

108TH CONGRESS
1ST SESSION

H. R. 3319

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to permit the Administrator of the Environmental Protection Agency to register a Canadian pesticide.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 16, 2003

Mr. REHBERG (for himself, Mr. POMEROY, Mr. CASE, Mr. GREEN of Wisconsin, Mr. PAUL, Mr. SHERWOOD, and Mr. JANKLOW) introduced the following bill; which was referred to the Committee on Agriculture

A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to permit the Administrator of the Environmental Protection Agency to register a Canadian pesticide.

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. REGISTRATION OF CANADIAN PESTICIDES.**

4 (a) IN GENERAL.—Section 3 of the Federal Insecti-
5 cide, Fungicide, and Rodenticide Act (7 U.S.C. 136a) is
6 amended by adding at the end the following:

7 “(i) REGISTRATION OF CANADIAN PESTICIDES.—

8 “(1) DEFINITIONS.—In this subsection:

1 “(A) CANADIAN PESTICIDE.—The term
2 ‘Canadian pesticide’ means a pesticide that—

3 “(i) is registered for use as a pesticide
4 in Canada;

5 “(ii) is identical or substantially simi-
6 lar in its composition to a comparable do-
7 mestic pesticide registered under this sec-
8 tion; and

9 “(iii) is registered in Canada by the
10 registrant of the comparable domestic pes-
11 ticide or by an affiliated entity of the reg-
12 istrant.

13 “(B) COMPARABLE DOMESTIC PES-
14 TICIDE.—The term ‘comparable domestic pes-
15 ticide’ means a pesticide—

16 “(i) that is registered under this sec-
17 tion;

18 “(ii) the registration of which is not
19 under suspension;

20 “(iii) that is not subject to—

21 “(I) a notice of intent to cancel
22 or suspend under any provision of this
23 Act;

24 “(II) a notice for voluntary can-
25 cellation under section 6(f); or

1 “(III) an enforcement action
2 under any provision of this Act;

3 “(iv) that is used as the basis for
4 comparison for the determinations required
5 under paragraph (4);

6 “(v) that is registered for use on each
7 site of application for which registration is
8 sought under this subsection;

9 “(vi) for which no use is the subject
10 of a pending interim administrative review
11 under subsection (c)(8);

12 “(vii) that is not subject to any limita-
13 tion on production or sale agreed to by the
14 Administrator and the registrant or im-
15 posed by the Administrator for risk mitiga-
16 tion purposes; and

17 “(viii) that is not classified as a re-
18 stricted use pesticide under subsection (d).

19 “(2) AUTHORITY TO REGISTER CANADIAN PES-
20 TICIDES.—

21 “(A) IN GENERAL.—The Administrator
22 may register a Canadian pesticide if the reg-
23 istration—

24 “(i) complies with this subsection;

25 “(ii) is consistent with this Act; and

1 “(iii) has not previously been dis-
2 approved by the Administrator.

3 “(B) PRODUCTION OF ANOTHER PES-
4 TICIDE.—A pesticide registered under this sub-
5 section shall not be used to produce a pesticide
6 registered under this section or section 24(c).

7 “(C) REGISTRANT.—

8 “(i) IN GENERAL.—The Administrator
9 may register a Canadian pesticide under
10 this subsection on the application of any
11 person.

12 “(ii) APPLICATION.—If the Adminis-
13 trator registers a Canadian pesticide under
14 this subsection on application of any per-
15 son, the applicant shall be considered to be
16 the registrant of the Canadian pesticide for
17 all purposes of this Act.

18 “(D) ADMINISTRATOR.—Not later than 60
19 days after a person submits a complete applica-
20 tion for the registration of a Canadian pesticide
21 under this subsection, the Administrator shall—

22 “(i) approve the application; or

23 “(ii)(I) disapprove the application;

24 and

1 “(II) provide the applicant with a
2 statement of the reasons for the dis-
3 approval.

4 “(E) DELEGATION.—

5 “(i) IN GENERAL.—Subject to clause
6 (ii), the Administrator may delegate a
7 function of the Administrator under this
8 subsection.

9 “(ii) APPROVAL.—The Administrator
10 shall approve or disapprove any final ac-
11 tion taken under this subsection as the re-
12 sult of a function delegated to a State.

13 “(3) APPLICANT REQUIREMENTS.—A person
14 seeking registration of a Canadian pesticide under
15 this subsection shall—

16 “(A) demonstrate to the Administrator
17 that the Canadian pesticide is identical or sub-
18 stantially similar in its composition to a com-
19 parable domestic pesticide; and

20 “(B) submit to the Administrator a copy
21 of—

22 “(i) the label approved by the Pes-
23 ticide Management Regulatory Agency for
24 the Canadian pesticide; and

1 “(ii) the label approved by the Admin-
2 istrator for the comparable domestic pes-
3 ticide.

4 “(4) CRITERIA FOR REGISTRATION.—The Ad-
5 ministrator may register a Canadian pesticide under
6 this subsection if the Administrator—

7 “(A) obtains the confidential statement of
8 formula for the Canadian pesticide;

9 “(B) determines that the Canadian pes-
10 ticide is identical or substantially similar in
11 composition to a comparable domestic pesticide;

12 “(C) for each food or feed use authorized
13 by the registration—

14 “(i) determines that there exists an
15 adequate tolerance or exemption under the
16 Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 301 et seq.) that permits the resi-
18 dues of the pesticide on the food or feed;
19 and

20 “(ii) identifies the tolerances or ex-
21 emptions in the notification submitted
22 under subparagraph (E);

23 “(D) obtains a label approved by the Ad-
24 ministrator that—

1 “(i) includes all statements, other
2 than the establishment number, from the
3 approved labeling of the comparable do-
4 mestic pesticide that are relevant to the
5 uses registered by the Administrator; and

6 “(ii) excludes all labeling statements
7 relating to uses that are not registered by
8 the Administrator; and

9 “(E) not later than 10 business days after
10 the issuance of the registration, publish in the
11 Federal Register a written notification of the
12 action of the Administrator that includes—

13 “(i) a description of the determination
14 made under this paragraph; and

15 “(ii) a statement of the effective date
16 of the registration;

17 “(5) LABELING OF CANADIAN PESTICIDES.—

18 “(A) IN GENERAL.—Each container con-
19 taining a Canadian pesticide registered by the
20 Administrator shall bear the label that is ap-
21 proved by the Administrator under this sub-
22 section.

23 “(B) DISPLAY OF LABEL.—The label shall
24 be securely attached to the container and shall
25 be the only label visible on the container.

1 “(C) ORIGINAL CANADIAN LABEL.—The
2 original Canadian label on the container shall
3 be preserved underneath the label approved by
4 the Administrator.

5 “(D) PREPARATION AND USE OF LA-
6 BELS.—After a Canadian pesticide is registered
7 under this subsection, the registrant shall—

8 “(i) prepare labels approved by the
9 Administrator for the Canadian pesticide;
10 and

11 “(ii) conduct or supervise all labeling
12 of the Canadian pesticide with the ap-
13 proved labeling.

14 “(E) REGISTERED ESTABLISHMENTS.—
15 Labeling of a Canadian pesticide under this
16 subsection shall be conducted at an establish-
17 ment registered by the registrant under section
18 7.

19 “(6) REVOCATION.—

20 “(A) IN GENERAL.—After the registration
21 of a Canadian pesticide, if the Administrator
22 finds that the Canadian pesticide is not iden-
23 tical or substantially similar in composition to
24 a comparable domestic pesticide, the Adminis-

1 trator may issue an emergency order revoking
2 the registration of the Canadian pesticide.

3 “(B) TERMS OF ORDER.—The order—

4 “(i) shall be effective immediately;

5 “(ii) may prohibit the sale, distribu-
6 tion, and use of the Canadian pesticide in
7 a State; and

8 “(iii) may require the registrant of the
9 Canadian pesticide to purchase and dispose
10 of any unopened product subject to the
11 order.

12 “(C) REQUEST FOR HEARING.—Not later
13 than 10 days after issuance of the order, the
14 registrant of the Canadian pesticide subject to
15 the order may request a hearing on the order.

16 “(D) FINAL ORDER.—If a hearing is not
17 requested in accordance with subparagraph (C),
18 the order shall become final and shall not be
19 subject to judicial review.

20 “(E) JUDICIAL REVIEW.—If a hearing is
21 requested on the order, judicial review may be
22 sought only at the conclusion of the hearing on
23 the order and following the issuance by the Ad-
24 ministrator of a final revocation order.

1 “(F) PROCEDURE.—A final revocation
2 order issued following a hearing shall be review-
3 able in accordance with section 16.

4 “(7) LIMITS ON LIABILITY.—No action for
5 monetary damages may be heard in any Federal or
6 State court against—

7 “(A) the Administrator acting as a reg-
8 istering agency under the authority of and con-
9 sistent with this subsection for injury or dam-
10 age resulting from the use of a product reg-
11 istered by the Administrator under this sub-
12 section; or

13 “(B) a registrant for damages resulting
14 from adulteration or compositional alteration of
15 a Canadian pesticide registered under this sub-
16 section if the registrant did not have and could
17 not reasonably have obtained knowledge of the
18 adulteration or compositional alteration.

19 “(8) PROVISION OF INFORMATION BY REG-
20 ISTRANTS OF COMPARABLE DOMESTIC PES-
21 TICIDES.—

22 “(A) IN GENERAL.—On request by the Ad-
23 ministrator the registrant of a comparable do-
24 mestic pesticide shall provide to the Adminis-
25 trator that is seeking to register a Canadian

1 pesticide under this subsection information that
2 is necessary for the Administrator to make the
3 determinations required by paragraph (4).

4 “(B) PENALTY FOR NONCOMPLIANCE.—

5 “(i) IN GENERAL.—If the registrant
6 of a comparable domestic pesticide fails to
7 provide to the Administrator, not later
8 than 15 days after receipt of a written re-
9 quest by the Administrator, information
10 possessed by or reasonably accessible to
11 the registrant that is necessary to make
12 the determinations required by paragraph
13 (4), the Administrator may assess a pen-
14 alty against the registrant of the com-
15 parable pesticide.

16 “(ii) AMOUNT.—The amount of the
17 penalty shall be equal to the product ob-
18 tained by multiplying—

19 “(I) the difference between the
20 per-acre cost of the application of the
21 comparable domestic pesticide and the
22 application of the Canadian pesticide,
23 as determined by the Administrator;
24 and

1 “(II) the number of acres in the
2 United States devoted to the com-
3 modity for which the registration is
4 sought.

5 “(C) NOTICE AND OPPORTUNITY FOR
6 HEARING.—No penalty under this paragraph
7 shall be assessed unless the registrant is given
8 notice and opportunity for a hearing in accord-
9 ance with section 14(a)(3).

10 “(D) ISSUES AT HEARING.—The only
11 issues for resolution at the hearing shall be—

12 “(i) whether the registrant of the
13 comparable domestic pesticide failed to
14 timely provide to the Administrator the in-
15 formation possessed by or reasonably ac-
16 cessible to the registrant that was nec-
17 essary to make the determinations required
18 by paragraph (4); and

19 “(ii) the amount of the penalty.

20 “(9) PENALTY FOR DISCLOSURE.—

21 “(A) IN GENERAL.—The Administrator
22 shall not make public information obtained
23 under paragraph (8) that is privileged and con-
24 fidential and contains or relates to trade secrets
25 or commercial or financial information.

1 “(B) DISCLOSURE.—Any employee of the
2 Environmental Protection Agency who willfully
3 discloses information described in subparagraph
4 (A) shall be subject to penalties described in
5 section 10(f).

6 “(10) DATA COMPENSATION.—The Adminis-
7 trator and a person registering a Canadian pesticide
8 under this subsection shall not be liable for com-
9 pensation for data supporting the registration if the
10 registration of the Canadian pesticide in Canada and
11 the registration of the comparable domestic pesticide
12 are held by the same registrant or by affiliated enti-
13 ties.

14 “(11) FORMULATION CHANGES.—

15 “(A) IN GENERAL.—The registrant of a
16 comparable domestic pesticide shall notify the
17 Administrator of any change in the formulation
18 of a comparable domestic pesticide or a Cana-
19 dian pesticide registered by the registrant or an
20 affiliated entity not later than 30 days before
21 any sale or distribution of the pesticide con-
22 taining the new formulation.

23 “(B) STATEMENT OF FORMULA.—The reg-
24 istrant of the comparable domestic pesticide
25 shall submit, with the notice required under

1 subparagraph (A), a confidential statement of
2 the formula for the new formulation if the reg-
3 istrant has possession of or reasonable access to
4 the information.

5 “(C) SUSPENSION OF REGISTRATION FOR
6 NONCOMPLIANCE.—

7 “(i) IN GENERAL.—If the registrant
8 fails to provide notice or submit a con-
9 fidential statement of formula as required
10 by this paragraph, the Administrator may
11 issue a notice of intent to suspend the reg-
12 istration of the comparable domestic pes-
13 ticide for a period of not less than 1 year.

14 “(ii) EFFECTIVE DATE.—The suspen-
15 sion shall become final not later than the
16 end of the 30-day period beginning on the
17 date of the issuance by the Administrator
18 of the notice of intent to suspend the reg-
19 istration, unless during the period the reg-
20 istrant requests a hearing.

21 “(iii) HEARING PROCEDURE.—If a
22 hearing is requested, the hearing shall be
23 conducted in accordance with section 6(d).

24 “(iv) ISSUES.—The only issues for
25 resolution at the hearing shall be whether

1 the registrant has failed to provide notice
 2 or submit a confidential statement of for-
 3 mula as required by this paragraph.”.

4 (b) TECHNICAL AND CONFORMING AMENDMENT.—
 5 The table of contents in section 1(b) of the Federal Insec-
 6 ticide, Fungicide, and Rodenticide Act (7 U.S.C. prec.
 7 121) is amended by adding at the end of the items relating
 8 to section 3 the following:

- “ (4) Mixtures of nitrogen stabilizers and fertilizer products.
- “(g) Registration review.
- “(h) Registration requirements for antimicrobial pesticides.
 - “ (1) Evaluation of process.
 - “ (2) Review time period reduction goal.
 - “ (3) Implementation.
 - “ (4) Annual report.
- “(i) Registration of Canadian pesticides.
 - “ (1) Definitions.
 - “ (2) Authority to register Canadian pesticides.
 - “ (3) Applicant requirements.
 - “ (4) Criteria for registration.
 - “ (5) Labeling of Canadian pesticides.
 - “ (6) Revocation.
 - “ (7) Limits on liability.
 - “ (8) Provision of information by registrants of comparable domestic pesticides.
 - “ (9) Penalty for disclosure.
 - “ (10) Data compensation.
 - “ (11) Formulation changes.”.

9 (c) EFFECTIVE DATE.—This section and the amend-
 10 ments made by this section take effect 180 days after the
 11 date of enactment of this Act.

○