

106TH CONGRESS
1ST SESSION

S. 1464

To amend the Federal Food, Drug, and Cosmetic Act to establish certain requirements regarding the Food Quality Protection Act of 1996, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 29, 1999

Mr. HAGEL (for himself, Mrs. LINCOLN, Mr. ROBERTS, Ms. LANDRIEU, Mr. HUTCHINSON, Mr. COCHRAN, Mr. GRAMS, Mr. ABRAHAM, Mr. SMITH of Oregon, Mr. HOLLINGS, Mr. CRAIG, Mr. GORTON, Mr. GRASSLEY, Mr. CRAPO, Mr. BURNS, Mr. FRIST, Mr. BREAUX, Mr. ASHCROFT, Mr. COVERDELL, Mr. HELMS, and Mr. LOTT) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish certain requirements regarding the Food Quality Protection Act of 1996, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Regulatory Openness and Fairness Act of 1999”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

- Sec. 1. Short title; table of contents.
 Sec. 2. Findings.

TITLE I—ISSUANCE AND CONTINUATION OF TOLERANCES

- Sec. 101. Transition analysis and description of basis for decisions relating to tolerance reviews.
 Sec. 102. Interim procedures for reviews of tolerances.
 Sec. 103. Implementation rules and guidance.
 Sec. 104. Data in support of tolerances and registrations.
 Sec. 105. Expedited action.

TITLE II—STUDIES AND REPORTS

- Sec. 201. Definitions.
 Sec. 202. Priorities and resources.
 Sec. 203. International trade effects.
 Sec. 204. Advisory committee.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) The Food Quality Protection Act of 1996
 4 (Public Law 104–170; 110 Stat. 1489), enacted on
 5 August 3, 1996, made many major modifications to
 6 section 408 of the Federal Food, Drug, and Cos-
 7 metic Act (21 U.S.C. 346a) that require the Admin-
 8 istrator of the Environmental Protection Agency to
 9 consider new kinds of information and use additional
 10 criteria in regulating pesticide chemical residues and
 11 in reviewing tolerances for pesticide chemical resi-
 12 dues that had previously been found to be adequate
 13 to protect the public health.

14 (2)(A) Amendments made by the Food Quality
 15 Protection Act of 1996 prescribe the use of a num-
 16 ber of new risk assessment criteria that require the
 17 development of major modifications to regulatory

1 policies and procedures used by the Administrator to
2 regulate pesticide chemical residues.

3 (B) Since the enactment of the Food Quality
4 Protection Act of 1996, it has become clear that sev-
5 eral of the new concepts embodied in that Act in-
6 volve a high degree of complexity.

7 (C) Practical implementation of the concepts
8 demands new scientific tools in addition to the tools
9 that were available when the Food Quality Protec-
10 tion Act of 1996 was enacted.

11 (3)(A) To reach sound, suitably protective deci-
12 sions on tolerance reviews under the new criteria,
13 the Administrator also will need a great deal of new
14 data, not only on the newly considered nondietary
15 routes of exposure, but also, in some cases, on die-
16 tary exposure and toxicity, so that the Administrator
17 can determine whether pesticide chemicals residues
18 that were found safe under the former criteria sat-
19 isfy the new criteria as well.

20 (B) Some data collection efforts are underway
21 to obtain new data for tolerance reviews, but will not
22 yield results for 1 or more years.

23 (C) In some areas, the need for new data de-
24 pends on decisions not yet made by the Adminis-
25 trator about what kinds of tests should be conducted

1 and which compounds should be tested, for tolerance
2 reviews.

3 (4)(A) The Administrator has instituted public
4 proceedings, relating to the regulations and toler-
5 ance reviews, on such topics as what new interpreta-
6 tions and policies are needed, what new kinds of
7 data are needed, how the new data would be used,
8 and how the needed regulatory transition can be
9 achieved.

10 (B) These proceedings are not yet finished, and
11 on some issues public notice and comment pro-
12 ceedings have been scheduled but have not yet
13 begun.

14 (5)(A) The Food Quality Protection Act of
15 1996 amended the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 301 et seq.) by adding several
17 provisions that provide flexibility to the Adminis-
18 trator in making the transition to the new approach
19 to regulating pesticide chemical residues.

20 (B) The Federal Food, Drug, and Cosmetic Act
21 allows a continuing process of refinement and im-
22 provement in tolerance decisionmaking, as additional
23 information is collected and as new policies and
24 methods are developed and adopted for the practical
25 implementation of the new requirements in that Act.

1 (C) The Federal Food, Drug, and Cosmetic Act
2 provides that the data requirements for tolerances
3 must be set out clearly in regulations and guidelines,
4 so that the regulated community will know what
5 types of information the Administrator requires and
6 what testing procedures should be used to develop
7 the information.

8 (D) Amendments made by the Food Quality
9 Protection Act of 1996 relating to risk assessments
10 affecting tolerances allow only the use of reliable in-
11 formation regarding nondietary exposure routes,
12 which were not previously considered in risk assess-
13 ments affecting tolerances.

14 (E) Congress did not anticipate that a tolerance
15 would be revoked because of reliance by the Admin-
16 istrator on estimates or assumptions stemming from
17 absence of that information, without first providing
18 notice of what information is needed and a reason-
19 able opportunity to collect the information.

20 (F) When a tolerance is under review and the
21 Administrator determines that additional informa-
22 tion is needed to support the continuation of the tol-
23 erance, the Federal Food, Drug, and Cosmetic Act
24 authorizes the Administrator to postpone the effec-
25 tive date of any tolerance rule resulting from the re-

1 view, and this authority can be utilized as appro-
2 priate in cases in which additional information is
3 pertinent to a tolerance review.

4 (G) The Federal Food, Drug, and Cosmetic Act
5 permits the Administrator to conduct a tolerance re-
6 view in stages, as allowed by the available, reliable
7 information.

8 (6)(A) Although the authorities described in
9 subparagraphs (F) and (G) of paragraph (5) already
10 are provided by law, it appears that further congres-
11 sional guidance is needed to ensure that decisions of
12 the Administrator relating to tolerance reviews are
13 reasonable, well supported, and balanced, and to
14 avoid disruptions in agriculture, other sectors of the
15 economy, and international trade.

16 (B) During the transition to revised standards,
17 procedures, and requirements for the regulation of
18 pesticide chemical residues, the Administrator must
19 ensure that decisions are balanced, reasonable, and
20 understandable, and are based on and supported by
21 sound information, in order to avoid unnecessary
22 disruptions in agriculture, the economy, and inter-
23 national trade, and to maintain the public trust in
24 the food supply.

1 (7) Unless the Administrator implements sec-
2 tion 408 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 346a) carefully and wisely, decisions
4 made under that section could cause great harm
5 to—

6 (A) the safe and affordable food supply of
7 the United States;

8 (B) the agricultural system of the United
9 States (including food, fiber, nursery, and for-
10 estry production, food storage, and transpor-
11 tation);

12 (C) related industries; and

13 (D) other private and public sector activi-
14 ties, such as—

15 (i) public health protection against
16 bacteria and other microorganisms;

17 (ii) control of insects and diseases;

18 and

19 (iii) residential and business pest con-
20 trol.

1 **TITLE I—ISSUANCE AND CON-**
2 **TINUATION OF TOLERANCES**

3 **SEC. 101. TRANSITION ANALYSIS AND DESCRIPTION OF**
4 **BASIS FOR DECISIONS RELATING TO TOLER-**
5 **ANCE REVIEWS.**

6 Section 408 of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 346a) is amended by adding at the end
8 the following:

9 “(t) TRANSITION ANALYSIS AND DESCRIPTIONS OF
10 BASIS FOR DECISIONS RELATING TO TOLERANCE RE-
11 VIEWS.—

12 “(1) APPLICATION OF REQUIREMENTS TO CER-
13 TAIN DOCUMENTS.—

14 “(A) IN GENERAL.—Except as provided in
15 subparagraph (B), this subsection applies to
16 any proposed or final rule, order, notice, report,
17 guidance document, or risk assessment (re-
18 ferred to in this subsection as a ‘document’)
19 that is—

20 “(i) based on, or results from, any re-
21 view (including a reassessment) by the Ad-
22 ministrator of a tolerance or of the uses of
23 a pesticide chemical for which a tolerance
24 is in effect; and

1 “(ii) issued or disclosed as described
2 in paragraph (2).

3 “(B) EXCEPTION.—This subsection does
4 not apply to any document in which the Admin-
5 istrator determines or recommends that no rev-
6 ocation or denial of a tolerance, or other ad-
7 verse action regarding a tolerance, is required.

8 “(2) PERIOD OF APPLICABILITY.—This sub-
9 section applies to a document that the Administrator
10 issues or otherwise discloses to any member of the
11 public during the period beginning on January 1,
12 1999, and ending on the date of completion of the
13 process of reviewing tolerances under subsection (q).

14 “(3) TRANSITION ANALYSIS REPORT.—

15 “(A) TRANSITION ANALYSIS.—Before
16 issuing any document to which this subsection
17 applies, the Administrator shall conduct a tran-
18 sition analysis of the findings and regulatory
19 steps recommended by or set forth in the docu-
20 ment.

21 “(B) REPORT.—The Administrator shall
22 prepare a report, to be issued with the docu-
23 ment, that—

24 “(i) describes the results of the anal-
25 ysis;

1 “(ii) describes the extent to which the
2 conclusions in the document are tentative,
3 preliminary, or subject to possible modi-
4 fication because of policy reevaluation, cor-
5 rection of data deficiencies, or use of new
6 data to replace assumptions; and

7 “(iii) contains the information de-
8 scribed in subparagraphs (C) and (D).

9 “(C) CONTENTS OF REPORT RELATING TO
10 BASIS FOR FINDINGS AND REGULATORY
11 STEPS.—A transition analysis report prepared
12 under this paragraph shall describe the extent
13 to which any finding or regulatory step rec-
14 ommended by or set forth in the analyzed docu-
15 ment is based in whole or in part on—

16 “(i) any assumption, if the Adminis-
17 trator is in possession of data that would
18 make use of the assumption unnecessary;

19 “(ii) any information about possible
20 exposure from drinking water, or another
21 nonoccupational, nondietary exposure
22 route, that is derived from use of—

23 “(I) a worst-case assumption;

24 “(II) a computation or modeling
25 result that is—

1 “(aa) based on a high-end or
2 upper-bound input; or

3 “(bb) designed to be a
4 worst-case, high-end, or upper-
5 bound estimate; or

6 “(III) information that otherwise
7 is not reasonably representative of
8 risks to consumers or to major identi-
9 fiable subgroups of consumers, on a
10 national or regional basis;

11 “(iii) any assumption about exposure
12 from drinking water, or another non-
13 occupational, nondietary exposure route, if
14 data that would make use of the assump-
15 tion unnecessary, and would likely dem-
16 onstrate a lower level of exposure than that
17 used in the assumption—

18 “(I) are being developed and will
19 be submitted to the Administrator
20 within a reasonable period—

21 “(aa) in accordance with a
22 request by the Administrator
23 under subsection (f) or any of the
24 authorities referred to in that
25 subsection; or

1 “(bb) at the initiative of an
2 interested person; or

3 “(II) could be obtained by the
4 Administrator by an action taken in
5 accordance with subsection (f);

6 “(iv) any assumption regarding the
7 method for determining the aggregate ex-
8 posure to a pesticide chemical or the cu-
9 mulative effect of exposure to 2 or more
10 pesticide chemicals having a common
11 mechanism of toxicity, if the use of the as-
12 sumption is based in whole or in part on
13 the absence of data that could be obtained
14 by the Administrator by an action taken in
15 accordance with subsection (f), unless the
16 data that would eliminate the need for use
17 of the assumption have been identified and
18 made known by the Administrator to inter-
19 ested persons and sufficient time has been
20 provided to allow the data to be developed,
21 submitted, and subsequently evaluated by
22 the Administrator;

23 “(v) any calculation developed by use
24 of the margin of safety described in sub-
25 section (b)(2)(C), if the use of the margin

1 of safety is based in whole or in part on
2 the absence of data that could be obtained
3 by the Administrator by an action taken in
4 accordance with subsection (f), unless the
5 data that would eliminate the need for use
6 of the margin of safety have been identi-
7 fied and made known by the Administrator
8 to interested persons and sufficient time
9 has been provided to allow the data to be
10 developed, submitted, and subsequently
11 evaluated by the Administrator; or

12 “(vi) any information about an alleged
13 adverse effect relating to a pesticide chem-
14 ical, if the information is anecdotal,
15 unverified, or scientifically implausible, or
16 comes from any study whose design and
17 conduct has not been found by the Admin-
18 istrator to be scientifically sound with re-
19 gard to design, conduct, reporting, and
20 data availability.

21 “(D) ADDITIONAL CONTENTS OF RE-
22 PORT.—A transition analysis report prepared
23 under this paragraph shall contain
24 information—

1 “(i) summarizing and responding
2 briefly to comments received by the Admin-
3 istrator from any other person regarding
4 the applicability of any provision of sub-
5 paragraph (C) to the document analyzed
6 under this subsection;

7 “(ii) describing briefly the availability
8 and suitability of pesticidal and nonpes-
9 ticidal alternatives to the pesticide chem-
10 ical uses being reviewed, including a de-
11 scription of—

12 “(I) the extent to which (as de-
13 termined by the Administrator, in
14 consultation with the Secretary of Ag-
15 riculture) an alternative to the use for
16 which the tolerance under review has
17 been approved that is effective and ec-
18 onomical; and

19 “(II) whether revocation or modi-
20 fication of the tolerance will result
21 in—

22 “(aa) a significant regional
23 shift of production of food within
24 the United States;

1 “(bb) an increase in imports
2 of corresponding commodities;

3 “(cc) an increase in pest
4 control costs;

5 “(dd) an increase in pest
6 crop damage and yield loss, in-
7 cluding quality degradation, due
8 to the lack of an effective alter-
9 native; or

10 “(ee) a disruption of domes-
11 tic production of an adequate,
12 wholesome, and economical food
13 supply;

14 “(iii) identifying the data that, if
15 available, would make unnecessary any re-
16 liance on any information, assumption, or
17 calculation that is described in clause (ii),
18 (iii), (iv), or (v) of subparagraph (C) and
19 identified in the report;

20 “(iv) describing the extent to which
21 any finding or regulatory step rec-
22 ommended by or set forth in the document
23 is based in whole or in part on any as-
24 sumption about toxicity, dietary exposure,
25 or risk from dietary exposure, if data that

1 would make use of the assumption
2 unnecessary—

3 “(I) are being developed and will
4 be submitted to the Administrator
5 within a reasonable period—

6 “(aa) in accordance with a
7 request by the Administrator
8 under subsection (f) or any of the
9 authorities referred to in that
10 subsection; or

11 “(bb) at the initiative of an
12 interested person; or

13 “(II) could be obtained by the
14 Administrator by an action taken in
15 accordance with subsection (f); and

16 “(v) describing the extent to which
17 any finding or regulatory step rec-
18 ommended by or set forth in the document
19 is based in whole or in part on—

20 “(I) any use of data on the pres-
21 ence or absence of nonadverse effects,
22 rather than data on the presence or
23 absence of adverse effects, as the
24 basis for calculation of allowable expo-
25 sure levels; or

1 “(II) any policy that the Admin-
 2 istrator may revise after completion of
 3 any reevaluation of that policy that is
 4 being conducted or is scheduled to be
 5 conducted.

6 “(4) DEFINITION.—In this subsection and sub-
 7 section (u), the term ‘tolerance’ has the meaning
 8 given the term in section 201 of the Regulatory
 9 Openness and Fairness Act of 1999.”.

10 **SEC. 102. INTERIM PROCEDURES FOR REVIEWS OF TOLER-**
 11 **ANCES.**

12 Section 408 of the Federal Food, Drug, and Cosmetic
 13 Act, as amended by section 101, is further amended by
 14 adding at the end the following:

15 “(u) INTERIM PROCEDURES FOR REVIEWS OF TOL-
 16 ERANCES.—

17 “(1) APPLICATION OF REQUIREMENTS TO CER-
 18 TAIN ACTIONS.—This subsection applies to—

19 “(A) any review (including a reassessment)
 20 by the Administrator of a tolerance, whether
 21 initiated by the Administrator or by petition by
 22 another person; and

23 “(B) any review (including a reassessment)
 24 by the Administrator of any registration of a
 25 pesticide chemical under the Federal Insecti-

1 cide, Fungicide, and Rodenticide Act (7 U.S.C.
 2 136 et seq.) that is associated with or results
 3 from such a tolerance review;
 4 that the Administrator issues during the period de-
 5 scribed in paragraph (2).

6 “(2) PERIOD OF APPLICABILITY.—The period
 7 referred to in paragraph (1) is the period beginning
 8 on January 1, 1999, and ending on the date of com-
 9 pletion of the process of reviewing tolerances under
 10 subsection (q).

11 “(3) LIMITATION.—Notwithstanding any other
 12 provision of law—

13 “(A) in any tolerance review (including a
 14 reassessment) to which this subsection applies,
 15 the Administrator may not base the revocation
 16 or denial of, or other adverse action regarding,
 17 a tolerance on any information, calculation, or
 18 assumption described in subsection (t)(3)(C);
 19 and

20 “(B) in any review (including a reassess-
 21 ment) to which this subsection applies of the
 22 registration of a pesticide chemical under the
 23 Federal Insecticide, Fungicide, and Rodenticide
 24 Act (7 U.S.C. 136 et seq.), the Administrator
 25 may not base any adverse action regarding a

1 registration on any such information, calcula-
 2 tion, or assumption.”.

3 **SEC. 103. IMPLEMENTATION RULES AND GUIDANCE.**

4 Section 408(e) of the Federal Food, Drug, and Cos-
 5 metic Act (21 U.S.C. 346a(e)) is amended by adding at
 6 the end the following:

7 “(3) IMPLEMENTATION RULES AND GUID-
 8 ANCE.—

9 “(A) IN GENERAL.—In establishing gen-
 10 eral procedures and requirements to implement
 11 this section in accordance with paragraph
 12 (1)(C), the Administrator shall issue rules and
 13 guidance, including guidance regarding the pro-
 14 visions of this Act regarding aggregate exposure
 15 to pesticide chemicals and cumulative effects of
 16 exposure to 2 or more pesticide chemicals hav-
 17 ing a common mechanism of toxicity. The Ad-
 18 ministrator shall include in such rules and guid-
 19 ance general procedures and requirements to
 20 implement the provisions of this Act that were
 21 added by amendments made by the Regulatory
 22 Openness and Fairness Act of 1999.

23 “(B) ISSUANCE.—The Administrator shall
 24 issue—

1 “(i) proposed rules and guidance de-
 2 scribed in subparagraph (A) not later than
 3 180 days after the date of enactment of
 4 the Regulatory Openness and Fairness Act
 5 of 1999;

6 “(ii) final rules and guidance de-
 7 scribed in subparagraph (A) not later than
 8 1 year after the date of enactment of the
 9 Regulatory Openness and Fairness Act of
 10 1999; and

11 “(iii) such revisions to the rules and
 12 guidance as the Administrator determines
 13 to be necessary and appropriate.”.

14 **SEC. 104. DATA IN SUPPORT OF TOLERANCES AND REG-**
 15 **ISTRATIONS.**

16 (a) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—
 17 Section 408(f) of the Federal Food, Drug, and Cosmetic
 18 Act (21 U.S.C. 346a(f)) is amended by adding at the end
 19 the following:

20 “(3) ISSUANCE OF GUIDELINES.—

21 “(A) IN GENERAL.—The Administrator
 22 shall issue guidelines specifying the kinds of in-
 23 formation that will be required to support the
 24 issuance or continuation of a tolerance for a
 25 pesticide chemical residue or the exemption

from the requirement of such a tolerance, established under this section. The Administrator shall revise the guidelines from time to time. The guidelines shall specify the conditions under which data requirements will apply to particular types of pesticide chemical residues.

“(B) PROCEDURES.—In issuing the guidelines described in subparagraph (A), the Administrator shall provide notice and an opportunity for comment, except for those guidelines that already have been issued after notice and an opportunity for comment under section 3(c)(2)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)(2)(A)).”.

(b) FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT.—The first sentence of section 3(c)(2)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c)(2)(A)) is amended by striking the period and inserting “, after providing notice and an opportunity for comment on the guidelines or revisions by interested parties.”.

SEC. 105. EXPEDITED ACTION.

(a) EXPEDITED ACTION TO PROVIDE EFFECTIVE, ECONOMIC ALTERNATIVES.—Section 3(c)(3) of the Fed-

1 eral Insecticide, Fungicide, and Rodenticide Act (7 U.S.C.
2 136a(c)(3)) is amended by adding at the end the following:

3 “(E) EXPEDITED ACTION TO PROVIDE EF-
4 FECTIVE, ECONOMIC ALTERNATIVES.—The Ad-
5 ministrators shall expedite the review of any
6 complete application for registration or amend-
7 ed registration of a pesticide under this section,
8 for an experimental use permit under section 5,
9 or for an emergency exemption under section
10 18, if the application seeks approval for the reg-
11 istration or use of a pesticide—

12 “(i) that, in the opinion of the Admin-
13 istrator, is likely to provide an effective
14 and economic alternative to the use of a
15 pesticide that has been or is likely to be re-
16 moved from the market as a result of a re-
17 view conducted under section 408 of the
18 Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 346a); and

20 “(ii) for which—

21 “(I) there is no registered effec-
22 tive and economical alternative (as of
23 the date of submission of the applica-
24 tion); or

1 “(II) the number of the alter-
 2 natives is insufficient to avoid prob-
 3 lems such as pest resistance.”.

4 (b) COORDINATION.—Section 408(d)(4)(B) of the
 5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 6 346a(d)(4)(B)) is amended—

7 (1) by striking “tolerance or exemption for”
 8 and inserting “tolerance or exemption—
 9 “(i) for”;

10 (2) by striking the period at the end and insert-
 11 ing “; or”; and

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

13 “(ii) that is needed in connection with
 14 an application under section 3(c)(3)(E) of
 15 the Federal Insecticide, Fungicide, and
 16 Rodenticide Act (7 U.S.C. 136a(c)(3)(E))
 17 for approval of an effective and economic
 18 alternative.”.

19 (c) TOLERANCES FOR EMERGENCY USES.—Section
 20 408(l)(6) of the Federal Food, Drug, and Cosmetic Act
 21 (21 U.S.C. 346a(l)(6)) is amended—

22 (1) by inserting before the first sentence the
 23 following:

24 “(A) IN GENERAL.—”;

1 (2) by inserting before the third sentence the
 2 following:

3 “(B) PROCEDURE.—”;

4 (3) by inserting before the fifth sentence the
 5 following:

6 “(C) SAFETY STANDARD.—”;

7 (4) in the fifth sentence, by striking the period
 8 and inserting “, except as described in subparagraph
 9 (D).”; and

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

11 “(D) EMERGENCY EXEMPTIONS.—The Ad-
 12 ministrator may establish a tolerance for a pes-
 13 ticide chemical residue associated with an emer-
 14 gency exemption without regard to other toler-
 15 ances for a pesticide chemical residue and be-
 16 fore reviewing those other tolerances, if the Ad-
 17 ministrator determines that any incremental ex-
 18 posure that may result from the tolerance asso-
 19 ciated with the emergency exemption will not
 20 pose any significant risk to food consumers.”.

21 **TITLE II—STUDIES AND** 22 **REPORTS**

23 **SEC. 201. DEFINITIONS.**

24 In this title:

1 (1) ADMINISTRATOR.—The term “Adminis-
2 trator” means the Administrator of the Environ-
3 mental Protection Agency.

4 (2) PESTICIDE CHEMICAL; PESTICIDE CHEM-
5 ICAL RESIDUE.—The terms “pesticide chemical” and
6 “pesticide chemical residue” have the meanings
7 given the terms in section 201 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 321).

9 (3) SECRETARY.—The term “Secretary” means
10 the Secretary of Agriculture.

11 (4) TOLERANCE.—The term “tolerance” means
12 a tolerance for a pesticide chemical residue or an ex-
13 emption from the requirement of such a tolerance,
14 established under section 408 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 346a).

16 **SEC. 202. PRIORITIES AND RESOURCES.**

17 (a) ENVIRONMENTAL PROTECTION AGENCY PRO-
18 POSAL.—The Administrator shall prepare a proposal for
19 revising the priorities of and resources available to the Ad-
20 ministrator that will allow the Administrator—

21 (1) to process promptly all—

22 (A) applications for registration of pes-
23 ticide chemicals under the Federal Insecticide,
24 Fungicide, and Rodenticide Act (7 U.S.C. 136
25 et seq.);

1 (B) petitions for tolerances (including ex-
2 emptions) under section 408 of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C.
4 346a);

5 (C) requests for experimental use permits,
6 for approval of new inert ingredients, and for
7 emergency exemptions, relating to pesticide
8 chemicals under an Act described in subpara-
9 graph (A) or (B); and

10 (D) requests for decisions on the merits of
11 the applications, petitions, and requests de-
12 scribed in subparagraphs (A) through (C); and

13 (2) to perform tolerance reviews (including re-
14 assessments) and other duties relating to pesticide
15 chemicals, as required by the Federal Food, Drug,
16 and Cosmetic Act or the Federal Insecticide, Fun-
17 gicide, and Rodenticide Act.

18 (b) DEPARTMENT OF AGRICULTURE PROPOSAL.—
19 The Secretary shall prepare a proposal for revising the
20 priorities of and resources available to the Secretary that
21 will allow the Secretary—

22 (1) to obtain and provide to the Administrator
23 adequate and timely information on food consump-
24 tion, pesticide chemical residues in or on food and
25 drinking water, and pesticide chemical use;

1 (2) to review actions proposed by the Adminis-
2 trator under section 408 of the Federal Food, Drug,
3 and Cosmetic Act and the Federal Insecticide, Fun-
4 gicide, and Rodenticide Act; and

5 (3) to perform other duties related to the regu-
6 lation of pesticide chemicals (including pesticide
7 chemical residues).

8 (c) REPORT.—The Administrator and the Secretary
9 shall prepare and submit to Congress a report containing
10 the proposals described in subsections (a) and (b) not later
11 than 180 days after the date of enactment of this Act.

12 **SEC. 203. INTERNATIONAL TRADE EFFECTS.**

13 (a) ASSESSMENT.—

14 (1) ASSESSMENT PROGRAM.—The Secretary
15 shall establish and administer a program to continu-
16 ously assess the strength of major United States ag-
17 ricultural commodities and products in the inter-
18 national marketplace. The commodities and products
19 assessed shall include fruits and vegetables, corn,
20 wheat, cotton, rice, soybeans, and nursery and forest
21 products.

22 (2) FACTORS.—In carrying out paragraph (1),
23 the Secretary shall examine factors pertinent to as-
24 sessing the sustainability and competitive strength of
25 each commodity and product in the international

1 marketplace and the relationship of the factors to
2 regulatory actions taken under the Federal Food,
3 Drug, and Cosmetic Act and the Federal Insecticide,
4 Fungicide, and Rodenticide Act. The factors exam-
5 ined for each commodity and product shall include
6 commodity changes, regional changes, prices, qual-
7 ity, input costs and availability, and the ratio of im-
8 ports to exports.

9 (b) REPORT.—The Secretary shall prepare periodic
10 reports describing the results obtained from the assess-
11 ment program conducted under subsection (a). The Sec-
12 retary shall submit the reports to the Committee on Agri-
13 culture of the House of Representatives and the Com-
14 mittee on Agriculture, Nutrition, and Forestry of the Sen-
15 ate. The Secretary shall submit the reports not later than
16 October 1, 2000, and October 1 of every second year
17 thereafter through 2010.

18 **SEC. 204. ADVISORY COMMITTEE.**

19 (a) ESTABLISHMENT.—There is established an advi-
20 sory committee to be known as the Pesticide Advisory
21 Committee (referred to in this section as the “Advisory
22 Committee”).

23 (b) MEMBERSHIP.—

24 (1) COMPOSITION.—The Advisory Committee
25 shall be composed of 20 members, appointed by the

1 Administrator and the Secretary. The members of
2 the Advisory Committee shall represent a wide vari-
3 ety of interests and viewpoints and shall be ap-
4 pointed from among individuals who are representa-
5 tives of organizations who are interested in the regu-
6 lation of pesticide chemicals, including representa-
7 tives of—

8 (A) organizations that represent—

9 (i) food consumers;

10 (ii) persons with a special interest in
11 environmental protection;

12 (iii) farmworkers;

13 (iv) agricultural producers (including
14 persons engaged in crop production, live-
15 stock and poultry production, or nursery
16 and forestry production);

17 (v) nonagricultural pesticide chemical
18 users;

19 (vi) food manufacturers and proc-
20 essors;

21 (vii) food distributors and marketers;

22 and

23 (viii) manufacturers of agricultural
24 and nonagricultural pesticide chemicals;

25 and

1 (B) Federal and State agencies.

2 (2) PUBLICATION.—The Administrator shall
3 publish in the Federal Register the name, address,
4 and professional affiliation of each member of the
5 Advisory Committee.

6 (3) TERMS OF APPOINTMENT.—Each member
7 of the Advisory Committee shall serve for a term of
8 years determined by the Administrator and the Sec-
9 retary, except that—

10 (A) the terms of service of the members
11 initially appointed shall be (as specified by the
12 Administrator and the Secretary) for such
13 fewer number of years as will provide for the
14 expiration of terms on a staggered basis;

15 (B) a member appointed to fill a vacancy
16 occurring prior to the expiration of the term for
17 which a predecessor was appointed, shall be ap-
18 pointed for the remainder of the term; and

19 (C) the Secretary and the Administrator
20 may extend the term of a member of the Advi-
21 sory Committee until a new member is ap-
22 pointed to fill the vacancy.

23 (4) VACANCIES.—Any vacancy occurring in the
24 membership of the Advisory Committee shall be
25 filled in the same manner as the original appoint-

1 ment. The vacancy shall not affect the power of the
2 remaining members to execute the duties of the Ad-
3 visory Committee.

4 (c) DUTIES.—The Advisory Committee shall—

5 (1) provide advice to the Administrator and the
6 Secretary on matters related to implementation of
7 section 408 of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 346a) and the Federal Insecti-
9 cide, Fungicide, and Rodenticide Act (7 U.S.C. 136
10 et seq.), including proposed and final rules, policies,
11 procedures, and testing guidelines used to regulate
12 tolerances and pesticide chemical registrations;

13 (2) foster communication between the Adminis-
14 trator, the Secretary, and the various organizations
15 who represent persons having particular interest in
16 the regulation of pesticide chemicals under the Fed-
17 eral Food, Drug, and Cosmetic Act and the Federal
18 Insecticide, Fungicide, and Rodenticide Act; and

19 (3) carry out the functions performed by the
20 Tolerance Reassessment Advisory Committee.

21 (d) MEETINGS.—

22 (1) FREQUENCY.—The Advisory Committee
23 shall meet at least 2 times per year, at times deter-
24 mined jointly by the Administrator and the Sec-
25 retary. Not later than 14 days before the date of

1 each meeting, the Administrator shall publish a no-
2 tice regarding the meeting in the Federal Register.

3 (2) OPEN MEETINGS.—The Advisory Com-
4 mittee shall conduct its principal business—

5 (A) in meetings that are—

6 (i) open to the public; and

7 (ii) in facilities that can accommodate
8 the reasonably foreseeable number of per-
9 sons attending; or

10 (B) by teleconference, with open access.

11 (3) FACILITIES.—The Secretary shall be re-
12 sponsible for providing or making arrangements for
13 the meeting facilities or teleconferences.

14 (e) COMMUNICATIONS.—The Administrator or the
15 Secretary shall ensure that written communications be-
16 tween the Administrator or Secretary, respectively, and
17 the Advisory Committee, are recorded and made available
18 to any person upon request.

19 (f) CHAIRPERSON.—The Advisory Committee shall
20 select a Chairperson from among its members.

21 (g) POWERS OF THE ADVISORY COMMITTEE.—

22 (1) HEARINGS.—The Advisory Committee may
23 hold such hearings, sit and act at such times and
24 places, take such testimony, and receive such evi-

dence as the Advisory Committee considers advisable to carry out this section.

(2) INFORMATION FROM FEDERAL AGENCIES.—

Except as otherwise provided in Federal law, the Advisory Committee may secure directly from any Federal department or agency such information as the Advisory Committee considers necessary to carry out this section. Upon request of the Chairperson of the Advisory Committee, the head of the department or agency shall furnish the information to the Advisory Committee.

(3) POSTAL SERVICES.—The Advisory Com-

mittee may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(4) GIFTS.—The Advisory Committee may ac-

cept, use, and dispose of gifts or donations of services or property.

(h) ADVISORY COMMITTEE PERSONNEL MATTERS.—

(1) TRAVEL EXPENSES.—

(A) IN GENERAL.—The members of the

Advisory Committee shall not receive compensation for the performance of services for the Advisory Committee, but shall be allowed travel expenses, including per diem in lieu of subsist-

1 ence, at rates authorized for employees of agen-
2 cies under subchapter I of chapter 57 of title 5,
3 United States Code, while away from their
4 homes or regular places of business in the per-
5 formance of services for the Advisory Com-
6 mittee.

7 (B) FUNDS.—Funds used to provide travel
8 expenses under subparagraph (A) shall be paid
9 by the Administrator from appropriations avail-
10 able for those purposes.

11 (2) DETAIL OF GOVERNMENT EMPLOYEES.—
12 Any employee of the Department of Agriculture (and
13 no other Federal employee) may be detailed to the
14 Advisory Committee without reimbursement, and the
15 detail shall be without interruption or loss of civil
16 service status or privilege.

17 (i) PERMANENT COMMITTEE.—Section 14 of the
18 Federal Advisory Committee Act (5 U.S.C. App.) shall not
19 apply to the Advisory Committee.

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