

3980

1 **SEC. 603. ENACTMENT OF CHRONIC WASTING DISEASE RE-**  
2 **SEARCH AND MANAGEMENT ACT.**

3 The provisions of H.R. 5608 of the 117th Congress,  
4 as engrossed in the House of Representatives on Decem-  
5 ber 8, 2021, are hereby enacted into law.

6 **TITLE VI—PESTICIDES**  
7 **Subtitle A—Pesticide Registration**  
8 **Improvement Act of 2022**

9 **SEC. 701. SHORT TITLE.**

10 This title may be cited as the “Pesticide Registration  
11 Improvement Act of 2022”.

12 **SEC. 702. BILINGUAL LABELING.**

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

16 “(5) BILINGUAL LABELING.—

17 “(A) REQUIREMENT.—

18 “(i) IN GENERAL.—Subject to clause  
19 (ii), not later than the applicable deadline  
20 described in subparagraph (B), each reg-  
21 istered pesticide product released for ship-  
22 ment shall include—

23 “(I) the translation of the parts  
24 of the labeling contained in the Span-  
25 ish Translation Guide described in

3981

1 subparagraph (G) on the product con-  
2 tainer; or

3 “(II) a link to such translation  
4 via scannable technology or other elec-  
5 tronic methods readily accessible on  
6 the product label.

7 “(ii) EXCEPTIONS.—Notwithstanding  
8 clause (i)—

9 “(I) an antimicrobial pesticide  
10 product may, in lieu of including a  
11 translation or a link under clause (i),  
12 provide a link to the safety data  
13 sheets in Spanish via scannable tech-  
14 nology or other electronic methods  
15 readily accessible on the product label;  
16 or

17 “(II) a non-agricultural pesticide  
18 product that is not classified by the  
19 Administrator as restricted use under  
20 subsection (d)(1)(A) may, in lieu of  
21 including a translation or a link under  
22 clause (i), provide a link to the safety  
23 data sheets in Spanish via scannable  
24 technology or other electronic methods  
25 readily accessible on the product label.

1                   “(B) DEADLINES FOR BILINGUAL LABEL-  
2                   ING.—

3                   “(i) PESTICIDE PRODUCTS CLASSI-  
4                   FIED AS RESTRICTED USE.—In the case of  
5                   pesticide products classified by the Admin-  
6                   istrator as restricted use under subsection  
7                   (d)(1)(A), the deadline specified in this  
8                   subparagraph is the date that is 3 years  
9                   following the date of enactment of this  
10                  paragraph.

11                  “(ii) PESTICIDE PRODUCTS NOT CLAS-  
12                  SIFIED AS RESTRICTED USE.—In the case  
13                  of pesticide products not classified by the  
14                  Administrator as restricted use under sub-  
15                  section (d)(1)(A), the deadline specified in  
16                  this subparagraph shall be as follows:

17                                 “(I) AGRICULTURAL.—

18   “(aa) ACUTE TOXICITY CAT-  
19   EGORY I.—For agricultural pes-  
20   ticides classified as Acute Tox-  
21   icity Category I, the date that is  
22   3 years after the date of enact-  
23   ment of this paragraph.

24   “(bb) ACUTE TOXICITY CAT-  
25   EGORY II.—For agricultural pes-

3983

1 pesticides classified as Acute Tox-  
2 icity Category II, the date that is  
3 5 years after the date of enact-  
4 ment of this paragraph.

5 “(II) ANTIMICROBIAL AND NON-  
6 AGRICULTURAL.—

7 “(aa) ACUTE TOXICITY CAT-  
8 EGORY I.—For antimicrobial and  
9 non-agricultural pesticide prod-  
10 ucts classified as Acute Toxicity  
11 Category I, the date that is 4  
12 years after the date of enactment  
13 of this paragraph.

14 “(bb) ACUTE TOXICITY CAT-  
15 EGORY II.—For antimicrobial  
16 and non-agricultural pesticide  
17 products classified as Acute Tox-  
18 icity Category II, the date that is  
19 6 years after the date of enact-  
20 ment of this paragraph.

21 “(III) OTHER PESTICIDE PROD-  
22 UCTS.—With respect to pesticide  
23 products not described in subclause  
24 (I) or (II), the date that is 8 years

3984

1 after the date of enactment of this  
2 paragraph.

3 “(C) IMPLEMENTATION.—

4 “(i) NON-NOTIFICATION.—

5 “(I) IN GENERAL.—In carrying  
6 out this paragraph, the Administrator  
7 shall allow translations of the parts of  
8 the label of a pesticide contained in  
9 the Spanish Translation Guide de-  
10 scribed in subparagraph (G) and  
11 scannable technology or other elec-  
12 tronic methods to be added using non-  
13 notification procedures.

14 “(II) NON-NOTIFICATION PROCE-  
15 DURE DEFINED.—In this clause, the  
16 term ‘non-notification procedure’ re-  
17 fers to a procedure under which a  
18 change may be made to a pesticide  
19 label without notifying the Adminis-  
20 trator.

21 “(ii) COOPERATION AND CONSULTA-  
22 TION.—In carrying out this paragraph, the  
23 Administrator shall cooperate and consult  
24 with State lead agencies for pesticide regu-  
25 lation for the purpose of implementing bi-

3985

1                   lingual labeling as provided in this para-  
2                   graph as expeditiously as possible.

3                   “(iii) END USE LABELING.—The la-  
4                   beling requirements of this paragraph shall  
5                   apply to end use product labels.

6                   “(iv) INCORPORATION TIMEFRAME.—  
7                   After initial translation deadlines provided  
8                   in subparagraph (B), updates to the Span-  
9                   ish Translation Guide described in sub-  
10                  paragraph (G) shall be incorporated into  
11                  labeling on the earlier of—

12                  “(I) in the case of agricultural  
13                  use pesticide labels, as determined by  
14                  the Administrator—

15                  “(aa) 1 year after the date  
16                  of publication of the updated  
17                  Spanish Label Translation Guide  
18                  described in subparagraph (G);  
19                  or

20                  “(bb) the released for ship-  
21                  ment date specified on the EPA  
22                  Stamped Approved Label after  
23                  the pesticide label is next  
24                  changed or amended following  
25                  the date of publication of the up-

3986

1 dated Spanish Label Translation  
2 Guide described in subparagraph  
3 (G); and

4 “(II) in the case of antimicrobial  
5 and non-agricultural use pesticide la-  
6 bels, as determined by the Adminis-  
7 trator—

8 “(aa) 2 years after the date  
9 of publication of the updated  
10 Spanish Label Translation Guide  
11 described in subparagraph (G);  
12 or

13 “(bb) the released for ship-  
14 ment date specified on the EPA  
15 Stamped Approved Label after  
16 the pesticide label is next  
17 changed or amended following  
18 the date of publication of the up-  
19 dated Spanish Label Translation  
20 Guide described in subparagraph  
21 (G).

22 “(v) NOTIFICATION OF UPDATES TO  
23 THE SPANISH TRANSLATION GUIDE FOR  
24 PESTICIDE LABELING.—Not later than 10  
25 days after updating the Spanish Trans-

3987

1           lation Guide described in subparagraph  
2           (G), the Administrator shall notify reg-  
3           istrants of the update to such guide.

4           “(D) ACCESSIBILITY OF BILINGUAL LA-  
5           BELING FOR FARM WORKERS.—Not later than  
6           180 days after the date of enactment of this  
7           paragraph, to the maximum extent practicable,  
8           the Administrator shall seek stakeholder input  
9           on ways to make bilingual labeling required  
10          under this paragraph accessible to farm work-  
11          ers.

12          “(E) PLAN.—Not later than 3 years after  
13          the date of enactment of this paragraph, the  
14          Administrator shall implement a plan to ensure  
15          that farm workers have access to the bilingual  
16          labeling required under this paragraph.

17          “(F) REPORTING.—Not later than 2 years  
18          after the date of enactment of this paragraph,  
19          the Administrator shall develop and implement,  
20          and make publicly available, a plan for tracking  
21          the adoption of the bilingual labeling required  
22          under this paragraph.

23          “(G) SPANISH TRANSLATION GUIDE DE-  
24          SCRIBED.—The Spanish Translation Guide de-  
25          scribed in this subparagraph is the Spanish

3988

1 Translation Guide for Pesticide Labeling issued  
2 in October 2019, as in effect on the date of en-  
3 actment of the Pesticide Registration Improve-  
4 ment Act of 2022, and any successor guides or  
5 amendments to such guide.”.

6 **SEC. 703. EXTENSION AND MODIFICATION OF MAINTENANCE FEE AUTHORITY.**  
7

8 (a) **EXTENSION AND MODIFICATION OF MAINTENANCE FEE AUTHORITY.**—Section 4(i) of the Federal In-  
9 secticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a-  
10 1(i)) is amended—  
11

12 (1) in paragraph (1)—

13 (A) in subparagraph (C), by striking  
14 “2023” and inserting “2022, and \$42,000,000  
15 for each of fiscal years 2023 through 2027”;

16 (B) in subparagraph (D)—

17 (i) in clause (i), by striking “2023”  
18 and inserting “2022, and \$172,000 for  
19 each of fiscal years 2023 through 2027”;  
20 and

21 (ii) in clause (ii), by striking “2023”  
22 and inserting “2022, and \$277,200 for  
23 each of fiscal years 2023 through 2027”;

24 (C) in subparagraph (E)(i)—

3989

1 (i) in subclause (I), by striking  
2 “2023” and inserting “2022, and  
3 \$105,000 for each of fiscal years 2023  
4 through 2027”; and

5 (ii) in subclause (II), by striking  
6 “2023” and inserting “2022, and  
7 \$184,800 for each of fiscal years 2023  
8 through 2027”;

9 (D) by redesignating subparagraphs (G),  
10 (H), and (I) as subparagraphs (L), (M), and  
11 (N);

12 (E) by inserting after subparagraph (F)  
13 the following:

14 “(G) FARM WORKER TRAINING AND EDU-  
15 CATION GRANTS.—

16 “(i) SET-ASIDE.—In addition to  
17 amounts otherwise available, for fiscal  
18 years 2023 through 2027, the Adminis-  
19 trator shall use not more than \$7,500,000  
20 of the amounts collected under this para-  
21 graph to provide grants to organizations  
22 described in clause (ii) for purposes of fa-  
23 cilitating—

24 “(I) training of farm workers;

3990

1 “(II) education of farm workers  
2 with respect to—

3 “(aa) rights of farm workers  
4 relating to pesticide safety; and

5 “(bb) the worker protection  
6 standard under part 170 of title  
7 40, Code of Federal Regulations  
8 (or successor regulations);

9 “(III) the development of new in-  
10 formational materials;

11 “(IV) the development of training  
12 modules; and

13 “(V) the development of innova-  
14 tive methods of delivery of such infor-  
15 mational materials and training mod-  
16 ules.

17 “(ii) ELIGIBILITY.—To be eligible to  
18 receive a grant under this subparagraph,  
19 an organization shall have demonstrated  
20 experience in—

21 “(I) providing training and edu-  
22 cation services for farm workers or  
23 handlers of pesticides; or

3991

1                   “(II) developing informational  
2 materials for farm workers or han-  
3 dlers of pesticides.

4                   “(iii) COMMUNITY-BASED ORGANIZA-  
5 TIONS.—

6                   “(I) COMMUNITY-BASED NON-  
7 PROFIT FARM WORKER ORGANIZATION  
8 GRANTS.—The Administrator shall  
9 use funds available under clause (i) to  
10 provide grants to community-based  
11 non-profit farm worker organizations.

12                   “(II) APPLICATION OF FUNDS.—  
13 The Administrator shall apply the  
14 unspent balance of funds available (up  
15 to \$1,800,000) under clause (i) in fis-  
16 cal years 2025 through 2027 to carry  
17 out subclause (I).

18                   “(iv) INTERIM FUNDING.—In addition  
19 to amounts otherwise available, the Admin-  
20 istrator may use not more than \$1,200,000  
21 in fiscal years 2023 and 2024 to fund ex-  
22 isting cooperative agreements that were  
23 authorized under section 33(c)(3)(B), as  
24 such section was in effect as of March 8,  
25 2019.

3992

1           “(v) PARTNERSHIPS.—Organizations  
2           described in clause (ii) may apply for a  
3           grant under this subparagraph as a part-  
4           nership with another organization, pro-  
5           vided such organizations, at the time of  
6           application, have entered into an agree-  
7           ment designating—

8                   “(I) a member of the partnership  
9                   that will enter into the assistance  
10                  agreement with the Environmental  
11                  Protection Agency for the purposes of  
12                  accountability for the proper expendi-  
13                  ture of Federal funds;

14                  “(II) performance of the assist-  
15                  ance agreement;

16                  “(III) liability for claims for re-  
17                  covery of unallowable costs incurred  
18                  under the agreement; and

19                  “(IV) specifying roles in per-  
20                  forming the proposed scope of work  
21                  for the assistance agreement.

22           “(H) HEALTH CARE PROVIDER TRAIN-  
23           ING.—

24                   “(i) SET-ASIDE.—In addition to other  
25                   amounts available, for the period of fiscal

3993

1 years 2023 through 2027, the Adminis-  
2 trator shall use not more than \$2,500,000  
3 of the amounts collected under this para-  
4 graph to provide grants to nonprofit orga-  
5 nizations described in clause (ii) for pur-  
6 poses of facilitating—

7 “(I) technical assistance and  
8 training of health care providers relat-  
9 ing to the recognition, treatment, and  
10 management of pesticide-related inju-  
11 ries and illnesses;

12 “(II) the development of informa-  
13 tional materials for technical assist-  
14 ance and training described in sub-  
15 clause (I); and

16 “(III) the development of out-  
17 reach and delivery methods relating to  
18 the recognition, treatment, and man-  
19 agement of pesticide-related illnesses.

20 “(ii) ELIGIBILITY.—To be eligible to  
21 receive a grant under this subparagraph, a  
22 nonprofit organization shall have dem-  
23 onstrated experience in providing technical  
24 assistance and training to health care pro-  
25 viders who serve farm worker populations.

3994

1           “(iii) PARTNERSHIPS.—Organizations  
2           described in clause (ii) may apply for a  
3           grant under this subparagraph as a part-  
4           nership with another organization, pro-  
5           vided such organizations, at the time of  
6           application, have entered into an agree-  
7           ment designating—

8                   “(I) a member of the partnership  
9                   that will enter into the assistance  
10                  agreement with the Environmental  
11                  Protection Agency for the purposes of  
12                  accountability for the proper expendi-  
13                  ture of Federal funds;

14                  “(II) performance of the assist-  
15                  ance agreement;

16                  “(III) liability for claims for re-  
17                  covery of unallowable costs incurred  
18                  under the agreement; and

19                  “(IV) roles in performing the  
20                  proposed scope of work for the assist-  
21                  ance agreement.

22           “(I) PARTNERSHIP GRANTS.—In addition  
23           to funds otherwise available, for each of fiscal  
24           years 2023 through 2027, the Administrator  
25           shall use not more than \$500,000 of the

3995

1 amounts collected under this paragraph for  
2 partnership grants.

3 “(J) PESTICIDE SAFETY EDUCATION PRO-  
4 GRAM.—In addition to amounts otherwise avail-  
5 able, for each of fiscal years 2023 through  
6 2027, the Administrator shall use not more  
7 than \$500,000 of the amounts collected under  
8 this paragraph to carry out the pesticide safety  
9 education program.

10 “(K) TECHNICAL ASSISTANCE TO GRANT-  
11 EES.—

12 “(i) SET-ASIDE.—In addition to other  
13 amounts available, for fiscal years 2023  
14 through 2027, the Administrator shall use  
15 not more than \$1,750,000 of the amounts  
16 collected under this paragraph to provide  
17 grants to nonprofit organizations, subject  
18 to such conditions as the Administrator es-  
19 tablishes to prevent conflicts of interest, to  
20 provide easily accessible technical assist-  
21 ance to grantees receiving, and potential  
22 grantees applying for, grants under sub-  
23 paragraphs (G) and (H).

24 “(ii) CONSIDERATIONS.—In evalu-  
25 ating requests for grants under this sub-

3996

1 paragraph, the Administrator shall con-  
2 sider, at a minimum, the extent to which—

3 “(I) the organization applying for  
4 the grant has experience providing  
5 technical assistance to farm worker or  
6 clinician-training organizations; and

7 “(II) the proposed project would  
8 make specific technical assistance  
9 available to organizations seeking in-  
10 formation and assistance con-  
11 cerning—

12 “(aa) the grant application  
13 process;

14 “(bb) the drafting of grant  
15 applications; and

16 “(cc) compliance with grant  
17 management and reporting re-  
18 quirements.

19 “(iii) NO SUITABLE ORGANIZATION.—  
20 If no suitable organization requests a  
21 grant under this subparagraph, the Admin-  
22 istrator shall provide technical assistance  
23 described in clause (i) using the amounts  
24 made available by that clause.

## 3997

1                   “(iv) STAKEHOLDER INPUT.—In for-  
2                   mulating requests for proposals for grants  
3                   under subparagraphs (G) and (H) for a  
4                   fiscal year, the Administrator shall solicit  
5                   and consider, in an open and transparent  
6                   manner that does not provide a competitive  
7                   advantage to any person or persons, input  
8                   from persons who conduct farm worker  
9                   education and training, or technical assist-  
10                  ance and training of clinicians, regarding  
11                  the request for proposals.”; and

12                  (F) in subparagraph (N) (as so redesign-  
13                  ated), by striking “2023” and inserting  
14                  “2027”; and

15                  (2) in paragraph (2)—

16                         (A) by striking “section 33(b)(3)” and in-  
17                         serting “section 33(b)(3)(B)”; and

18                         (B) by striking “the Pesticide Registration  
19                         Improvement Extension Act of 2018 and ending  
20                         on September 30, 2025” and inserting “the  
21                         Pesticide Registration Improvement Act of  
22                         2022 and ending on September 30, 2029”.

23                  (b) EXTENSION OF PROHIBITION ON TOLERANCE  
24                  FEES.—Section 408(m)(3) of the Federal Food, Drug,  
25                  and Cosmetic Act (21 U.S.C. 346a(m)(3)) is amended by

3998

1 striking “the Pesticide Registration Improvement Renewal  
2 Act and ending on September 30, 2023” and inserting  
3 “the Pesticide Registration Improvement Act of 2022 and  
4 ending on September 30, 2027”.

5 **SEC. 704. REREGISTRATION AND EXPEDITED PROCESSING**  
6 **FUND.**

7 Section 4(k) of the Federal Insecticide, Fungicide,  
8 and Rodenticide Act (7 U.S.C. 136a–1(k)) is amended—

9 (1) in paragraph (2)(A), in the first sentence,  
10 by inserting “including, to the maximum extent  
11 practicable, during periods in which Environmental  
12 Protection Agency employees are on shutdown or  
13 emergency furlough as a result of a lapse in appro-  
14 priations,” after “limitation,”;

15 (2) by striking paragraphs (3) and (4) and in-  
16 serting the following:

17 “(3) REVIEW OF REGISTRANT SUBMISSIONS  
18 NOT COVERED BY SECTION 33(B)(3)(B).—

19 “(A) DEFINITION OF SUBMISSION NOT  
20 COVERED BY SECTION 33(B)(3)(B).—In this  
21 paragraph, the term ‘submission not covered by  
22 section 33(b)(3)(B)’ means any submission filed  
23 by a registrant with the Administrator relating  
24 to a registration that is not covered by a fee  
25 table under section 33(b)(3)(B).

3999

1 “(B) SET-ASIDE.—

2 “(i) IN GENERAL.—In addition to  
3 amounts otherwise available for each of fis-  
4 cal years 2023 through 2027, the Adminis-  
5 trator shall use approximately  $\frac{1}{8}$  of the  
6 amounts made available to the Adminis-  
7 trator in the Reregistration and Expedited  
8 Processing Fund for the activities de-  
9 scribed in clause (ii).

10 “(ii) ACTIVITIES.—In addition to  
11 amounts otherwise available, the Adminis-  
12 trator shall use amounts made available  
13 under clause (i) to obtain sufficient per-  
14 sonnel and resources to process submis-  
15 sions not covered by section 33(b)(3)(B) to  
16 meet the applicable deadlines described  
17 in—

18 “(I) the notice of the Adminis-  
19 trator entitled ‘Pesticide Registration  
20 Notice (PR) 98–10: Notifications,  
21 Non-Notifications and Minor Formu-  
22 lation Amendments’ and dated Octo-  
23 ber 22, 1998 (and any successor  
24 amendments to such notice); and

4000

1 “(II) subsections (c)(3)(B) and  
2 (h) of section 3.

3 “(4) DEVELOPMENT OF PUBLIC HEALTH PER-  
4 FORMANCE STANDARDS FOR ANTIMICROBIAL PES-  
5 TICIDE DEVICES.—

6 “(A) SET-ASIDE.—In addition to amounts  
7 otherwise available, for each of fiscal years  
8 2023 through 2027, the Administrator shall use  
9 not more than \$500,000 of the amounts made  
10 available to the Administrator in the Rereg-  
11 istration and Expedited Processing Fund for  
12 the activities described in subparagraph (B).

13 “(B) ANTIMICROBIAL PESTICIDE DE-  
14 VICES.—The Administrator shall use amounts  
15 made available under subparagraph (A) to de-  
16 velop efficacy test methods for antimicrobial  
17 pesticide devices making public health claims.”;

18 (3) in paragraph (5)(A), by striking “2018  
19 through 2023” and inserting “2023 through 2027”;

20 (4) by redesignating paragraphs (6) and (7) as  
21 paragraphs (9) and (10), respectively;

22 (5) by inserting after paragraph (5) the fol-  
23 lowing:

24 “(6) AGENCY TRAINING AND STAFF.—

## 4001

1           “(A) SET-ASIDE.—In addition to amounts  
2 otherwise available, for each of fiscal years  
3 2023 through 2027, the Administrator shall use  
4 not more than \$500,000 of the amounts made  
5 available to the Administrator in the Rereg-  
6 istration and Expedited Processing Fund for  
7 the activities described in subparagraph (B).

8           “(B) ACTIVITIES.—The Administrator  
9 shall use amounts made available under sub-  
10 paragraph (A) to carry out the following activi-  
11 ties:

12                   “(i) TRAINING FOR AGENCY EMPLOY-  
13 EES.—The Administrator shall administer  
14 training and education programs for em-  
15 ployees of the Environmental Protection  
16 Agency, relating to the regulatory respon-  
17 sibilities and policies established by this  
18 Act, including programs—

19                           “(I) for improving the scientific,  
20 technical, and administrative skills of  
21 officers and employees authorized to  
22 administer programs under this Act;

23                           “(II) to align competencies iden-  
24 tified by the Administrator for mis-  
25 sion accomplishment;

4002

1                   “(III) for addressing best prac-  
2                   tices for operational performance and  
3                   improvement;

4                   “(IV) for improving administra-  
5                   tive processes and procedures and ad-  
6                   dressing efficiency issues;

7                   “(V) to promote consistent regu-  
8                   latory decision-making; and

9                   “(VI) for educating registrants  
10                  and regulated stakeholders on regu-  
11                  latory procedures.

12                  “(ii) AGREEMENTS WITH INSTITU-  
13                  TIONS OF HIGHER EDUCATION.—Not later  
14                  than 1 year, to the maximum extent prac-  
15                  ticable, after the date of enactment of the  
16                  Pesticide Registration Improvement Act of  
17                  2022, the Administrator shall establish a  
18                  competitive grant program to develop  
19                  training curricula and programs in accord-  
20                  ance with clause (i) through financial as-  
21                  sistance agreements with 1 or more of the  
22                  following institutions of higher education:

23                  “(I) Non-land-grant colleges of  
24                  agriculture (as defined in section  
25                  1404 of the National Agricultural Re-

4003

1 search, Extension, and Teaching Pol-  
2 icy Act of 1977 (7 U.S.C. 3103)).

3 “(II) Land-grant colleges and  
4 universities (as defined in section  
5 1404 of the National Agricultural Re-  
6 search, Extension, and Teaching Pol-  
7 icy Act of 1977 (7 U.S.C. 3103)).

8 “(III) 1994 Institutions (as de-  
9 fined in section 532 of the Equity in  
10 Educational Land-Grant Status Act  
11 of 1994 (7 U.S.C. 301 note; Public  
12 Law 103–382)).

13 “(7) VECTOR EXPEDITED REVIEW VOUCH-  
14 ERS.—

15 “(A) SET-ASIDE.—In addition to amounts  
16 otherwise available, for each of fiscal years  
17 2023 through 2027, the Administrator shall use  
18 not more than \$500,000 of the amounts made  
19 available to the Administrator in the Rereg-  
20 istration and Expedited Processing Fund to es-  
21 tablish and carry out the Vector Expedited Re-  
22 view Voucher program in accordance with sub-  
23 paragraph (B).

24 “(B) VECTOR EXPEDITED REVIEW VOUCH-  
25 ER PROGRAM.—

4004

1                   “(i) DEFINITIONS.—In this subpara-  
2 graph:

3                   “(I) PROGRAM.—The term ‘pro-  
4 gram’ means the Vector Expedited  
5 Review Voucher program established  
6 under clause (ii).

7                   “(II) VOUCHER.—The term  
8 ‘voucher’ means a voucher—

9                   “(aa) issued under the pro-  
10 gram by the Administrator to a  
11 pesticide registration applicant  
12 that entitles the holder to an ex-  
13 pedited review described under  
14 clause (vi) of a single different  
15 pesticide registration action; and

16                   “(bb) the entitlement to  
17 which may be transferred (in-  
18 cluding by sale) by the holder of  
19 the voucher, without limitation  
20 on the number of times the  
21 voucher may be transferred, be-  
22 fore the voucher is redeemed.

23                   “(ii) ESTABLISHMENT.—Not later  
24 than one year after the date of enactment  
25 of the Pesticide Registration Improvement

4005

1 Act of 2022, the Administrator, acting  
2 though the Office of Pesticide Programs,  
3 shall establish a program to be known as  
4 the Vector Expedited Review Voucher pro-  
5 gram.

6 “(iii) PURPOSE.—The purpose of the  
7 program is to incentivize the development  
8 of new insecticides to control and prevent  
9 the spread of vector borne disease by expe-  
10 diting reviews by decreasing decision re-  
11 view times provided in section 33(b)(3)(B).

12 “(iv) ISSUANCE OF VOUCHERS.—

13 “(I) IN GENERAL.—For each of  
14 fiscal years 2023 through 2027, the  
15 Administrator shall issue a voucher to  
16 a pesticide registration applicant for a  
17 new active ingredient if the applicant  
18 submits and has successfully reg-  
19 istered a mosquito-control product  
20 that—

21 “(aa) demonstrates a proven  
22 efficacy against pyrethroid or  
23 other insecticide-resistant mos-  
24 quitoes;

4006

1                   “(bb) prevents, mitigates,  
2 destroys, or repels pyrethroid or  
3 other insecticide-resistant mos-  
4 quitoes, with a novel or unique  
5 mechanism or mode of action,  
6 different from other insecticides  
7 already registered by the Admin-  
8 istrator for mosquito control;

9                   “(cc) targets mosquitoes ca-  
10 pable of spreading such diseases  
11 as Malaria, Dengue, Zika,  
12 Chikungunya, St. Louis enceph-  
13 alitis, Eastern encephalitis, West-  
14 ern encephalitis, West Nile en-  
15 cephalitis, Cache Valley enceph-  
16 alitis, LaCrosse encephalitis, and  
17 Yellow Fever;

18                   “(dd) the registrant has  
19 submitted a global access plan  
20 that will be made publicly avail-  
21 able for the active ingredient and  
22 that includes—

23                   “(AA) manufacturing  
24 locations, including any li-

4007

1 censed third-party manufac-  
2 turers;

3 “(BB) distribution and  
4 procurement processes for  
5 malaria vector control pro-  
6 grams in selected countries;  
7 and

8 “(CC) the prices for  
9 common quantities of the  
10 product;

11 “(ee) meets the appropriate  
12 guidelines as being effective in  
13 the primary vector control inter-  
14 vention areas, including insecti-  
15 cide-treated nets and indoor re-  
16 sidual spray;

17 “(ff) is made accessible for  
18 use in—

19 “(AA) the United  
20 States, including territories  
21 or possessions of the United  
22 States; and

23 “(BB) countries where  
24 mosquito-borne diseases,

4008

1                   such as malaria, are preva-  
2                   lent;

3                   “(gg) meets registration re-  
4                   quirements for human health and  
5                   environmental effects, labeling,  
6                   and presents no unreasonable ad-  
7                   verse effects to the environment;

8                   “(hh) broadens the adoption  
9                   of integrated pest management  
10                  strategies, such as insecticide re-  
11                  sistance management, or makes  
12                  those strategies more effective;

13                  “(ii) is not contained in any  
14                  pesticide product registered by  
15                  the Administrator as of the date  
16                  of the enactment of the Pesticide  
17                  Registration Improvement Act of  
18                  2022; or

19                  “(jj) does not contain as at-  
20                  tested to by the registrant, an ac-  
21                  tive ingredient approved in the 2-  
22                  year period preceding the date of  
23                  registration by any global strin-  
24                  gent regulatory authority for the

4009

1 same uses, vectors, and applica-  
2 tions.

3 “(II) MOSQUITO VECTOR PRI-  
4 ORITY.—For each of fiscal years 2023  
5 through 2027, the focus of the pro-  
6 gram shall be to incentivize the devel-  
7 opment of insecticides to control and  
8 prevent the spread of mosquitoes  
9 bearing diseases described in sub-  
10 clause (I)(cc).

11 “(III) EXCEPTION.—If the Ad-  
12 ministrator determines that there is a  
13 significant public health benefit, an  
14 active ingredient that is registered for  
15 agricultural use that is repurposed  
16 and submitted for control of mosqui-  
17 toes and that otherwise meets the re-  
18 quirements of subclause (I) (excluding  
19 items (bb) and (jj)) as determined  
20 necessary by the Administrator, shall  
21 be considered a mosquito control  
22 product meeting the criteria specified  
23 in such subclause.

24 “(IV) ELIGIBILITY CRITERIA  
25 MODIFICATIONS.—

4010

1                   “(aa) IN GENERAL.—Begin-  
2                   ning in fiscal year 2028, the Ad-  
3                   ministrator shall review the pro-  
4                   gram and recommend—

5                   “(AA) modifications to  
6                   the requirements described  
7                   in subclause (I); and

8                   “(BB) additional vec-  
9                   tors to be included in the  
10                  program, prioritizing vectors  
11                  that pose the most signifi-  
12                  cant population health risks.

13                  “(bb) PUBLIC INVOLVE-  
14                  MENT.—In carrying out item  
15                  (aa), the Administrator shall so-  
16                  licit the involvement of reg-  
17                  istrants, nongovernmental organi-  
18                  zations, and governmental agen-  
19                  cies engaged in vector-borne dis-  
20                  ease mitigation and treatment.

21                  “(v) REDEMPTION OF VOUCHERS.—

22                  To redeem a voucher, the holder shall—

23                  “(I) notify the Administrator of  
24                  the intent of the holder to submit a  
25                  pesticide application with a voucher

4011

1 for expedited review not less than 90  
2 days before the submission of the ap-  
3 plication; and

4 “(II) pay the applicable registra-  
5 tion service fee under section 33(b).

6 “(vi) EXPEDITED REVIEW.—On re-  
7 demption of a voucher, in furtherance of  
8 the purpose described in clause (iii), the  
9 Administrator shall expedite decision re-  
10 view times as follows:

11 “(I) 6 months less than the deci-  
12 sion review time for Category R010,  
13 New Active Ingredient, Food use.

14 “(II) 6 months less than the de-  
15 cision review time for Category R020,  
16 New Active Ingredient, Food use; re-  
17 duced risk.

18 “(III) 6 months less than the de-  
19 cision review time for Category R060,  
20 New Active Ingredient, Non-food use;  
21 outdoor.

22 “(IV) 6 months less than the de-  
23 cision review time for Category R110,  
24 New Active Ingredient, Non-food use;  
25 indoor.

4012

1                   “(V) 4 months less than the deci-  
2                   sion review time for Category R070,  
3                   New Active Ingredient, Non-food use;  
4                   outdoor; reduced risk.

5                   “(VI) 2 months less than the de-  
6                   cision review time for Category R120,  
7                   New Active Ingredient, Non-food use;  
8                   indoor; reduced risk.

9                   “(vii) REPORTS.—Not later than Sep-  
10                  tember 30, 2025, and not later than Sep-  
11                  tember 30 of each year thereafter, the Ad-  
12                  ministrators shall issue a report on the pro-  
13                  gram, including—

14                   “(I) the number of submissions  
15                   seeking a voucher;

16                   “(II) the total time in review for  
17                   each such submission;

18                   “(III) the number of such vouch-  
19                   ers awarded;

20                   “(IV) the number of such vouch-  
21                   ers redeemed; and

22                   “(V) with respect to each such  
23                   redeemed voucher—

24                   “(aa) the decision review  
25                   time for the pesticide application

4013

1 for which the voucher was re-  
2 deemed; and

3 “(bb) the average standard  
4 decision review time for the ap-  
5 plicable pesticide category.

6 “(C) UNUSED AMOUNTS.—Any unused  
7 amounts made available under this paragraph  
8 at the end of each fiscal year shall be made  
9 available to the Administrator to carry out  
10 other activities for which amounts in the Rereg-  
11 istration and Expedited Processing Fund are  
12 authorized to be used.

13 “(8) PESTICIDE SURVEILLANCE PROGRAM.—In  
14 addition to amounts otherwise available, for each of  
15 fiscal years 2023 through 2027, the Administrator  
16 shall use not more than \$500,000 of the amounts  
17 made available to the Administrator in the Rereg-  
18 istration and Expedited Processing Fund to support  
19 the interagency agreement with the National Insti-  
20 tute for Occupational Safety and Health to support  
21 the Sentinel Event Notification System for Occupa-  
22 tional Risk pesticides program—

23 “(A) with a goal of increasing the number  
24 of participating States, prioritizing expansion in

1 States with the highest numbers of agricultural  
2 workers; and

3 “(B) to improve reporting by participating  
4 States.”; and

5 (6) in paragraph (10) (as so redesignated), in  
6 the first sentence, by striking “(2), (3), (4), and  
7 (5)” and inserting “(2) through (8)”.

8 **SEC. 705. PESTICIDE REGISTRATION SERVICE FEES.**

9 (a) EXTENSION AND MODIFICATION OF FEE AU-  
10 THORITY.—

11 (1) IN GENERAL.—Section 33(b) of the Federal  
12 Insecticide, Fungicide, and Rodenticide Act (7  
13 U.S.C. 136w–8(b)) is amended—

14 (A) in paragraph (2)(E)(iii), by striking  
15 “after review” and inserting “on completion of,  
16 where appropriate, the initial screening of the  
17 contents of the application or the preliminary  
18 technical screening”;

19 (B) by striking “paragraph (3)” each place  
20 it appears and inserting “paragraph (3)(B)”;

21 (C) in paragraph (3), by striking “Subject  
22 to paragraph (6),” and inserting the following:

23 “(A) DATA EVALUATION RECORDS.—At  
24 the decision review time under a fee table speci-  
25 fied in subparagraph (B) or as agreed upon

4015

1 under subsection (f)(5), for each covered appli-  
2 cation under a fee table specified in such sub-  
3 paragraph (B), the Administrator shall—

4 “(i) complete data evaluation records  
5 for studies submitted by the applicant in  
6 support of the application; and

7 “(ii) release those data evaluation  
8 records to the applicant, using appropriate  
9 protections for confidential business infor-  
10 mation.

11 “(B) SCHEDULE, ACTIONS, AND FEES.—  
12 Subject to paragraph (6),”;

13 (D) in paragraph (6)—

14 (i) by amending subparagraph (A) to  
15 read as follows: “Subject to the following  
16 sentence, effective for a covered application  
17 received during the period beginning on  
18 October 1, 2024, and ending on September  
19 30, 2026, the Administrator may increase  
20 by 5 percent the registration service fee  
21 payable for the application under para-  
22 graph (3). No adjustment may be made  
23 under the preceding sentence until the date  
24 on which the Administrator begins to im-

4016

1           plement clauses (i) and (ii) of subsection  
2           (k)(2)(A).”; and

3                   (ii) by amending subparagraph (B) to  
4           read as follows: “Subject to the following  
5           sentence, effective for a covered application  
6           received on or after October 1, 2026, the  
7           Administrator may increase by an addi-  
8           tional 5 percent the registration service fee  
9           in effect as of September 30, 2026. No ad-  
10          justment may be made under the preceding  
11          sentence until the date on which the Ad-  
12          ministrator begins to implement any rec-  
13          ommendations for process improvements  
14          contained in the report under subsection  
15          (c)(4), as appropriate.”; and

16                   (E) in paragraph (7)(A), by striking  
17          “(commonly referred to as a Gold Seal letter)”  
18          and inserting “(including a Gold Seal letter and  
19          a Certificate of Establishment)”.

20          (2) CONFORMING AMENDMENT.—Section 33 of  
21          the Federal Insecticide, Fungicide, and Rodenticide  
22          Act (7 U.S.C. 136w–8) is amended by striking “sub-  
23          section (b)(3)” each place it appears and inserting  
24          “subsection (b)(3)(B)”.

4017

1 (b) PESTICIDE REGISTRATION FUND.—Section 33(c)  
2 of the Federal Insecticide, Fungicide, and Rodenticide Act  
3 (7 U.S.C. 136w–8(c)) is amended—

4 (1) in paragraph (3), by striking subparagraph  
5 (B) and inserting the following:

6 “(B) ENDANGERED SPECIES REVIEW OF  
7 OUTDOOR USE OF PESTICIDE PRODUCTS.—

8 “(i) IN GENERAL.—The Administrator  
9 shall use the amounts made available in  
10 the Fund to develop, receive comments  
11 with respect to, and finalize, guidance to  
12 registrants regarding analysis necessary to  
13 support the review of outdoor uses of pes-  
14 ticide products under the Endangered Spe-  
15 cies Act of 1973 (16 U.S.C. 1531 et seq.).

16 “(ii) DEADLINES FOR GUIDANCE.—  
17 The Administrator shall issue final guid-  
18 ance required by clause (i) in accordance  
19 with the following:

20 “(I) With respect to new active  
21 ingredients or any registration review  
22 decision proposed for 1 or more out-  
23 door uses, not later than 9 months  
24 after the date of enactment of the

4018

1 Pesticide Registration Improvement  
2 Act of 2022.

3 “(II) With respect to new out-  
4 door uses of a registered pesticide, not  
5 later than 1 year after the date of en-  
6 actment of the Pesticide Registration  
7 Improvement Act of 2022.

8 “(III) With respect to anti-  
9 microbial pesticide products, not later  
10 than 3 years after the date of enact-  
11 ment of the Pesticide Registration Im-  
12 provement Act of 2022.

13 “(C) INDEPENDENT THIRD PARTY ASSESS-  
14 MENTS.—

15 “(i) IN GENERAL.—The Administrator  
16 shall use the amounts made available in  
17 the Fund to carry out the activities de-  
18 scribed in clauses (ii) and (iii).

19 “(ii) WORKFORCE ASSESSMENT.—

20 “(I) IN GENERAL.—The Admin-  
21 istrator shall procure a competitive  
22 contract with a qualified, independent  
23 contractor with expertise in assessing  
24 public sector workforce data analysis  
25 and reporting to conduct an assess-

4019

1                   ment of current methodologies and  
2                   data or metrics available to represent  
3                   the workforce implementing the Pes-  
4                   ticide Registration Improvement Act  
5                   of 2022 and the amendments made by  
6                   that Act, including an assessment of  
7                   filled and vacant positions and full-  
8                   time equivalent employees relating to  
9                   that implementation.

10                   “(II) REPORT.—Not later than 2  
11                   years after the date of enactment of  
12                   the Pesticide Registration Improve-  
13                   ment Act of 2022—

14                   “(aa) the contractor selected  
15                   under subclause (I) shall submit  
16                   to the Administrator a report de-  
17                   scribing—

18                   “(AA) the findings  
19                   from the assessment under  
20                   that subclause; and

21                   “(BB) recommenda-  
22                   tions for improved meth-  
23                   odologies to represent full-  
24                   time equivalent resources de-

4020

1                   scribed in that subclause;

2                   and

3                   “(bb) the Administrator  
4 shall publish the report sub-  
5 mitted under item (aa) on the  
6 website of the Environmental  
7 Protection Agency.

8                   “(iii) PROCESS ASSESSMENT.—

9                   “(I) IN GENERAL.—

10                   “(aa) CONTRACTS.—Within  
11 1 year of the date of enactment  
12 of the Pesticide Registration Im-  
13 provement Act of 2022, to the  
14 extent practicable, the Adminis-  
15 trator shall issue a competitive  
16 contract to a private, inde-  
17 pendent consulting firm—

18                   “(AA) to conduct the  
19 assessment described in sub-  
20 clause (II); and

21                   “(BB) to submit to the  
22 Administrator a report de-  
23 scribing the findings of the  
24 assessment and the proc-  
25 esses and performance of

4021

1 the Environmental Protec-  
2 tion Agency relating to the  
3 implementation of the Pes-  
4 ticide Registration Improve-  
5 ment Act of 2022 and the  
6 amendments made by that  
7 Act.

8 “(bb) ELIGIBILITY.—The  
9 firm described in item (aa) shall  
10 be capable of performing the  
11 technical analysis, management  
12 assessment, and program evalua-  
13 tion tasks required to address the  
14 scope of the assessment under  
15 subclause (II).

16 “(II) ASSESSMENT.—

17 “(aa) IN GENERAL.—The  
18 Administrator, applicants, and  
19 registrants shall participate in a  
20 targeted assessment of the proc-  
21 ess for the review of applications  
22 submitted under this Act.

23 “(bb) CONSULTATION.—The  
24 firm selected under subclause (I)  
25 shall consult with the Adminis-

4022

1 trator and applicants at the start  
2 of the assessment under item  
3 (aa) and prior to submission of  
4 the report under subclause  
5 (I)(aa)(BB).

6 “(cc) REQUIREMENTS.—The  
7 assessment under item (aa) shall  
8 evaluate and make recommenda-  
9 tions regarding—

10 “(AA) the initial con-  
11 tent screen;

12 “(BB) the preliminary  
13 technical screen;

14 “(CC) performance,  
15 processes, and progress to-  
16 ward reducing renegotiation  
17 rates and the average length  
18 of renegotiations;

19 “(DD) performance,  
20 processes, and progress to-  
21 ward eliminating the backlog  
22 of registrant submissions  
23 not covered by subsection  
24 (b)(3);

4023

1                   “(EE) performance,  
2 processes, and progress to-  
3 ward ensuring that all reg-  
4 istrant submissions not cov-  
5 ered by subsection (b)(3) are  
6 completed by the applicable  
7 deadlines described in the  
8 notice of the Administrator  
9 entitled ‘Pesticide Registra-  
10 tion Notice (PR) 98–10: No-  
11 tifications, Non-Notifications  
12 and Minor Formulation  
13 Amendments’ and dated Oc-  
14 tober 22, 1998 (and any  
15 successor amendments to  
16 that notice) and described in  
17 subsections (c)(3)(B) and  
18 (h) of section 3;

19                   “(FF) compliance with  
20 the provisions of this Act re-  
21 lating to renegotiations and  
22 registrant submissions not  
23 covered by subsection (b)(3);

24                   “(GG) information  
25 technology systems;

4024

1                   “(HH) recommended  
2                   improvements to employee  
3                   training;

4                   “(II) performance,  
5                   progress, and processes in  
6                   completing registration re-  
7                   view; and

8                   “(JJ) other appropriate  
9                   issues, such as submissions  
10                  by inert suppliers and fast-  
11                  track amendments under  
12                  subsections (c)(3)(B) and  
13                  (h) of section 3.

14                  “(III) REPORT TO CONGRESS.—  
15                  Not later than 1 year after the receipt  
16                  of an assessment required under this  
17                  section, the Administrator shall sub-  
18                  mit to the Committee on Agriculture,  
19                  Nutrition, and Forestry of the Senate  
20                  and the Committee on Agriculture of  
21                  the House of Representatives—

22                         “(aa) a copy of each such  
23                         assessment; and

24                         “(bb) the Administrator’s  
25                         evaluation of the findings and

4025

1 recommendations contained in  
2 each such assessment.

3 “(IV) RECOMMENDATIONS.—The  
4 Administrator shall include with the  
5 report submitted under subclause  
6 (III) a classification of each rec-  
7 ommendation described in the report  
8 as—

9 “(aa) can be implemented  
10 through administrative action of  
11 the Administrator; or

12 “(bb) requires a statutory  
13 change.”; and

14 (2) in paragraph (4)—

15 (A) in subparagraph (A), by striking  
16 “and” at the end;

17 (B) by redesignating subparagraph (B) as  
18 subparagraph (C); and

19 (C) by inserting after subparagraph (A)  
20 the following:

21 “(B) shall be available during periods in  
22 which Environmental Protection Agency em-  
23 ployees are on shutdown or emergency furlough  
24 as a result of a lapse in appropriations; and”.

1 (c) ASSESSMENT OF FEES.—Section 33(d)(2) of the  
2 Federal Insecticide, Fungicide, and Rodenticide Act (7  
3 U.S.C. 136w–8(d)(2)) is amended—

4 (1) by striking “(as in existence in fiscal year  
5 2012)”; and

6 (2) by striking “the amount of appropriations  
7 for covered functions for fiscal year 2012 (excluding  
8 the amount of any fees appropriated for the fiscal  
9 year).” and inserting “\$166,000,000.”.

10 (d) REFORMS TO REDUCE DECISION TIME REVIEW  
11 PERIODS AND PREVENT DOUBLE PAYMENT OF REG-  
12 ISTRATION FEES.—Section 33(e) of the Federal Insecti-  
13 cide, Fungicide, and Rodenticide Act (7 U.S.C. 136w–  
14 8(e)) is amended—

15 (1) by striking the subsection designation and  
16 heading and all that follows through “To the max-  
17 imum” and inserting the following:

18 “(e) REFORMS TO REDUCE DECISION TIME REVIEW  
19 PERIODS AND PREVENT DOUBLE PAYMENT OF REG-  
20 ISTRATION FEES.—

21 “(1) REDUCTION OF DECISION TIME REVIEW  
22 PERIODS.—To the maximum”; and

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

24 “(2) PREVENTION OF DOUBLE PAYMENT OF  
25 REGISTRATION SERVICE FEES.—The Administrator

1 shall develop and implement a process to determine  
2 the appropriate fee category or categories for an ap-  
3 plication that qualifies for more than one fee cat-  
4 egory in order to assist applicants and prevent un-  
5 necessary payment of fees for multiple categories for  
6 a single application.”.

7 (e) DECISION TIME REVIEW PERIODS.—Section  
8 33(f) of the Federal Insecticide, Fungicide, and  
9 Rodenticide Act (7 U.S.C. 136w–8(f)) is amended—

10 (1) in paragraph (1), by striking “Pesticide  
11 Registration Improvement Extension Act of 2018”  
12 and inserting “Pesticide Registration Improvement  
13 Act of 2022”;

14 (2) in paragraph (4)—

15 (A) in subparagraph (B)—

16 (i) in clause (i), by adding at the end  
17 the following:

18 “(III) FINAL FEE CATEGORY.—

19 The fee category of a covered applica-  
20 tion or other actions may not be  
21 changed, without providing the infor-  
22 mation to the applicant, after comple-  
23 tion of the preliminary technical  
24 screening described in clause (iv).”;

4028

1 (ii) in clause (iii), in the matter pre-  
2 ceding subclause (I), by inserting “auto-  
3 mate the process, to the maximum extent  
4 practicable, and” before “determine”; and  
5 (iii) in clause (iv)—

6 (I) in the matter preceding sub-  
7 clause (I), by striking “shall deter-  
8 mine if—” and inserting “shall—”;

9 (II) in subclause (I)—

10 (aa) by inserting “determine  
11 if” before “the application and”;  
12 and

13 (bb) by striking “and” at  
14 the end;

15 (III) in subclause (II)—

16 (aa) by inserting “determine  
17 if” before “the application,  
18 data,”; and

19 (bb) by striking the period  
20 at the end and inserting a semi-  
21 colon; and

22 (IV) by adding at the end the fol-  
23 lowing:

24 “(III) determine, if applicable,  
25 whether an application qualifies for a

4029

1 reduced risk determination under sub-  
2 section (c)(10) or (h) of section 3;

3 “(IV) grant or deny any data  
4 waiver requests submitted by the ap-  
5 plicant with the application;

6 “(V) verify and validate the accu-  
7 racy of the fee category selected by  
8 the applicant; and

9 “(VI) notify the applicant, in  
10 writing, if a new or different fee cat-  
11 egory is required and calculate the  
12 new decision review time based on the  
13 original submission date.”; and

14 (B) by striking subparagraph (E) and in-  
15 serting the following:

16 “(E) APPLICATIONS FOR REDUCED  
17 RISK.—

18 “(i) FEE.—If an application for a re-  
19 duced risk new active ingredient or a re-  
20 duced risk new use is determined not to  
21 qualify as reduced risk, the applicant shall  
22 pay the difference in fee for the cor-  
23 responding non-reduced risk application.

24 “(ii) DECISION REVIEW TIME PE-  
25 RIOD.—After receipt by the Administrator

4030

1 of the original covered reduced risk appli-  
2 cation and fee, the decision time review pe-  
3 riod for the corresponding non-reduced  
4 risk application shall begin within the time  
5 periods described in subparagraph (A),  
6 based on the submission date of the origi-  
7 nal covered reduced risk application.”; and

8 (3) by striking paragraph (5) and inserting the  
9 following:

10 “(5) EXTENSION OF DECISION TIME REVIEW  
11 PERIOD.—

12 “(A) NOTIFICATION.—If the Administrator  
13 cannot meet a decision time review period under  
14 this subsection, the Administrator shall notify  
15 the applicant, in writing, of—

16 “(i) the reasons why additional time is  
17 needed; and

18 “(ii) the number of days needed that  
19 would allow the Administrator to make a  
20 regulatory decision.

21 “(B) EXTENSION BY NEGOTIATION OR MU-  
22 TUAL AGREEMENT.—The Administrator, acting  
23 solely through the Director of the Office of Pes-  
24 ticide Programs, and the applicant may mutu-

4031

1           ally agree, in writing, to extend a decision time  
2           review period under this subsection if—

3                   “(i) there is new or additional data or  
4                   information from the applicant that is nec-  
5                   essary for the Administrator to make a de-  
6                   cision on the application that cannot be  
7                   made available within the original decision  
8                   time review period; or

9                   “(ii) a public comment period associ-  
10                  ated with the application generates signifi-  
11                  cant comments that cannot be addressed  
12                  within the original decision time review pe-  
13                  riod.

14                  “(C) PRIORITY.—Once a decision time re-  
15                  view period for a covered action described in  
16                  subsection (b)(3)(B) is missed or extended, the  
17                  Administrator shall make any action on the ap-  
18                  plication a priority.”.

19           (f) REPORTS AND INFORMATION TECHNOLOGY.—  
20   Section 33 of the Federal Insecticide, Fungicide, and  
21   Rodenticide Act (7 U.S.C. 136w–8) is amended by strik-  
22   ing subsection (k) and inserting the following:

23           “(k) REPORTS AND INFORMATION TECHNOLOGY.—

24                   “(1) REPORTS.—

4032

1           “(A) IN GENERAL.—Not later than 120  
2 days after the last day of each of fiscal years  
3 2023 through 2027, the Administrator shall  
4 publish an annual report describing—

5                   “(i) actions taken under this section;

6                   “(ii) registrant submissions not cov-  
7 ered by subsection (b)(3)(B);

8                   “(iii) the initial content and prelimi-  
9 nary technical screenings required in sub-  
10 section (f)(4)(B); and

11                   “(iv) staffing relating to implementing  
12 the Pesticide Registration Improvement  
13 Act of 2022 and the amendments made by  
14 that Act.

15           “(B) CONTENTS.—Each report published  
16 under subparagraph (A) shall include a sum-  
17 mary of the following information:

18                   “(i) ACTIONS UNDER THIS SEC-  
19 TION.—To the extent practicable, data for  
20 each action taken under this section that is  
21 completed during the fiscal year covered by  
22 the report or pending at the conclusion of  
23 that fiscal year, organized by registering  
24 division, including—

25                   “(I) the Action Code;

4033

1 “(II) the application receipt date;

2 “(III) the electronic portal track-  
3 ing number assigned to the applica-  
4 tion at the time of submission to the  
5 electronic submission portal or the  
6 Environmental Protection Agency  
7 tracking number;

8 “(IV) the original decision due  
9 date based on the Action Code;

10 “(V) the dates of any renegoti-  
11 ations and the renegotiated due dates,  
12 if applicable;

13 “(VI) the reasons for each re-  
14 negotiation, if applicable;

15 “(VII) if the submission had to  
16 be recoded, reassigned codes, if appli-  
17 cable;

18 “(VIII) the date that the submis-  
19 sion was recoded, if applicable;

20 “(IX) the decision completion  
21 date, if the action has been completed;

22 “(X) the status of the action,  
23 which may be—

24 “(aa) failed initial content  
25 screen;

4034

1                   “(bb) failed preliminary  
2                   technical screen;

3                   “(cc) approved;

4                   “(dd) withdrawn;

5                   “(ee) denied;

6                   “(ff) do not grant; or

7                   “(gg) pending;

8                   “(XI) the reason for any denial  
9                   or do not grant decision, if applicable;

10                  “(XII) a review of the progress  
11                  made in carrying out each require-  
12                  ment of subsections (e) and (f), in-  
13                  cluding, to the extent determined ap-  
14                  propriate by the Administrator and  
15                  consistent with the authorities of the  
16                  Administrator and limitations on dele-  
17                  gation of functions by the Adminis-  
18                  trator, recommendations for the allow-  
19                  ance and use of summaries of acute  
20                  toxicity studies;

21                  “(XIII) a review of the progress  
22                  in carrying out section 3(g), includ-  
23                  ing—

24                               “(aa) the number of pes-  
25                               ticides or pesticide cases reviewed

4035

1 and the number of registration  
2 review decisions completed, in-  
3 cluding—

4 “(AA) the number of  
5 cases cancelled;

6 “(BB) the number of  
7 cases requiring risk mitiga-  
8 tion measures;

9 “(CC) the number of  
10 cases removing risk mitiga-  
11 tion measures;

12 “(DD) the number of  
13 cases with no risk mitigation  
14 needed; and

15 “(EE) the number of  
16 cases in which risk mitiga-  
17 tion has been fully imple-  
18 mented;

19 “(XIV) a review of the progress  
20 made toward implementing enhance-  
21 ments to—

22 “(aa) the electronic tracking  
23 of conditional registrations; and

24 “(bb) the endangered species  
25 database;

4036

1           “(XV) a review of the progress  
2           made in updating the Pesticide Inci-  
3           dent Data System, including progress  
4           toward making the information con-  
5           tained in the System available to the  
6           public (as the Administrator deter-  
7           mines is appropriate);

8           “(XVI) an assessment of the  
9           public availability of summary pes-  
10          ticide usage data;

11          “(XVII) the number of the active  
12          ingredients approved, new uses, and  
13          pesticide end use products granted in  
14          connection with the Design for the  
15          Environment program (or any suc-  
16          cessor program) of the Environmental  
17          Protection Agency;

18          “(XVIII) with respect to funds in  
19          the Reregistration and Expedited  
20          Processing Fund described under sec-  
21          tion 4(k), a review that includes—

22                  “(aa) a description of the  
23                  amount and use of such funds—

24                          “(AA) to carry out ac-  
25                          tivities relating to worker

4037

1 protection under subpara-  
2 graphs (G) and (H) of sec-  
3 tion 4(i)(1);

4 “(BB) to award part-  
5 nership grants under sub-  
6 paragraph (I) of such sec-  
7 tion; and

8 “(CC) to carry out the  
9 pesticide safety education  
10 program under subpara-  
11 graph (J) of such section;

12 “(bb) an evaluation of the  
13 appropriateness and effectiveness  
14 of the activities, grants, and pro-  
15 gram under subparagraphs (G),  
16 (H), (I), and (J) of such section;

17 “(cc) a description of how  
18 stakeholders are engaged in the  
19 decision to fund such activities,  
20 grants, and program in accord-  
21 ance with the stakeholder input  
22 provided under such subpara-  
23 graphs; and

24 “(dd) with respect to activi-  
25 ties relating to worker protection

4038

1 carried out under subparagraphs  
2 (G) and (H) of section 4(i)(1), a  
3 summary of the analyses from  
4 stakeholders, including from  
5 worker community-based organi-  
6 zations, on the appropriateness  
7 and effectiveness of such activi-  
8 ties.

9 “(XIX) beginning two years after  
10 enactment, report on the progress of  
11 meeting the deadlines listed in para-  
12 graph (5) of section 3(f); and

13 “(XX) a review of progress made  
14 in implementing the pesticide surveil-  
15 lance program referred to in para-  
16 graph (8) of section 4(k).

17 “(ii) REGISTRANT SUBMISSIONS NOT  
18 COVERED BY SECTION 33(B)(3)(B).—Each  
19 registrant submission not covered by sub-  
20 section (b)(3)(B), that is completed during  
21 the fiscal year covered by the report or  
22 pending at the conclusion of that fiscal  
23 year, organized by registering division, in-  
24 cluding—

25 “(I) the submission date;

4039

1                   “(II) the electronic portal track-  
2                   ing number assigned to the applica-  
3                   tion at the time of the submission of  
4                   the application to the electronic sub-  
5                   mission portal;

6                   “(III) the type of regulatory ac-  
7                   tion, as defined by statute or guidance  
8                   document, and the specific label ac-  
9                   tion;

10                   “(IV) the status of the action;

11                   “(V) the due date;

12                   “(VI) the reason for the outcome;

13                   and

14                   “(VII) the completion date, if ap-  
15                   plicable.

16                   “(iii) SCREENING PROCESS.—Data for  
17                   the initial content screens and preliminary  
18                   technical screens that are completed during  
19                   the fiscal year covered by the report or  
20                   pending at the conclusion of that fiscal  
21                   year, organized by registering division, in-  
22                   cluding—

23                   “(I) the number of applications  
24                   successfully passing each type of  
25                   screen;

4040

1           “(II) the number of applications  
2           that failed the screening process for  
3           each type of screen;

4           “(III) the number of notifications  
5           issued by the Administrator under  
6           subsection (f)(4)(B)(ii)(II);

7           “(IV) the number of notifications  
8           issued by the Administrator under  
9           subsection (f)(4)(B)(ii)(I) and the  
10          number of applications resulting in a  
11          rejection; and

12          “(V) the number of notifications  
13          issued under section 152.105 of title  
14          40, Code of Federal Regulations (or  
15          successor regulations), and to the ex-  
16          tent practicable, the reasons for that  
17          issuance.

18          “(iv) STAFFING.—Data on the staff-  
19          ing relating to work covered under the Pes-  
20          ticide Registration Improvement Act of  
21          2022 and the amendments made by that  
22          Act, organized by registering division, in-  
23          cluding—

24                 “(I) the number of new hires and  
25                 personnel departures;

4041

1                   “(II) the number of full-time  
2                   equivalents at the end of each fiscal  
3                   year;

4                   “(III) the number of full-time  
5                   equivalents working on registration  
6                   review activities; and

7                   “(IV) the number of full-time  
8                   equivalents working on registrant sub-  
9                   missions not covered by subsection  
10                  (b)(3)(B).

11                  “(C) PUBLICATION.—The Administrator  
12                  shall publish each report under subparagraph  
13                  (A)—

14                   “(i) on the website of the Environ-  
15                   mental Protection Agency; and

16                   “(ii) by such other methods as the  
17                   Administrator determines to be the most  
18                   effective for efficiently disseminating the  
19                   report.

20                  “(2) INFORMATION TECHNOLOGY.—

21                   “(A) SYSTEM.—Not later than 1 year after  
22                   the date of enactment of the Pesticide Registra-  
23                   tion Improvement Act of 2022, the Adminis-  
24                   trator shall establish an information technology  
25                   system that—

4042

1 “(i) includes all registering divisions  
2 in the Office of Pesticide Programs;

3 “(ii) provides a real-time, accurate,  
4 tracking system for all regulatory submis-  
5 sions to the Office of Pesticide Programs;

6 “(iii) provides a real-time, accessible  
7 information that provides each applicant  
8 confidential, online access to the status  
9 and progress of the regulatory submissions  
10 of the applicant; and

11 “(iv) updates the electronic submis-  
12 sion portal—

13 “(I) to ensure that label reviews  
14 are limited to current label changes,  
15 to the maximum extent practicable;

16 “(II) to automate, to the extent  
17 practicable, minor, low risk regulatory  
18 actions; and

19 “(III) to allow self-certification of  
20 certain regulatory actions, as deter-  
21 mined by the Administrator.

22 “(B) ACCESS TO REGISTRATION DATA AND  
23 DECISIONS.—The Administrator shall imple-  
24 ment efforts to expand existing, and develop  
25 new, information technology tools and data-

1 bases to improve access by Environmental Pro-  
2 tection Agency employees to data used to fulfill  
3 registrations, and public access to information  
4 about regulatory decisionmaking tools, includ-  
5 ing opportunities for—

6 “(i) analysis of the impact of sub-  
7 mitted studies on Environmental Protec-  
8 tion Agency assessments and decisions;

9 “(ii) facilitation of read-across or  
10 computational model development to help  
11 fill information gaps;

12 “(iii) tracking and reporting submis-  
13 sion and decision metrics relating to the  
14 use and acceptance of test methods; and

15 “(iv) drafting and publication of poli-  
16 cies communicating Environmental Protec-  
17 tion Agency acceptance of novel tech-  
18 nologies or approaches.”.

19 (g) TERMINATION OF EFFECTIVENESS.—Section  
20 33(m) of the Federal Insecticide, Fungicide, and  
21 Rodenticide Act (7 U.S.C. 136w–8(m)) is amended—

22 (1) by striking “2023” each place it appears  
23 and inserting “2027”; and

24 (2) in paragraph (2)—

25 (A) in subparagraph (A)—

4044

1 (i) in the subparagraph heading, by  
2 striking “2024” and inserting “2028” ; and

3 (ii) by striking “2024” and inserting  
4 “2028”; and

5 (B) in each of subparagraphs (B) and  
6 (C)—

7 (i) in the subparagraph heading, by  
8 striking “2025” each place it appears and  
9 inserting “2029”; and

10 (ii) by striking “2025” each place it  
11 appears and inserting “2029”.

12 **SEC. 706. REVISION OF TABLES REGARDING COVERED PES-**  
13 **TICIDE REGISTRATION APPLICATIONS AND**  
14 **OTHER COVERED ACTIONS AND THEIR COR-**  
15 **RESPONDING REGISTRATION SERVICE FEES.**

16 Section 33(b)(3) of the Federal Insecticide, Fun-  
17 gicide, and Rodenticide Act (7 U.S.C. 136w-8(b)(3)) (as  
18 amended by section 705(a)(1)(C)) is amended by striking  
19 subparagraph (B) and inserting the following:

20 “(B) SCHEDULE, ACTIONS, AND FEES.—

21 Subject to paragraph (6), the schedule of reg-  
22 istration applications and other covered actions  
23 and their corresponding registration service fees  
24 shall be as follows:

4045

“TABLE 1. — REGISTRATION DIVISION (RD) — NEW ACTIVE INGREDIENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R010	1	New Active Ingredient, Food use. (2) (3)	36	1,079,356
R020	2	New Active Ingredient, Food use; reduced risk. (2) (3)	27	899,464
R040	3	New Active Ingredient, Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3) (4)	18	662,883
R060	4	New Active Ingredient, Non-food use; outdoor. (2) (3)	30	749,886
R070	5	New Active Ingredient, Non-food use; outdoor; reduced risk. (2) (3)	24	624,905

4046

“TABLE 1. — REGISTRATION DIVISION (RD) — NEW ACTIVE INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R090	6	New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3) (4)	16	463,930
R110	7	New Active Ingredient, Non-food use; indoor. (2) (3) (4)	20	417,069
R120	8	New Active Ingredient, Non-food use; indoor; reduced risk. (2) (3) (4)	14	347,556
R121	9	New Active Ingredient, Non-food use; indoor; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3) (4)	18	261,322

4047

“TABLE 1. — REGISTRATION DIVISION (RD) — NEW ACTIVE INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R122	10	Enriched isomer(s) of registered mixed-isomer active ingredient. (2) (3)	27	454,526
R123	11	New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; non-food use, not requiring a tolerance. (2) (3)	27	676,296
R126	12 (new)	New Active Ingredient, Seed treatment only; limited uptake into raw agricultural commodities; use requiring a tolerance. (2) (3)	31	743,925

4048

“TABLE 1. — REGISTRATION DIVISION (RD) — NEW ACTIVE INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R125	13	New Active Ingredient, Seed treatment; Experimental Use Permit application; submitted before application for registration; credit 45% of fee toward new active ingredient application that follows. (3) (4)	16	463,930

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant’s initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

## 4049

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

“TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R130	14	First food use; indoor; food/food handling. (2) (3) (5)	23	274,388
R140	15	Additional food use; Indoor; food/food handling. (3) (4) (5)	17	64,028
R150	16	First food use. (2) (3) (5)	23	454,490
R155	17	First food use, Experimental Use Permit application; active ingredient registered for non-food use. (3) (4) (5)	21	378,742

## 4050

“TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R160	18	First food use; reduced risk. (2) (3) (5)	18	378,742
R170	19	Additional food use. (3) (4) (5)	17	113,728
R175	20	Additional food uses covered within a crop group resulting from the conversion of existing approved crop group(s) to one or more revised crop groups. (3) (4) (5)	14	94,774
R180	21	Additional food use; reduced risk. (3) (4) (5)	12	94,774
R190	22	Additional food uses; 6 or more submitted in one application. (3) (4) (5)	17	682,357
R200	23	Additional Food Use; 6 or more submitted in one application; Reduced Risk. (3) (4) (5)	12	568,632

## 4051

“TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R210	24	Additional food use; Experimental Use Permit application; establish temporary tolerance; no credit toward new use registration. (3) (4) (5)	12	70,210
R220	25	Additional food use; Experimental Use Permit application; crop destruct basis; no credit toward new use registration. (3) (4) (5)	6	28,434
R230	26	Additional use; non-food; outdoor. (3) (4) (5)	16	45,453
R240	27	Additional use; non-food; outdoor; reduced risk. (3) (4) (5)	10	37,878
R250	28	Additional use; non-food; outdoor; Experimental Use Permit application; no credit toward new use registration. (3) (4) (5)	6	28,434

4052

“TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R251	29	Experimental Use Permit application which requires no changes to the tolerance(s); non-crop destruct basis. (3) (5)	8	28,434
R260	30	New use; non-food; indoor. (3) (4) (5)	12	21,954
R270	31	New use; non-food; indoor; reduced risk. (3) (4) (5)	9	18,296
R271	32	New use; non-food; indoor; Experimental Use Permit application; no credit toward new use registration. (3) (4) (5)	6	13,940
R273	33	Additional use; seed treatment only; use not requiring a new tolerance; includes crops with established tolerances (e.g., for soil or foliar application). (3) (4) (5)	12	72,302

4053

“TABLE 2. — REGISTRATION DIVISION (RD) — NEW USES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R274	34	Additional use; seed treatment only; 6 or more submitted in one application; uses not requiring new tolerances; includes crops with established tolerances (e.g., for soil or foliar application). (3) (4) (5)	12	433,793
R276	35 (new)	Additional use, seed treatment only; limited uptake into raw agricultural commodities; use requiring a tolerance. (3) (4) (5)	14	79,560
R277	36 (new)	Additional use, seed treatment only; 6 or more submitted in one application; limited uptake into raw agricultural commodities; use requiring a tolerance. (3) (4) (5)	14	477,360

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

## 4054

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

## 4055

(5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

“TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT AND OTHER TOLERANCES

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R280	37	Establish tolerances for residues in imported commodities; new active ingredient or first food use. (2)	22	457,311
R290	38	Establish tolerances for residues in imported commodities; Additional new food use.	16	91,465
R291	39	Establish tolerances for residues in imported commodities; additional food uses; 6 or more crops submitted in one petition.	16	548,773

4056

“TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT  
AND OTHER TOLERANCES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registra- tion Service Fee (\$)</b>
R292	40	Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex Maximum Residue Limits; domestic or import; applicant-initiated.	12	64,987
R293	41	Establish tolerance(s) for inadvertent residues in one crop; applicant-initiated.	13	76,656
R294	42	Establish tolerances for inadvertent residues; 6 or more crops submitted in one application; applicant-initiated.	13	459,922

4057

“TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT AND OTHER TOLERANCES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R295	43	Establish tolerance(s) for residues in one rotational crop in response to a specific rotational crop application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated. (3) (4)	16	94,774
R296	44	Establish tolerances for residues in rotational crops in response to a specific rotational crop petition; 6 or more crops submitted in one application; submission of corresponding label amendments which specify the necessary plant-back restrictions; applicant-initiated. (3) (4)	16	568,632

4058

“TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT AND OTHER TOLERANCES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R297	45	Amend 6 or more established tolerances (e.g., decrease or increase) in one petition; domestic or import; applicant-initiated.	12	389,897
R298	46	Amend an established tolerance (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3) (4)	14	83,940
R299	47	Amend 6 or more established tolerances (e.g., decrease or increase); domestic or import; submission of corresponding amended labels (requiring science review). (3) (4)	14	408,853

4059

“TABLE 3. — REGISTRATION DIVISION (RD) — IMPORT AND OTHER TOLERANCES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R281	48 (new)	Establish tolerances for residues in imported commodities; additional new food use; submission of residue chemistry data review conducted by Codex or other competent national regulatory authority.	12	68,599
R282	49 (new)	Establish tolerances for residues in imported commodities; additional new food uses; 6 or more crops submitted in one petition; submission of residue chemistry data review conducted by Codex or other competent national regulatory authority.	12	411,580

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

## 4060

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) Amendment applications to add the revised use pattern(s) to registered product labels are covered by the base fee for the category. All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the amendment application package is subject to the registration service fee for a new product or a new inert approval. However, if an amendment application only proposes to register the amendment for a new product and there are no amendments in the application, then review of one new product application is covered by the base fee. All such associated applications that are submitted together will be subject to the category decision review time.

## 4061

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R300	50	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; no data review on acute toxicity, efficacy or child-resistant packaging — only product chemistry data; cite-all data citation, or selective data citation where applicant owns all required data, or applicant submits specific authorization letter from data owner. Category also includes 100% repackage of registered end-use or manufacturing-use product that requires no data submission nor data matrix. (2) (3)	4	2,270

4062

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R301	51	New product; or similar combination product (already registered) to an identical or substantially similar in composition and use to a registered product; registered source of active ingredient; selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy (identical data citation and claims to cited product(s)), where applicant does not own all required data and does not have a specific authorization letter from data owner. (2) (3)	4	2,720

4063

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R310	52	<p>New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>4. Child-resistant packaging and/or</li> <li>4. pest(s) requiring efficacy – for up to 3 target pests.</li> </ol> <p>(2) (3) (4)</p>	7	10,466

4064

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R314	53	<p>New end-use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy (4) for up to 3 target pests. (2) (3)</li> </ol>	8	12,364

4065

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R319	54	<p>New end-use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy (4) - for 4 to 7 target pests. (2) (3)</li> </ol>	10	18,097

4066

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R318	55	<p>New end-use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy – for up to 3 target pests.</li> </ol> <p>(2) (3) (4)</p>	9	18,994

4067

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R321	56	<p>New end-use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy (4) - for 4 to 7 target pests. (2) (3)</li> </ol>	11	24,727

4068

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R315	57	New end-use on-animal product, registered source of active ingredient(s) with submission of data and/or waivers for only: <ol style="list-style-type: none"> <li>1. animal safety and</li> <li>2. pest(s) requiring efficacy and/or</li> <li>3. product chemistry and/or</li> <li>4. acute toxicity and/or</li> <li>5. child resistant packaging. (2) (3) (4)</li> </ol>	9	14,075

4069

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R316	58	New end-use or manufacturing-use product with registered source(s) of active ingredient(s) including products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; and requires review of data and/or waivers for only: <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy - for 4 to 7 target pests.</li> </ol> (2) (3) (4)	9	16,199

4070

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R317	59	New end-use or manufacturing-use product with registered source(s) of active ingredient(s) including products containing two or more registered active ingredients previously combined in other registered products; excludes products requiring or citing an animal safety study; and requires review of data and/or waivers for only: <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. child resistant packaging and/or</li> <li>4. Pest(s) requiring efficacy - for greater than 7 target pests, (2) (3) (4)</li> </ol>	10	21,932
R320	60	New product; new physical form; requires data review in science divisions. (2) (3) (5)	12	18,958

4071

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R331	61	New product; re-pack of identical registered end-use product as a manufacturing-use product; same registered uses only. (2) (3)	3	3,627
R332	62	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of completely new generic data package; registered uses only; requires review in RD and science divisions. (2) (3)	24	405,919
R333	63	New product; manufacturing-use product or end-use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data. (2) (3)	11	28,434

4072

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R334	64	New product; manufacturing-use product or end-use product with unregistered source of the active ingredient; requires science data review; new physical form; etc. Selective data citation. (2) (3)	12	33,108

4073

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R361	65 (new)	<p>New end-use product containing up to three registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. Child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy – for more than 7 target pests. (2) (3) (4)</li> </ol>	12	23,400

4074

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R362	66 (new)	<p>New end-use product containing four or more registered active ingredients never before registered as this combination in a formulated product; new product label is identical or substantially similar to the labels of currently registered products which separately contain the respective component active ingredients; excludes products requiring or citing an animal safety study; requires review of data package within RD only; includes data and/or waivers of data for only:</p> <ol style="list-style-type: none"> <li>1. product chemistry and/or</li> <li>2. acute toxicity and/or</li> <li>3. Child resistant packaging and/or</li> <li>4. pest(s) requiring efficacy – for more than 7 target pests. (2) (3) (4)</li> </ol>	13	25,350

4075

“TABLE 4. — REGISTRATION DIVISION (RD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R363	67 (new)	New product; re-pack of identical registered manufacturing-use product as an end-use product; same registered uses only, with no additional data. (2) (3)	6	7,800

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant’s written or electronic confirmation of agreement to the Agency.

(4) For the purposes of classifying proposed registration actions into PRIA categories, “pest(s) requiring efficacy” are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, subpart R of part 158 of title 40, Code of Federal Regulations. This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in the Pesticide Registration Notice 2002-1. To determine the number of pests for the PRIA categories, pest groups, subgroups, and pest specific claims as listed in part 158 of title 40, Code of Federal Regulations, should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, etc.), each group will count as 1. If seeking a claim against a pest subgroup (e.g., small biting flies, filth flies, etc.) or specific pests (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each subgroup or specific pest will count as 1.

## 4076

(5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

“TABLE 5. — REGISTRATION DIVISION (RD) — AMENDMENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R340	68	Amendment requiring data review within RD (e.g., changes to precautionary label statements); includes adding/modifying pest(s) claims for up to 2 target pests; excludes products requiring or citing an animal safety study. (2) (3)	4	7,150
R341	69	Amendment requiring data review within RD (e.g., changes to precautionary label statements), includes adding/modifying pest(s) claims for greater than 2 target pests; excludes products requiring or citing an animal safety study. (2) (3)	6	8,584

4077

“TABLE 5. — REGISTRATION DIVISION (RD) —  
AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R345	70	Amending on-animal products previously registered, with the submission of data and/or waivers for only: 1. animal safety and 2. pest(s) requiring efficacy and/or 3. product chemistry and/or 4. acute toxicity and/or 5. child resistant packaging. (2) (3) (4)	7	12,643
R350	71	Amendment requiring data review in science divisions (e.g., changes to Restricted Entry Interval, or Personal Protective Equipment, or Preharvest Interval, or use rate, or number of applications; or add aerial application; or modify Ground Water/Surface Water advisory statement). (2) (3) (5)	9	18,958

4078

“TABLE 5. — REGISTRATION DIVISION (RD) —  
AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
R351	72	Amendment adding a new unregistered source of active ingredient. (2) (3)	8	18,958
R352	73	Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data. (2) (3)	8	18,958
R371	74	Amendment to Experimental Use Permit; (does not include extending a permit's time period). (3)	6	14,463

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

## 4079

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) For the purposes of classifying proposed registration actions into PRIA categories, “pest(s) requiring efficacy” are both invertebrate and vertebrate pests. Invertebrate public health pests (e.g., ticks, mosquitoes, cockroaches, flies, etc.), structural pests (e.g., termites, carpenter ants, and wood-boring beetles) and certain invasive invertebrate species (e.g., Asian Longhorned beetle, Emerald Ashborer) are listed in the product performance rule, subpart R of part 158 of title 40, Code of Federal Regulations. This list may be updated/refined as invasive pest needs arise. All other pests (e.g., vertebrates) are listed in the Pesticide Registration Notice 2002-1. To determine the number of pests for the PRIA categories, pest groups, subgroups, and pest specific claims as listed in part 158 of title 40, Code of Federal Regulations, should be counted as follows. If seeking a label claim against a general pest group (e.g., cockroaches, mosquitoes, termites, etc.), each group will count as 1. If seeking a claim against a pest subgroup (e.g., small biting flies, filth flies, etc.) or specific pests (e.g., smokybrown cockroach, house fly, etc.) without a general claim, then each subgroup or specific pest will count as 1.

(5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

“TABLE 6. — REGISTRATION DIVISION (RD) — OTHER ACTIONS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R124	75	Conditional Ruling on Pre-application Study Waivers; applicant-initiated.	6	3,627

4080

“TABLE 6. — REGISTRATION DIVISION (RD) — OTHER ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R272	76	Review of Study Protocol applicant- initiated; excludes Data Analysis Reporting Tool, pre- registration conference, Rapid Response review, developmental neurotoxicity protocol review, protocol needing Human Studies Review Board review, companion animal safety protocol.	3	3,627
R275	77	Rebuttal of Agency reviewed protocol, applicant initiated.	3	3,627
R278	78 (new)	Review of Protocol for companion animal safety study.	5	4,927

4081

“TABLE 6. — REGISTRATION DIVISION (RD) — OTHER ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
R279	79 (new)	Comparative product determination for reduced risk submission, applicant initiated; submitted before application for reduced risk new active ingredient or reduced risk new use.	3	5,200

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

“TABLE 7. — ANTIMICROBIAL DIVISION (AD) — NEW ACTIVE INGREDIENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A380	80	New Active Ingredient; Indirect Food use; establish tolerance or tolerance exemption if required. (2) (3) (4)	26	227,957
A390	81	New Active Ingredient; Direct Food use; establish tolerance or tolerance exemption if required. (2) (3) (4)	26	329,265

4082

“TABLE 7. — ANTIMICROBIAL DIVISION (AD) — NEW ACTIVE INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A410	82	New Active Ingredient Non-food use. (2) (3) (4)	23	278,659
A431	83	New Active Ingredient, Non-food use; low-risk. (2) (3) (4)	14	114,984

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant’s initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant’s written or electronic confirmation of agreement to the Agency.

## 4083

(4) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

“TABLE 8. — ANTIMICROBIAL DIVISION (AD) — NEW USES

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
A440	84	New Use, Indirect Food Use, establish tolerance or tolerance exemption. (2) (3) (4) (6)	23	45,737
A441	85	Additional Indirect food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3) (4) (5) (6)	23	164,639
A450	86	New use, Direct food use, establish tolerance or tolerance exemption. (2) (3) (4) (6)	23	137,198
A451	87	Additional Direct food uses; establish tolerances or tolerance exemptions if required; 6 or more submitted in one application. (3) (4) (5) (6)	22	261,333

4084

“TABLE 8. — ANTIMICROBIAL DIVISION (AD) — NEW USES—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
A500	88	New use, non-food. (4) (5) (6)	15	45,737
A501	89	New use, non-food; 6 or more submitted in one application. (4) (5) (6)	17	109,764

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant’s initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) If EPA data rules are amended to newly require clearance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.

## 4085

(4) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

(6) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

4086

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A530	90	New product, identical or substantially similar in composition and use to a registered product; no data review or only product chemistry data; cite all data citation or selective data citation where applicant owns all required data; or applicant submits specific authorization letter from data owner. Category also includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission nor data matrix. (2) (3)	4	1,833

4087

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A531	91	New product; identical or substantially similar in composition and use to a registered product; registered source of active ingredient: selective data citation only for data on product chemistry and/or acute toxicity and/or public health pest efficacy, where applicant does not own all required data and does not have a specific authorization letter from data owner. (2) (3)	4	2,616

4088

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A532	92	New product; identical or substantially similar in composition and use to a registered product; registered active ingredient; unregistered source of active ingredient; cite-all data citation except for product chemistry; product chemistry data submitted. (2) (3)	5	7,322
A550	93	New end-use product; uses other than FIFRA §2(mm); non-FQPA product. (2) (3) (5)	9	18,958
A560	94	New manufacturing-use product; registered active ingredient; selective data citation. (2) (3)	6	18,054

4089

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A565	95	New manufacturing-use product; registered active ingredient; unregistered source of active ingredient; submission of new generic data package; registered uses only; requires science review. (2) (3)	18	26,135
A572	96	New Product or amendment requiring data review for risk assessment by Science Branch (e.g., changes to Restricted Entry Interval, or Personal Protective Equipment, or use rate). (2) (3) (4) (7)	9	18,958
A460	97 (new)	New end-use product; FIFRA §2(mm) uses only; 0 to 10 public health organisms. (2) (3) (5) (6)	5	7,322

## 4090

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A461	98 (new)	New end-use product; FIFRA §2(mm) uses only; 11 to 20 public health organisms. (2) (3) (5) (6)	6	10,158
A462	99 (new)	New end-use product; FIFRA §2(mm) uses only; 21 to 30 public health organisms. (2) (3) (5) (6)	7	12,995
A463	100 (new)	New end-use product; FIFRA §2(mm) uses only; 31 to 40 public health organisms. (2) (3) (5) (6)	9	15,831
A464	101 (new)	New end-use product; FIFRA §2(mm) uses only; 41 to 50 public health organisms. (2) (3) (5) (6)	10	18,668
A465	102 (new)	New end-use product; FIFRA §2(mm) uses only; 51 or more public health organisms. (2) (3) (5) (6)	11	21,505

## 4091

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A470	103 (new)	Label amendment requiring data review; 0 to 10 public health organisms. (3) (4) (5) (6)	4	5,493
A471	104 (new)	Label amendment requiring data review; 11 to 20 public health organisms. (3) (4) (5) (6)	5	8,506
A472	105 (new)	Label amendment requiring data review; 21 to 30 public health organisms. (3) (4) (5) (6)	6	10,219
A473	106 (new)	Label amendment requiring data review; 31 to 40 public health organisms. (3) (4) (5) (6)	7	11,933
A474	107 (new)	Label amendment requiring data review; 41 to 50 public health organisms. (3) (4) (5) (6)	8	13,646

4092

“TABLE 9. — ANTIMICROBIAL DIVISION (AD) — NEW PRODUCTS AND AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A475	108 (new)	Label amendment requiring data review; 51 or more public health organisms. (3) (4) (5) (6)	9	15,766

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant’s written or electronic confirmation of agreement to the Agency.

(4) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98–10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(5) The applicant must identify the substantially similar product if opting to use cite-all or the selective method to support acute toxicity data requirements.

(6) Once an application for an amendment or a new product with public health organisms has been submitted and classified into any of categories A460 through A465 or A470 through A475, additional organisms submitted for the same product before the first application is granted will result in combination and reclassification of both the original and subsequent submissions into the appropriate new category based on the sum of the number of organisms in both submissions. Submission of additional organisms would result in a new PRIA start date and may require additional fees to meet the fee of a new category.

## 4093

(7) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

“TABLE 10. — ANTIMICROBIAL DIVISION (AD) —  
EXPERIMENTAL USE PERMITS AND OTHER ACTIONS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A520	109	Experimental Use Permit application, non-food use. (2) (3)	9	9,151
A521	110	Review of public health efficacy study protocol within AD, per AD Internal Guidance for the Efficacy Protocol Review Process; Code will also include review of public health efficacy study protocol; applicant-initiated; Tier 1.	6	6,776
A522	111	Review of public health efficacy study protocol outside AD by members of AD Efficacy Protocol Review Expert Panel; Code will also include review of public health efficacy study protocol; applicant-initiated; Tier 2.	12	17,424

4094

“TABLE 10. — ANTIMICROBIAL DIVISION (AD) — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS—  
Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A537	112	New Active Ingredient/New Use, Experimental Use Permit application; Direct food use; Establish tolerance or tolerance exemption if required. Credit 45% of fee toward new active ingredient/new use application that follows. (3)	18	219,512
A538	113	New Active Ingredient/New Use, Experimental Use Permit application; Indirect food use; Establish tolerance or tolerance exemption if required Credit 45% of fee toward new active ingredient/new use application that follows. (3)	18	137,198

## 4095

“TABLE 10. — ANTIMICROBIAL DIVISION (AD) — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS—  
Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
A539	114	New Active Ingredient/New Use, Experimental Use Permit application; Nonfood use. Credit 45% of fee toward new active ingredient/new use application that follows. (3)	15	132,094
A529	115	Amendment to Experimental Use Permit; requires data review or risk assessment. (2) (3)	9	16,383
A523	116	Review of protocol other than a public health efficacy study (i.e., Toxicology or Exposure Protocols).	9	17,424
A571	117	Science reassessment: refined ecological risk, and/or endangered species; applicant-initiated. (3)	18	137,198
A533	118	Exemption from the requirement of an Experimental Use Permit. (2)	4	3,559

## 4096

“TABLE 10. — ANTIMICROBIAL DIVISION (AD) — EXPERIMENTAL USE PERMITS AND OTHER ACTIONS—  
Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
A534	119	Rebuttal of Agency reviewed protocol, applicant initiated.	4	6,776
A535	120	Conditional ruling on pre-application study waiver or data bridging argument; applicant-initiated.	6	3,454
A536	121	Conditional ruling on pre-application direct food, indirect food, nonfood use determination; applicant-initiated.	4	3,559
A575	122 (new)	Efficacy similarity determination; if two products can be bridged or if confirmatory efficacy data are needed.	4	3,389

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

## 4097

(2) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

3) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

“TABLE 11. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW ACTIVE INGREDIENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B580	123	New active ingredient; petition to establish a tolerance. (2) (3) (4)	22	73,173
B590	124	New active ingredient; petition to establish a tolerance exemption. (2) (3) (4)	20	45,737

4098

“TABLE 11. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW ACTIVE INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
B600	125	New active ingredient; no change to a permanent tolerance or tolerance exemption (includes non-food uses). (2) (3) (4)	15	27,443
B610	126	New active ingredient; Experimental Use Permit application; petition to establish a permanent or temporary tolerance or temporary tolerance exemption. (3) (4)	12	18,296
B620	127	New active ingredient; Experimental Use Permit application; non-food use (includes crop destruct). (3) (4)	9	9,151

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

## 4099

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(4) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

## 4100

“TABLE 12. — BIOPESTICIDES AND POLLUTION  
PREVENTION DIVISION (BPPD) — NEW USES

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registra- tion Service Fee (\$)</b>
B630	128	First food use; petition to es- tablish/amend a tolerance ex- emption. (2) (4) (5)	13	18,296
B640	129	First food use; petition to es- tablish/amend a tolerance. (2) (4) (5)	19	27,443
B644	130	New use, no change to an established tol- erance or tol- erance exemp- tion (includes non-food uses). (3) (4) (5)	8	18,296
B645	131	New use; Experi- mental Use Permit; peti- tion to estab- lish a perma- nent or tem- porary toler- ance or toler- ance exemp- tion. (4) (5)	12	18,296
B646	132	New use; Experi- mental Use Permit; non- food use (in- cludes crop de- struct). (4) (5)	7	9,151

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

## 4101

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screen, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

(4) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

## 4102

(5) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

“TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW PRODUCTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
B660	133	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption; no data submission or data matrix (or submission of product chemistry data only). (2) (3)	6	1,833
B670	134	New product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption; (including non-food); Must address Product-Specific Data Requirements. (2) (3)	9	7,322

## 4103

“TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B672	135	New product; unregistered source of at least one active ingredient (or registered source with new generic data package); no change in an established tolerance or tolerance exemption (including non-food); must address Product-Specific and Generic Data Requirements. (2) (3)	15	13,069
B673	136	New product; unregistered source of active ingredient(s); citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency; requires an Agency determination that the cited data support the new product. (2) (3)	12	7,322

## 4104

“TABLE 13. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — NEW PRODUCTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B674	137	New product; repack of identical registered end-use product or repack of an end-use product as a manufacturing-use product; same registered uses only. (2) (3)	4	1,833
B677	138	New end-use non-food animal product with submission of two or more target animal safety studies; includes data and/or waivers of data for only: 1. product chemistry and/or 2. acute toxicity and/or 3. public health pest efficacy and/or 4. animal safety studies and/or 5. child resistant packaging. (2) (3)	12	12,643

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

## 4105

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

“TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — AMENDMENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B621	139	Amendment; Experimental Use Permit; no change to an established temporary or permanent tolerance or tolerance exemption. (3) (4)	7	7,322
B622	140	Amendment; Experimental Use Permit; petition to amend a permanent or temporary tolerance or tolerance exemption. (3) (4)	11	18,296
B641	141	Amendment; changes to an established tolerance or tolerance exemption. (4)	13	18,296

## 4106

“TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B680	142	Amendment; registered sources of active ingredient(s); no new use(s); no changes to an established tolerance or tolerance exemption; requires data submission. (2) (3)	5	7,322
B681	143	Amendment; unregistered source of active ingredient(s); no change to an established tolerance or tolerance exemption; requires data submission. (2) (3)	7	8,714

4107

“TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B683	144	Amendment; no change to an established tolerance or tolerance exemption; requires review/update of previous risk assessment(s) without data submission (e.g., labeling changes to Restricted Entry Interval, Personal Protective Equipment, Preharvest Interval). (2) (3)	6	7,322
B684	145	Amending non-food animal product that includes submission of target animal safety data; previously registered. (2) (3)	8	12,643

4108

“TABLE 14. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — AMENDMENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B685	146	Amendment; add a new bio-chemical un-registered source of active ingredient or a new microbial production site; requires submission of analysis of samples data and source/production site-specific manufacturing process description. (3)	5	7,322

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(3) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

## 4109

(4) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

“TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — STRAIGHT-CHAIN LEPIDOPTERAN PHEROMONES (SCLP)

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B690	147	SCLP; new active ingredient; food or non-food use. (2) (6) (7)	7	3,662
B700	148	SCLP; Experimental Use Permit application; new active ingredient or new use. (6) (7)	7	1,833
B701	149	SCLP; Extend or amend Experimental Use Permit. (6) (7)	4	1,833

## 4110

“TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — STRAIGHT-CHAIN LEPIDOPTERAN PHEROMONES (SCLP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B710	150	SCLP; new product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption; no data submission or data matrix (or only product chemistry data); (Includes 100% re-pack; re-pack of registered end-use product as a manufacturing-use product). (3) (6)	4	1,833

4111

“TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — STRAIGHT-CHAIN LEPIDOPTERAN PHEROMONES (SCLP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B720	151	SCLP; new product; registered source of active ingredient(s); no change in an established tolerance or tolerance exemption (including non-food); Must address Product-Specific Data Requirements. (3) (6)	5	1,833
B721	152	SCLP: new product; unregistered source of active ingredient; no change in an established tolerance or tolerance exemption (including non-food); must address Product-Specific and Generic Data Requirements. (3) (6)	7	3,836
B722	153	SCLP; new use and/or amendment; petition to establish a tolerance or tolerance exemption. (4) (5) (6) (7)	7	3,552

4112

“TABLE 15. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — STRAIGHT-CHAIN LEPIDOPTERAN PHEROMONES (SCLP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B730	154	SCLP; amendment requiring data submission. (4) (6)	5	1,833

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the Agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant’s initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

(3) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(4) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

## 4113

(5) Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the preliminary technical screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

(6) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(7) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

## 4114

“TABLE 16. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — OTHER ACTIONS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
B614	155	Pre-application; Conditional Ruling on rationales for addressing a data requirement in lieu of data; applicant-initiated; applies to one (1) rationale at a time.	3	3,627
B682	156	Protocol review; applicant initiated; excludes time for Human Studies Review Board review (Includes rebuttal of protocol review).	3	3,487
B616	157 (new)	Pre-application; Conditional Ruling on a non-food use determination.	5	4,715
B617	158 (new)	Pre-application; biochemical classification determination.	5	4,715

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

4115

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B740	159	Experimental Use Permit application; no petition for tolerance/tolerance exemption; includes: <ol style="list-style-type: none"> <li>1. non-food/feed use(s) for a new (2) or registered (3) PIP (12);</li> <li>2. food/feed use(s) for a new or registered PIP with crop destruct;</li> <li>3. food/feed use(s) for a new or registered PIP in which an established tolerance/tolerance exemption exists for the intended use(s). (4) (5) (12)</li> </ol>	9	137,198

## 4116

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B750	160	Experimental Use Permit application; with a petition to establish a temporary or permanent tolerance/tolerance exemption for the active ingredient. Includes new food/feed use for a registered (3) PIP. (4) (12)	12	182,927
B771	161	Experimental Use Permit application; new (2) PIP; with petition to establish a temporary tolerance/tolerance exemption for the active ingredient; credit 75% of B771 fee toward registration application for a new active ingredient that follows. (5) (12)	13	182,927

## 4117

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B772	162	Application to amend or extend a PIP Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12)	3	18,296
B773	163	Application to amend or extend a PIP Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)	9	45,737
B780	164	Registration application; new (2) PIP; non-food/feed or food/feed without tolerance petition based on an existing permanent tolerance exemption. (5) (12) (14)	16	228,657

4118

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B800	165	Registration application; new (2) PIP; with petition to establish permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (5) (12) (14)	17	246,949
B820	166	Registration application; new (2) PIP; with petition to establish or amend a permanent tolerance/tolerance exemption of an active ingredient. (5) (12) (14)	19	292,682

4119

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B851	167	Registration application; new event of a previously registered PIP active ingredient(s); no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (12)	9	182,927
B870	168	Registration application; registered (3) PIP; new product; new use; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (4) (12) (14)	9	54,881

4120

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B880	169	Registration application; registered (3) PIP; new product or new terms of registration; additional data submitted; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5) (6) (7) (12) (14)	9	45,737
B883	170	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption. (5) (8) (12) (14)	13	182,927

## 4121

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B884	171	Registration application; new (2) PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient. (5) (8) (12) (14)	19	228,657
B885	172	Registration application; registered (2) PIP, seed increase; breeding stack of previously approved PIPs, same crop; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (9) (12)	6	45,737

4122

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B890	173	Application to amend a seed increase registration; converts registration to commercial registration; no petition since permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5) (12) (14)	9	91,465
B900	174	Application to amend a registration, including actions such as modifying an IRM plan, or adding an insect to be controlled. (5) (10) (11) (12)	6	18,296
B902	175	PIP Protocol review.	3	9,151
B903	176	Inert ingredient permanent tolerance exemption; e.g., a marker such as NPT II; reviewed in BPPD.	12	91,465

4123

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B904	177	Import tolerance or tolerance exemption; processed commodities/food only (inert or active ingredient).	12	182,927
B905	178	FIFRA Scientific Advisory Panel Review.	6	91,465
B906	179	Petition to establish a temporary tolerance/tolerance exemption for one or more active ingredients.	9	45,733
B907	180	Petition to establish a permanent tolerance/tolerance exemption for one or more active ingredients based on an existing temporary tolerance/tolerance exemption.	9	18,296

## 4124

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B909	181 (new)	PIP tolerance exemption determination; applicant-initiated; request to determine if an existing tolerance exemption applies to a PIP.	6	18,296
B910	182 (new)	Biotechnology Notification for small-scale field testing of genetically engineered microbes.	3	9,151

4125

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B921	183 (new)	Experimental Use Permit application; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); non-food/feed. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. Credit 75% of B921 fee toward registration application for the new active ingredient that follows (B922). (5) (12) (13)	12	182,927

## 4126

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B922	184 (new)	Registration application; new active ingredient; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); non-food/feed. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. (5) (12) (13) (14)	16	228,657

4127

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B923	185 (new)	Experimental Use Permit application; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); with petition to establish a temporary or permanent tolerance/tolerance exemption of an active ingredient. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. Credit 75% of B923 fee toward registration application for the new active ingredient that follows (B924). (5) (12) (13) (14)	15	228,658

4128

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B924	186 (new)	Registration application; new active ingredient; genetic modifications in animals intended for use as a pesticide (e.g., for pest population control); with petition to establish a permanent tolerance/tolerance exemption of an active ingredient. This category would cover substances produced and used in animals that are intended for use as a pesticide, such as for pest population control, including the genetic material in such animals. (5) (12) (13) (14)	19	292,682

4129

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B925	187 (new)	Experimental Use Permit application; exogenous applications of RNA to elicit the RNA interference pathway in pests; non-food/feed; credit 75% of B925 fee toward registration application for the new active ingredient that follows (B926). (5) (12)	11	27,452
B926	188 (new)	Registration application; new active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; non-food/feed. (5) (12) (14)	17	82,329

4130

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B927	189 (new)	Experimental Use Permit application; exogenous applications of RNA to elicit the RNA interference pathway in pests; with petition to establish a temporary or permanent tolerance/tolerance exemption of an active ingredient; credit 75% of B927 fee toward registration application for the new active ingredient that follows (B928). (5) (12)	14	54,889

4131

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B928	190 (new)	Registration application; new active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; with petition to establish a permanent tolerance/tolerance exemption of an active ingredient. (5) (12) (14)	22	137,210
B929	191 (new)	Registration application; new product, registered active ingredient; exogenous applications of RNA to elicit the RNA interference pathway in pests; no petition since a permanent tolerance/tolerance exemption is already established for the active ingredient(s). (5) (12)	10	7,322

4132

“TABLE 17. — BIOPESTICIDES AND POLLUTION PREVENTION DIVISION (BPPD) — PLANT-INCORPORATED PROTECTANTS (PIP)—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
B930	192 (new)	Application to amend or extend a non-PIP Emerging Technologies Experimental Use Permit; no petition since the established tolerance/tolerance exemption for the active ingredient is unaffected. (12)	3	18,296
B931	193 (new)	Application to amend or extend a non-PIP Emerging Technologies Experimental Use Permit; with petition to extend a temporary tolerance/tolerance exemption for the active ingredient. (12)	9	45,737
B932	194 (new)	Amendment; application to amend a non-PIP Emerging Technologies registration. (4) (5) (12)	6	18,296

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) ‘New PIP’ means a PIP with an active ingredient that has not been registered.

(3) ‘Registered PIP’ means a PIP with an active ingredient that is currently registered.

(4) Transfer registered PIP through conventional breeding for new food/feed use, such as from field corn to sweet corn.

## 4133

(5) If, during review of the application, it is determined that review by the FIFRA Scientific Advisory Panel (SAP) is needed, the applicant will submit an application for category B905, which will be processed concurrently, and the decision review time for both applications will be the longer of the two associated applications. The scientific data involved in this category are complex. EPA often seeks technical advice from the SAP on risks that pesticides pose to wild-life, farm workers, pesticide applicators, non-target species, insect resistance, and novel scientific issues surrounding new technologies. The scientists of the SAP neither make nor recommend policy decisions. They provide advice on the science used to make these decisions. Their advice is invaluable to the EPA as it strives to protect humans and the environment from risks posed by pesticides. Due to the time it takes to schedule and prepare for meetings with the SAP, additional time and costs are needed.

(6) Registered PIPs stacked through conventional breeding.

(7) Deployment of a registered PIP with a different Insecticide Resistance Management (IRM) plan (e.g., seed blend).

(8) The negotiated acreage cap will depend upon EPA's determination of the potential environmental exposure, risk(s) to non-target organisms, and the risk of targeted pest developing resistance to the pesticidal substance. The uncertainty of these risks may reduce the allowable acreage, based upon the quantity and type of non-target organism data submitted and the lack of insect resistance management data, which is usually not required for seed-increase registrations. Registrants are encouraged to consult with EPA prior to submission of a registration application in this category.

(9) Application can be submitted prior to or concurrently with an application for commercial registration.

(10) For example, IRM plan modifications that are applicant-initiated.

(11) (a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under Pesticide Registration (PR) Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

(12) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(13) This category does not include genetic modifications in animals not intended for use as a pesticide, e.g., genetic modifications in animals intended for food use or animals intended for use as companion animals.

(14) If the Administrator determines that endangered species analysis is required for this action, using guidance finalized according to section 33(c)(3)(B) for this specific type of action, the decision review time can be extended for endangered species assessment one time only for up to 50%, upon written notification to the applicant, prior to completion of the technical screening. To the extent practicable, any reason for renegotiation should be resolved during the same extension.

4134

“TABLE 18. — INERT INGREDIENTS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
I001	195	Approval of new food use inert ingredient. (2) (3)	15	38,698
I002	196	Amend currently approved inert ingredient tolerance or exemption from tolerance; new data. (2)	13	10,750
I003	197	Amend currently approved inert ingredient tolerance or exemption from tolerance; no new data. (2)	11	4,742
I004	198	Approval of new non-food use inert ingredient. (2)	6	15,803
I005	199	Amend currently approved non-food use inert ingredient with new use pattern; new data. (2)	6	7,903
I006	200	Amend currently approved non-food use inert ingredient with new use pattern; no new data. (2)	4	4,742

4135

“TABLE 18. — INERT INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
I007	201	Approval of substantially similar non-food use inert ingredients when original inert is compositionally similar with similar use pattern. (2)	5	2,371
I008	202	Approval of new or amended polymer inert ingredient, food use. (2)	7	5,374
I009	203	Approval of new or amended polymer inert ingredient, non-food use. (2)	4	4,427
I010	204	Petition to amend a single tolerance exemption descriptor, or single non-food use descriptor, to add ≤ 10 CASRNs; no new data. (2)	7	2,371
I011	205	Approval of new food use safener with tolerance or exemption from tolerance. (2)	26	856,631
I012	206	Approval of new non-food use safener. (2)	21	595,147

4136

“TABLE 18. — INERT INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
I013	207	Approval of additional food use for previously approved safener with tolerance or exemption from tolerance. (2)	17	90,260
I014	208	Approval of additional non-food use for previously approved safener. (2)	15	36,074
I015	209	Approval of new generic data for previously approved food use safener. (2)	26	386,589
I016	210	Approval of amendment(s) to tolerance and label for previously approved safener. (2)	15	79,942
I017	211 (new)	Add new source of previously approved safener.	8	18,958

4137

“TABLE 18. — INERT INGREDIENTS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
I018	212 (new)	Petition to add one approved inert ingredient (CASRN) to the Commodity Inert Ingredient List; no data. (4)	3	2,371

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.

(3) If EPA data rules are amended to newly require clearance under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) for an ingredient of an antimicrobial product where such ingredient was not previously subject to such a clearance, then review of the data for such clearance of such product is not subject to a registration service fee for the tolerance action for two years from the effective date of the rule.

(4) Due to low fee and short time frame this category is not eligible for small business waivers.

“TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
M001	213	Study protocol requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of a currently registered active ingredient.	14	11,378

4138

“TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
M002	214	Completed study requiring Human Studies Review Board review as defined in 40 CFR Part 26 in support of an active ingredient. (2)	14	11,378
M003	215	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of less than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (3)	12	91,651

4139

“TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
M004	216	External technical peer review of new active ingredient, product, or amendment (e.g., consultation with FIFRA Scientific Advisory Panel) for an action with a decision timeframe of greater than 12 months. Applicant initiated request based on a requirement of the Administrator, as defined by FIFRA § 25(d), in support of a novel active ingredient, or unique use pattern or application technology. Excludes PIP active ingredients. (3)	18	91,651

4140

“TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
M005	217	New Product: Combination, Contains a combination of active ingredients from a registered and/or unregistered source; conventional, antimicrobial and/or biopesticide. Requires coordination with other regulatory divisions to conduct review of data, label and/or verify the validity of existing data as cited. Only existing uses for each active ingredient in the combination product. (4) (5) (6)	9	31,604
M006	218	Request for up to 5 letters of certification (Gold Seal) for one actively registered product (excludes distributor products). (7)	1	398

4141

“TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sub>(1)</sub></b>	<b>Registration Service Fee (\$)</b>
M007	219	Request to extend Exclusive Use of data as provided by FIFRA Section 3(e)(1)(F)(ii).	12	7,903
M008	220	Request to grant Exclusive Use of data as provided by FIFRA Section 3(e)(1)(F)(vi) for a minor use, when a FIFRA Section 2(l)(2) determination is required.	15	2,371
M009	221	Non-FIFRA Regulated Determination; applicant-initiated, per product.	6	3,389
M010	222	Conditional ruling on pre-application, product substantial similarity.	4	3,389
M011	223	Label amendment to add the DfE logo; requires data review; no other label changes. (8)	4	5,230

4142

“TABLE 19. — EXTERNAL REVIEW AND MISCELLANEOUS ACTIONS—Continued

<b>EPA No.</b>	<b>New CR No.</b>	<b>Action</b>	<b>Decision Review Time (Months)<sup>(1)</sup></b>	<b>Registration Service Fee (\$)</b>
M012	224 (new)	Request for up to 5 letters of certification (Certificate of Establishment) for one actively registered product or one product produced for export (excludes distributor products). (7)	1	398
M013	225 (new)	Cancer reassessment; applicant-initiated.	18	284,144
M014	227 (new)	Pre-application nano-particle determination.	8	17,424

(1) A decision review time that would otherwise end on a Saturday, Sunday, or Federal holiday, will be extended to end on the next business day.

(2) Any other covered application that is associated with and dependent on the review by the Human Studies Review Board will be subject to its separate registration service fee. The decision review times for the associated actions run concurrently, but will end at the date of the latest review time.

(3) Any other covered application that is associated with and dependent on the FIFRA Scientific Advisory Panel review will be subject to its separate registration service fee. The decision review time for the associated action will be extended by the decision review time for the SAP review.

(4) If another covered application is submitted that depends upon an application to approve an inert ingredient, each application will be subject to its respective registration service fee. The decision review time for both submissions will be the longest of the associated applications. If the application covers multiple ingredients grouped by EPA into one chemical class, a single registration service fee will be assessed for approval of those ingredients.

(5) An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

(6) Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent re-submission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

(7) Due to low fee and short time frame this category is not eligible for small business waivers.

(8) This category includes amendments the sole purpose of which is to add 'Design for the Environment' (DfE) (or equivalent terms that do not use 'safe' or derivatives of 'safe') logos to a label. DfE is a voluntary program. A label bearing a DfE logo is not considered an Agency endorsement because the ingredients in the qualifying product must meet objective, scientific criteria established and widely publicized by EPA.”.

## 1 **SEC. 707. INFORMATION.**

2 Not later than 180 days after the date of enactment  
3 of this title, the Administrator of the Environmental Pro-  
4 tection Agency shall post on a single webpage of the  
5 website of the Environmental Protection Agency aggre-  
6 gated information on pesticide regulation under the Fed-  
7 eral Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.  
8 136 et seq.), including—

9 (1) all guidance relating to risk assessment,  
10 risk mitigation, benefits assessments, and cost-ben-  
11 efit balancing;

12 (2) hyperlinks to resources, including the De-  
13 partment of Agriculture's “national list of allowed  
14 and prohibited substances” for organic crop and  
15 livestock production;



1 creases shall be effective beginning on October 1,  
2 2022.

3 (b) SET-ASIDES.—With respect to any set-asides  
4 specified in subsection (i) or (k) of section 4 of the Federal  
5 Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.  
6 136a–1), such set-asides shall be effective beginning on  
7 October 1, 2022.

## 8 **Subtitle B—Other Matters Relating** 9 **to Pesticides**

### 10 **SEC. 711. REGISTRATION REVIEW DEADLINE EXTENSION.**

11 (a) IN GENERAL.—Notwithstanding section  
12 3(g)(1)(A)(iii)(I) of the Federal Insecticide, Fungicide,  
13 and Rodenticide Act (7 U.S.C. 136a(g)(1)(A)(iii)(I)), the  
14 Administrator of the Environmental Protection Agency  
15 (referred to in this section as the “Administrator”) shall  
16 complete the initial registration review of each pesticide  
17 or pesticide case covered by that section not later than  
18 October 1, 2026.

19 (b) INTERIM REGISTRATION REVIEW DECISION RE-  
20 QUIREMENTS.—

21 (1) DEFINITION OF COVERED INTERIM REG-  
22 ISTRATION REVIEW DECISION.—In this subsection,  
23 the term “covered interim registration review deci-  
24 sion” means an interim registration review deci-  
25 sion—

1 (A) that is associated with an initial reg-  
2 istration review described in subsection (a);

3 (B) that is noticed in the Federal Register  
4 during the period beginning on the date of en-  
5 actment of this Act and ending on October 1,  
6 2026; and

7 (C) for which the Administrator has not,  
8 as of the date on which the decision is noticed  
9 in the Federal Register, made effects deter-  
10 minations or completed any necessary consulta-  
11 tion under section 7(a)(2) of the Endangered  
12 Species Act of 1973 (16 U.S.C. 1536(a)(2)).

13 (2) REQUIREMENTS.—Any covered interim reg-  
14 istration review decision shall include, where applica-  
15 ble, measures to reduce the effects of the applicable  
16 pesticide on—

17 (A) species listed under the Endangered  
18 Species Act of 1973 (16 U.S.C. 1531 et seq.);

19 or

20 (B) any designated critical habitat.

21 (3) CONSULTATION.—In developing measures  
22 described in paragraph (2), the Administrator shall  
23 take into account the input received from the Sec-  
24 retary of Agriculture and other members of the  
25 interagency working group established under section

4147

1 3(c)(11) of the Federal Insecticide, Fungicide, and  
2 Rodenticide Act (7 U.S.C. 136a(c)(11)).

3 **DIVISION JJ—NORTH ATLANTIC**  
4 **RIGHT WHALES**  
5 **TITLE I—NORTH ATLANTIC**  
6 **RIGHT WHALES AND REGULA-**  
7 **TIONS**

8 **SEC. 101. NORTH ATLANTIC RIGHT WHALES AND REGULA-**  
9 **TIONS.**

10 (a) IN GENERAL.—Notwithstanding any other provi-  
11 sion of law except as provided in subsection (b), for the  
12 period beginning on the date of enactment of this Act and  
13 ending on December 31, 2028, the Final Rule amending  
14 the regulations implementing the Atlantic Large Whale  
15 Take Reduction Plan (86 Fed. Reg. 51970) shall be  
16 deemed sufficient to ensure that the continued Federal  
17 and State authorizations of the American lobster and  
18 Jonah crab fisheries are in full compliance with the Ma-  
19 rine Mammal Protection Act of 1972 (16 U.S.C. 1361 et  
20 seq.) and the Endangered Species Act of 1973 (16 U.S.C.  
21 1531 et seq.). The National Marine Fisheries Service  
22 shall—

23 (1) throughout the period described in the pre-  
24 ceding sentence, in consultation with affected States  
25 and fishing industry participants, promote the inno-

1 vation and adoption of gear technologies in the fish-  
2 eries described in the preceding sentence, in order to  
3 implement additional whale protection measures by  
4 December 31, 2028;

5 (2) promulgate new regulations for the Amer-  
6 ican lobster and Jonah crab fisheries consistent with  
7 the Marine Mammal Protection Act of 1972 (16  
8 U.S.C. 1361 et seq.) and the Endangered Species  
9 Act of 1973 (16 U.S.C. 1531 et seq.) that take ef-  
10 fect by December 31, 2028, utilizing existing and in-  
11 novative gear technologies, as appropriate; and

12 (3) in consultation with affected States, submit  
13 an annual report to Congress on the status of North  
14 Atlantic Right Whales, the actions taken and plans  
15 to implement measures expected to not exceed Po-  
16 tential Biological Removal by December 31, 2028,  
17 the amount of serious injury and mortality by fish-  
18 ery and country, and the proportion of the American  
19 lobster and Jonah crab fisheries that have  
20 transitioned to innovative gear technologies that re-  
21 duce harm to the North Atlantic Right Whale.

22 (b) EXCEPTION.—The provisions of subsection (a)  
23 shall not apply to an existing emergency rule, or any ac-  
24 tion taken to extend or make final an emergency rule that

1 is in place on the date of enactment of this Act, affecting  
2 lobster and Jonah crab.

## 3 **TITLE II—GRANT AUTHORITY**

### 4 **SEC. 201. CONSERVATION AND MITIGATION ASSISTANCE.**

5 (a) ASSISTANCE.—

6 (1) IN GENERAL.—Not later than 180 days  
7 after the date of enactment of this Act, the Sec-  
8 retary of Commerce, acting through the Under Sec-  
9 retary of Commerce for Oceans and Atmosphere (in  
10 this title referred to as the “Under Secretary”) shall  
11 establish a program to provide competitive financial  
12 assistance, on an annual basis, and cooperative  
13 agreements including multiyear grants and direct  
14 payment, to eligible entities for eligible uses, such as  
15 projects designed to reduce the lethal and sub-lethal  
16 effects of human activities on North Atlantic right  
17 whales.

18 (2) USE OF EXISTING AUTHORITIES.—Assist-  
19 ance provided under this section shall be carried out  
20 in a manner consistent with authorities available to  
21 the Secretary under the Endangered Species Act of  
22 1973 (16 U.S.C. 1531 et seq.) and the Marine  
23 Mammal Protection Act of 1972 (16 U.S.C. 1361 et  
24 seq.).