II

104TH CONGRESS
1ST SESSION

S. 1491

To reform antimicrobial pesticide registration, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 20, 1995

Mr. GRAMS (for himself, Mr. HEFLIN, Mr. PRYOR, Mr. MCCONNELL, Mr. CONRAD, Mr. COVERDELL, and Mr. SANTORUM) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

---

A BILL

To reform antimicrobial pesticide registration, 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 ''Antimicrobial Pesticide Registration Reform Act of 1995''.

SEC. 2. DEFINITIONS.

Section 2 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136) is amended—

(1) in subsection (k), by striking ''yeast, and bacteria'' and inserting ''and yeast'';

(2) in subsection (u), by adding at the end the following: ''The term 'pesticide' does not include liquid chemical sterilant products for use on a critical or semi-critical medical or dental device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).''; and

(3) by adding at the end the following:

''(hh) ANTIMICROBIAL PESTICIDE.—

''(1) IN GENERAL.—The term 'antimicrobial pesticide' means a pesticide that—

''(A) is intended to—

''(i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or

''(ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

''(B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 408 or 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a and 348).

''(2) EXCLUDED PRODUCTS.—The term 'antimicrobial pesticide' does not include—

''(A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addition to an activity described in paragraph (1) is made;

''(B) an agricultural fungicide product; or

''(C) an aquatic herbicide product.

''(3) INCLUDED PRODUCTS.—The term 'antimicrobial pesticide' does include any other chemical sterilant product (other than liquid chemical sterilant products exempt under subsection (u)), any other disinfectant product, any other industrial microbiocide product, and any other preservative product that is not excluded by paragraph (2).''.

SEC. 3. FEDERAL AND STATE DATA COORDINATION.

Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)(2)(B)) is amended by adding at the end the following:

''(vi) COORDINATION OF DATA REQUIREMENTS.—

''(I) IN GENERAL.—If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regu-

latory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

''(II) COOPERATIVE AGREEMENT.—The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

''(III) DISPARITIES.—Not later than 1 year after the date of enactment of this clause, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.''.

SEC. 4. LABEL AND LABELING.

Section 3(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)) is amended by adding at the end the following:

''(9) LABELING.—

''(A) ADDITIONAL STATEMENTS.—Subject to subparagraphs (B) and (C), it shall not be

a violation of this Act for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

''(B) REQUIREMENTS.—Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

''(C) NOTIFICATION AND DISAPPROVAL.—

''(i) NOTIFICATION.—A registration may be modified under subparagraph (A) if—

''(I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and

''(II) the Administrator does not disapprove of the modification under clause (ii).

''(ii) DISAPPROVAL.—Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

''(iii) RESTRICTION ON SALE.—A registrant may not sell or distribute a product bearing a disapproved modification.

''(iv) OBJECTION.—A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

''(v) FINAL ACTION.—A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

''(D) USE DILUTION.—The label or labeling required under this Act for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that—

''(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

''(ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.''.

SEC. 5. REGISTRATION REQUIREMENTS FOR ANTIMICROBIAL PESTICIDES.

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a) is amended by adding at the end the following:

''(g) REGISTRATION REQUIREMENTS FOR ANTIMICROBIAL PESTICIDES.—

''(1) EVALUATION OF PROCESS.—To the maximum extent practicable consistent with the degrees of risk presented by a antimicrobial pesticide and the type of review appropriate to evaluate the risks,

the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of the date of enactment of this subsection for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including—

"(A) new antimicrobial active ingredients;

"(B) new antimicrobial end-use products;

"(C) substantially similar or identical antimicrobial pesticides; and

"(D) amendments to antimicrobial pesticide registrations.

"(2) REVIEW TIME PERIOD REDUCTION GOAL.—Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than—

"(A) 540 days for a new antimicrobial active ingredient pesticide registration;

"(B) 270 days for a new antimicrobial use of a registered active ingredient;

"(C) 120 days for any other new antimicrobial product;

''(D) 90 days for a substantially similar or identical antimicrobial product;

''(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

''(F) 90 to 180 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

''(3) IMPLEMENTATION.—

''(A) PROPOSED RULEMAKING.—

''(i) ISSUANCE.—Not later than 270 days after the date of enactment of this subsection, the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

''(ii) REQUIREMENTS.—Proposed regulations issued under clause (i) shall—

''(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional

disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

''(II) differentiate the types of review undertaken for antimicrobial pesticides;

''(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this Act, considering the use patterns of the product, toxicity, expected exposure, and product type;

''(IV) ensure that the registration process is sufficient to maintain

antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

"(V) implement effective and reliable deadlines for process management.

"(iii) COMMENTS.—In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

"(B) FINAL REGULATIONS.—

"(i) ISSUANCE.—The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

"(ii) FAILURE TO MEET GOAL.—If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

''(iii) REQUIREMENTS.—In issuing final regulations, the Administrator shall—

''(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

''(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

''(III) use all appropriate and cost-effective review mechanisms, including—

''(aa) expanded use of notification and non-notification procedures;

''(bb) revised procedures for application review; and

''(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

"(IV) clarify criteria for determination of the completeness of an application.

"(C) EXPEDITED REVIEW.—This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3).

"(D) ALTERNATIVE REVIEW PERIODS.—If the final regulations to carry out this paragraph are not effective 630 days after the date of enactment of this subsection, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be—

"(i) 2 years for a new antimicrobial active ingredient pesticide registration;

"(ii) 1 year for a new antimicrobial use of a registered active ingredient;

"(iii) 180 days for any other new antimicrobial product;

"(iv) 90 days for a substantially similar or identical antimicrobial product;

"(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

"(vi) 240 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

"(E) WOOD PRESERVATIVES.—An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 2(hh)(1) is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

"(F) NOTIFICATION.—

"(i) IN GENERAL.—Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final

day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

''(ii) FINAL DECISION.—If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under section 706(1) of title 5, United States Code.

''(iii) EXEMPTION.—This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) prior to 90 days after the date of enactment of this subsection.

''(4) ANNUAL REPORT.—

''(A) SUBMISSION.—Beginning on the date of enactment of this subsection and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Com-

mittee on Agriculture, Nutrition, and Forestry of the Senate.

''(B) REQUIREMENTS.—A report submitted under subparagraph (A) shall include a description of—

''(i) measures taken to reduce the backlog of pending registration applications;

''(ii) progress toward achieving reforms under this subsection; and

''(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.''.

SEC. 6. DISPOSAL OF HOUSEHOLD, INDUSTRIAL, OR INSTITUTIONAL ANTIMICROBIAL PRODUCTS.

Section 19(h) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136q(h)) is amended—

(1) by striking ''Nothing in'' and inserting the following:

''(1) IN GENERAL.—Nothing in''; and

(2) by adding at the end the following:

''(2) ANTIMICROBIAL PRODUCTS.—A household, industrial, or institutional antimicrobial product that is not subject to regulation under the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.) shall not be

subject to the provisions of subsections (a), (e), and (f), unless the Administrator determines that such product must be subject to such provisions to prevent an unreasonable adverse effect on the environment.''.

○