

103<sup>D</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4362

To amend the Federal Food, Drug, and Cosmetic Act to revise the authority under that Act to regulate pesticide chemical residues in food.

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IN THE HOUSE OF REPRESENTATIVES

MAY 5, 1994

Mr. WAXMAN (by request) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise the authority under that Act to regulate pesticide chemical residues in food.

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,  
17           whichever occurs 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 10-fold 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 5 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 multi-residue  
25 method for detecting and measuring

1 the levels of such pesticide chemical  
2 residue in or on a food that will meas-  
3 ure the residue at the level established  
4 by 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 2 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 5 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 States 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 pesticide  
3 chemical residue in or on the food, which meth-  
4 ods meet the requirements of subsection  
5 (b)(2)(E);

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

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

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

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

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

25           “(3) ACTIONS ON PETITIONS.—

1 “(A) FILING DETERMINATION.—

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

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

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

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

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

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

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

21 “(ii) issue a proposed regulation es-  
22 tablishing, modifying, or revoking a toler-  
23 ance or exemption for the pesticide chemi-  
24 cal residue, which tolerance or exemption

1 is different from the tolerance or exemp-  
2 tion requested in the petition; or

3 “(iii) issue an order denying the peti-  
4 tion.

5 “(C) COMMENTS.—If the Administrator is-  
6 sues a notice of the filing of a petition under  
7 subparagraph (A)(i) or a proposed regulation  
8 under subparagraph (B)(ii), the Administrator  
9 shall allow at least 30 days for comments on  
10 such notice or proposed regulation.

11 “(D) FINAL REGULATION.—If the Admin-  
12 istrator issues a proposed regulation under sub-  
13 paragraph (B)(ii), the Administrator shall issue  
14 a final regulation within 180 days of the date  
15 of the publication of the proposed regulations.

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

24 “(4) ACTION ON THE ADMINISTRATOR’S INITIA-  
25 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 30  
10          days for public comment on the proposed regu-  
11          lation unless the Administrator finds that such  
12          notice and comment would be contrary to the  
13          public interest and states the reasons for the  
14          finding in the notice of the final regulation. If  
15          the Administrator makes such a finding and is-  
16          sues such a regulation, the Administrator shall  
17          provide at least 30 days for comment on the  
18          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           times 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,

14 as will enable the Administrator to evaluate the safety of  
15 such article in the event of the filing of an application  
16 pursuant to this section. Such regulations, among other  
17 things, shall set forth the conditions (if any) upon which  
18 food treated with such pesticide chemicals may be mar-  
19 keted 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 are 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), 30 days  
16            before disclosing data or information claimed as  
17            privileged or confidential under subparagraph  
18            (A), the Administrator shall notify the person  
19            who submitted or cited the data or information  
20            of the intent to disclose the data or information  
21            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 an order may  
10 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 with-  
13 in 60 days of the issuance of such order or regulation.  
14 Judicial review shall be in accordance with sections 701  
15 through 706 of title 5, United States Code, and the chal-  
16 lenged order or regulation shall be sustained unless it is  
17 found to be arbitrary, capricious, and an abuse of discre-  
18 tion or not in accordance with law. Orders and regulations  
19 of the Administrator with respect to which review could  
20 have been obtained under this subsection shall not be sub-  
21 ject to judicial review in civil or criminal proceedings for  
22 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 Department has  
4 reason to believe that any article of food is adulterated  
5 within the meaning of section 402(a)(2)(B), the officer or  
6 employee may order the food detained (in accordance with  
7 regulations prescribed by the Secretary) for a reasonable  
8 period which may not exceed 20 days (or 10 days, in the  
9 case of a perishable food) unless the Secretary determines  
10 that a longer period of detention is required to institute  
11 an action under subsection (a) or section 302, in which  
12 case the Secretary may authorize a detention period of not  
13 more than 30 days (or not more than 15 days, in the case  
14 of a perishable food). Regulations of the Secretary shall  
15 require that before a food may be detained, the Secretary  
16 or an officer or employee designated by the Secretary shall  
17 approve the detention order. Such an order may require  
18 the labeling or marking of a food during the period of its  
19 detention for the purpose of identifying the food as de-  
20 tained.”.

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

24 (1) in subparagraph (A), by striking “a device  
25 subject to a detention order issued under paragraph

1 (1)” and inserting “an article subject to a detention  
2 order under paragraph (1) or (2)”,

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

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

10 (c) PROHIBITED ACT.—Section 301(r) (21 U.S.C.  
11 331(r)) is amended by inserting “or a food” after “device”  
12 each time it appears.

13 **SEC. 5. CIVIL MONEY PENALTIES.**

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

15 (1) by redesignating paragraphs (2), (3), and  
16 (4) as paragraphs (3), (4), and (5), respectively,

17 (2) by inserting after paragraph (1) the follow-  
18 ing:

19 “(2) Any person who introduces into interstate com-  
20 merce or delivers for introduction into interstate com-  
21 merce an article of food that is adulterated within the  
22 meaning of section 402(a)(2)(B) shall be subject, in addi-  
23 tion to any other penalties that may be prescribed by law,  
24 to a civil money penalty of not more than \$50,000 in the

1 case of an individual and \$250,000 in the case of any  
2 other person for such introduction or delivery.”,

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

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

9 **SEC. 6. RECALL.**

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

11 (1) by redesignating sections 309 and 310 as  
12 section 310 and 311, respectively, and

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

14 “RECALL

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

1       “(b) REPORT.—Manufacturers, processors, and dis-  
2 tributors shall report promptly to the Secretary any recall  
3 of a food undertaken by the manufacturer, processor, or  
4 distributor, including any recall required under subsection  
5 (a) or section 302 and any recall conducted at the initia-  
6 tive of the manufacturer, processor, or distributor on the  
7 grounds that the food may be adulterated within the  
8 meaning of section 402(a)(2)(B).

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

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

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

18 **SEC. 7. EVALUATION OF EXISTING PESTICIDE CHEMICAL**

19                   **RESIDUE TOLERANCES AND EXEMPTIONS.**

20       (a) CLASSIFICATION.—

21           (1) IDENTIFICATION.—Within 180 days of the  
22 date of enactment of this Act, the Administrator of  
23 the Environmental Protection Agency shall, for each  
24 pesticide chemical residue that has a tolerance or ex-  
25 emption in effect on such date, identify each toler-

1       ance or exemption which does not appear to meet  
2       the requirements of section 408(b)(2) or 408(c)(2)  
3       of the Federal Food, Drug, and Cosmetic Act and  
4       publish a notice summarizing the data and analysis  
5       upon which such determination is made. The notice  
6       published pursuant to this paragraph shall include  
7       all tolerances for a pesticide chemical, if the cumu-  
8       lative risk from exposure for any pesticide chemical  
9       residue, calculated by the methodology in paragraph  
10      (2), appears not to meet the requirements of section  
11      408(b)(2) of the Federal Food, Drug, and Cosmetic  
12      Act.

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

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

23           (B) assume that all food for which the pes-  
24      ticide chemical residue has a tolerance bears or  
25      contains residues of the pesticide chemical equal

1 to the levels established by their respective tol-  
2 erances.

3 (3) OBJECTIONS.—Any person adversely af-  
4 fected by the Administrator’s action under para-  
5 graph (1) may file objections to the action with the  
6 Administrator. Such objections must be filed within  
7 30 days of publication of the notice required in para-  
8 graph (1). The Administrator shall act on such ob-  
9 jections within 60 days of the receipt of the objec-  
10 tions.

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

24 (b) DATA SUBMISSION.—

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

12          (2) DEADLINE FOR SUBMISSION OF DATA ON  
13          ALL OTHER PESTICIDE CHEMICAL RESIDUES.—For  
14          any other pesticide chemical residue that had a tol-  
15          erance or exemption from a tolerance on the date of  
16          enactment of this Act, any person wanting to main-  
17          tain the tolerance or exemption for such pesticide  
18          chemical residue shall have not more than 5 years  
19          from such date of enactment, subject to any sched-  
20          ule imposed under paragraph (3), to submit data or  
21          information relative to the safety standards in such  
22          section 408(b)(2) or 408(c)(2) of the Federal Food,  
23          Drug, and Cosmetic Act.

24          (3) SCHEDULE.—For any pesticide chemical  
25          residue for which the Administrator does not make

1 the identification described in subsection (a), the  
2 Administrator may establish a schedule for the sub-  
3 mission of data for the tolerance or exemption for  
4 such pesticide chemical residue which data shall be  
5 the basis for a determination by the Administrator  
6 as to whether the tolerance or exemption meets the  
7 requirements of such section 408(b)(2) or 408(c)(2)  
8 of the Federal Food, Drug, and Cosmetic Act.

9 (4) EXTENSIONS.—

10 (A) REQUEST.—Any person may request  
11 the Administrator to issue an order to extend a  
12 deadline established under paragraph (1), (2),  
13 or (3) before expiration of the deadline.

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

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

22 (i) the Administrator may extend the  
23 deadline for a period no longer than such  
24 time as is necessary for such person to  
25 submit the data; and

1                   (ii) the Administrator may extend the  
2                   deadline in paragraph (1) for no more than  
3                   1 year and any deadline established under  
4                   paragraph (2) or (3) so long as such exten-  
5                   sion does not extend the deadline beyond 6  
6                   years from the date of enactment of the  
7                   Act.

8                   (c) DEADLINES FOR ACTION.—

9                   (1) 3-YEAR DEADLINE.—Within 3 years of the  
10                  date of enactment of this Act, the Administrator  
11                  shall issue a final decision for 75 percent of the tol-  
12                  erances and exemptions of the pesticide chemical  
13                  residues identified in subsection (a)(1) by classifying  
14                  such tolerances and exemptions as meeting or not  
15                  meeting the requirements of section 408(b)(2) or  
16                  408(c)(2) of the Federal Food, Drug, and Cosmetic  
17                  Act. Such decisions shall be based only on data re-  
18                  ceived by the Administrator before the deadline in  
19                  subsection (b)(1) or before the expiration of an ex-  
20                  tension granted under subsection (b)(4), whichever  
21                  is later.

22                  (2) 4-YEAR DEADLINE.—Within 4 years of the  
23                  date of enactment of the Act, the Administrator  
24                  shall issue a final decision for 100 percent of the tol-  
25                  erances and exemptions of the pesticide chemical

1 residues identified in subsection (a)(1) by classifying  
2 such tolerances and exemptions as meeting or not  
3 meeting the requirements of section 408(b)(2) or  
4 408(c)(2) of the Federal Food, Drug, and Cosmetic  
5 Act. Such decision shall be based only on data re-  
6 ceived by the Administrator before the deadline in  
7 subsection (b)(1) or before the expiration of an ex-  
8 tension granted under subsection (b)(4), whichever  
9 is later.

10 (3) DEADLINE FOR SUBSEQUENTLY IDENTIFI-  
11 FIED TOLERANCES AND EXEMPTIONS.—Within 4  
12 years of the date of identification of a tolerance or  
13 exemption under subsection (a)(4) or 7 years from  
14 the date of enactment, whichever is sooner, the Ad-  
15 ministrator shall issue a final decision classifying  
16 such tolerance or exemption as meeting or not meet-  
17 ing the requirements of section 408(b)(2) or  
18 408(c)(2) of the Federal Food, Drug, and Cosmetic  
19 Act. Such decision shall be based only on data re-  
20 ceived by the Administrator before the deadline in  
21 subsection (b)(1) or before the expiration of an ex-  
22 tension granted under subsection (b)(4), whichever  
23 is later.

24 (4) 7-YEAR DEADLINE.—Within 7 years of the  
25 date of the enactment of this Act, the Administrator

1 shall determine if each tolerance or exemption in ex-  
2 istence on the date of enactment of this Act and not  
3 identified in subsection (a) meets the requirements  
4 of section 408(b)(2) or 408(c)(2) of the Federal  
5 Food, Drug, and Cosmetic Act. Such determination  
6 shall be based only on data received by the Adminis-  
7 trator before the deadline in subsection (b)(2) or the  
8 deadline in a schedule established by the Adminis-  
9 trator for the pesticide chemical residue under sub-  
10 section (b)(3) or the expiration of an extension  
11 granted under subsection (b)(4), whichever is later.

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

20 (d) EXPIRATION OF A TOLERANCE OR EXEMP-  
21 TION.—

22 (1) GENERAL RULE.—No later than 6 and ½  
23 years but not before 6 years after the date of the en-  
24 actment of this Act, the Administrator shall publish  
25 a list of tolerances and exemptions for pesticide

1 chemical residues which shall expire 7 years after  
2 such date of enactment, unless the Administrator—

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

7 (B) has granted an extension under para-  
8 graph (2).

9 (2) EXTENSION.—Upon petition of any person,  
10 the Administrator may grant an extension beyond  
11 the 7-year period in section (d)(1), of not more than  
12 1 year for the term of a tolerance or exemption for  
13 a pesticide chemical residue if the Administrator  
14 finds that a person seeking to support such toler-  
15 ance or exemption has met all applicable require-  
16 ments for the submission of information or data re-  
17 quired by subsection (b), the Administrator has not  
18 completed review of the data submitted pursuant to  
19 subsection (b), and the extension would not ad-  
20 versely affect public health. Any tolerance granted  
21 an extension under this paragraph shall expire when  
22 the extension expires, unless prior to expiration of  
23 the extension the Administrator makes the finding  
24 in subparagraph (A).

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

15           (4) OBJECTIONS.—Any person adversely af-  
16 fected by the Administrator’s action under para-  
17 graph (1) may file objections to the action with the  
18 Administrator. The person filing the objection must  
19 file it within 30 days of the publication of the list  
20 under paragraph (1) and must demonstrate, using  
21 the methodology specified in subsection (a)(2)(B)  
22 and considering only data submitted on or before the  
23 expiration of the deadlines for data submission in  
24 subsection (b), that the tolerance or exemption  
25 which was identified under subsection (a)(1) or

1 (a)(4) should not be included on the list under para-  
2 graph (1). The Administrator shall act on such ob-  
3 jections within 60 days of the receipt of the  
4 objections.

5 (e) TRANSITIONAL REVOCATION RULE.—

6 (1) GENERAL RULE.—If the Administrator de-  
7 termines under section 408 of the Federal Food,  
8 Drug, and Cosmetic Act that a tolerance for a pes-  
9 ticide chemical residue should be revoked or if a tol-  
10 erance will expire within 1 year based on operation  
11 of subsection (d), the Administrator may, upon a pe-  
12 tition from any person, extend the tolerance for a  
13 period not longer than 5 years after such determina-  
14 tion if the Administrator finds—

15 (A) the risk to health presented by expo-  
16 sure to such residue is equal to or less than 10  
17 times the risk allowed under section 408(b)(2)  
18 of such Act, and

19 (B)(i) that the health benefits to the per-  
20 son exposed to such residue are greater than  
21 the dietary risks to health presented to such  
22 person by such exposure, or

23 (ii) that such extension is necessary to  
24 avoid a significant disruption in domestic food  
25 production.

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

4 (2) MODIFICATION.—The Administrator may  
5 modify or revoke a tolerance or exemption extended  
6 under paragraph (1), if the Administrator deter-  
7 mines that circumstances no longer justify the con-  
8 tinuation of such tolerance or exemption as ex-  
9 tended.

10 (3) DEFINITIONS.—For purposes of this sub-  
11 section, the term “health benefits” means the bene-  
12 fits which occur when the application of a pesticide  
13 chemical residue to a food directly reduces the inci-  
14 dence of illness or disease but such term does not in-  
15 clude benefits from an adequate, wholesome, or eco-  
16 nomical food supply.

17 (f) DEADLINE SUITS, JUDICIAL REVIEW.—

18 (1) DEADLINE SUITS.—Any person may com-  
19 mence a civil action on such person’s own behalf  
20 against the Administrator in the United States Dis-  
21 trict Court for the District of Columbia where there  
22 is alleged a failure of the Administrator to perform  
23 any of the nondiscretionary acts required by sub-  
24 sections (c)(2), (c)(3), or (c)(4). The court shall  
25 have jurisdiction in actions brought under this para-

1 graph to order the Administrator to perform such  
2 act. For suits involving subsections (c)(2) or (c)(3),  
3 if the court finds that the Administrator has failed  
4 to perform a nondiscretionary act, the court shall  
5 have jurisdiction to order the Administrator to per-  
6 form such act within a specified period of time, but  
7 that period may not exceed 8 years after the date of  
8 enactment of this Act. Suits involving subsections  
9 (c)(2) or (c)(3) must be brought within 6 years of  
10 the date of the enactment of this Act. No action may  
11 be commenced prior to 60 days after the plaintiff  
12 has given notice of such action to the Administrator.

13 (2) JUDICIAL REVIEW.—A petition for review of  
14 a final action of the Administrator under subsection  
15 (a)(3), (a)(4), (d)(2), (d)(3), or (e)(1) may be filed  
16 by any adversely affected person only in the United  
17 States Court of Appeals for the District of Columbia  
18 Circuit. Any such petition for review must be filed  
19 within 60 days of the issuance of the final action.  
20 Judicial review shall be in accordance with sections  
21 701 through 706 of title 5 of the United States  
22 Code, and the challenged action shall be sustained  
23 unless it is found to be arbitrary, capricious, an  
24 abuse of discretion, or not in accordance with law.  
25 Any determinations made by the Administrator

1 under subsections (b) or (c), shall be subject to judi-  
2 cial review only in a petition for review of a final ac-  
3 tion of the Administrator under section 408(d) of  
4 the Federal Food, Drug, and Cosmetic Act pursuant  
5 to section 408(j) of such Act. In reviewing a final  
6 action of the Administrator under subsection (a)(3),  
7 the court may not extend the deadline for data sub-  
8 mission in subsection (b)(1). Actions of the Adminis-  
9 trator with respect to which review could have been  
10 obtained under this subsection shall not be subject  
11 to judicial review in civil or criminal proceedings for  
12 enforcement or other judicial proceedings.

13 (g) REPORT TO CONGRESS.—The Administrator shall  
14 annually submit a report to Congress that lists the toler-  
15 ances which have been revoked pursuant to Tolerance Re-  
16 view. The report shall also provide an analysis of the im-  
17 pacts of tolerance revocation.

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

22 **SEC. 8. FEES.**

23 (a) GENERAL RULE.—The Administrator of the En-  
24 vironmental Protection Agency shall by regulation require  
25 the payment of such fees as will in the aggregate, in the

1 judgment of the Administrator, be sufficient over a rea-  
2 sonable term to provide, equip, and maintain an adequate  
3 service for the performance of the functions of the Admin-  
4 istrator under this Act. The fee requirement of this sub-  
5 section shall not apply to any agency of the Federal Gov-  
6 ernment.

7 (b) DEPOSIT, ETC.—Such fees shall be deposited in  
8 the Treasury and shall be credited to the appropriation  
9 account of the Administrator for salaries and expenses  
10 and shall be available for costs incurred in carrying out  
11 this section in accordance with appropriation Acts until  
12 expended without fiscal year limitation.

13 **SEC. 9. GENERAL DEFINITIONS.**

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

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

19 (2) DIETARY EXPOSURE.—The term “dietary  
20 exposure” means dietary exposure as determined  
21 under section 408(b)(2)(C) of the Federal Food,  
22 Drug, and Cosmetic Act.

23 (3) EXEMPTION.—The term “exemption”  
24 means an exemption from the requirement for a tol-

1       erance under section 408 of the Federal Food, Drug,  
2       and Cosmetic Act.

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