

104TH CONGRESS
1ST SESSION

H. R. 1680

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

IN THE HOUSE OF REPRESENTATIVES

MAY 18, 1995

Mr. ROBERTS (for himself, Mr. DE LA GARZA, Mr. EMERSON, and Mr. CONDIT) introduced the following bill; which was referred to the Committee on Agriculture

A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act, 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. REFERENCE.**

7 Whenever in this Act an amendment or repeal is ex-
8 pressed in terms of an amendment to, or repeal of, a sec-
9 tion or other provision, the reference shall be considered

1 to be made to a section or other provision of the Federal
2 Insecticide, Fungicide, and Rodenticide Act.

3 **SEC. 3. ANTIMICROBIAL PRODUCTS.**

4 (a) DEFINITIONS.—AMENDMENTS TO THE ACT.—
5 Section 2 (7 U.S.C. 136) is amended by adding at the
6 end the following new subsection:

7 “(hh) ANTIMICROBIAL PESTICIDE.—The term
8 ‘antimicrobial pesticide’ means a pesticide, including but
9 not limited to an antimicrobial active ingredient or an
10 antimicrobial end-use product (including composition,
11 packaging, and labeling), that—

12 “(1) is intended to—

13 “(A) disinfect, sanitize, reduce, or mitigate
14 growth or development of microbiological orga-
15 nisms; or

16 “(B) protect inanimate objects, industrial
17 processes or systems, surfaces, water or other
18 chemical substances from contamination, deg-
19 radation, fouling, inefficiency, or deterioration
20 caused by microbiological organisms (including,
21 but not limited to bacteria, viruses, fungi, algae
22 or composite slime); and

23 “(2) in the intended use is exempt from, or oth-
24 erwise not subject to, a tolerance under section 408

1 or section 409 of the Federal Food, Drug, and Cos-
2 metic Act (21 U.S.C. 346a or 348).”.

3 (b) REQUIREMENTS FOR REGISTRATION.—Section 3
4 (7 U.S.C. 136a) is amended by adding at the end the fol-
5 lowing new subsection:

6 “(g) REGISTRATION REQUIREMENTS FOR
7 ANTIMICROBIAL PESTICIDES.—

8 “(1) EVALUATION OF PROCESS.—The Adminis-
9 trator shall identify and evaluate reforms to the
10 antimicrobial registration process that will reduce
11 current review periods for—

12 “(A) new antimicrobial active ingredients;

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

14 “(C) substantially similar or identical
15 antimicrobial pesticides; and

16 “(D) amendments to existing antimicrobial
17 pesticide registrations; by the maximum extent
18 practicable consistent with the degree and type
19 of review appropriate to the risks presented by
20 the antimicrobial pesticide.

21 “(2) REVIEW TIME PERIOD REDUCTION
22 GOAL.—The reforms identified under paragraph (1)
23 shall be designed to achieve the goal of reducing the
24 review periods for each of the antimicrobial pesticide
25 registration actions described below to the shorter of

1 either a 75 percent reduction from the current re-
2 view time period or the following specific review
3 periods:

4 “(A) 12 months for a new antimicrobial
5 active ingredient pesticide registration.

6 “(B) 6 months for a new antimicrobial use
7 of a registered active ingredient.

8 “(C) 3 months for a new antimicrobial use
9 of a registered end-use product.

10 “(D) 3 months for a new antimicrobial
11 end-use product registration.

12 “(E) 3 months for a substantially similar
13 or identical antimicrobial product.

14 “(F) 3 months for an amendment to a cur-
15 rent antimicrobial registration that requires sci-
16 entific review of data.

17 “(G) 1 month for an application for an
18 amendment to a current antimicrobial registra-
19 tion that does not require scientific review of
20 data.

21 “(3) ADVANCE NOTICE OF PROPOSED RULE-
22 MAKING.—Not later than 90 days after the date of
23 enactment of this subsection, the Administrator shall
24 publish in the Federal Register an advance notice of

1 proposed rulemaking to solicit input for rulemaking
2 to—

3 “(A) define the different classes of
4 antimicrobial use patterns, including but not
5 limited to household and similarly-formulated
6 industrial and institutional disinfectants and
7 sanitizing pesticides, preservatives, water treat-
8 ment, and pulp and paper mill additives;

9 “(B) differentiate the types of review (such
10 as those described in paragraphs (1) and (2))
11 undertaken for antimicrobial pesticides;

12 “(C) conform and degree and type of re-
13 view to the risks and benefits presented by
14 antimicrobial pesticides and the function of re-
15 view under this Act considering the use pat-
16 terns of the product, toxicity, and product type;

17 “(D) ensure that the review process is suf-
18 ficient to maintain antimicrobial pesticide effi-
19 cacy and that household and similarly-formu-
20 lated industrial and institutional disinfectant
21 and sanitizing pesticides continue to meet prod-
22 uct performance standards and specific effec-
23 tiveness levels reflected in subdivision G of the
24 Agency’s Pesticide Assessment Guidelines for
25 each type of label claim made; and

1 “(E) implement effective deadlines for
2 process management, that can be relied upon by
3 both the registrant and the Agency.

4 “(4) IMPLEMENTATION.—

5 “(A) REGULATIONS.—Within 1 year of the
6 date of enactment of this subsection, the Ad-
7 ministrator shall propose regulations, to be ef-
8 fective within 180 days of their publication in
9 the Federal Register, to carry out and meet the
10 goals set forth in paragraph (2). The Adminis-
11 trator shall consider the establishment of a cer-
12 tification process for regulatory actions involv-
13 ing risks that can be responsibly managed con-
14 sistent with their degree in the most cost effi-
15 cient manner. The Administrator shall also con-
16 sider, as an adjunct to the review process, the
17 establishment of a certification process by ap-
18 proved laboratories. In addition to considering
19 certification processes, the Administrator shall
20 also utilize all appropriate and cost effective re-
21 view mechanisms, including—

22 “(i) expanded use of notification and
23 non-notification procedures;

24 “(ii) revised procedures for application
25 review; and

1 “(iii) allocation of appropriate and
2 sufficient resources to ensure streamlined
3 management of antimicrobial pesticide reg-
4 istrations.

5 “(B) TRANSITION PERIOD.—In the case of
6 an antimicrobial pesticide application filed after
7 90 days after the date of enactment of this sub-
8 section, the following shall apply:

9 “(i) The review period for the reg-
10 istration of an antimicrobial end-use pes-
11 ticide that, if registered as proposed, would
12 be substantially similar or identical in com-
13 position and labeling to a currently-reg-
14 istered antimicrobial pesticide identified in
15 the application, or that would differ in
16 composition and labeling from such cur-
17 rently-registered antimicrobial pesticide
18 only in ways that would not significantly
19 increase the risk of unreasonable adverse
20 effects on the environment, shall be not
21 more than 135 days.

22 “(ii) The review period for an amend-
23 ment to a current registration that does
24 not require scientific review of data shall
25 be no more than 135 days.

1 “(iii) No rule promulgated under sub-
2 paragraph (A) may extend, absent consent
3 of the registrant, the time periods estab-
4 lished under this subparagraph.

5 “(C) ALTERNATIVE REVIEW PERIODS.—In
6 the case of antimicrobial pesticide applications
7 other than those described in subparagraph
8 (B), if the final rules to carry out this para-
9 graph are not effective 545 days after the date
10 of enactment of this subsection, the following
11 review periods, beginning on the date of receipt
12 by the Agency of a complete application, shall
13 apply:

14 “(i) 18 months for a new active ingre-
15 dient pesticide registration.

16 “(ii) 12 months for a new use of a
17 registered active ingredient.

18 “(iii) 6 months for a new use of a reg-
19 istered end-use product.

20 “(iv) 6 months for a new end-use
21 product registration.

22 “(v) 135 days for a substantially simi-
23 lar or identical product.

1 “(vi) 6 months for an amendment to
2 a current registration that requires sci-
3 entific review of data.

4 “(vii) 135 days for an application for
5 an amendment to a current registration
6 that does not require scientific review of
7 data.

8 “(D) NOTIFICATION.—

9 “(i) IN GENERAL.—The Administrator
10 shall notify the registrant prior to the end
11 of the appropriate review period specified
12 in subparagraph (B) or (C) whether an ap-
13 plication has been granted or denied.

14 “(ii) FINAL DECISION.—If the Admin-
15 istrator fails to timely notify the registrant
16 under clause (i) whether an application has
17 been granted or denied, the application
18 shall be deemed to be denied and such de-
19 nial shall be considered a final agency ac-
20 tion subject to judicial review under section
21 551 of title 5, United States Code, et seq.

22 “(E) OVERSIGHT.—The Committee on Ag-
23 riculture of the House of Representatives and
24 the Committee on Agriculture, Nutrition, and
25 Forestry of the Senate shall thereafter conduct

1 such oversight as is necessary to ensure that
2 the reform goal for the antimicrobial registra-
3 tion process are met.

4 “(5) ANNUAL REPORT.—Not later than March
5 1 of each year after date of enactment of this sub-
6 section until the reform goals specified in this sub-
7 section have been achieved, the Administrator shall
8 prepare and submit an annual report to the Commit-
9 tee on Agriculture of the House of Representatives
10 and the Committee on Agriculture, Nutrition, and
11 Forestry of the Senate. This report shall include
12 those measures taken to reduce the backlog of pend-
13 ing registration applications, progress toward achiev-
14 ing the reforms, and recommendations to improve
15 the activities of the Agency pertaining to
16 antimicrobial registrations.”.

17 “(c) LABEL AND LABELING STATEMENTS.—Section
18 3(c) (7 U.S.C. 136a(c)) is amended by adding at the end
19 the following new paragraph:

20 “(9) LABEL AND LABELING STATEMENTS.—

21 “(A) ADDITIONAL STATEMENTS.—A reg-
22 istrant of an antimicrobial pesticide may not
23 change the label or labeling statements required
24 under this Act or by regulation including the
25 pesticidal claims, ingredient statement, direc-

1 tions for use, warning and caution statements
2 and Agency registration numbers, without the
3 approval of the Administrator. A registrant of
4 an antimicrobial pesticide may make or alter
5 other label or labeling statements or amend-
6 ments that are truthful and not misleading and
7 that do not relate to or affect such required
8 label or labeling statements.

9 “(B) USE DILUTION.—For antimicrobial
10 pesticides that are or may be diluted for use,
11 the label or labeling required under this Act
12 may have a different statement of caution or
13 protective measures for use of recommended di-
14 luted solutions of the pesticide than for the use
15 of concentrates of the pesticide. Such a pre-
16 cautionary statement shall provide adequate
17 protection for exposure to the diluted solution
18 of the pesticide.”.

19 (d) DISPOSAL AND HOUSEHOLD AND SIMILARLY
20 FORMULATED INDUSTRIAL AND INSTITUTIONAL DIS-
21 INFECTANT AND SANITIZER PRODUCTS.—Section 19(h)
22 (7 U.S.C. 136q(h)) is amended by adding at the end the
23 following new sentence: “Household and similarly-formu-
24 lated industrial and institutional disinfectant and sanitizer
25 products which are not otherwise subject to regulation

1 under the Solid Waste Disposal Act (42 U.S.C. 6901 et.
2 seq.) shall not be subject to regulation under this sec-
3 tion.”.

4 (e) DATA COORDINATION AND SYNCHRONIZATION.—
5 Section 3(c)(2)(B) (7 U.S.C. 136a(c)(2)(B)) is amended
6 by adding at the end the following new clause:

7 “(vi) Whenever data of a type specified in the
8 guidelines published under subparagraph (A) is re-
9 quired by one or more State or Federal agencies,
10 the Administrator shall, to the extent practicable,
11 share data and information and shall coordinate and
12 synchronize such data requests including, but not
13 limited to, test protocols, timetables, and standards
14 of review among the agencies so as to reduce bur-
15 dens and to avoid unnecessary repetition and redun-
16 dancy. In addition, within one year after the date of
17 enactment of this clause, the Administrator shall, by
18 rule, develop and implement procedures for such co-
19 ordination and synchronization by the Administrator
20 so as to result in identical and concurrent data re-
21 quirements by all the agencies. Nothing in this
22 clause shall be interpreted as affecting the authority
23 of States to regulate pesticides as provided in section
24 24(a).”.

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