

103^D CONGRESS
2^D SESSION

S. 2084

To amend the Federal Food, Drug, and Cosmetic Act, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 5 (legislative day, MAY 2), 1994

Mr. KENNEDY introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To amend the Federal Food, Drug, and Cosmetic Act, 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; REFERENCE; TABLE OF CON-**
4 **TENTS.**

5 (a) SHORT TITLE.—This Act may be cited as the
6 “Pesticide Reform Act of 1994”.

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

1 sion of the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 301 et seq.).

3 (c) TABLE OF CONTENTS.—The table of contents of
4 this Act is as follows:

- Sec. 1. Short title; reference; table of contents.
- Sec. 2. Definitions.
- Sec. 3. Tolerances and exemptions for pesticide chemical residues.
 - “Sec. 408. Tolerances and exemptions for pesticide chemical residues.
 - “(a) Requirement for tolerance or exemption.
 - “(b) Tolerances.
 - “(c) Exemptions.
 - “(d) Petitions and action on the initiative of the Administrator.
 - “(e) Temporary tolerance or exemption.
 - “(f) Confidentiality of data.
 - “(g) Existing pesticide chemical residues.
 - “(h) Food and Drug Administration monitoring of pesticide chemical residues.
 - “(i) Fees.
 - “(j) Judicial review”.
- Sec. 4. Embargo authority.
- Sec. 5. Civil Money Penalties.
- Sec. 6. Recall.
- Sec. 7. Evaluation of existing pesticide chemical residue tolerances and exemptions.
- Sec. 8. Fees.
- Sec. 9. General definitions.

5 **SEC. 2. DEFINITIONS.**

6 (a) PESTICIDE.—

7 (1) PESTICIDE CHEMICAL.—Section 201(q) (21
8 U.S.C. 321(q)) is amended to read as follows:

9 “(q)(1) The term ‘pesticide chemical’ means any sub-
10 stance that is a pesticide, as defined in section 2(u) of
11 the Federal Insecticide, Fungicide, and Rodenticide Act
12 (7 U.S.C. 136(u)), including each active ingredient and
13 inert ingredient, as defined in paragraphs (a) and (m) of
14 section 2 of such Act, of the pesticide.

1 “(2) The term ‘pesticide chemical residue’ means a
2 residue in or on food of—

3 “(A) any pesticide chemical or a component of
4 such chemical; or

5 “(B) any other substance that is present in or
6 on the commodity or food as a result of the metabo-
7 lism or other degradation of a pesticide chemical.”.

8 (2) PERSON.—Section 201(s) (21 U.S.C.
9 321(s)) is amended—

10 (A) by striking paragraphs (1) and (2) and
11 inserting the following:

12 “(1) pesticide chemical residue; or”; and

13 (B) by redesignating paragraphs (3), (4),
14 and (5) as paragraphs (2), (3), and (4), respec-
15 tively.

16 (3) RAW AGRICULTURAL COMMODITY.—Para-
17 graph (r) of section 201 (21 U.S.C. 321) is repealed.

18 (b) CONFORMING AMENDMENTS.—

19 (1) Section 201 (21 U.S.C. 321) is amended by
20 adding at the end the following:

21 “(gg) The term ‘Administrator’ means the Adminis-
22 trator of the Environmental Protection Agency.”.

23 (2) Section 402(a)(2) (21 U.S.C. 342(a)(2)) is
24 amended—

1 (A) in clause (A)(i), to read as follows: “(i)
2 a pesticide chemical residue”;

3 (B) in clause (B), to read as follows: “(B)
4 if it bears or contains a pesticide chemical resi-
5 due that is unsafe within the meaning of sec-
6 tion 408(a);”; and

7 (C) in clause (C), by striking “: *Provided*,
8 That where a pesticide chemical” through “sec-
9 tion 512”.

10 (3) Section 403(l) (21 U.S.C. 343(l)) is amend-
11 ed by striking “raw agricultural commodity” and
12 “commodity” each time it occurs and inserting
13 “food”.

14 **SEC. 3. TOLERANCES AND EXEMPTIONS FOR PESTICIDE**
15 **CHEMICAL RESIDUES.**

16 Section 408 (21 U.S.C. 346a) is amended to read as
17 follows:

18 **“SEC. 408. TOLERANCES AND EXEMPTIONS FOR PESTICIDE**
19 **CHEMICAL RESIDUES.**

20 “(a) REQUIREMENT FOR TOLERANCE OR EXEMP-
21 TION.—

22 “(1) GENERAL RULE.—Any pesticide chemical
23 residue shall be deemed unsafe for the purpose of
24 section 402(a)(2)(B) unless—

1 “(A) a tolerance for such residue is in ef-
2 fect under this section and such residue con-
3 forms with such tolerance; or

4 “(B) an exemption for such residue is in
5 effect under this section and such residue con-
6 forms with such exemption.

7 “(2) EFFECT OF A TOLERANCE OR EXEMP-
8 TION.—While a tolerance or exemption from the re-
9 quirement for a tolerance is in effect under this sec-
10 tion for a pesticide chemical residue with respect to
11 any food, such food shall not by reason of bearing
12 or containing any amount of such residue be consid-
13 ered to be adulterated within the meaning of section
14 402(a)(1).

15 “(3) DERIVED FOOD.—A tolerance or exemp-
16 tion for a pesticide chemical residue established for
17 a food shall apply to all foods derived from such
18 food unless a tolerance specifies otherwise.

19 “(b) TOLERANCES.—

20 “(1) AUTHORITY.—

21 “(A) IN GENERAL.—The Administrator
22 may promulgate regulations establishing, modi-
23 fying, or revoking a tolerance for a pesticide
24 chemical residue—

1 “(i) in response to a petition filed
2 under subsection (d)(1); or

3 “(ii) on the initiative of the Adminis-
4 trator under subsection (d)(4).

5 “(B) EXPIRATION DATE.—A regulation
6 under this paragraph shall contain an expira-
7 tion date for a tolerance for a pesticide chemi-
8 cal established by the regulation. Such date
9 shall be not later than—

10 “(i) the expiration date (if any) for
11 such pesticide chemical established by the
12 Administrator under section 3 of the Fed-
13 eral Insecticide, Fungicide, and
14 Rodenticide Act, or

15 “(ii) 18 years after the date such tol-
16 erance is established, whichever occurs
17 first.

18 “(C) SEPARATE TOLERANCES.—Under
19 subparagraph (A), the Administrator may es-
20 tablish a separate tolerance, which more closely
21 reflects actual exposure or which is necessary
22 for more efficient enforcement, and which is
23 based on reliable data and information relating
24 to the appropriate sampling, for a pesticide
25 chemical residue with respect to food at any

1 point in the chain of production or marketing,
2 including—

3 “(i) at the time the food is harvested,

4 “(ii) at the time the food is purchased
5 at retail, and

6 “(iii) after the food is processed.

7 “(2) STANDARD.—

8 “(A) ASSURANCE OF SAFETY.—

9 “(i) GENERAL RULE.—A tolerance for
10 a pesticide chemical residue in or on food
11 shall not be established or left in effect un-
12 less the residue permitted under the toler-
13 ance is safe.

14 “(ii) CANCER.—For pesticides found
15 to induce cancer when ingested by humans
16 or animals or determined on the basis of
17 reliable scientific evidence to pose a poten-
18 tial dietary risk of cancer in humans, a tol-
19 erance shall not be established or left in ef-
20 fect unless the Administrator finds on the
21 basis of conservative methods of risk as-
22 sessment that the risk is negligible for all
23 anticipated consumer exposures to such
24 residue, including all other anticipated
25 consumer exposures for which there is reli-

1 able information, and taking into account
2 information concerning the special
3 vulnerabilities of children and sensitive
4 subpopulations.

5 “(iii) RISK OTHER THAN CANCER.—
6 For pesticide chemical residues that may
7 pose a potential dietary risk of adverse
8 health effects other than cancer in hu-
9 mans, a tolerance shall provide an ample
10 margin of safety.

11 “(iv) DEFINITIONS.—As used in this
12 section:

13 “(I) SAFE.—The term ‘safe’
14 means with respect to a tolerance for
15 a pesticide chemical residue that there
16 is a reasonable certainty that no harm
17 will result from all anticipated
18 consumer exposures to such residue,
19 including all anticipated dietary expo-
20 sures and all other anticipated expo-
21 sures for which there is reliable infor-
22 mation, and taking into account infor-
23 mation concerning the special
24 vulnerabilities of children and sen-
25 sitive subpopulations.

1 “(II) MARGIN OF SAFETY.—A
2 margin of safety is considered ample
3 if the Administrator determines there
4 is a reasonable certainty of no harm
5 to significant subpopulations from ex-
6 posure to the pesticide chemical resi-
7 due in the diet and from exposure to
8 the pesticide chemical by other path-
9 ways. In making this determination,
10 the Administrator shall give due con-
11 sideration to the exposure level which
12 is determined not to cause adverse ef-
13 fects in animal studies or in observa-
14 tions of exposed humans and to the
15 application of appropriate factors.
16 These factors may include factors to
17 account for differences in sensitivity
18 between and within species, adequacy
19 of the study or studies, and complete-
20 ness of the available data to assess
21 potential for adverse effects.

22 “(III) RISK ASSESSMENT PROCE-
23 DURES.—The Administrator shall pe-
24 riodically review the risk assessment
25 procedures used to make safety deter-

1 minations under this paragraph, in-
2 cluding methodologies with respect to
3 estimating exposure to pesticide
4 chemicals and evaluating risks to sig-
5 nificant subpopulations. The Adminis-
6 trator periodically shall revise the risk
7 assessment procedures accordingly to
8 incorporate advances in science and
9 risk assessment. The Administrator
10 may determine that a method of risk
11 assessment different from the method
12 required by subclause (II) is appro-
13 priate if the Administrator finds that
14 the alternative risk assessment meth-
15 od will fully protect the public health.

16 “(B) FACTORS.—In determining whether
17 to establish, modify, or revoke a tolerance under
18 subparagraph (A) for a pesticide chemical resi-
19 due on a food, the Administrator—

20 “(i) except as provided in clause (ii),
21 shall in estimating the anticipated dietary
22 exposure to such residue assume that all
23 food for which the pesticide chemical resi-
24 due has or will have a tolerance bears or
25 contains residues of the pesticide chemical

1 equal to the levels established by their re-
2 spective tolerances and where separate tol-
3 erances for a pesticide chemical residue in
4 the same food are established for different
5 points in the chain of production or mar-
6 keting pursuant to subsection (b)(1)(C),
7 the Administrator shall assume that the
8 food bears or contains residues of the pes-
9 ticide chemical equal to the level estab-
10 lished by the tolerance set at the point
11 closest to the time the food is purchased at
12 retail;

13 “(ii) may use data regarding the per-
14 cent of a crop treated by a pesticide chemi-
15 cal to estimate dietary exposure to such
16 residue only if the Administrator—

17 “(I) finds that the data are reli-
18 able and provide a valid basis to show
19 what percentage of the food derived
20 from such crop is likely to contain
21 such pesticide chemical residue;

22 “(II) finds that the exposure esti-
23 mate does not understate exposure for
24 any significant subpopulation group;

1 “(III) if data are available on
2 pesticide use and consumption of food
3 in a particular area, finds that the
4 population in such area is not
5 dietarily exposed to residues above
6 those estimated by the Administrator;
7 and

8 “(IV) provides for the periodic
9 reevaluation of the estimate of antici-
10 pated dietary exposure;

11 “(iii) shall fully account for available
12 information on the probable consumption
13 of foods for which there is or will be a tol-
14 erance for residues of the pesticide chemi-
15 cal, including, to the extent possible, con-
16 sumption by significant subpopulations
17 with differing food consumption patterns,
18 including infants, children, and other sub-
19 populations with disproportionately high
20 consumption of particular foods;

21 “(iv) shall fully account for available
22 information on the cumulative effect of
23 such residue and any chemically or phar-
24 macologically related substances in the
25 human diet, and other ways in which the

1 consumer may be exposed to such residue
2 and substances, including, to the extent
3 representative data permit, through drink-
4 ing water;

5 “(v) shall fully account for valid sci-
6 entific information regarding any estro-
7 genic or other hormonal effects associated
8 with the residue; and

9 “(vi) shall apply safety factors which
10 after consultation with experts qualified by
11 scientific training and experience to evalu-
12 ate the safety of pesticide chemical resi-
13 dues determine are appropriate for use in
14 connection with animal experimentation or
15 other relevant data.

16 “(C) EXPOSURE OF INFANTS AND CHIL-
17 DREN.—In determining whether to establish,
18 modify, or revoke a tolerance for a pesticide
19 chemical residue, the Administrator, in addition
20 to the requirements of subparagraph (B)—

21 “(i) shall assess the risk of the pes-
22 ticide chemical residue based on the follow-
23 ing:

24 “(I) Available information about
25 consumption patterns among infants

1 and children that are likely to result
2 in disproportionately high consump-
3 tion of foods containing or bearing
4 such residue among infants and chil-
5 dren in comparison to the general
6 population.

7 “(II) Available information con-
8 cerning the special susceptibility of in-
9 fants and children to the pesticide
10 chemical residues, including neuro-
11 logical differences between infants and
12 children and adults, and effects of in
13 utero exposure to pesticide chemicals.

14 “(III) Available information con-
15 cerning the cumulative effects on in-
16 fants and children of such residues
17 and other substances that have a com-
18 mon mechanism of toxicity;

19 “(ii) shall—

20 “(I) ensure that there is an
21 ample margin of safety for infants
22 and children and impose other re-
23 quirements necessary to ensure that
24 exposure to the pesticide chemical res-
25 idue will be safe; and

1 “(II) publish a specific deter-
2 mination regarding the safety of the
3 pesticide chemical residue for infants
4 and children.

5 The Secretary of Health and Human Services
6 and the Secretary of Agriculture, in consulta-
7 tion with the Administrator, shall conduct sur-
8 veys to document dietary exposure to pesticides
9 among infants and children. For the purpose of
10 subclause (I), an additional tenfold margin of
11 safety for the pesticide chemical residue and
12 other sources of exposure shall be applied for
13 children and infants to take into account poten-
14 tial pre- and post-natal toxicity and complete-
15 ness of the data with respect to exposure to in-
16 fants and children. Notwithstanding this re-
17 quirement for an additional factor, the Admin-
18 istrator may determine that a margin of safety
19 for a pesticide chemical residue is considered
20 ample for children and infants if, on the basis
21 of reliable data, such margin will fully protect
22 the public health.

23 “(D) UNAVOIDABLE PERSISTENCE.—If a
24 tolerance or an exemption from the requirement
25 for a tolerance for a pesticide chemical residue

1 is revoked and the Administrator finds the pes-
2 ticide chemical residue will unavoidably persist
3 in the environment and be found in food, the
4 Administrator shall establish a new tolerance
5 under subsection (d)(4) for the pesticide chemi-
6 cal residue. The level permitted by the tolerance
7 shall not be greater than and may be less than
8 the lowest level that permits only such unavoid-
9 able levels to remain in food. The Administrator
10 shall evaluate any such tolerance at least every
11 five years to determine whether modification of
12 such tolerance is necessary so that the tolerance
13 provides only for no greater than the level of
14 the pesticide chemical residue that is unavoid-
15 able.

16 “(E) PRACTICAL METHODS OF ANALY-
17 SIS.—

18 “(i) GENERAL RULE.—Except as pro-
19 vided in clause (ii), a tolerance for a pes-
20 ticide chemical residue shall not be estab-
21 lished or left in effect unless the Adminis-
22 trator determines, after consultation with
23 the Secretary, that—

24 “(I) there is a multiresidue meth-
25 od for detecting and measuring the

1 levels of such pesticide chemical resi-
2 due in or on a food that will measure
3 the residue at the level established by
4 the tolerance; and

5 “(II) such method can be per-
6 formed by the Secretary on a routine
7 basis as part of surveillance and com-
8 pliance sampling of foods for pesticide
9 chemical residues with the personnel,
10 equipment, and other resources avail-
11 able to the Secretary.

12 “(ii) EXCEPTION.—If the Adminis-
13 trator is not able to make the determina-
14 tion described in clause (i), the Adminis-
15 trator shall identify, after consultation
16 with the Secretary, the method for detect-
17 ing and measuring levels of such pesticide
18 chemical residue in or on a food that will
19 measure the residue at the level established
20 by the tolerance. The Administrator shall,
21 every two years after the date of the deter-
22 mination under this clause, reevaluate the
23 determination.

24 “(iii) PESTICIDE REFERENCE STAND-
25 ARD.—

1 “(I) PROVISION TO THE ADMIN-
2 ISTRATOR.—A registrant of a pes-
3 ticide chemical for which a tolerance
4 has been established shall provide the
5 Administrator, upon request, with an
6 appropriate pesticide reference stand-
7 ard for such pesticide chemical, in-
8 cluding standards for all residues of
9 toxicological significance. Each pes-
10 ticide reference standard provided to
11 the Administrator shall be certified by
12 a competent laboratory for both iden-
13 tity and purity.

14 “(II) ADMINISTRATOR AC-
15 TIONS.—The Administrator shall
16 maintain a repository of pesticide ref-
17 erence standards, audit the certifi-
18 cation of such standards, and make
19 such standards available to any pri-
20 vate, public, domestic, or foreign lab-
21 oratory requesting the standard. The
22 Administrator may also request pes-
23 ticide reference standards for pesticide
24 chemical manufactured or used in for-
25 eign countries. To the extent that the

1 Administrator obtains standards for
2 pesticide chemicals manufactured or
3 used in foreign countries, the Admin-
4 istrator shall certify such standards
5 for identity and purity and make
6 them available to any private, public,
7 domestic, or foreign laboratory re-
8 questing such standard.

9 “(III) DEFINITION.—For pur-
10 poses of this clause, the term ‘pes-
11 ticide reference standard’ means a
12 pesticide chemical of known identity,
13 purity, and composition that is re-
14 quired for comparison purposes in lab-
15 oratory analysis to measure the
16 amount and confirm the identity of a
17 pesticide chemical residue in food.

18 “(3) CONSISTENT APPLICATION.—The Adminis-
19 trator shall issue guidelines providing for the con-
20 sistent application of the requirements of paragraphs
21 (1) and (2). The lack of guidelines does not affect
22 the authority of the Administrator to implement
23 such paragraphs.

24 “(4) REEVALUATION PERIOD.—Each tolerance
25 for a pesticide chemical residue established under

1 this subsection shall prescribe the period (at least
2 every five years) for reevaluating the estimate of the
3 amount of dietary exposure to such residue made
4 under paragraph (2)(B)(ii).

5 “(5) TOLERANCES IN EFFECT ON DATE OF EN-
6 ACTMENT.—For pesticide chemical residue toler-
7 ances in effect on the date of enactment of the Pes-
8 ticide Reform Act of 1994 this subsection shall
9 apply as prescribed by section 7 of such Act.

10 “(c) EXEMPTIONS.—

11 “(1) AUTHORITY.—

12 “(A) IN GENERAL.—The Administrator
13 may promulgate regulations establishing or re-
14 voking an exemption from the requirement for
15 a tolerance for a pesticide chemical residue—

16 “(i) in response to a petition filed
17 under subsection (d)(1); or

18 “(ii) on the initiative of the Adminis-
19 trator under subsection (d)(4).

20 “(B) EXPIRATION DATE.—Such a regula-
21 tion may provide for an expiration date for the
22 exemption.

23 “(2) STANDARD.—

24 “(A) AUTHORITY AND RISK STANDARD.—

1 “(i) ESTABLISHMENT.—An exemption
2 may be established for a pesticide chemical
3 residue if such residue is not a human or
4 animal carcinogen and presents no risk to
5 human health at any level that is reason-
6 ably likely to occur under extreme condi-
7 tions of use, including the health of the
8 subpopulations identified in subsection
9 (b)(2)(B)(iii), from dietary exposure to
10 such residue.

11 “(ii) REVOCATION.—An exemption
12 shall be revoked unless the residue is not
13 a human or an animal carcinogen and oth-
14 erwise presents no risk to human health at
15 any level that is reasonably likely to occur
16 under extreme conditions of use, including
17 the health of subpopulations identified in
18 subsection (b)(2)(B)(iii), from dietary ex-
19 posure to such residue.

20 “(B) EXPOSURE.—For purposes of sub-
21 paragraph (A), in determining dietary exposure
22 to a pesticide chemical residue, the Adminis-
23 trator shall—

24 “(i) use only reliable information re-
25 garding the dietary exposure resulting

1 from the consumption of the food for
2 which the exemption for such residue is
3 proposed or is in effect;

4 “(ii) fully account for all other exemp-
5 tions in effect for such residue;

6 “(iii) fully account for all other
7 sources of dietary exposure to the pesticide
8 chemical and to chemically or pharma-
9 cologically related chemicals if there is ade-
10 quate information about such sources of
11 exposure; and

12 “(iv) consider the exposure to be the
13 level of exposure that would occur if
14 human exposure to the pesticide chemical
15 residue at the level that is reasonably likely
16 to occur under extreme conditions of use
17 occurs for a period equal to a lifetime.

18 “(3) CONSISTENT APPLICATION.—The Adminis-
19 trator shall issue guidelines providing for the con-
20 sistent application of the requirements of paragraphs
21 (1) and (2). The lack of guidelines does not affect
22 the authority of the Administrator to implement
23 such paragraphs.

24 “(4) EXEMPTIONS IN EFFECT ON DATE OF EN-
25 ACTMENT.—For pesticide chemical residue exemp-

1 tions in effect on the date of enactment of the Pes-
2 ticide Reform Act of 1994 this subsection shall
3 apply as prescribed by section 7 of such Act.

4 “(d) PETITIONS AND ACTION ON THE INITIATIVE OF
5 THE ADMINISTRATOR.—

6 “(1) GENERAL RULE.—Any person may file
7 with the Administrator a petition proposing the issu-
8 ance of a regulation establishing, modifying, or re-
9 voking a tolerance or exemption for a pesticide
10 chemical residue. Sections 553 and 554 of title 5,
11 United State Code, shall not apply with respect to
12 procedures concerning such petitions.

13 “(2) REQUIREMENTS FOR PETITIONS.—A peti-
14 tion under paragraph (1) to establish a tolerance or
15 exemption for a pesticide chemical residue shall con-
16 tain—

17 “(A) an informative summary of the peti-
18 tion and of the data, information, and argu-
19 ments submitted or cited in support of the peti-
20 tion, including—

21 “(i) a summary of the reports re-
22 quired under subparagraph (D); and

23 “(ii) a characterization of—

24 “(I) the exposure to the pesticide
25 chemical residue due to any tolerance

1 or exemption already granted for such
2 residue; and

3 “(II) the additional exposure to
4 such residue that would result if the
5 requested tolerance or exemption were
6 granted;

7 “(B) a proposed tolerance for such residue,
8 if a tolerance is proposed;

9 “(C) the name, chemical identity, and com-
10 position of the pesticide chemical that produces
11 such residue;

12 “(D) reports of tests and investigations
13 made with respect to the safety of such pes-
14 ticide chemical residue, including complete in-
15 formation as to the methods and controls used
16 in conducting such tests and investigations;

17 “(E) data showing the amount, frequency,
18 method, and time of application of such pes-
19 ticide chemical;

20 “(F) reports of tests and investigations
21 made with respect to the nature and amount of
22 the pesticide chemical residue that is likely to
23 remain in or on food when ready for sale to
24 consumers, including a description of the ana-
25 lytical methods used;

1 “(G) a description of methods for detecting
2 and measuring the levels of such chemical resi-
3 due in or on the food, which methods meet the
4 requirements of subsection (b)(2)(E);

5 “(H) reports of investigations conducted
6 on the effects of processing methods used to
7 produce food on the level and identity of such
8 pesticide chemical residue;

9 “(I) if the petition is for a pesticide chemi-
10 cal residue that is described in subsection
11 (b)(2)(A)(ii), all relevant data bearing on the
12 physical or other technical effect the pesticide
13 chemical involved is intended to have and the
14 quantity of the pesticide chemical residue re-
15 quired to accomplish such effect;

16 “(J) the pesticide reference standard (as
17 defined in subsection (b)(2)(E)(iii)) for the pes-
18 ticide chemical residue;

19 “(K) such other data and information as
20 the Administrator may require to support the
21 petition; and

22 “(L) the data referred to in subsection
23 (b)(2)(B)(ii)(III) if available.

24 “(3) ACTIONS ON PETITIONS.—

25 “(A) FILING DETERMINATION.—

1 “(i) IN GENERAL.—Within 45 days of
2 the filing of a petition under paragraph (1)
3 for the establishment, modification, or rev-
4 ocation of a tolerance or an exemption, the
5 Administrator shall determine if the peti-
6 tion complies with the requirements of
7 paragraph (2) or applicable requirements
8 for petitions to modify or revoke tolerances
9 or exemptions from tolerances. If the Ad-
10 ministrator determines that the petition
11 complies with such requirements, the Ad-
12 ministrator shall publish a notice of the fil-
13 ing of the petition. If the Administrator
14 determines that the petition does not com-
15 ply with such requirements, the Adminis-
16 trator shall notify the petitioner of such
17 determination.

18 “(ii) CONTENTS OF NOTICE OF FIL-
19 ING.—A notice under clause (i) shall—

20 “(I) if it is a notice of the filing
21 of a petition to establish a tolerance
22 or exemption, announce the availabil-
23 ity of a complete description of the
24 analytical methods available to the
25 Administrator for the detection and

1 measurement of the pesticide chemical
2 residue with respect to which the peti-
3 tion is filed and include the summary
4 required by paragraph (2)(A); and

5 “(II) if it is a notice of the filing
6 of a petition to modify or revoke a tol-
7 erance or exemption, contain the full
8 petition or a summary of the petition.

9 “(B) ACTION.—The Administrator shall,
10 within one year of the publication of a notice
11 under subparagraph (A) with respect to a peti-
12 tion, and after giving due consideration to the
13 petition, any comments on the petition, and any
14 other information available to the Adminis-
15 trator—

16 “(i) issue a final regulation in accord-
17 ance with the petition establishing, modify-
18 ing, or revoking a tolerance or exemption
19 for the pesticide chemical residue;

20 “(ii) issue a proposed regulation es-
21 tablishing, modifying, or revoking a toler-
22 ance or exemption for the pesticide chemi-
23 cal residue, which tolerance or exemption
24 is different from the tolerance or exemp-
25 tion requested in the petition; or

1 “(iii) issue an order denying the peti-
2 tion.

3 “(C) COMMENTS.—If the Administrator is-
4 sues a notice of the filing of a petition under
5 subparagraph (A)(i) or a proposed regulation
6 under subparagraph (B)(ii), the Administrator
7 shall allow at least thirty days for comments on
8 such notice or proposed regulation.

9 “(D) FINAL REGULATION.—If the Admin-
10 istrator issues a proposed regulation under sub-
11 paragraph (B)(ii), the Administrator shall issue
12 a final regulation within one hundred and
13 eighty days of the date of the publication of the
14 proposed regulations.

15 “(E) PRIORITIES.—The Administrator
16 shall give priority to petitions for the establish-
17 ment or modification of a tolerance for a pes-
18 ticide chemical residue that appears to pose a
19 significantly lower risk to human health from
20 dietary exposure than pesticide chemical resi-
21 dues that have tolerances in effect for the same
22 or similar uses.

23 “(4) ACTION ON THE ADMINISTRATOR’S INITIA-
24 TIVE.—

1 “(A) GENERAL RULE.—The Administrator
2 may, on the initiative of the Administrator,
3 issue a final regulation establishing, modifying,
4 or revoking a tolerance or exemption for a pes-
5 ticide chemical residue.

6 “(B) NOTICE.—Before issuing a final reg-
7 ulation under subparagraph (A), the Adminis-
8 trator shall issue a notice of proposed rule-
9 making and provide a period of not less than
10 thirty days for public comment on the proposed
11 regulation unless the Administrator finds that
12 such notice and comment would be contrary to
13 the public interest and states the reasons for
14 the finding in the notice of the final regulation.
15 If the Administrator makes such a finding and
16 issues such a regulation, the Administrator
17 shall provide at least thirty days for comment
18 on the regulation after it is issued.

19 “(5) EFFECTIVE DATE.—

20 “(A) GENERAL RULE.—Except as provided
21 in subparagraph (B), a final regulation issued
22 under paragraph (3) or (4) shall take effect
23 upon publication.

24 “(B) DELAY.—

1 “(i) GENERAL RULE.—If a regulation
2 issued under paragraph (3) or (4) revokes
3 or modifies a tolerance for a pesticide
4 chemical residue or revokes an exemption
5 for a pesticide chemical residue, the Ad-
6 ministrator may, in accordance with clause
7 (ii), delay the effective date of the regula-
8 tion to permit the tolerance or exemption
9 to remain in effect at a level not to exceed
10 the level in effect immediately before such
11 regulation is issued only—

12 “(I) for foods that contain such
13 pesticide chemical residue in an
14 amount that is not more than the
15 amount that would remain if the pes-
16 ticide chemical had been legally ap-
17 plied on the date the Administrator
18 acted under paragraph (3) or (4); and

19 “(II) if dietary exposure to the
20 pesticide chemical residue in or on the
21 foods described in subclause (I) is safe
22 during the period of delay of the effec-
23 tive date.

24 “(ii) PERIOD OF DELAY.—If the Ad-
25 ministrator finds that delay of the effective

1 date of such a revocation or modification is
2 consistent with the public health, the Ad-
3 ministrator may delay such date under
4 clause (i), for each type of food that con-
5 tains such pesticide chemical residue, for
6 the period that is required for such food to
7 be sold to consumers in the course of the
8 usual practice for persons engaged in the
9 production, processing, transportation,
10 storage, and distribution of the food.

11 “(6) REQUIRED SUBMISSION OF DATA.—

12 “(A) GENERAL RULE.—If the Adminis-
13 trator finds that additional data are required to
14 determine whether an existing tolerance or ex-
15 emption from a tolerance meets the safety
16 standard in subsection (b)(2) or (c)(2), the Ad-
17 ministrator shall publish an order—

18 “(i) requiring one or more interested
19 persons to notify the Administrator that
20 such person will submit the required data;

21 “(ii) describing the type of data re-
22 quired to be submitted;

23 “(iii) describing the reports required
24 to be made during and after the collection
25 of the data; and

1 “(iv) establishing deadlines for the ac-
2 tions described in clauses (i), (ii), and (iii).

3 “(B) DEADLINES.—If an order is issued
4 under subparagraph (A) with respect to a toler-
5 ance or an exemption and the Administrator
6 finds that a deadline or other condition in the
7 order is not met, the Administrator may revoke,
8 pursuant to the procedures in paragraph (4),
9 the tolerance or exemption for failure to comply
10 with such order.

11 “(C) EXTENSIONS.—

12 “(i) EXTENSION REQUEST.—Any per-
13 son may request the Administrator to issue
14 an order to extend the schedule established
15 under subparagraph (A) before the expira-
16 tion of a deadline in the schedule.

17 “(ii) GRANT OF REQUEST.—The Ad-
18 ministrator may grant a request under
19 clause (i) only if the Administrator finds
20 that extraordinary circumstances beyond
21 the control of such person prevented such
22 person from submitting the required data.

23 “(iii) EXTENSION.—If the Adminis-
24 trator issues an order extending a sched-
25 ule, the Administrator may extend the

1 deadline for a period no longer than such
2 time as is necessary for such person to
3 submit the data.

4 “(7) TOLERANCE FOR USE OF PESTICIDES
5 UNDER AN EMERGENCY EXEMPTION.—If the Admin-
6 istrator grants an exemption under section 18 of the
7 Federal Insecticide, Fungicide, and Rodenticide Act
8 (7 U.S.C. 136p) for a pesticide chemical, the Admin-
9 istrator shall establish a tolerance or exemption from
10 a tolerance for the residue of the pesticide chemical.
11 Such a tolerance or exemption from a tolerance shall
12 have an expiration date. The Administrator may es-
13 tablish such a tolerance or exemption without pro-
14 viding notice or a period for comment on the toler-
15 ance or exemption. The Administrator shall promul-
16 gate regulations within 365 days after the date of
17 the enactment of this paragraph governing the es-
18 tablishment of tolerances and exemptions under this
19 paragraph. Such regulations shall be consistent with
20 the safety standard under subsection (b)(2) and with
21 section 18 of the Federal Insecticide, Fungicide, and
22 Rodenticide Act.

23 “(e) EXPERIMENTAL PERMITS.—To the extent con-
24 sistent with the public health, the Administrator shall pro-
25 mulgate regulations for exempting from the operation of

1 this section new pesticide chemicals intended solely for in-
2 vestigational use by experts qualified by scientific training
3 and experience to investigate the safety of pesticide chemi-
4 cals. Such regulations may, in the discretion of the Admin-
5 istrator, among other conditions relating to the protection
6 of the public health, provide for—

7 “(1) conditioning such exemption upon the es-
8 tablishment and maintenance of such records, and

9 “(2) the making of such reports to the Sec-
10 retary, by the manufacturer or the sponsor of the in-
11 vestigation of such article, of data (including analyt-
12 ical reports by investigators) obtained as a result of
13 such investigational use of such article, as well as
14 enable the Administrator to evaluate the safety of
15 such article in the event of the filing of an applica-
16 tion pursuant to this section. Such regulations,
17 among other things, shall set forth the conditions (if
18 any) upon which food treated with such pesticide
19 chemicals may be marketed for food use.

20 “(f) CONFIDENTIALITY OF DATA.—

21 “(1) ACCESS TO DATA AND INFORMATION.—

22 “(A) GENERAL RULE.—Except as provided
23 in paragraphs (2) and (3), the Administrator
24 shall not make public data or information sub-
25 mitted to the Administrator or cited to the Ad-

1 administrator in a petition under subsection
2 (d)(1) and data and information otherwise con-
3 sidered by the Administrator in issuing a pro-
4 posed or final regulation or order under this
5 section which contains or relates to trade se-
6 crets or commercial or financial information ob-
7 tained from a person and is privileged or con-
8 fidential. The person submitting information
9 which they believe is privileged or confidential
10 information shall notify the Administrator of
11 such information. If a notice is not made to the
12 Administrator, the Administrator may make
13 such information public.

14 “(B) NOTICE.—Except as to data or infor-
15 mation disclosed under paragraph (2), thirty
16 days before disclosing data or information
17 claimed as privileged or confidential under sub-
18 paragraph (A), the Administrator shall notify
19 the person who submitted or cited the data or
20 information of the intent to disclose the data or
21 information to the public.

22 “(2) AUTHORIZED DISCLOSURE FOR GOVERN-
23 MENTAL PURPOSES.—Data and information that are
24 entitled to confidential treatment under paragraph
25 (1)—

1 “(A) shall be disclosed to either House of
2 Congress, to the extent of matter within its ju-
3 risdiction, to any committee or subcommittee of
4 the Congress, and to any joint committee of the
5 Congress or subcommittee of such a joint com-
6 mittee and to the Comptroller General of the
7 United States;

8 “(B) shall be disclosed to any officer or
9 employee of the United States or of any
10 State—

11 “(i) in connection with the official du-
12 ties of such officer or employee under any
13 law for the protection of health or the envi-
14 ronment, or

15 “(ii) for specific law enforcement pur-
16 poses;

17 “(C) shall be disclosed, under such security
18 requirements as the Administrator may provide,
19 to contractors with the United States and em-
20 ployees of such contractors, if such disclosure is
21 necessary for the satisfactory performance by
22 the contractor of a contract with the United
23 States or for work in connection with this sec-
24 tion or other statutes administered by the Ad-
25 ministrator;

1 “(D) shall be disclosed to the extent the
2 Administrator determines disclosure is nec-
3 essary to protect the public health; and

4 “(E) may be disclosed when relevant in
5 any proceeding under this section, except that
6 disclosure in such a proceeding shall be made in
7 such manner as to preserve confidentiality to
8 the extent practicable.

9 “(3) DISCLOSURE OF HEALTH EFFECTS DATA
10 AND RESIDUE DATA.—

11 “(A) GENERAL RULE.—All data and infor-
12 mation concerning any test of a pesticide chem-
13 ical residue or a pesticide chemical to determine
14 the potential effects of such residue or chemical
15 on human health or concerning the levels of
16 such residue in or on food shall be available for
17 disclosure to the public except to the extent
18 such data or information include—

19 “(i) manufacturing or quality control
20 processes,

21 “(ii) methods for detecting the quan-
22 tity of any deliberately added inert ingredi-
23 ent of a pesticide chemical other than
24 methods for detecting residues of the inert
25 ingredient in or on food, or

1 “(iii) the identity or quantity of any
2 deliberately added inert ingredient of a
3 pesticide chemical other than an inert in-
4 gredient which is the subject of a petition
5 under subsection (d)(1) or an action of the
6 Administrator under subsection (d)(4).

7 “(B) DATA AND INFORMATION ALSO SUB-
8 MITTED UNDER FIFRA.—Data and information
9 described in subparagraph (A) which were also
10 submitted to the Administrator under the Fed-
11 eral Insecticide, Fungicide, and Rodenticide Act
12 shall be available for disclosure to the public in
13 accordance with section 10(g) of such Act (7
14 U.S.C. 136h(g)).

15 “(g) EXISTING PESTICIDE CHEMICAL RESIDUES.—

16 “(1) PESTICIDE CHEMICAL RESIDUES UNDER
17 REGULATIONS UNDER SECTION 406.—Regulations af-
18 fecting pesticide chemical residues promulgated, in
19 accordance with sections 701(e) and 406, upon the
20 basis of public hearings instituted before January 1,
21 1953, shall be deemed to be tolerances issued under
22 this section and shall be subject to modification or
23 revocation under subsection (d).

24 “(2) PESTICIDE CHEMICAL RESIDUES UNDER
25 REGULATIONS.—Regulations establishing, modifying,

1 or revoking tolerances for pesticide chemical residues
2 under this section and section 409 or exemptions for
3 pesticide chemical residues under this section on or
4 before the date of the enactment of this section shall
5 be deemed to be tolerances or exemptions issued
6 under this section and shall be subject to modifica-
7 tion or revocation under subsection (d).

8 “(3) GENERALLY RECOGNIZED AS SAFE PES-
9 TICIDE CHEMICAL RESIDUES.—

10 “(A) GENERAL RULE.—Pesticide chemical
11 residues that, on the day before the date of the
12 enactment of the Pesticide Reform Act of 1994,
13 do not have tolerances or exemptions from tol-
14 erances under this section because the residues
15 are generally recognized as safe under this sec-
16 tion or section 201(s) shall, until the expiration
17 of the period prescribed by subparagraph (C),
18 not be considered unsafe under section
19 402(a)(2)(B) solely because the residues do not
20 have such a tolerance or exemption.

21 “(B) LIST.—The Administrator shall—

22 “(i) not later than 180 days after the
23 date of the enactment of such Act, publish
24 a list of all pesticide chemical residues that
25 the Administrator has determined are gen-

1 erally recognized, on the day before the
2 date of the enactment of such Act, as safe
3 under this section or section 201(s); and

4 “(ii) require that any person who, be-
5 fore the date of the enactment of such Act,
6 distributed in commerce as a pesticide
7 chemical, a pesticide chemical that pro-
8 duces a pesticide chemical residue that is
9 not on the list described in clause (i), and
10 that such person determined such pesticide
11 chemical is generally recognized as safe
12 under this section or section 201(s), shall
13 within 6 months of the date of the publica-
14 tion of the list under clause (i), report to
15 the Administrator the data that supports
16 the claim that the pesticide chemical resi-
17 due is generally recognized as safe.

18 “(C) DETERMINATION OF THE ADMINIS-
19 TRATOR.—Not later than 2½ years after the
20 date of the enactment of the Pesticide Reform
21 Act of 1994, the Administrator shall determine
22 if each pesticide chemical reported to the Ad-
23 ministrator in accordance with subparagraph
24 (B)(ii) is generally recognized as safe. If the
25 Administrator determines, by order, that such

1 pesticide chemical residue is generally recog-
2 nized as safe, the residue of such pesticide
3 chemical shall be considered a pesticide chemi-
4 cal residue subject to an exemption under this
5 section, which exemption shall be subject to
6 modification or revocation under subsection (d).

7 “(h) MONITORING OF PESTICIDE CHEMICAL RESI-
8 DUES.—

9 “(1) SAMPLING.—The Secretary shall conduct a
10 comprehensive surveillance and compliance enforce-
11 ment monitoring program for domestic and imported
12 food for pesticide chemical residues to determine if
13 the pesticide chemical residues are in compliance
14 with this section. In carrying out this paragraph, the
15 Secretary shall give priority to—

16 “(A) sampling foods for pesticide chemical
17 residues included in a notice under paragraph
18 (2);

19 “(B) sampling foods that are high con-
20 sumption items for infants and children;

21 “(C) analyzing pesticides most likely to re-
22 sult in violation of this section;

23 “(D) conducting incidence and level mon-
24 itoring; and

1 “(E) collecting data on dietary intake of
2 pesticide residues on food as it is consumed.

3 “(2) NOTIFICATION.—The Administrator shall
4 notify the Secretary of the pesticide chemical resi-
5 dues that the Administrator determines, in the ad-
6 ministration of this section—

7 “(A) are above the standard prescribed by
8 subsection (b)(2); or

9 “(B) are not above such standard but that
10 may under certain circumstances reach or ex-
11 ceed such standard.

12 “(i) FEES.—The Administrator shall by regulation
13 require the payment of such fees as will in the aggregate,
14 in the judgment of the Administrator, be sufficient over
15 a reasonable term to provide, equip, and maintain an ade-
16 quate service for the performance of the functions of the
17 Administrator under this section. Under such regulations,
18 the performance of the services or other functions of the
19 Administrator under this section may be conditioned upon
20 the payment of such fees. Such regulations may further
21 provide that the continuation in effect of a tolerance or
22 exemption shall be conditioned upon the payment of an
23 annual fee and for waiver or refund of fees in whole or
24 in part when, in the judgment of the Administrator, such
25 waiver or refund is equitable and not contrary to the pur-

1 poses of this subsection. Such fees shall be deposited in
2 the Treasury and shall be credited to the appropriation
3 account of the Administrator for salaries and expenses
4 and shall be available for costs incurred in carrying out
5 this section in accordance with appropriation Acts until
6 expended without fiscal year limitation.

7 “(j) JUDICIAL REVIEW.—A petition for review of any
8 final order of the Administrator issued under subsection
9 (d) or any regulation that is the subject of such an order
10 may be filed by any adversely affected person only in the
11 United States Court of Appeals for the District of Colum-
12 bia Circuit. Any such petition for review must be filed
13 within sixty days of the issuance of such order or regula-
14 tion. Judicial review shall be in accordance with sections
15 701 through 706 of title 5 of the United States Code, and
16 the challenged order or regulation shall be sustained un-
17 less it is found to be arbitrary, capricious, and abuse of
18 discretion, or not in accordance with law. Orders and regu-
19 lations of the Administrator with respect to which review
20 could have been obtained under this subsection shall not
21 be subject to judicial review in civil or criminal proceedings
22 for enforcement or other judicial proceedings.”.

23 **SEC. 4. EMBARGO AUTHORITY.**

24 (a) ADMINISTRATIVE EMBARGO AUTHORITY.—Sec-
25 tion 304(g) (21 U.S.C. 334(g)) is amended by redesignat-

1 ing paragraph (2) as paragraph (3) and adding after para-
2 graph (1) the following new paragraph:

3 “(2) If an officer or employee of the Depart-
4 ment has reason to believe that any article of food
5 is adulterated within the meaning of section
6 402(a)(2)(B), the officer or employee may order the
7 food detained (in accordance with regulations pre-
8 scribed by the Secretary) for a reasonable period
9 which may not exceed twenty days (or ten days, in
10 the case of a perishable food) unless the Secretary
11 determines that a longer period of detention is re-
12 quired to institute an action under subsection (a) or
13 section 302, in which case the Secretary may au-
14 thorize a detention period of not more than thirty
15 days (or not more than fifteen days, in the case of
16 a perishable food). Regulations of the Secretary shall
17 require that before a food may be detained, the Sec-
18 retary or an officer or employee designated by the
19 Secretary shall approve the detention order. Such an
20 order may require the labeling or marking of a food
21 during the period of its detention for the purpose of
22 identifying the food as detained.”.

23 (b) PROHIBITION ON REMOVAL.—Paragraph (3) of
24 section 304(g) (21 U.S.C. 334(g)), as redesignated by sub-
25 section (a), is amended—

1 (1) in subparagraph (A), by striking “a device
2 subject to a detention order issued under paragraph
3 (1)” and inserting “an article subject to a detention
4 order under paragraph (1) or (2)”,

5 (2) in the matter preceding clause (i) of sub-
6 paragraph (B), by striking “a device subject to a de-
7 tention order under paragraph (1)” and inserting
8 “an article subject to a detention order under para-
9 graph (1) or (2)”, and

10 (3) in subparagraph (B)(ii), by striking “if”
11 and inserting “in the case of a device”.

12 (c) PROHIBITED ACT.—Section 301(r) (21 U.S.C.
13 331(r)) is amended by inserting “or a food” after “device”
14 each time it appears.

15 **SEC. 5. CIVIL MONEY PENALTIES.**

16 Section 303(f) (21 U.S.C. 333(f)) is amended—

17 (1) by redesignating paragraphs (2), (3), and
18 (4) as paragraphs (3), (4), and (5), respectively,

19 (2) by inserting after paragraph (1) the follow-
20 ing:

21 “(2) Any person who introduces into interstate
22 commerce or delivers for introduction into interstate
23 commerce an article of food that is adulterated with-
24 in the meaning of section 402(a)(2)(B) shall be sub-
25 ject, in addition to any other penalties that may be

1 prescribed by law, to a civil money penalty of not
2 more than \$50,000 in the case of an individual and
3 \$250,000 in the case of any other person for such
4 introduction or delivery.”,

5 (3) in paragraph (3), as so redesignated, by
6 striking “paragraph (1)” each place it occurs and
7 inserting “paragraph (1) or (2)”, and

8 (4) in paragraph (5), as so redesignated, by
9 striking “(3)” each place it occurs and inserting
10 “(4)”.

11 **SEC. 6. RECALL.**

12 (a) **AUTHORITY.**—Chapter III is amended—

13 (1) by redesignating sections 309 and 310 as
14 section 310 and 311, respectively, and

15 (2) by adding after section 308 the following:

16 “RECALL
17 “SEC. 309. (a) **GENERAL RULE.**—If the Secretary
18 has reason to believe that an article of food is adulterated
19 within the meaning of section 402(a)(2)(B), the Secretary
20 may require the manufacturer, processor, or distributor
21 of such article to take immediately all action necessary to
22 recall such article from all wholesale and retail establish-
23 ments. A recall order of the Secretary under this sub-
24 section shall be a final agency action subject to review by
25 the United States district court for the judicial district
26 in which the manufacturer, processor, or distributor re-

1 sides or transacts business or in which is located the arti-
2 cle of food that is the subject of such order.

3 “(b) REPORT.—Manufacturers, processors, and dis-
4 tributors shall report promptly to the Secretary any recall
5 of a food undertaken by the manufacturer, processor, or
6 distributor, including any recall required under subsection
7 (a) or section 302 and any recall conducted at the initia-
8 tive of the manufacturer, processor, or distributor on the
9 grounds that the food may be adulterated within the
10 meaning of section 403(a)(2)(B).

11 “(c) SCOPE OF ORDER.—For purposes of this sec-
12 tion, an order under subsection (a) with respect to an arti-
13 cle of food shall include an order to retrieve or replace
14 such article.”.

15 (b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331)
16 is amended by adding at the end the following:

17 “(w) The failure to comply with a recall order under
18 section 309(a) or a requirement to report a recall under
19 section 309(b).”.

20 **SEC. 7. EVALUATION OF EXISTING PESTICIDE CHEMICAL**
21 **RESIDUE TOLERANCES AND EXEMPTIONS.**

22 (a) CLASSIFICATION.—

23 (1) IDENTIFICATION.—Within one hundred and
24 eighty days of the date of enactment of this Act, the
25 Administrator of the Environmental Protection

1 Agency shall, for each pesticide chemical residue
2 that has a tolerance or exemption in effect on such
3 date, identify each tolerance or exemption which
4 does not appear to meet the requirements of section
5 408(b)(2) or 408(c)(2) of the Federal Food, Drug,
6 and Cosmetic Act and publish a notice summarizing
7 the data and analysis upon which such determina-
8 tion is made. The notice published pursuant to this
9 paragraph shall include all tolerances for a pesticide
10 chemical, if the cumulative risk from exposure for
11 any pesticide chemical residue, calculated by the
12 methodology in paragraph (2), appears not to meet
13 the requirements of section 408(b)(2) of the Federal
14 Food, Drug, and Cosmetic Act.

15 (2) FACTORS.—In making the determination
16 under paragraph (1) with respect to tolerances for
17 a pesticide chemical residue, the Administrator
18 shall—

19 (A) use the toxicological conclusions, in-
20 cluding appropriate factors where applicable,
21 used in the most current risk assessment for
22 the pesticide chemical residue performed by the
23 Administrator on or before the date of enact-
24 ment;

1 (B) assume that all food for which the pes-
2 ticide chemical residue has a tolerance bears or
3 contains residues of the pesticide chemical equal
4 to the levels established by their respective tol-
5 erances.

6 (3) OBJECTIONS.—Any person adversely af-
7 fected by the Administrator’s action under para-
8 graph (1) may file objections to the action with the
9 Administrator. Such objections must be filed within
10 thirty days of publication of the notice required in
11 paragraph (1). The Administrator shall act on such
12 objections within sixty days of the receipt of the ob-
13 jections.

14 (4) SUBSEQUENT IDENTIFICATIONS.—On a
15 yearly basis in the four-year period after the date of
16 enactment of this Act, if the Administrator con-
17 cludes that any additional tolerances or exemptions
18 do not appear to meet the requirements of section
19 408(b)(2) and 408(c)(2) of the Federal Food, Drug,
20 and Cosmetic Act, the Administrator shall identify
21 such tolerances and exemptions and publish a notice
22 summarizing the data and analysis upon which such
23 identification is made. Prior to identifying any addi-
24 tional tolerances or exemptions under this para-

1 graph, the Administrator shall publish the identifica-
2 tion as a proposal and seek public comment.

3 (b) DATA SUBMISSION.—

4 (1) DEADLINE FOR SUBMISSION OF DATA ON
5 APPARENTLY UNACCEPTABLE PESTICIDE CHEMICAL
6 RESIDUES.—For any pesticide chemical residue for
7 which the Administrator makes the identification de-
8 scribed in subsection (a)(1) or (a)(4), any person
9 wanting to maintain the tolerance or exemption for
10 such pesticide chemical shall have two years from
11 the publication of the notices in subsection (a) to
12 submit data or information on such chemical relative
13 to the safety standard in section 408(b)(2) or
14 408(c)(2) of the Federal Food, Drug, and Cosmetic
15 Act.

16 (2) DEADLINE FOR SUBMISSION OF DATA ON
17 ALL OTHER PESTICIDE CHEMICAL RESIDUES.—For
18 any other pesticide chemical residue that had a tol-
19 erance or exemption from a tolerance on the date of
20 enactment of this Act, any person wanting to main-
21 tain the tolerance or exemption for such pesticide
22 chemical residue shall have not more than five years
23 from such date of enactment, subject to any sched-
24 ule imposed under paragraph (3), to submit data or
25 information relative to the safety standards in such

1 section 408(b)(2) or 408(c)(2) of the Federal Food,
2 Drug, and Cosmetic Act.

3 (3) SCHEDULE.—For any pesticide chemical
4 residue for which the Administrator does not make
5 the identification described in subsection (a), the
6 Administrator may establish a schedule for the sub-
7 mission of data for the tolerance or exemption for
8 such pesticide chemical residue which data shall be
9 the basis for a determination by the Administrator
10 as to whether the tolerance or exemption meets the
11 requirements of such section 408(b)(2) or 408(c)(2)
12 of the Federal Food, Drug, and Cosmetic Act.

13 (4) EXTENSIONS.—

14 (A) REQUEST.—Any person may request
15 the Administrator to issue an order to extend a
16 deadline established under paragraph (1), (2),
17 or (3) before expiration of the deadline.

18 (B) GRANT OF REQUEST.—The Adminis-
19 trator may grant such a request only if the Ad-
20 ministrator finds that extraordinary cir-
21 cumstances beyond the control of such person
22 prevented such person from submitting the re-
23 quired data.

24 (C) EXTENSION.—If the Administrator is-
25 sues an order extending a deadline—

1 (i) the Administrator may extend the
2 deadline for a period no longer than such
3 time as is necessary for such person to
4 submit the data; and

5 (ii) the Administrator may extend the
6 deadline in paragraph (1) for no more than
7 one year and any deadline established
8 under paragraph (2) or (3) so long as such
9 extension does not extend the deadline be-
10 yond six years from the date of enactment
11 of the Act.

12 (c) DEADLINES FOR ACTION.—

13 (1) THREE-YEAR DEADLINE.—Within three
14 years of the date of enactment of this Act, the Ad-
15 ministrator shall issue a final decision for 75 percent
16 of the tolerances and exemptions of the pesticide
17 chemical residues identified in subsection (a)(1) by
18 classifying such tolerances and exemptions as meet-
19 ing or not meeting the requirements of section
20 408(b)(2) or 408(c)(2) of the Federal Food, Drug,
21 and Cosmetic Act. Such decisions shall be based only
22 on data received by the Administrator before the
23 deadline in subsection (b)(1) or before the expiration
24 of an extension granted under subsection (b)(4),
25 whichever is later.

1 (2) FOUR-YEAR DEADLINE.—Within four years
2 of the date of enactment of the Act, the Adminis-
3 trator shall issue a final decision for 100 percent of
4 the tolerances and exemptions of the pesticide chem-
5 ical residues identified in subsection (a)(1) by
6 classifying such tolerances and exemptions as meet-
7 ing or not meeting the requirements of section
8 408(b)(2) or 408(c)(2) of the Federal Food, Drug,
9 and Cosmetic Act. Such decision shall be based only
10 on data received by the Administrator before the
11 deadline in subsection (b)(1) or before the expiration
12 of an extension granted under subsection (b)(4),
13 whichever is later.

14 (3) DEADLINE FOR SUBSEQUENTLY IDENTI-
15 FIED TOLERANCES AND EXEMPTIONS.—Within four
16 years of the date of identification of a tolerance or
17 exemption under subsection (a)(4) or seven years
18 from the date of enactment, whichever is sooner, the
19 Administrator shall issue a final decision classifying
20 such tolerance or exemption as meeting or not meet-
21 ing the requirements of section 408(b)(2) or
22 408(c)(2) of the Federal Food, Drug, and Cosmetic
23 Act. Such decision shall be based only on data re-
24 ceived by the Administrator before the deadline in
25 subsection (b)(1) or before the expiration of an ex-

1 tension granted under subsection (b)(4), whichever
2 is later.

3 (4) SEVEN-YEAR DEADLINE.—Within seven
4 years of the date of the enactment of this Act, the
5 Administrator shall determine if each tolerance or
6 exemption in existence on the date of enactment of
7 this Act and not identified in subsection (a) meets
8 the requirements of section 408(b)(2) or 408(c)(2)
9 of the Federal Food, Drug, and Cosmetic Act. Such
10 determination shall be based only on data received
11 by the Administrator before the deadline in sub-
12 section (b)(2) or the deadline in a schedule estab-
13 lished by the Administrator for the pesticide chemi-
14 cal residue under subsection (b)(3) or the expiration
15 of an extension granted under subsection (b)(4),
16 whichever is later.

17 (5) REVOCATION PROCEEDINGS.—If the Admin-
18 istrator determines under this subsection that any
19 tolerance or exemption does not meet the require-
20 ments of section 408(b)(2) or 408(c)(2) of the Fed-
21 eral Food, Drug, and Cosmetic Act, the Adminis-
22 trator shall promptly initiate revocation proceedings
23 for such tolerance or exemption under section
24 408(d) of such Act.

1 (d) EXPIRATION OF A TOLERANCE OR EXEMP-
2 TION.—

3 (1) GENERAL RULE.—No later than six and
4 one-half years but not before six years from the date
5 of the enactment of this Act, the Administrator shall
6 publish a list of tolerances and exemptions for pes-
7 ticides chemical residues which shall expire seven
8 years after such date of enactment, unless the Ad-
9 ministrator—

10 (A) has issued a decision finding that such
11 pesticide chemical residue meets the require-
12 ments of section 408(b)(2) or 408(c)(2) of the
13 Federal Food, Drug, and Cosmetic Act, or

14 (B) has granted an extension under para-
15 graph (2).

16 (2) EXTENSION.—Upon petition of any person,
17 the Administrator may grant an extension beyond
18 the seven-year period in section (d)(1), of not more
19 than one year for the term of a tolerance or exemp-
20 tion for a pesticide chemical residue if the Adminis-
21 trator finds that a person seeking to support such
22 tolerance or exemption has met all applicable re-
23 quirements for the submission of information or
24 data required by subsection (b), the Administrator
25 has not completed review of the data submitted pur-

1 suant to subsection (b), and the extension would not
2 adversely affect public health. Any tolerance granted
3 an extension under this paragraph shall expire when
4 the extension expires, unless prior to expiration of
5 the extension the Administrator makes the finding
6 in subparagraph (A).

7 (3) LIST.—The Administrator shall include on
8 the list established under paragraph (1) each toler-
9 ance and exemption which was identified under sub-
10 section (a)(1) or (a)(4) for which the Administrator
11 has not issued a decision classifying it as meeting or
12 not meeting the requirements of section 408(b)(2) or
13 408(c)(2) of the Federal Food, Drug, and Cosmetic
14 Act, and which the Administrator now determines do
15 not appear to meet such requirements. The Adminis-
16 trator shall develop such list using the methodology
17 specified in subsection (a)(2)(B) and is only required
18 to consider data submitted on or before the expira-
19 tion of the deadlines for data submission in sub-
20 section (b).

21 (4) OBJECTIONS.—Any person adversely af-
22 fected by the Administrator's action under para-
23 graph (1) may file objections to the action with the
24 Administrator. The person filing the objection must
25 file it within thirty days of the publication of the list

1 specified in paragraph (1), and must demonstrate,
2 using the methodology specified in subsection
3 (a)(2)(B) and considering only data submitted on or
4 before the expiration of the deadlines for data sub-
5 mission in subsection (b), that the tolerance or ex-
6 emption which was identified under subsection (a)(1)
7 or (a)(4) should not be included on the list under
8 paragraph (1). The Administrator shall act on such
9 objections within sixty days of the receipt of the ob-
10 jections.

11 (e) TRANSITIONAL REVOCATION RULE.—

12 (1) GENERAL RULE.—If the Administrator de-
13 termines under section 408 of the Federal Food,
14 Drug, and Cosmetic Act that a tolerance for a pes-
15 ticide chemical residue should be revoked or if a tol-
16 erance will expire within one year based on operation
17 of subsection (d), the Administrator may, upon a pe-
18 tition from any person, extend the tolerance for a
19 period not longer than five years after such deter-
20 mination if the Administrator finds—

21 (A) the risk to health presented by expo-
22 sure to such residue is equal to or less than ten
23 times the risk allowed under section 408(b)(2)
24 of such Act, and

1 (B)(i) that the health benefits to the per-
2 son exposed to such residue are greater than
3 the dietary risks to health presented to such
4 person by such exposure, or

5 (ii) that such extension is necessary to
6 avoid a significant disruption in domestic food
7 production.

8 The Administrator may not extend a tolerance under
9 this paragraph for a period which extends beyond
10 ten years after the date of enactment of this Act.

11 (2) MODIFICATION.—The Administrator may
12 modify or revoke a tolerance or exemption extended
13 under paragraph (1), if the Administrator deter-
14 mines that circumstances no longer justify the con-
15 tinuation of such tolerance or exemption as ex-
16 tended.

17 (3) DEFINITIONS.—For the purposes of this
18 subsection, the term “health benefits” means the
19 benefits which occur when the application of a pes-
20 ticide chemical residue to a food directly reduces the
21 incidence of illness or disease but such term does not
22 include benefits from an adequate, wholesome, or ec-
23 onomical food supply.

24 (f) DEADLINE SUITS, JUDICIAL REVIEW.—

1 (1) DEADLINE SUITS.—Any person may com-
2 mence a civil action on such person’s own behalf
3 against the Administrator in the United States Dis-
4 trict Court for the District of Columbia where there
5 is alleged a failure of the Administrator to perform
6 any of the nondiscretionary acts required by sub-
7 sections (c)(2), (c)(3), or (c)(4). The court shall
8 have jurisdiction in actions brought under this para-
9 graph to order the Administrator to perform such
10 act. For suits involving subsections (c)(2) or (c)(3),
11 if the court finds that the Administrator has failed
12 to perform a nondiscretionary act, the court shall
13 have jurisdiction to order the Administrator to per-
14 form such act within a specified period of time, but
15 that period may not exceed eight years after the
16 date of enactment of this Act. Suits involving sub-
17 sections (c)(2) or (c)(3) must be brought within six
18 years of the date of the enactment of this Act. No
19 action may be commenced prior to sixty days after
20 the plaintiff has given notice of such action to the
21 Administrator.

22 (2) JUDICIAL REVIEW.—A petition for review of
23 a final action of the Administrator under subsection
24 (a)(3), (a)(4), (d)(2), (d)(3) or (e)(1) may be filed
25 by any adversely affected person only in the United

1 States Court of Appeals for the District of Columbia
2 Circuit. Any such petition for review must be filed
3 within sixty days of the issuance of the final action.
4 Judicial review shall be in accordance with sections
5 701 through 706 of title 5 of the United States
6 Code, and the challenged action shall be sustained
7 unless it is found to be arbitrary, capricious, an
8 abuse of discretion, or not in accordance with law.
9 Any determinations made by the Administrator
10 under subsections (b) or (c), shall be subject to judi-
11 cial review only in a petition for review of a final ac-
12 tion of the Administrator under section 408(d) of
13 the Federal Food, Drug, and Cosmetic Act pursuant
14 to section 408(j) of such Act. In reviewing a final
15 action of the Administrator under subsection (a)(3),
16 the court may not extend the deadline for data sub-
17 mission in subsection (b)(1). Actions of the Adminis-
18 trator with respect to which review could have been
19 obtained under this subsection shall not be subject
20 to judicial review in civil or criminal proceedings for
21 enforcement or other judicial proceedings.

22 (g) REPORT TO CONGRESS.—The Administrator shall
23 annually submit a report to Congress that lists the toler-
24 ances which have been revoked pursuant to tolerance re-

1 view. The report shall also provide an analysis of the im-
2 pacts of tolerance revocation.

3 (h) CONSTRUCTION.—Any reference under this sec-
4 tion to any provision of section 408 of the Federal Food,
5 Drug, and Cosmetic Act is a reference to such provision
6 as amended by this Act.

7 **SEC. 8. FEES.**

8 (a) GENERAL RULE.—The Administrator of the En-
9 vironmental Protection Agency shall by regulation require
10 the payment of such fees as will in the aggregate, in the
11 judgment of the Administrator, be sufficient over a rea-
12 sonable term to provide, equip, and maintain an adequate
13 service for the performance of the functions of the Admin-
14 istrator under this Act. The fee requirement of this sub-
15 section shall not apply to any agency of the Federal Gov-
16 ernment.

17 (b) DEPOSIT, AND SO FORTH.—Such fees shall be de-
18 posited in the Treasury and shall be credited to the appro-
19 priation account of the Administrator for salaries and ex-
20 penses and shall be available for costs incurred in carrying
21 out this section in accordance with appropriation Acts
22 until expended without fiscal year limitation.

23 **SEC. 9. GENERAL DEFINITIONS.**

24 As used in sections 4 and 5 of this Act:

1 (1) IN GENERAL.—The terms that are also used
2 in section 408 of the Federal Food, Drug, and Cos-
3 metic Act shall have the meanings given the terms
4 by sections 201 and 408 of such Act.

5 (2) DIETARY EXPOSURE.—The term “dietary
6 exposure” means dietary exposure as determined
7 under section 408(b)(2)(C) of the Federal Food,
8 Drug, and Cosmetic Act.

9 (3) EXEMPTION.—The term “exemption”
10 means an exemption from the requirement for a tol-
11 erance under section 408 of the Federal Food, Drug,
12 and Cosmetic Act.

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