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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. REGISTRATION OF CANADIAN PESTICIDES.

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

"(i) REGISTRATION OF CANADIAN PESTICIDES.—

"(1) DEFINITIONS.—In this subsection:

"(A) CANADIAN PESTICIDE.—The term 'Canadian pesticide' means a pesticide that—

"(i) is registered for use as a pesticide in Canada;

"(ii) is identical or substantially similar in its composition to a comparable domestic pesticide registered under this section; and

"(iii) is registered in Canada by the registrant of the comparable domestic pesticide or by an affiliated entity of the registrant.

"(B) COMPARABLE DOMESTIC PESTICIDE.—The term 'comparable domestic pesticide' means a pesticide—

"(i) that is registered under this section;

"(ii) the registration of which is not under suspension;

"(iii) that is not subject to—

"(I) a notice of intent to cancel or suspend under any provision of this Act;

"(II) a notice for voluntary cancellation under section 6(f); or

"(III) an enforcement action under any provision of this Act;

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

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

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

"(vii) that is not subject to any limitation on production or sale agreed to by the Administrator and the registrant or imposed by the Administrator for risk mitigation purposes; and

"(viii) that is not classified as a restricted use pesticide under subsection (d).

"(2) AUTHORITY TO REGISTER CANADIAN PESTICIDES.—

"(A) IN GENERAL.—The Administrator may register a Canadian pesticide if the registration—

"(i) complies with this subsection;

"(ii) is consistent with this Act; and

"(iii) has not previously been disapproved by the Administrator.

"(B) PRODUCTION OF ANOTHER PESTICIDE.—A pesticide registered under this subsection shall not be used to produce a pesticide registered under this section or section 24(c).

"(C) REGISTRANT.—

"(i) IN GENERAL.—The Administrator may register a Canadian pesticide under this subsection on the application of any person.

"(ii) APPLICATION.—If the Administrator registers a Canadian pesticide under this subsection on application of any person, the applicant shall be considered to be the registrant of the Canadian pesticide for all purposes of this Act.

"(D) ADMINISTRATOR.—Not later than 60 days after a person submits a complete application for the registration of a Canadian pesticide under this subsection, the Administrator shall—

"(i) approve the application; or

"(ii)(I) disapprove the application; and

"(II) provide the applicant with a statement of the reasons for the disapproval.

"(E) DELEGATION.—

"(i) IN GENERAL.—Subject to clause (ii), the Administrator may delegate a function of the Administrator under this subsection.

"(ii) APPROVAL.—The Administrator shall approve or disapprove any final action taken under this subsection as the result of a function delegated to a State.

"(3) APPLICANT REQUIREMENTS.—A person seeking registration of a Canadian pesticide under this subsection shall—

"(A) demonstrate to the Administrator that the Canadian pesticide is identical or substantially similar in its composition to a comparable domestic pesticide; and

"(B) submit to the Administrator a copy of—

"(i) the label approved by the Pesticide Management Regulatory Agency for the Canadian pesticide; and

"(ii) the label approved by the Administrator for the comparable domestic pesticide.

"(4) CRITERIA FOR REGISTRATION.—The Administrator may register a Canadian pesticide under this subsection if the Administrator—

"(A) obtains the confidential statement of formula for the Canadian pesticide;

"(B) determines that the Canadian pesticide is identical or substantially similar in composition to a comparable domestic pesticide;

"(C) for each food or feed use authorized by the registration—

"(i) determines that there exists an adequate tolerance or exemption under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that permits the residues of the pesticide on the food or feed; and

"(ii) identifies the tolerances or exemptions in the notification submitted under subparagraph (E);

"(D) obtains a label approved by the Administrator that—

"(i) includes all statements, other than the establishment number, from the approved labeling of the comparable domestic pesticide that are relevant to the uses registered by the Administrator; and

"(ii) excludes all labeling statements relating to uses that are not registered by the Administrator; and

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

"(i) a description of the determination made under this paragraph; and

"(ii) a statement of the effective date of the registration;

"(5) LABELING OF CANADIAN PESTICIDES.—

"(A) IN GENERAL.—Each container containing a Canadian pesticide registered by the Administrator shall bear the label that is approved by the Administrator under this subsection.

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

"(C) ORIGINAL CANADIAN LABEL.—The original Canadian label on the container shall be preserved underneath the label approved by the Administrator.

"(D) PREPARATION AND USE OF LABELS.—After a Canadian pesticide is registered under this subsection, the registrant shall—

"(i) prepare labels approved by the Administrator for the Canadian pesticide; and

"(ii) conduct or supervise all labeling of the Canadian pesticide with the approved labeling.

"(E) REGISTERED ESTABLISHMENTS.—Labeling of a Canadian pesticide under this subsection shall be conducted at an establishment registered by the registrant under section 7.

"(6) REVOCATION.—

"(A) IN GENERAL.—After the registration of a Canadian pesticide, if the Administrator finds that the Canadian pesticide is not identical or substantially similar in composition to a comparable domestic pesticide, the Adminis-

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

"(B) TERMS OF ORDER.—The order—

"(i) shall be effective immediately;

"(ii) may prohibit the sale, distribution, and use of the Canadian pesticide in a State; and

"(iii) may require the registrant of the Canadian pesticide to purchase and dispose of any unopened product subject to the order.

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

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

"(E) JUDICIAL REVIEW.—If a hearing is requested on the order, judicial review may be sought only at the conclusion of the hearing on the order and following the issuance by the Administrator of a final revocation order.

"(F) PROCEDURE.—A final revocation order issued following a hearing shall be reviewable in accordance with section 16.

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

"(A) the Administrator acting as a registering agency under the authority of and consistent with this subsection for injury or damage resulting from the use of a product registered by the Administrator under this subsection; or

"(B) a registrant for damages resulting from adulteration or compositional alteration of a Canadian pesticide registered under this subsection if the registrant did not have and could not reasonably have obtained knowledge of the adulteration or compositional alteration.

"(8) PROVISION OF INFORMATION BY REGISTRANTS OF COMPARABLE DOMESTIC PESTICIDES.—

"(A) IN GENERAL.—On request by the Administrator the registrant of a comparable domestic pesticide shall provide to the Administrator that is seeking to register a Canadian

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

"(B) PENALTY FOR NONCOMPLIANCE.—

"(i) IN GENERAL.—If the registrant of a comparable domestic pesticide fails to provide to the Administrator, not later than 15 days after receipt of a written request by the Administrator, information possessed by or reasonably accessible to the registrant that is necessary to make the determinations required by paragraph (4), the Administrator may assess a penalty against the registrant of the comparable pesticide.

"(ii) AMOUNT.—The amount of the penalty shall be equal to the product obtained by multiplying—

"(I) the difference between the per-acre cost of the application of the comparable domestic pesticide and the application of the Canadian pesticide, as determined by the Administrator; and

"(II) the number of acres in the United States devoted to the commodity for which the registration is sought.

"(C) NOTICE AND OPPORTUNITY FOR HEARING.—No penalty under this paragraph shall be assessed unless the registrant is given notice and opportunity for a hearing in accordance with section 14(a)(3).

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

"(i) whether the registrant of the comparable domestic pesticide failed to timely provide to the Administrator the information possessed by or reasonably accessible to the registrant that was necessary to make the determinations required by paragraph (4); and

"(ii) the amount of the penalty.

"(9) PENALTY FOR DISCLOSURE.—

"(A) IN GENERAL.—The Administrator shall not make public information obtained under paragraph (8) that is privileged and confidential and contains or relates to trade secrets or commercial or financial information.

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

"(10) DATA COMPENSATION.—The Administrator and a person registering a Canadian pesticide under this subsection shall not be liable for compensation for data supporting the registration if the registration of the Canadian pesticide in Canada and the registration of the comparable domestic pesticide are held by the same registrant or by affiliated entities.

"(11) FORMULATION CHANGES.—

"(A) IN GENERAL.—The registrant of a comparable domestic pesticide shall notify the Administrator of any change in the formulation of a comparable domestic pesticide or a Canadian pesticide registered by the registrant or an affiliated entity not later than 30 days before any sale or distribution of the pesticide containing the new formulation.

"(B) STATEMENT OF FORMULA.—The registrant of the comparable domestic pesticide shall submit, with the notice required under

subparagraph (A), a confidential statement of the formula for the new formulation if the registrant has possession of or reasonable access to the information.

"(C) SUSPENSION OF REGISTRATION FOR NONCOMPLIANCE.—

"(i) IN GENERAL.—If the registrant fails to provide notice or submit a confidential statement of formula as required by this paragraph, the Administrator may issue a notice of intent to suspend the registration of the comparable domestic pesticide for a period of not less than 1 year.

"(ii) EFFECTIVE DATE.—The suspension shall become final not later than the end of the 30-day period beginning on the date of the issuance by the Administrator of the notice of intent to suspend the registration, unless during the period the registrant requests a hearing.

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

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

the registrant has failed to provide notice or submit a confidential statement of formula as required by this paragraph.''.

(b) TECHNICAL AND CONFORMING AMENDMENT.—The table of contents in section 1(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. prec. 121) is amended by adding at the end of the items relating 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.''.

(c) EFFECTIVE DATE.—This section and the amendments made by this section take effect 180 days after the date of enactment of this Act.

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