

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Antimicrobial Pesticide
5 Registration Reform Act of 1995”.

6 **SEC. 2. DEFINITIONS.**

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

9 (1) in subsection (k), by striking “yeast, and
10 bacteria” and inserting “and yeast”;

1 (2) in subsection (u), by adding at the end the
2 following: “The term ‘pesticide’ does not include liq-
3 uid chemical sterilant products for use on a critical
4 or semi-critical medical or dental device, as defined
5 in section 201 of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 321).”; and

7 (3) by adding at the end the following:

8 “(hh) ANTIMICROBIAL PESTICIDE.—

9 “(1) IN GENERAL.—The term ‘antimicrobial
10 pesticide’ means a pesticide that—

11 “(A) is intended to—

12 “(i) disinfect, sanitize, reduce, or miti-
13 gate growth or development of
14 microbiological organisms; or

15 “(ii) protect inanimate objects, indus-
16 trial processes or systems, surfaces, water,
17 or other chemical substances from con-
18 tamination, fouling, or deterioration caused
19 by bacteria, viruses, fungi, protozoa, algae,
20 or slime; and

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

1 “(2) EXCLUDED PRODUCTS.—The term
2 ‘antimicrobial pesticide’ does not include—

3 “(A) a wood preservative or antifouling
4 paint product for which a claim of pesticidal ac-
5 tivity other than or in addition to an activity
6 described in paragraph (1) is made;

7 “(B) an agricultural fungicide product; or

8 “(C) an aquatic herbicide product.

9 “(3) INCLUDED PRODUCTS.—The term
10 ‘antimicrobial pesticide’ does include any other
11 chemical sterilant product (other than liquid chemi-
12 cal sterilant products exempt under subsection (u)),
13 any other disinfectant product, any other industrial
14 microbiocide product, and any other preservative
15 product that is not excluded by paragraph (2).”.

16 **SEC. 3. FEDERAL AND STATE DATA COORDINATION.**

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

20 “(vi) COORDINATION OF DATA RE-
21 QUIREMENTS.—

22 “(I) IN GENERAL.—If data re-
23 quired to support registration of a
24 pesticide under subparagraph (A) is
25 requested by a Federal or State regu-

1 latory authority, the Administrator
2 shall, to the extent practicable, coordi-
3 nate data requirements, test protocols,
4 timetables, and standards of review
5 and reduce burdens and redundancy
6 caused to the registrant by multiple
7 requirements on the registrant.

8 “(II) COOPERATIVE AGREE-
9 MENT.—The Administrator may enter
10 into a cooperative agreement with a
11 State to carry out subclause (I).

12 “(III) DISPARITIES.—Not later
13 than 1 year after the date of enact-
14 ment of this clause, the Administrator
15 shall develop a process to identify and
16 assist in alleviating future disparities
17 between Federal and State data re-
18 quirements.”.

19 **SEC. 4. LABEL AND LABELING.**

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

23 “(9) LABELING.—

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

1 a violation of this Act for a registrant to modify
2 the labeling of an antimicrobial pesticide prod-
3 uct to include relevant information on product
4 efficacy, product composition, container com-
5 position or design, or other characteristics that
6 do not relate to any pesticidal claim or pes-
7 ticidal activity.

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

15 “(C) NOTIFICATION AND DISAPPROVAL.—

16 “(i) NOTIFICATION.—A registration
17 may be modified under subparagraph (A)
18 if—

19 “(I) the registrant notifies the
20 Administrator in writing not later
21 than 60 days prior to distribution or
22 sale of a product bearing the modified
23 labeling; and

1 “(II) the Administrator does not
2 disapprove of the modification under
3 clause (ii).

4 “(ii) DISAPPROVAL.—Not later than
5 30 days after receipt of a notification
6 under clause (i), the Administrator may
7 disapprove the modification by sending the
8 registrant notification in writing stating
9 that the proposed language is not accept-
10 able and stating the reasons why the Ad-
11 ministrator finds the proposed modification
12 unacceptable.

13 “(iii) RESTRICTION ON SALE.—A reg-
14 istrant may not sell or distribute a product
15 bearing a disapproved modification.

16 “(iv) OBJECTION.—A registrant may
17 file an objection in writing to a disapproval
18 under clause (ii) not later than 30 days
19 after receipt of notification of the dis-
20 approval.

21 “(v) FINAL ACTION.—A decision by
22 the Administrator following receipt and
23 consideration of an objection filed under
24 clause (iv) shall be considered a final agen-
25 cy action.

1 “(D) USE DILUTION.—The label or label-
 2 ing required under this Act for an antimicrobial
 3 pesticide that is or may be diluted for use may
 4 have a different statement of caution or protec-
 5 tive measures for use of the recommended di-
 6 luted solution of the pesticide than for use of a
 7 concentrate of the pesticide if the Administrator
 8 determines that—

9 “(i) adequate data have been submit-
 10 ted to support the statement proposed for
 11 the diluted solution uses; and

12 “(ii) the label or labeling provides
 13 adequate protection for exposure to the di-
 14 luted solution of the pesticide.”.

15 **SEC. 5. REGISTRATION REQUIREMENTS FOR ANTI-**
 16 **MICROBIAL PESTICIDES.**

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

20 “(g) REGISTRATION REQUIREMENTS FOR
 21 ANTIMICROBIAL PESTICIDES.—

22 “(1) EVALUATION OF PROCESS.—To the maxi-
 23 mum extent practicable consistent with the degrees
 24 of risk presented by a antimicrobial pesticide and
 25 the type of review appropriate to evaluate the risks,

1 the Administrator shall identify and evaluate re-
2 forms to the antimicrobial registration process that
3 would reduce review periods existing as of the date
4 of enactment of this subsection for antimicrobial
5 pesticide product registration applications and appli-
6 cations for amended registration of antimicrobial
7 pesticide products, including—

8 “(A) new antimicrobial active ingredients;

9 “(B) new antimicrobial end-use products;

10 “(C) substantially similar or identical
11 antimicrobial pesticides; and

12 “(D) amendments to antimicrobial pes-
13 ticide registrations.

14 “(2) REVIEW TIME PERIOD REDUCTION
15 GOAL.—Each reform identified under paragraph (1)
16 shall be designed to achieve the goal of reducing the
17 review period following submission of a complete ap-
18 plication, consistent with the degree of risk, to a pe-
19 riod of not more than—

20 “(A) 540 days for a new antimicrobial ac-
21 tive ingredient pesticide registration;

22 “(B) 270 days for a new antimicrobial use
23 of a registered active ingredient;

24 “(C) 120 days for any other new
25 antimicrobial product;

1 “(D) 90 days for a substantially similar or
2 identical antimicrobial product;

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

6 “(F) 90 to 180 days for an amendment to
7 an antimicrobial registration that requires sci-
8 entific review of data and that is not otherwise
9 described in this paragraph.

10 “(3) IMPLEMENTATION.—

11 “(A) PROPOSED RULEMAKING.—

12 “(i) ISSUANCE.—Not later than 270
13 days after the date of enactment of this
14 subsection, the Administrator shall publish
15 in the Federal Register proposed regula-
16 tions to accelerate and improve the review
17 of antimicrobial pesticide products de-
18 signed to implement, to the extent prac-
19 ticable, the goals set forth in paragraph
20 (2).

21 “(ii) REQUIREMENTS.—Proposed reg-
22 ulations issued under clause (i) shall—

23 “(I) define the various classes of
24 antimicrobial use patterns, including
25 household, industrial, and institutional

1 disinfectants and sanitizing pesticides,
2 preservatives, water treatment, and
3 pulp and paper mill additives, and
4 other such products intended to dis-
5 infect, sanitize, reduce, or mitigate
6 growth or development of
7 microbiological organisms, or protect
8 inanimate objects, industrial processes
9 or systems, surfaces, water, or other
10 chemical substances from contamina-
11 tion, fouling, or deterioration caused
12 by bacteria, viruses, fungi, protozoa,
13 algae, or slime;

14 “(II) differentiate the types of re-
15 view undertaken for antimicrobial pes-
16 ticides;

17 “(III) conform the degree and
18 type of review to the risks and bene-
19 fits presented by antimicrobial pes-
20 ticides and the function of review
21 under this Act, considering the use
22 patterns of the product, toxicity, ex-
23 pected exposure, and product type;

24 “(IV) ensure that the registration
25 process is sufficient to maintain

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

6 “(V) implement effective and reli-
7 able deadlines for process manage-
8 ment.

9 “(iii) COMMENTS.—In developing the
10 proposed regulations, the Administrator
11 shall solicit the views from registrants and
12 other affected parties to maximize the ef-
13 fectiveness of the rule development process.

14 “(B) FINAL REGULATIONS.—

15 “(i) ISSUANCE.—The Administrator
16 shall issue final regulations not later than
17 240 days after the close of the comment
18 period for the proposed regulations.

19 “(ii) FAILURE TO MEET GOAL.—If a
20 goal described in paragraph (2) is not met
21 by the final regulations, the Administrator
22 shall identify the goal, explain why the goal
23 was not attained, describe the element of
24 the regulations included instead, and iden-
25 tify future steps to attain the goal.

1 “(iii) REQUIREMENTS.—In issuing
2 final regulations, the Administrator shall—

3 “(I) consider the establishment of
4 a certification process for regulatory
5 actions involving risks that can be re-
6 sponsibly managed, consistent with
7 the degree of risk, in the most cost-ef-
8 ficient manner;

9 “(II) consider the establishment
10 of a certification process by approved
11 laboratories as an adjunct to the re-
12 view process;

13 “(III) use all appropriate and
14 cost-effective review mechanisms, in-
15 cluding—

16 “(aa) expanded use of notifi-
17 cation and non-notification proce-
18 dures;

19 “(bb) revised procedures for
20 application review; and

21 “(cc) allocation of appro-
22 priate resources to ensure
23 streamlined management of
24 antimicrobial pesticide registra-
25 tions; and

1 “(IV) clarify criteria for deter-
2 mination of the completeness of an
3 application.

4 “(C) EXPEDITED REVIEW.—This sub-
5 section does not affect the requirements or ex-
6 tend the deadlines or review periods contained
7 in subsection (c)(3).

8 “(D) ALTERNATIVE REVIEW PERIODS.—If
9 the final regulations to carry out this paragraph
10 are not effective 630 days after the date of en-
11 actment of this subsection, until the final regu-
12 lations become effective, the review period, be-
13 ginning on the date of receipt by the Agency of
14 a complete application, shall be—

15 “(i) 2 years for a new antimicrobial
16 active ingredient pesticide registration;

17 “(ii) 1 year for a new antimicrobial
18 use of a registered active ingredient;

19 “(iii) 180 days for any other new
20 antimicrobial product;

21 “(iv) 90 days for a substantially simi-
22 lar or identical antimicrobial product;

23 “(v) 90 days for an amendment to an
24 antimicrobial registration that does not re-
25 quire scientific review of data; and

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

5 “(E) WOOD PRESERVATIVES.—An applica-
6 tion for the registration, or for an amendment
7 to the registration, of a wood preservative prod-
8 uct for which a claim of pesticidal activity listed
9 in section 2(hh)(1) is made (regardless of any
10 other pesticidal claim that is made with respect
11 to the product) shall be reviewed by the Admin-
12 istrator within the same period as that estab-
13 lished under this paragraph for an
14 antimicrobial pesticide product application, con-
15 sistent with the degree of risk posed by the use
16 of the wood preservative product, if the applica-
17 tion requires the applicant to satisfy the same
18 data requirements as are required to support an
19 application for a wood preservative product that
20 is an antimicrobial pesticide.

21 “(F) NOTIFICATION.—

22 “(i) IN GENERAL.—Subject to clause
23 (iii), the Administrator shall notify an ap-
24 plicant whether an application has been
25 granted or denied not later than the final

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

4 “(ii) FINAL DECISION.—If the Admin-
5 istrator fails to notify an applicant within
6 the period of time required under clause
7 (i), the failure shall be considered an agen-
8 cy action unlawfully withheld or unreason-
9 ably delayed for purposes of judicial review
10 under section 706(1) of title 5, United
11 States Code.

12 “(iii) EXEMPTION.—This subpara-
13 graph does not apply to an application for
14 an antimicrobial pesticide that is filed
15 under subsection (c)(3)(B) prior to 90
16 days after the date of enactment of this
17 subsection.

18 “(4) ANNUAL REPORT.—

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

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

3 “(B) REQUIREMENTS.—A report submit-
4 ted under subparagraph (A) shall include a de-
5 scription of—

6 “(i) measures taken to reduce the
7 backlog of pending registration applica-
8 tions;

9 “(ii) progress toward achieving re-
10 forms under this subsection; and

11 “(iii) recommendations to improve the
12 activities of the Agency pertaining to
13 antimicrobial registrations.”.

14 **SEC. 6. DISPOSAL OF HOUSEHOLD, INDUSTRIAL, OR INSTI-**
15 **TUTIONAL ANTIMICROBIAL PRODUCTS.**

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

18 (1) by striking “Nothing in” and inserting the
19 following:

20 “(1) IN GENERAL.—Nothing in”; and

21 (2) by adding at the end the following:

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

1 subject to the provisions of subsections (a), (e), and
2 (f), unless the Administrator determines that such
3 product must be subject to such provisions to pre-
4 vent an unreasonable adverse effect on the environ-
5 ment.”.

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