

104TH CONGRESS
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H. R. 1352

To amend the Federal Insecticide, Fungicide, and Rodenticide Act with respect to the minor use of a pesticide.

IN THE HOUSE OF REPRESENTATIVES

MARCH 29, 1995

Mr. DE LA GARZA (for himself, Mr. ROBERTS, Mr. EMERSON, Mr. CONDIT, Mr. STENHOLM, Mr. BOEHNER, Mrs. THURMAN, Mr. CANADY of Florida, Mr. ROSE, Mr. EWING, Mr. DOOLEY, and Mr. POMEROY) introduced the following bill; which was referred to the Committee on Agriculture

A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act with respect to the minor use of a 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. SHORT TITLE.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Minor Use Crop Protection Act of 1995”.

6 (b) REFERENCE.—Whenever in this Act an amend-
7 ment or repeal is expressed in terms of an amendment
8 to, or repeal of, a section or other provision, the reference
9 shall be considered to be made to a section or other provi-

1 sion of the Federal Insecticide, Fungicide, and
2 Rodenticide Act.

3 **SEC. 2. MINOR CROP PROTECTION.**

4 (a) DEFINITION.—Section 2 (7 U.S.C. 136) is
5 amended by adding at the end the following:

6 “(hh) MINOR USE.—The term ‘minor use’ means the
7 use of a pesticide on an animal, on a commercial agricul-
8 tural crop or site, or for the protection of public health
9 where—

10 “(1) the total United States acreage for the
11 crop is less than 300,000 acres; or

12 “(2) the Administrator, in consultation with the
13 Secretary of Agriculture, determines that, based on
14 information provided by an applicant for registration
15 or a registrant, the use does not provide sufficient
16 economic incentive to support the initial registration
17 or continuing registration of a pesticide for such use;
18 and—

19 “(A) there are insufficient efficacious alter-
20 native registered pesticides available for the
21 use; or

22 “(B) the alternatives to the pesticide pose
23 greater risks to the environment or human
24 health; or

1 “(C) the pesticide plays or will play, a sig-
2 nificant part in managing pest resistance; or

3 “(D) the pesticide plays or will play a sig-
4 nificant part in an integrated pest management
5 program.

6 The status as a minor use under this subsection
7 shall continue as long as the Administrator has not
8 determined that, based on existing data, such use
9 may cause an unreasonable adverse effect on the en-
10 vironment and the use otherwise qualifies for such
11 status.”.

12 (b) EXCLUSIVE USE OF MINOR USE PESTICIDES.—
13 Section 3(c)(1)(F) (7 U.S.C. 136a(c)(1)(F)) is amended
14 by redesignating clauses (ii) and (iii) as clauses (iii) and
15 (iv), respectively, and by inserting after clause (i) the fol-
16 lowing:

17 “(ii) The period of exclusive data use
18 for data submitted to support the applica-
19 tion for the original registration of a pes-
20 ticide under clause (i) shall be extended
21 one additional year for each 3 minor uses
22 registered after the date of enactment of
23 this clause and, before the expiration of
24 the period of exclusive use under this
25 clause, up to a total of 3 additional years

1 for all minor uses registered by the Admin-
2 istrator if the Administrator in consulta-
3 tion with the Secretary of Agriculture de-
4 termines that, based on information pro-
5 vided by an applicant for registration or a
6 registrant, that:

7 “(I) there are insufficient effica-
8 cious alternative registered pesticides
9 available for the use; or

10 “(II) the alternatives to the pes-
11 ticide pose greater risks to the envi-
12 ronment or human health; or

13 “(III) the pesticide plays or will
14 play a significant part in managing
15 pest resistance; or

16 “(IV) the pesticide plays or will
17 play a significant part in an inte-
18 grated pest management program.

19 The registration of a pesticide for a minor
20 use on a crop grouping established by the
21 Administrator shall be considered for pur-
22 poses of this clause one minor use for each
23 representative crop for which data are pro-
24 vided in the crop grouping. Any additional
25 exclusive use period under this clause shall

1 be modified as appropriate or terminated if
2 the registrant voluntarily cancels the prod-
3 uct or deletes from the registration the
4 minor uses which formed the basis for the
5 extension of the additional exclusive use
6 period or if the Administrator determines
7 that the registrant is not actually market-
8 ing the product for such minor uses.”.

9 (c) TIME EXTENSIONS FOR DEVELOPMENT OF
10 MINOR USE DATA.—

11 (1) DATA CALL-IN.—Subparagraph (B) of sec-
12 tion 3(c)(2) (7 U.S.C. 136a(c)(2)(B)) is amended by
13 adding at the end the following:

14 “(vi) Upon the request of a registrant
15 the Administrator shall, in the case of a
16 minor use, extend the deadline for the pro-
17 duction of residue chemistry data under
18 this subparagraph for data are required
19 solely to support that minor use until the
20 final deadline for submission of data under
21 section 4 for the other uses of the pesticide
22 established as of the date of enactment of
23 the Minor Use Crop Protection Amend-
24 ments of 1995, if—

1 “(I) the data to support other
2 uses of the pesticide on a food are
3 being provided;

4 “(II) the registrant, in submit-
5 ting a request for such an extension,
6 provides a schedule, including interim
7 dates to measure progress, to assure
8 that the data production will be com-
9 pleted before the expiration of the ex-
10 tension period;

11 “(III) the Administrator has de-
12 termined that such extension will not
13 significantly delay the Administrator’s
14 schedule for issuing a reregistration
15 eligibility determination required
16 under section 4; and

17 “(IV) the Administrator has de-
18 termined in writing that based on ex-
19 isting data, such extension would not
20 significantly increase the risk of any
21 unreasonable adverse effect on the en-
22 vironment.

23 If the Administrator grants an extension
24 under this clause, the Administrator shall
25 monitor the development of the data and

1 shall ensure that the registrant is meeting
2 the schedule for the production of the
3 data. If the Administrator determines that
4 the registrant is not meeting or has not
5 met the schedule for the production of
6 such data, the Administrator may proceed
7 in accordance with clause (iv) regarding
8 the continued registration of the affected
9 products with the minor use and shall in-
10 form the public of such action. Notwith-
11 standing the provisions of this clause, the
12 Administrator may take action to modify
13 or revoke the extension under this clause if
14 the Administrator determines that the ex-
15 tension for the minor use may cause an
16 unreasonable adverse effect on the environ-
17 ment. In such circumstance, the Adminis-
18 trator shall provide, in writing to the reg-
19 istrant, a notice revoking the extension of
20 time for submission of data. Such data
21 shall instead be due in accordance with the
22 date than established by the Administrator
23 for the submission of the data.”.

24 (2) REREGISTRATION.—Sections 4(d)(4)(B),
25 4(e)(2)(B), and 4(f)(2)(B) (7 U.S.C. 136a-

1 1(d)(4)(B), (e)(2)(B), and (f)(2)(B)) are each
2 amended by adding at the end the following: “Upon
3 the request of a registrant, the Administrator shall,
4 in the case of a minor use, extend the deadline for
5 the production of residue chemistry data under this
6 subparagraph for data required solely to support
7 that minor use until the final deadline for submis-
8 sion of data under this section for the other uses of
9 the pesticide established as of the date of enactment
10 of the Minor Use Crop Protection Amendments of
11 1995 if—

12 “(i) the data to support other uses of
13 the pesticide on a food are being provided;

14 “(ii) the registrant, in submitting a
15 request for such an extension provides a
16 schedule, including interim dates to meas-
17 ure progress, to assure that the data pro-
18 duction will be completed before the expi-
19 ration of the extension period;

20 “(iii) the Administrator has deter-
21 mined that such extension will not signifi-
22 cantly delay the Administrator’s schedule
23 for issuing a reregistration eligibility deter-
24 mination required under this section; and

1 “(iv) the Administrator has deter-
2 mined in writing that based on existing
3 data, such extension would not signifi-
4 cantly increase the risk of any unreason-
5 able adverse effect on the environment.

6 If the Administrator grants an extension under
7 this subparagraph, the Administrator shall
8 monitor the development of the data and shall
9 ensure that the registrant is meeting the sched-
10 ule for the production of the data. If the Ad-
11 ministrator determines that the registrant is
12 not meeting or has not met the schedule for the
13 production of such data, the Administrator may
14 proceed in accordance with clause (iv) of section
15 3(c)(2)(B) or other provisions of this section, as
16 appropriate, regarding the continued registra-
17 tion of the affected products with the minor use
18 and shall inform the public of such action. Not-
19 withstanding the provisions of this subpara-
20 graph, the Administrator may take action to
21 modify or revoke the extension under this sub-
22 paragraph if the Administrator determines that
23 the extension for the minor use may cause an
24 unreasonable adverse affect on the environment.
25 In such circumstance, the Administrator shall

1 provide, in writing to the registrant, a notice re-
2 voking the extension of time for submission of
3 data. Such data shall instead be due in accord-
4 ance with the date then established by the Ad-
5 ministrator for submission of the data.”.

6 (d) MINOR USE WAIVER.—Section 3(c)(2) (7 U.S.C.
7 136a(c)(2)) is amended—

8 (1) by inserting “IN GENERAL.—” after “(A)”,
9 by inserting “ADDITIONAL DATA.—” after “(B)”,
10 and by inserting “SIMPLIFIED PROCEDURES.—”
11 after “(C)”, and

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

13 “(E) MINOR USE WAIVER.—In handling
14 the registration of a pesticide for a minor use,
15 the Administrator may waive otherwise applica-
16 ble data requirements if the Administrator de-
17 termines that the absence of such data will not
18 prevent the Administrator from determining—

19 “(i) the incremental risk presented by
20 the minor use of the pesticide, and

21 “(ii) that such risk, if any, would not
22 be an unreasonable adverse effect on the
23 environment.”.

24 (e) EXPEDITING MINOR USE REGISTRATIONS.—Sec-
25 tion 3(c)(3) (7 U.S.C. 136a(c)(3)) is amended—

1 (1) by inserting after “(A)” the following: “IN
2 GENERAL.—”;

3 (2) by inserting after “(B)” the following:
4 “IDENTICAL OR SUBSTANTIALLY SIMILAR.—”; and

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

6 “(C) MINOR USE REGISTRATION.—

7 “(i) The Administrator shall, as expe-
8 ditiously as possible, review and act on any
9 complete application—

10 “(I) that proposes the initial reg-
11 istration of a new pesticide active in-
12 gredient if the active ingredient is
13 proposed to be registered solely for
14 minor uses, or proposes a registration
15 amendment solely for minor uses to
16 an existing registration, or

17 “(II) for a registration or a reg-
18 istration amendment that proposes
19 significant minor uses.

20 “(ii) For the purposes of clause (i)—

21 “(I) the term ‘as expeditiously as
22 possible’ means that the Adminis-
23 trator shall to the greatest extent
24 practicable complete a review and
25 evaluation of all data, submitted with

1 a complete application, within 12
2 months after the submission of the
3 complete application, and the failure
4 of the Administrator to complete such
5 a review and evaluation under clause
6 (i) shall not be subject to judicial re-
7 view, and

8 “(II) the term ‘significant minor
9 uses’ means 3 or more minor uses
10 proposed for every non-minor use, a
11 minor use that would, in the judgment
12 of the Administrator, serve as a re-
13 placement for any use which has been
14 canceled in the 5 years preceding the
15 receipt of the application, or a minor
16 use that in the opinion of the Admin-
17 istrator would avoid the reissuance of
18 an emergency exemption under section
19 18 for that minor use.

20 “(D) ADEQUATE TIME FOR SUBMISSION OF
21 MINOR USE DATA.—If a registrant makes a re-
22 quest for a minor use waiver, regarding data re-
23 quired by the Administrator, pursuant to para-
24 graph (2)(E), and if the Administrator denies
25 in whole or in part such data waiver request,

1 the registrant shall have a full time period for
2 providing such data. For purposes of this sub-
3 paragraph, the term ‘full time period’ means
4 the time period originally established by the Ad-
5 ministrator for submission of such data, begin-
6 ning with the date of receipt by the registrant
7 of the Administrator’s notice of denial.”.

8 (f) TEMPORARY EXTENSION OF REGISTRATION FOR
9 UNSUPPORTED MINOR USES.—

10 (1) REREGISTRATION.—

11 (A) Sections 4(d)(6) and 4(f)(3) (7 U.S.C.
12 136a–1(d)(6) and (f)(3)) are each amended by
13 adding at the end the following: “If the reg-
14 istrant does not commit to support a specific
15 minor use of the pesticide, but is supporting
16 and providing data in a timely and adequate
17 fashion to support uses of the pesticide on a
18 food, or if all uses of the pesticide are nonfood
19 uses and the registrant does not commit to sup-
20 port a specific minor use of the pesticide but is
21 supporting and providing data in a timely and
22 adequate fashion to support other nonfood uses
23 of the pesticide, the Administrator, at the writ-
24 ten request of the registrant, shall not take any
25 action pursuant to this paragraph in regard to

1 such unsupported minor use until the final
2 deadline established as of the date of enactment
3 of the Minor Use Crop Protection Amendments
4 of 1995, for the submission of data under this
5 section for the supported uses identified pursu-
6 ant to this paragraph unless the Administrator
7 determines that the absence of the data is sig-
8 nificant enough to cause human health or envi-
9 ronmental concerns. On such a determination
10 the Administrator may refuse the request for
11 extension by the registrant. Upon receipt of the
12 request from the registrant, the Administrator
13 shall publish in the Federal Register a notice of
14 the receipt of the request and the effective date
15 upon which the uses not being supported will be
16 voluntarily deleted from the registration pursu-
17 ant to section 6(f)(1). If the Administrator
18 grants an extension under this paragraph, the
19 Administrator shall monitor the development of
20 the data for the uses being supported and shall
21 ensure that the registrant is meeting the sched-
22 ule for the production of such data. If the Ad-
23 ministrator determines that the registrant is
24 not meeting or has not met the schedule for the
25 production of such data, the Administrator may

1 proceed in accordance with clause (iv) of section
2 3(c)(2)(B) regarding the continued registration
3 of the affected products with the minor and
4 other uses and shall inform the public of such
5 action in accordance with section 6(f)(2). Not-
6 withstanding the provision of this subpara-
7 graph, the Administrator may deny, modify, or
8 revoke the temporary extension under this para-
9 graph if the Administrator determines that the
10 continuation of the minor use may cause an un-
11 reasonable adverse effect on the environment.
12 In the event of modification or revocation the
13 Administrator shall provide, in writing, to the
14 registrant, a notice revoking the temporary ex-
15 tension and establish a new effective date by
16 which the minor use shall be deleted from the
17 registration.

18 (B) Section 4(e)(3)(A) (7 U.S.C. 136a-
19 (e)(3)(A)) is amended by adding at the end the
20 following: “If the registrant does not commit to
21 support a specific minor use of the pesticide,
22 but is supporting and providing data in a timely
23 and adequate fashion to support uses of the
24 pesticide on a food, or if all uses of the pes-
25 ticide are nonfood uses and the registrant does

1 not commit to support a specific minor use of
2 the pesticide but is supporting and providing
3 data in a timely and adequate fashion to sup-
4 port other nonfood uses of the pesticide, the
5 Administrator, at the written request of the
6 registrant, shall not take any action pursuant
7 to this subparagraph in regard to such unsup-
8 ported minor use until the final deadline estab-
9 lished as of the date of enactment of the Minor
10 Use Crop Protection Amendments of 1995, for
11 the submission of data under this section for
12 the supported uses identified pursuant to this
13 subparagraph unless the Administrator deter-
14 mines that the absence of the data is significant
15 enough to cause human health or environmental
16 concerns. On the basis of such determination
17 the Administrator may refuse the request for
18 extension by the registrant. Upon receipt of the
19 request from the registrant, the Administrator
20 shall publish in the Federal Register a notice
21 of the receipt of the request and the effective
22 date upon which the uses not being supported
23 will be voluntarily deleted from the registration
24 pursuant to section 6(f)(1). If the Adminis-
25 trator grants an extension under this subpara-

1 graph, the Administrator shall monitor the de-
2 velopment of the data for the uses being sup-
3 ported and shall ensure that the registrant is
4 meeting the schedule for the production of such
5 data. If the Administrator determines that the
6 registrant is not meeting or has not met the
7 schedule for the production of such data, the
8 Administrator may proceed in accordance with
9 clause (iv) of section 3(c)(2)(B) regarding the
10 continued registration of the affected products
11 with the minor and other uses and shall inform
12 the public of such action in accordance with
13 section 6(f)(2). Notwithstanding the provisions
14 of this subparagraph, the Administrator may
15 deny, modify, or revoke the temporary extension
16 under this subparagraph if the Administrator
17 determines that the continuation of the minor
18 use may cause an unreasonable adverse effect
19 on the environment. In the event of modifica-
20 tion or revocation, the Administrator shall pro-
21 vide, in writing, to the registrant, a notice re-
22 voking the temporary extension and establish a
23 new effective date by which the minor use shall
24 be deleted from the registration.

1 (2) DATA.—Section 3(c)(2)(B) (7 U.S.C.
2 136a(c)(2)(B)), as amended by subsection (c), is
3 further amended by adding at the end the following:

4 “(vii) If the registrant does not com-
5 mit to support a specific minor use of the
6 pesticide, but is supporting and providing
7 data in a timely and adequate fashion to
8 support uses of the pesticide on a food, or
9 if all uses of the pesticide are nonfood uses
10 and the registrant does not commit to sup-
11 port a specific minor use of the pesticide
12 but is supporting and providing data in a
13 timely and adequate fashion to support
14 other nonfood uses of the pesticide, the
15 Administrator, at the written request of
16 the registrant, shall not take any action
17 pursuant to this clause in regard to such
18 unsupported minor use until the final
19 deadline established as of the date of en-
20 actment of the Minor Use Crop Protection
21 Amendments of 1995, for the submission
22 of data under section 4 for the supported
23 uses identified pursuant to this clause un-
24 less the Administrator determines that the
25 absence of the data is significant enough to

1 cause human health or environmental con-
2 cerns. On the basis of such determination,
3 the Administrator may refuse the request
4 for extension by the registrant. Upon re-
5 ceipt of the request from the registrant,
6 the Administrator shall publish in the Fed-
7 eral Register a notice of the receipt of the
8 request and the effective date upon which
9 the uses not being supported will be volun-
10 tarily deleted from the registration pursu-
11 ant to section 6(f)(1). If the Administrator
12 grants an extension under this clause, the
13 Administrator shall monitor the develop-
14 ment of the data for the uses being sup-
15 ported and shall ensure that the registrant
16 is meeting the schedule for the production
17 of such data. If the Administrator deter-
18 mines that the registrant is not meeting or
19 has not met the schedule for the produc-
20 tion of such data, the Administrator may
21 proceed in accordance with clause (iv) of
22 this subparagraph regarding the continued
23 registration of the affected products with
24 the minor and other uses and shall inform
25 the public of such action in accordance

1 with section 6(f)(2). Notwithstanding the
2 provisions of this clause, the Administrator
3 may deny, modify, or revoke the temporary
4 extension under this subparagraph if the
5 Administrator determines that the continu-
6 ation of the minor use may cause an un-
7 reasonable adverse effect on the environ-
8 ment. In the event of modification or rev-
9 ocation, the Administrator shall provide, in
10 writing, to the registrant, a notice revoking
11 the temporary extension and establish a
12 new effective date by which the minor use
13 shall be deleted from the registration.

14 (g) UTILIZATION OF DATA FOR VOLUNTARILY CAN-
15 CELED CHEMICALS.—Section 6(f) (7 U.S.C. 136d) is
16 amended by adding at the end the following:

17 “(4) UTILIZATION OF DATA FOR VOLUNTARILY
18 CANCELED CHEMICALS.—When an application is
19 filed with the Administrator for the registration of
20 a pesticide for a minor use and another registrant
21 subsequently voluntarily cancels its registration for
22 an identical or substantially similar pesticide for an
23 identical or substantially similar use, the Adminis-
24 trator shall process, review, and evaluate the pend-
25 ing application as if the voluntary cancellation had

1 not yet taken place, except that the Administrator
2 shall not take such action if the Administrator deter-
3 mines that such minor use may cause an unreason-
4 able adverse effect on the environment. In order to
5 rely on this paragraph, the applicant must certify
6 that it agrees to satisfy any outstanding data re-
7 quirements necessary to support the reregistration of
8 the pesticide in accordance with the data submission
9 schedule established by the Administrator.”.

10 (h) ENVIRONMENTAL PROTECTION AGENCY MINOR
11 USE PROGRAM.—The Federal Insecticide, Fungicide, and
12 Rodenticide Act (7 U.S.C. 136 et seq.) is amended by re-
13 designating sections 30 and 31 as sections 32 and 33, re-
14 spectively and adding after section 29 the following:

15 **“SEC. 30. ENVIRONMENTAL PROTECTION AGENCY MINOR**
16 **USE PROGRAM.**

17 “The Administrator shall assure coordination of
18 minor use issues through the establishment of a minor use
19 program within the Office of Pesticide Programs. Such of-
20 fice shall be responsible for coordinating the development
21 of minor use programs and policies and consulting with
22 growers regarding minor use issues and registrations and
23 amendments which are submitted to the Environmental
24 Protection Agency.”.

1 (i) DEPARTMENT OF AGRICULTURE MINOR USE
2 PROGRAM.—The Federal Insecticide, Fungicide, and
3 Rodenticide Act (7 U.S.C. 136 et seq.), as amended by
4 subsection (h), is amended by adding after section 30 the
5 following:

6 **“SEC. 31. DEPARTMENT OF AGRICULTURE MINOR USE PRO-**
7 **GRAM.**

8 “(a) IN GENERAL.—The Secretary of Agriculture
9 (hereinafter in this section referred to as the ‘Secretary’)
10 shall ensure the coordination of the responsibilities of the
11 Department of Agriculture related to minor uses of pes-
12 ticides, including—

13 “(1) carrying out the Inter-Regional Project
14 Number 4 (IR-4) as described in section 2(e) of the
15 Act entitled ‘An Act to facilitate the work of the De-
16 partment of Agriculture, and for other purposes’ (7
17 U.S.C. 4501(e)) and the national pesticide resistance
18 monitoring program established under section 1651
19 of the Food, Agriculture, Conservation, and Trade
20 Act of 1990 (7 U.S.C. 5882);

21 “(2) supporting integrated pest management
22 research;

23 “(3) consulting with growers to develop data for
24 minor uses; and

1 “(4) providing assistance for minor use reg-
2 istrations, tolerances, and reregistrations with the
3 Environmental Protection Agency.

4 “(b) MATCHING FUND PROGRAM.—

5 “(1) ESTABLISHMENT.—The Secretary of Agri-
6 culture, in consultation with the Administrator, shall
7 establish and administer a minor use matching fund
8 program. The matching fund program shall be uti-
9 lized to ensure the continued availability of minor
10 use crop protection chemical, including the develop-
11 ment of data to support minor use pesticide registra-
12 tions and reregistrations. Access to the matching
13 fund program shall be available to any entity which
14 desires to develop data to support minor use reg-
15 istrations. Priority for access to the fund shall be
16 given those entities that do not directly receive funds
17 from the sale of products registered on minor uses.
18 Any entity that seeks such funding under this para-
19 graph shall be required to match such funds with an
20 equal amount of its own funds. Any data developed
21 through the matching fund program shall be jointly
22 owned by the Department of Agriculture and by the
23 entity that receives such funding. Any data devel-
24 oped under this subsection shall be subject to the
25 provisions of section 3(c)(1)(F). All compensation

1 received by the Department of Agriculture in return
2 for the use of such data under the matching fund
3 program shall be returned to a revolving fund which
4 will support the matching fund program.

5 “(2) AUTHORIZATION.—There is authorized to
6 be appropriated for the revolving fund for the
7 matching fund program an annual sum not to ex-
8 ceed \$10,000,000.”.

○