQPA Implementation Act of 1999''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) The Food Quality Protection Act of 1996, enacted on August 3, 1996, made a number of significant modifications to section 408 of the Federal Food, Drug, and Cosmetic Act (''the Act''). Section 408 as amended sets forth new criteria and procedures for use by the Administrator of the Environmental Protection Agency in assessing and reassessing the acceptability of tolerances that govern the level of pesticide chemical residues that may be present in or on any food that enters or is present in interstate commerce or is imported into the United States.

(2) Under section 408 of the Act as amended, the Administrator must use these new criteria and procedures in deciding whether new tolerances may be issued, and thus whether new pesticides or new pesticide uses may be approved for use under the Federal Insecticide, Fungicide, and Rodenticide Act. Such section also requires that all tolerances in effect on the date of the enactment of the 1996 amendment be reassessed under the new criteria and procedures.

(3) The Food Quality Protection Act of 1996 requires the use of a number of important new risk

assessment criteria and concepts that had never previously been used by the Administrator and that require the development of major modifications to existing Agency practices. New regulatory concepts introduced by such Act include, but are not limited to, those associated with new statutory terms such as ''exposures for which there is reliable information'', ''aggregate exposure'', ''reasonable certainty that no harm will result'', ''common mechanism of toxicity'', ''cumulative effects'', ''potential pre- and post-natal toxicity'', ''completeness of the data with respect to exposure and toxicity'', ''significant subpopulation group'', ''additional data or information [that] are reasonably required to support the continuation of a tolerance'', and ''pose the greatest risk to human health''. How these terms are defined and used by the Administrator, singly and in combination, will greatly affect the outcome of the assessments and reassessments required to be conducted under the Act as amended.

(4) The Act as amended requires the Environmental Protection Agency to revoke tolerances now in effect if the Administrator finds that the sum of the exposure from all the tolerances exceeds safe levels. However, the Act as amended does not provide

any criteria for determining which of the tolerances should be revoked in such situations in order to reduce the exposure sufficiently. Nor does the Act as amended establish procedures for providing pesticide producers, agricultural producers, food processors and distributors, and non-food pesticide users the opportunity to participate in such decision making before proposed rules are issued by the Administrator.

(5) Under the revised criteria of the Act as amended, entirely new categories of data regarding toxicity, metabolism, cumulative effects, and dietary, drinking water, and other nonoccupational exposure levels are required to allow the Administrator to reach sound, accurate, valid, and understandable decisions on tolerance assessments and reassessments. In some areas, massive data collection efforts are underway but will not yield results for another year or more. In other 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 the subjects of these new test requirements.

(6) The Administrator has instituted public proceedings to discuss how the new criteria of the

Act as amended should be interpreted and amended, what new kinds of data are needed and how the new data would be used once available, how criteria can be made more transparent, equitable, and understandable, how the Administrator should use available authority to be flexible, how to decide which tolerances should be revoked when some action is decided to be necessary, and how to provide needed transition periods in case some existing products or product uses should be removed from the market. These proceedings are not yet finished and in some cases planned public proceedings have been scheduled but have not yet begun.

(7) Unless the Administrator implements section 408 of the Act as amended carefully and wisely, decisions made under it could cause great harm to American agriculture, to food production, food storage and transportation, and related industries, and to other business. Such decisions could reduce availability of fruits and vegetables, and other foods known to aid human health, and could also have highly disruptive and problematic effects on a variety of other important public and private areas such as public health protection against insects and other disease vectors and residential and business pest

control. A major concern is that some products will be removed from the market that are essential in integrated pest management programs or pesticide resistance management programs, and that pest species will more easily develop resistance to the fewer remaining products that remain available.

(8) The regulatory requirements under the Food Quality Protection Act of 1996 could have both short and long term deleterious effects on U.S. agricultural products as these producers move to a free market system as envisioned by the Freedom to Farm Act.

(9) These disruptive and harmful effects could occur without necessarily bringing about any significant health benefits or risk reductions. The Administrator is now engaged in making decisions on tolerance assessments and reassessments at the same time that the Administrator is conducting a massive program of policy development and reevaluation, and while the Administrator is determining what data would be needed under the new criteria and policies to answer some of the new questions. If these decisions on individual pesticides are issued and put into effect before the new policies are in place or before the needed data are available, they may be based on

outdated and overly stringent policies, worst-case assumptions, or both. These actions may be accompanied by adverse publicity that could lead to unwarranted concern and could effectively destroy the marketability of products that in fact are safe.

(10) The Act as amended has caused a major slowing of the process for approval of new pesticide chemicals, new uses of pesticides already registered for other uses, and applications for emergency exemptions from the need for registration. This is traceable to—

(A) the Agency's need to develop new criteria and procedures;

(B) the diversion of resources to developing such criteria and procedures and to the reassessment of existing tolerances and registrations;

(C) the requirement that no new tolerance can be issued until the Administrator determines that all existing tolerances for the pesticide have been reassessed and found safe; and

(D) the priority choices and resource allocation decisions that are either dictated by the Act as amended or chosen by the Administrator as a matter of discretion.

(11) Congressional guidance for the Administrator is needed to ensure that decisions are reasonable, well supported, and balanced; to avoid disruptions in agriculture, other sectors of the economy, and international trade caused by prematurely implemented decisions or by public misunderstanding or unwarranted speculation about tentative decisions. Much of the potential problem can be avoided if the Administrator uses available authority to resolve policy issues, announce data needs, avoid unneeded use of assumptions in lieu of data, make clear the tentative and preliminary nature of findings made in the short term, and provide extended implementation periods for adverse decisions when appropriate.

SEC. 3. SPECIAL DATA REQUIREMENTS; REQUIREMENT FOR CALLING IN ADDITIONAL DATA.

(a) IN GENERAL.—Section 408(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(f)) is amended—

(1) by redesignating paragraph (2) as paragraph (3); and

(2) by striking ''(1) REQUIRING SUBMISSION'' and all that follows through ''(A) issue a notice requiring the person'' and inserting the following:

"(1) REQUIRING SUBMISSION OF ADDITIONAL DATA.—

"(A) CONTINUATION OF TOLERANCE OR EXEMPTION.—If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall obtain additional data or information through any of the methods described in paragraph (2).

"(B) MODIFYING, SUSPENDING, OR REVOKING TOLERANCE OR EXEMPTION.—If the Administrator makes a determination that there may be grounds for modifying, suspending, or revoking a tolerance or exemption in effect under this section for a pesticide chemical residue in or on food, the Administrator may not modify, suspend, or revoke the tolerance or exemption until the Administrator has considered additional data or information obtained by the Administrator (after making such determination). The Administrator shall obtain the required additional data or information through any of the methods described in paragraph (2).

''(2) METHODS OF OBTAINING ADDITIONAL DATA.—For purposes of obtaining additional data or information under subparagraph (A) or (B) of paragraph (1), the Administrator shall—

''(A) issue a notice requiring the person''.

(b) CONFORMING AMENDMENTS.—Section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) is amended—

(1) in subsection (b)(2)(E)(ii), by striking ''(f)(2)'' and inserting ''(f)(3)''; and

(2) in subsection (g), in each of paragraphs (1) and (2)(A), by striking ''(f)(2)'' and inserting ''(f)(3)''.

SEC. 4. REVIEW.

(a) AGENCY AUTHORITY FOR CERTAIN PUBLIC-INTEREST DETERMINATIONS.—Section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) is amended in subparagraph (C) of subsection (q)(1) by striking the period at the end and inserting a comma, and in the matter immediately after and below such subparagraph by inserting before the sentence the following: ''except that such requirements relating to periods of time apply only to the extent determined by the Administrator to be in the public interest. Any such determination shall

be published in the Federal Register, together with a statement of the reasons underlying the determination.''.

(b) PUBLIC INPUT.—Section 408(q)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(q)(1)) is amended in the matter after and below subparagraph (C) by inserting before the period at the end the following: '', except that before issuing a final rule under subsection (d)(4) the Administrator shall issue a proposed rule with a period of 60 days for public comment, and before issuing a proposed rule under subsection (e) the Administrator shall issue an advance notice of proposed rulemaking in order to provide for a preliminary exchange of information and comments between the Administrator and the public''.

SEC. 5. TOLERANCES FOR EMERGENCY USES.

Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act is amended in the last sentence by inserting before the period the following: '', except that the Administrator may issue such a tolerance or exemption associated with an emergency exemption without regard to other tolerances or exemptions for the pesticide chemical residue and before reassessing such tolerances or exemptions, if the Administrator determines that any incremental exposure that may result from the tolerance or exemption asso-

ciated with the emergency exemption alone will not pose any significant dietary risk''.

SEC. 6. REPORTS ON RESOURCES AND PRIORITIES.

(a) ENVIRONMENTAL PROTECTION AGENCY.—

(1) IN GENERAL.—Not later than January 15, 2000, the Administrator of the Environmental Protection Agency (in this subsection referred to as the ''Administrator'') shall submit to the Congress a report specifying the financial resources needed by the Administrator for the fiscal years 2001 through 2005 in order to carry out the amendments made by the Food Quality Protection Act of 1996 to the Federal Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act, including providing for the prompt processing of all registration applications and petitions for tolerances, requests for experimental use permits, and requests for emergency exemptions and for decisions on the merits of such applications, petitions, and requests, in addition to performing tolerance reassessments and other duties required by such amendments.

(2) DETERMINATION OF EFFECTS OF NOT RECEIVING INCREASED AMOUNT OF APPROPRIATIONS; REALLOCATION OF RESOURCES.—The report under paragraph (1) shall, in addition to provisions re-

quired in such paragraph, contain a determination of the effects with respect to carrying out the amendments referred to in such paragraph that would occur if relative to fiscal year 2000 an increased amount of appropriations is not made available to the Administrator for carrying out the amendments, including a description of the reallocations of existing resources of the Environmental Protection Agency that would be required in order to carry out the amendments.

(b) DEPARTMENT OF AGRICULTURE.—

(1) IN GENERAL.—Not later than January 15, 2000, the Secretary of Agriculture (in this section referred to as the ''Secretary'') shall submit to the Congress a report specifying the financial resources needed by the Secretary for the fiscal years 2001 through 2005 in order to carry out the responsibilities of the Secretary under the Food Quality Protection Act of 1996.

(2) DETERMINATION OF EFFECTS OF NOT RECEIVING INCREASED AMOUNT OF APPROPRIATIONS; REALLOCATION OF RESOURCES.—The report under paragraph (1) shall, in addition to provisions required in such paragraph, contain a determination of the effects with respect to carrying out the respon-

sibilities referred to in such paragraph that would occur if relative to fiscal year 2000 an increased amount of appropriations is not made available to the Secretary for carrying out the responsibilities, including a description of the reallocations of existing resources of the Department of Agriculture that would be required in order to carry out the responsibilities.

SEC. 7. INTERNATIONAL TRADE EFFECTS.

(a) STUDY.—

(1) IN GENERAL.—The Secretary of Agriculture (in this section referred to as the ''Secretary''), after consultation with the Administrator of the Environmental Protection Agency and the United States Trade Representative, 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 but are not limited to fruits and vegetables, corn, wheat, cotton, rice, soybeans, and nursery crops.

(2) CERTAIN FACTORS.—In carrying out the requirements of paragraph (1), the Secretary shall examine factors pertinent to assessing, by sector, the sustainability and competitive strength in the inter-

national marketplace and the relationship of such factors to regulatory decisions issued under the amendments made by the Food Quality Protection Act of 1996. Such factors include but are not limited to sector changes, regional changes, price, quality, and ratio of imports to exports.

(b) REPORTS.—The Secretary shall prepare periodic reports addressing the requirements and factors of paragraphs (1) and (2) of subsection (a). Each such report shall be submitted to the Congress, with referrals to the committees of jurisdiction in the House of Representatives and the Senate. The first report shall be submitted not later than October 1, 2000, and subsequent reports shall be submitted biennially thereafter.

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