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H. R. 4091

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 18, 1994

Mr. WAXMAN (for himself, Mr. SYNAR, and Mr. TORRES) introduced the following bill; which was referred to the Committee on Energy and Commerce

MAY 23, 1994

Additional sponsors: Mr. MILLER of California, Mr. YATES, Mrs. SCHROEDER, Mr. FILNER, Mr. FORD of Tennessee, Mr. SABO, Mr. STARK, and Mr. DELLUMS

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 Food Safety Act of 1994”.

1 (b) REFERENCE.—Whenever in this Act an amend-
2 ment or repeal is expressed in terms of an amendment
3 to, or repeal of, a section or other provision, the reference
4 shall be considered to be made to a section or other provi-
5 sion of the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 301 et seq.).

7 (c) TABLE OF CONTENTS.—The table of contents of
8 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. 4. Evaluation of existing pesticide chemical residue tolerances and exemp-
tions.

Sec. 5. Review of existing methods of analysis.

Sec. 6. Fees.

Sec. 7. General definitions.

9 **SEC. 2. DEFINITIONS.**

10 (a) PESTICIDE.—

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

13 “(q)(1) The term ‘pesticide chemical’ means—

14 “(A) any substance that is a pesticide, as de-
15 fined in section 2(u) of the Federal Insecticide, Fun-
16 gicide, and Rodenticide Act (7 U.S.C. 136(u)); and

17 “(B) each active ingredient and inert ingredi-
18 ent, as defined in subsections (a) and (m), respec-
19 tively, of section 2 of the Federal Insecticide, Fun-
20 gicide, and Rodenticide 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

4 “(B) any other substance that is present in the
5 commodity or food as a result of the metabolism or
6 other degradation of a pesticide chemical,

7 regardless of whether the residue may be detected.”.

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 (b) CONFORMING AMENDMENTS.—

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

19 “(gg) The term ‘processed food’ means any food that
20 has been subject to processing from a raw agricultural
21 commodity.

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

24 (2) Section 402(a)(2) (21 U.S.C. 342(a)(2)) is
25 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 is, or it bears or contains, a pesticide chem-
5 ical residue unsafe within the meaning of sec-
6 tion 408(a);”; and

7 (C) in clause (C)—

8 (i) by striking “: *Provided*, That
9 where a pesticide chemical” and inserting
10 “, except that if a pesticide chemical”; and

11 (ii) by striking “sections 406 and
12 409” and inserting “section 406”.

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

15 (a) TOLERANCES AND EXEMPTIONS.—Section 408
16 (21 U.S.C. 346a) is amended to read as follows:

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

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

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

1 “(A) a tolerance for such residue is in ef-
2 fect under this section and the quantity of such
3 residue is within the limits of such tolerance; or

4 “(B) an exemption for such residue is in
5 effect under this section and such residue com-
6 plies 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) if such residue on such food complies with
15 such tolerance or exemption.

16 “(b) TOLERANCES.—

17 “(1) AUTHORITY.—

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

22 “(i) in response to a petition filed
23 under subsection (k)(1); or

24 “(ii) on the initiative of the Adminis-
25 trator under subsection (k)(4).

1 “(B) EXPIRATION DATE.—A regulation
2 under this paragraph may provide for an expi-
3 ration date for the tolerance.

4 “(C) SEPARATE TOLERANCES.—The Ad-
5 ministrator may establish a separate tolerance
6 under subparagraph (A) for a pesticide chemi-
7 cal residue with respect to food at each of the
8 following times:

9 “(i) At the time the food is harvested.

10 “(ii) At the time the food is purchased
11 at retail.

12 “(iii) After the food is processed.

13 “(2) STANDARD.—

14 “(A) GENERAL RULE.—Except as provided
15 in subparagraph (F)—

16 “(i) a tolerance may be established for
17 a pesticide chemical residue only if the risk
18 to human health from dietary exposure to
19 the pesticide chemical residue is negligible;
20 and

21 “(ii) the tolerance for a pesticide
22 chemical residue shall be revoked or modi-
23 fied unless the risk to human health from
24 dietary exposure to the pesticide chemical
25 residue is negligible.

1 “(B) NEGLIGIBLE RISK.—

2 “(i) GENERAL RULE.—For purposes
3 of this paragraph, a risk to human health
4 from dietary exposure to a pesticide chemi-
5 cal residue is negligible only if dietary ex-
6 posure to the residue is reasonably certain
7 to cause no harm to human health and the
8 tolerance for such residue meets the re-
9 quirements of clause (ii) or (iii).

10 “(ii) THRESHOLD PESTICIDES.—

11 “(I) IN GENERAL.—If the Ad-
12 ministrator is able to identify a level
13 at which a pesticide chemical residue
14 will not cause or contribute to any
15 known or anticipated harm to human
16 health, the Administrator may estab-
17 lish or leave in effect a level for a tol-
18 erance for such residue only if the Ad-
19 ministrator finds that such tolerance
20 will provide an ample margin of safe-
21 ty, for each population group set out
22 in subparagraph (E).

23 “(II) CONSIDERATIONS.—The
24 level described in subclause (I) shall
25 be based on consideration of—

1 “(aa) the nature of the toxic
2 effects caused by such residue
3 and data regarding the preva-
4 lence of the same effects caused
5 by other chemicals;

6 “(bb) the validity, complete-
7 ness, and the reliability of the
8 data about the pesticide chemical
9 residue;

10 “(cc) the variability of indi-
11 vidual sensitivities and the sen-
12 sitivities of population subgroups
13 to the adverse effects from such
14 residue; and

15 “(dd) the possibility that
16 human susceptibility to such ad-
17 verse effects is significantly
18 greater than that of test animals.

19 “(III) MARGIN OF SAFETY.—For
20 purposes of this clause, a margin of
21 safety for a level of a pesticide chemi-
22 cal residue is not ample unless human
23 exposure per unit of body measure-
24 ment, to the pesticide chemical resi-
25 due and other chemicals that cause

1 the same effect, is at least 100 times
2 less than the no observable effect level
3 in animals on which the pesticide
4 chemical residue was tested, and, if
5 human data are available, at least 10
6 times less than the no observable ef-
7 fect level in humans exposed to such
8 residue. The no observable effect level
9 is the level of exposure to a pesticide
10 chemical that reliable data, derived
11 from exposure of humans or animals
12 to the pesticide chemical, demonstrate
13 will cause no adverse effect. An addi-
14 tional 10-fold margin of safety shall
15 be added unless the Administrator de-
16 termines, on the basis of complete and
17 reliable exposure and toxicity data
18 with respect to infants and children,
19 that a different margin will fully pro-
20 tect the public health.

21 “(iii) NONTRESHOLD PESTICIDES.—
22 If the Administrator is not able to identify
23 a level at which a pesticide chemical resi-
24 due will not cause or contribute to any
25 known or anticipated harm to human

1 health or if the Administrator finds that a
2 pesticide chemical residue causes cancer in
3 animals or humans, the Administrator may
4 establish a level for a tolerance for such
5 residue or leave a level in effect for such
6 residue only if the Administrator finds that
7 such level—

8 “(I) will not cause or contribute
9 to, in individuals exposed to such pes-
10 ticide chemical residue, a lifetime risk
11 of an adverse human health effect
12 that occurs at a rate of one in a mil-
13 lion and will not cover a dispropor-
14 tionate accumulation of such risk dur-
15 ing the first 5 years of the life of an
16 exposed person, using conservative
17 risk assessment models;

18 “(II) is the lowest level reason-
19 ably required to allow the accomplish-
20 ment of the physical or other technical
21 effect for which the use of the pes-
22 ticide chemical involved is intended;
23 and

24 “(III) in the case of processed
25 food, is the lowest level that occurs if

1 such pesticide chemical residue is re-
2 moved to the extent possible in ac-
3 cordance with good manufacturing
4 practice.

5 “(iv) INFANTS AND CHILDREN.—In
6 issuing or denying any tolerance or exemp-
7 tion from a tolerance, the Administrator
8 shall fully account for the susceptibility of
9 infants and children to harm from pes-
10 ticide chemicals, including physiological
11 and behavioral differences between infants
12 and the effect of in utero exposure to pes-
13 ticide chemicals.

14 “(C) EXPOSURE.—Except as provided in
15 subparagraph (D), in determining dietary expo-
16 sure to a pesticide chemical residue for pur-
17 poses of this paragraph, the Administrator
18 shall—

19 “(i)(I) use only reliable, statistically
20 significant data regarding the dietary expo-
21 sure to persons who have consumed the
22 food for which the tolerance for the residue
23 is proposed or is in effect;

1 “(II) fully account for all other toler-
2 ances in effect for the same pesticide
3 chemical residue; and

4 “(III) fully account for the cumulative
5 exposure from all other sources including,
6 to the extent existing data permit, dietary,
7 drinking water, residential usage, and
8 other nondietary exposures; and

9 “(IV) fully account for the cumulative
10 effect of such residue and any other sub-
11 stances that are pharmacologically related,
12 have a common toxic mechanism, or have
13 a common toxic effect and that constitute
14 a part of the human diet or enter the
15 human body through other, nondietary
16 routes of exposure;

17 “(ii) consider the exposure to be the
18 level of exposure that would occur if—

19 “(I) all the food, for which the
20 tolerance for the pesticide chemical
21 residue is proposed or in effect, has
22 amounts of the pesticide chemical res-
23 idue equal to the tolerance proposed
24 or in effect;

1 “(II) all other sources of dietary
2 exposure to such residue described in
3 clause (i)(III) occur; and

4 “(III) human exposure to the
5 pesticide chemical residue at the toler-
6 ance level occurs for a period equal to
7 a lifetime; and

8 “(iii) consider food consumption pat-
9 terns of significant subpopulations, includ-
10 ing categories of infants and children as
11 described in subparagraph (E), that are
12 likely to result in disproportionately high
13 consumption of foods containing or bearing
14 residues in comparison to the general pop-
15 ulation.

16 For purposes of clause (i)(IV), if the Adminis-
17 trator identifies pesticides that are pharma-
18 cologically related or have a common toxic
19 mechanism or effect, the Administrator shall
20 treat such pesticides as having an additive dele-
21 terious action in the absence of evidence to the
22 contrary.

23 “(D) SPECIAL EXPOSURE RULE.—

24 “(i) DATE.—The Administrator may
25 calculate dietary exposure to a food based

1 on reliable data that provide the Adminis-
2 trator with a valid statistical basis to iden-
3 tify the percentage of the food in which the
4 pesticide chemical residue actually occurs.

5 “(ii) PERCENTAGE.—Such percentage
6 shall be not less than the percentage of the
7 food consumed in an appropriate locality,
8 identified by the Administrator, which per-
9 centage represents the highest level of ex-
10 posure to such residue in the United
11 States.

12 “(iii) REEVALUATION.—The Adminis-
13 trator shall reevaluate the determination
14 under this subparagraph every 2 years
15 after the date of the determination. If,
16 under such a reevaluation, the Adminis-
17 trator finds that the determination is not
18 justified, the Administrator shall promptly
19 issue a regulation requiring that the toler-
20 ance involved be set on the basis of the
21 new determination.

22 “(E) POPULATION COVERED.—In deter-
23 mining if the dietary exposure to a pesticide
24 chemical residue is negligible, the Administrator
25 shall evaluate the risk to—

- 1 “(i) infants of the age 0 to 1;
2 “(ii) children of the age 1 to 2;
3 “(iii) children of the age 2 to 3;
4 “(iv) children of the age 3 to 4;
5 “(v) children of the age 4 to 5;
6 “(vi) children of the age 6 to 10;
7 “(vii) adolescents of the age 11 to 18;
8 “(viii) other population groups that
9 have been identified by the Administrator
10 to have special food consumption patterns
11 or for which data are sufficient to dem-
12 onstrate special food consumption patterns;
13 and

14 “(ix) the entire population,
15 who consume food with such pesticide chemical
16 residue.

17 “(F) UNAVOIDABLE PERSISTENCE.—If a
18 tolerance or an exemption from the requirement
19 for a tolerance for a pesticide chemical residue
20 is revoked and the Administrator finds the pes-
21 ticide chemical residue will unavoidably persist
22 in the environment and contaminate food, the
23 Administrator shall establish a new tolerance
24 under subsection (k)(4) for the pesticide chemi-
25 cal residue. The level permitted by the tolerance

1 shall not be greater than the lowest level that
2 permits only such unavoidable levels to remain
3 in food. The Administrator shall evaluate any
4 such tolerance at least once a year to determine
5 whether modification of such tolerance is nec-
6 essary so that the tolerance provides only for
7 the level of the pesticide chemical residue that
8 is unavoidable.

9 “(G) PRACTICAL METHODS OF ANALY-
10 SIS.—

11 “(i) GENERAL RULE.—A tolerance for
12 a pesticide chemical residue shall not be
13 established or allowed to remain in effect
14 unless the Administrator determines, after
15 consultation with the Secretary, that—

16 “(I) there is a method for detect-
17 ing and measuring the levels of such
18 pesticide chemical residue in or on a
19 food that will detect the residue at the
20 level established by the tolerance; and

21 “(II) except as provided in clause
22 (ii), such method is the best available,
23 practical method.

24 “(ii) SPECIAL RULE.—If the Adminis-
25 trator determines that a practical method

1 of analysis for a pesticide chemical residue
2 is not available, the Administrator shall
3 identify the best available method that is
4 designed to identify the lowest detectable
5 amount of the pesticide chemical residue.
6 The Administrator shall, every 2 years
7 after the date of the determination under
8 this clause, reevaluate the determination.

9 “(iii) PRACTICAL METHOD.—A meth-
10 od shall be considered practical for pur-
11 poses of this subparagraph only if it is a
12 multiresidue method that can be performed
13 by the Secretary on a routine basis as part
14 of surveillance and compliance sampling of
15 foods for pesticide chemical residues with
16 the personnel, equipment, and other re-
17 sources available to the Secretary, or, if no
18 multiresidue method is available, only if it
19 can be so performed by the Secretary.

20 “(3) CONSISTENT APPLICATION.—The Adminis-
21 trator shall issue guidelines providing for the con-
22 sistent application of the requirements of paragraphs
23 (1) and (2).

24 “(c) PHASEOUT OF PESTICIDES THAT ARE KNOWN
25 OR PROBABLE HUMAN CARCINOGENS OR HAZARDOUS TO

1 HUMAN HEALTH.—The Administrator may not issue a
2 tolerance for any pesticide that contains an active or inert
3 ingredient that is a known or probable human carcinogen
4 or highly hazardous to human health. Subject to the ex-
5 ceptions in subsection (k), each tolerance for any pesticide
6 containing an active or inert ingredient that is classified
7 by the Administrator as—

8 “(1) a known or probable human carcinogen
9 pursuant to the guidelines for carcinogen risk as-
10 sessment published at 51 Fed. Reg. 33992, 34000
11 (1986) or a comparable classification based on
12 equivalent criteria, or

13 “(2) highly hazardous to human health,
14 is terminated 5 years after the date the Administrator so
15 classifies such ingredient or the date of the enactment of
16 the Pesticide Food Safety Act of 1994, whichever is later.

17 “(d) EXTENSION OF PHASEOUT TIME.—In response
18 to a petition by any person, the Administrator may, by
19 regulation, extend the tolerance of a pesticide to allow the
20 identification and implementation of alternatives to such
21 pesticide for a period not to exceed 3 years after the date
22 specified in subsection (c). Such an extension may be
23 granted only if the petitioner demonstrates, in a petition
24 filed no later than 3 years after the date of enactment
25 of the Pesticide Food Safety Act of 1994, or 3 years after

1 a pesticide is determined to meet the standard in sub-
2 section (c), whichever occurs later, by clear and convincing
3 evidence, for each use of the pesticide for which an exten-
4 sion is sought, that revocation of the tolerance will cause
5 a severe disruption of the availability of foods on the na-
6 tional market, and that—

7 “(1) there is no alternative effective pest man-
8 agement practice for the pesticide for which the tol-
9 erance is scheduled to be revoked;

10 “(2) the tolerance otherwise meets the require-
11 ments of this section; and

12 “(3) the proponent of the extension submits a
13 plan to assure that the quantity of the pesticide used
14 will be reduced by at least an average of 20 percent
15 per year over the 3-year period following the grant-
16 ing of the extension.

17 “(e) LISTS.—

18 “(1) KNOWN OR PROBABLE HUMAN CARCINO-
19 GENS.—No later than 60 days from the date of en-
20 actment of the Pesticide Food Safety Act of 1994,
21 the Administrator shall publish a list of active and
22 inert ingredients of pesticide chemicals that were
23 classified as known or probable human carcinogens
24 on the date of enactment of the Pesticide Food Safe-
25 ty Act of 1994. Such list shall be revised every 2

1 years to reflect new information, including data gen-
2 erated under subsection (m).

3 “(2) OTHER HUMAN HEALTH EFFECTS.—No
4 later than 6 months after the date of enactment of
5 the Pesticide Food Safety Act of 1994, the Adminis-
6 trator shall publish lists of active and inert ingredi-
7 ents—

8 “(A) of pesticide chemicals for which there
9 is limited evidence of carcinogenicity in animals,
10 and

11 “(B) of pesticide chemicals which are high-
12 ly hazardous to human health as determined by
13 the Administrator on the basis of the classifica-
14 tion that the pesticide chemicals are persistent,
15 (as defined in the Sixth Biennial Report on
16 Great Lakes Water Quality of the International
17 Joint Commission (1992)), bioaccumulative (as
18 defined by the Administrator in 58 Fed. Reg.
19 20858–63 (1993)), an endocrine disruptor, a
20 potent reproductive or developmental toxin (as
21 defined by the Administrator in 53 Fed. Reg.
22 24834–69 (1988) and 56 Fed. Reg. 63798–826
23 (1991)), or a potent neurotoxin (including tox-
24 ins identified in 40 C.F.R. 156.10(i)(A)
25 (1993)).

1 Within 1 year of the publication of the lists under
2 this subsection, the Administrator shall take appro-
3 priate measures to inform the public of its exposure
4 to pesticides in such lists.

5 “(3) ADDITIONAL HEALTH EFFECTS.—No later
6 than 3 years after the date of enactment of the Pes-
7 ticide Food Safety Act of 1994, the Administrator
8 shall publish a list of active and inert ingredients of
9 pesticide chemicals that are hazardous to human
10 health as determined by the Administrator on the
11 basis of data developed under protocols required
12 under subsections (n) and (o)

13 “(f) MODERN BEST SCIENCE PERIODIC REVIEW.—
14 The Administrator shall, within 4 years of the date of en-
15 actment of the Pesticide Food Safety Act of 1994, conduct
16 a review of the best available cancer data with respect to
17 all possible human carcinogens to determine whether they
18 are known or probable human carcinogens. Any person
19 may, prior to 2 years after the date of enactment of the
20 Pesticide Food Safety Act of 1994, petition the Adminis-
21 trator for a determination that a pesticide which is a po-
22 tential carcinogen is not a known or probable human car-
23 cinogen. For a pesticide identified as a potential carcino-
24 gen subsequent to the date of enactment of the Pesticide
25 Food Safety Act of 1994, any person may petition the Ad-

1 administrator for a determination that the pesticide is not
2 a known or probable human carcinogen 1 year after that
3 identification. Upon the filing of any such petition, the Ad-
4 ministrator shall determine within 2 years, in accordance
5 with the standards of this Act and based upon adequate
6 scientific data, whether the petitioner has demonstrated
7 that the pesticide is not a known or probable human car-
8 cinogen. If the Administrator does not adopt the regula-
9 tion granting a petition filed pursuant to this section, or
10 if no petition has been filed regarding a potential carcino-
11 gen, the pesticide shall be a known or probable human
12 carcinogen within the meaning of this Act and shall be
13 subject to subsection (l)(1).

14 “(g) PROTOCOLS FOR ENDOCRINE DISRUPTORS,
15 NEUROTOXIC, REPRODUCTIVELY AND DEVELOPMEN-
16 TALLY TOXIC SUBSTANCES.—The Administrator shall, no
17 later than 1 year of the date of enactment of the Pesticide
18 Food Safety Act of 1994, establish testing protocols ade-
19 quate to determine whether a pesticide disrupts the endo-
20 crine systems, is neurotoxic, or reproductively or devel-
21 opmentally toxic and shall require the submission of data
22 meeting such protocol as necessary to determine whether
23 a pesticide meets the requirements of this section. Prior
24 to promulgation of such protocols, the Administrator shall

1 make any classifications of pesticide chemicals as meeting
2 such criteria based upon the best available scientific data.

3 “(h) PROTOCOLS FOR DETERMINING FETAL, IN-
4 FANT, AND CHILD SENSITIVITY TO PESTICIDE CHEMI-
5 CALS.—No later than 1 year after the date of enactment
6 of the Pesticide Food Safety Act of 1994, the Adminis-
7 trator shall establish testing protocols adequate to deter-
8 mine whether a pesticide chemical has the potential to
9 cause chronic multigenerational, developmental, reproduc-
10 tive, neurotoxic, endocrine, carcinogenic, or other adverse
11 health effects that may result from exposure to pesticide
12 chemicals during fetal development, infancy, or early
13 childhood. The Administrator shall require the submission
14 of data meeting such protocols as necessary to determine
15 whether a pesticide chemical meets the requirements of
16 this section.

17 “(i) INERT INGREDIENTS.—No tolerance or exemp-
18 tion from a tolerance for a pesticide containing an inert
19 ingredient that is a known, probable, or possible human
20 carcinogen, which presents significant hazards to children
21 or which is highly hazardous to human health, may be es-
22 tablished for a new use on food. Existing tolerances or
23 exemptions from tolerances for a pesticide containing an
24 inert ingredient known to meet such criteria shall be ter-
25 minated no later than 2 years after the effective date of

1 the Pesticide Food Safety Act of 1994. Tolerances or ex-
2 emptions from tolerances for pesticides found to contain
3 an inert ingredient found subsequent to the date of the
4 enactment of the Pesticide Food Safety Act of 1994 to
5 meet such criteria shall terminate 2 years after such sub-
6 sequent determination unless terminated prior to that date
7 by the Administrator.”.

8 “(j) EXEMPTIONS.—

9 “(1) AUTHORITY.—

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

14 “(i) in response to a petition filed
15 under subsection (k)(1); or

16 “(ii) on the initiative of the Adminis-
17 trator under subsection (k)(4).

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

21 “(2) STANDARD.—

22 “(A) AUTHORITY AND RISK STANDARD.—

23 “(i) ESTABLISHMENT.—An exemption
24 may be established for a pesticide chemical
25 residue if such residue is not a human or

1 animal carcinogen and otherwise presents
2 no risk to human health, including the
3 health of individuals in the population
4 groups set out in subsection (b)(2)(E),
5 from dietary exposure to such residue.

6 “(ii) REVOCATION.—An exemption
7 shall be revoked unless the residue is not
8 a human or animal carcinogen and the res-
9 idue does not present any risk to human
10 health, including the health of individuals
11 in the population groups set out in sub-
12 section (b)(2)(E), from dietary exposure to
13 such residue.

14 “(iii) TOLERANCE.—No exemption
15 may be established or allowed to remain in
16 effect for a pesticide chemical residue for
17 which there is in effect a tolerance.

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

22 “(i) use only reliable, statistically sig-
23 nificant data regarding the dietary expo-
24 sure resulting from the consumption of the

1 food for which the exemption for such resi-
2 due is proposed or is in effect;

3 “(ii) take into account all other ex-
4 emptions in effect for such residue and all
5 other sources (including drinking water if
6 data demonstrating widespread or signifi-
7 cant regional contamination in drinking
8 water are available) of dietary exposure to
9 such residue; and

10 “(iii) consider the exposure to be the
11 level of exposure that would occur if—

12 “(I) all the food, for which the
13 tolerance for such residue is proposed
14 or in effect, has amounts of such resi-
15 due equal to the tolerance proposed or
16 in effect, respectively;

17 “(II) all other sources of dietary
18 exposure to such residue described in
19 clause (ii) occur; and

20 “(III) human exposure to the
21 pesticide chemical residue at the toler-
22 ance level occurs for a period equal to
23 a lifetime.

24 “(C) PRACTICAL METHODS OF ANALY-
25 SIS.—An exemption for a pesticide chemical

1 residue shall not be established or allowed to re-
2 main in effect unless the Administrator deter-
3 mines, after consultation with the Secretary,
4 that there is a method for detecting and meas-
5 uring the levels of such pesticide chemical resi-
6 due on a food and that such method is the best
7 available, practical method, as defined in sub-
8 section (b)(2)(G).

9 “(3) CONSISTENT APPLICATION.—The Adminis-
10 trator shall issue guidelines providing for the con-
11 sistent application of the requirements of paragraphs
12 (1) and (2).

13 “(k) PETITIONS AND ACTION ON THE INITIATIVE OF
14 THE ADMINISTRATOR.—

15 “(1) GENERAL RULE FOR PETITIONS.—Any
16 person may file with the Administrator a petition
17 proposing the issuance of a regulation establishing,
18 modifying, or revoking a tolerance or exemption for
19 a pesticide chemical residue.

20 “(2) REQUIREMENTS FOR PETITIONS TO ES-
21 TABLISH A TOLERANCE OR EXEMPTION.—

22 “(A) CONTENTS.—A petition under para-
23 graph (1) to establish a tolerance or exemption
24 for a pesticide chemical residue shall contain—

1 “(i) an informative summary of the
2 petition and of the data, information, and
3 arguments submitted or cited in support of
4 the petition, including—

5 “(I) a summary of the reports re-
6 quired under clause (iv) respecting the
7 safety of the pesticide chemical resi-
8 due; and

9 “(II) a characterization of—

10 “(aa) the exposure to the
11 pesticide chemical residue due to
12 any tolerance or exemption al-
13 ready granted for such residue;
14 and

15 “(bb) the additional expo-
16 sure to such residue that would
17 result if the requested tolerance
18 or exemption were granted;

19 “(ii) a proposed tolerance for such
20 residue, if a tolerance is proposed;

21 “(iii) the name, chemical identity, and
22 composition of the pesticide chemical that
23 produces such residue;

24 “(iv) reports of tests and investiga-
25 tions made with respect to the safety of

1 such pesticide chemical, including complete
2 information as to the methods and controls
3 used in conducting such tests and inves-
4 tigations;

5 “(v) data showing the amount, fre-
6 quency, method, and time of application of
7 such pesticide chemical;

8 “(vi) reports of tests and investiga-
9 tions made with respect to the nature and
10 amount of the pesticide chemical residue
11 that is likely to remain in or on food when
12 ready for sale to consumers, including a
13 description of the analytical methods used;

14 “(vii) a description of methods for de-
15 tecting and measuring the levels of such
16 pesticide chemical residue in or on the
17 food, which methods meet the require-
18 ments of subsection (b)(2)(G) or (j)(2)(C);

19 “(viii) reports of investigations con-
20 ducted on the effects of processing meth-
21 ods used to produce food on the level and
22 identity of such pesticide chemical residue;

23 “(ix) if the petition is for a pesticide
24 chemical residue that is described in sub-
25 section (b)(2)(B)(iii), all relevant data

1 bearing on the physical or other technical
2 effect the pesticide chemical involved is in-
3 tended to have and the quantity of the pes-
4 ticide chemical residue required to accom-
5 plish such effect; and

6 “(x) such other data and information
7 (including a sample of the pesticide chemi-
8 cal from which the pesticide chemical resi-
9 due is derived) as the Administrator may
10 require to support the petition.

11 “(B) INFORMATION AVAILABLE TO ADMIN-
12 ISTRATOR.—If information or data required by
13 this paragraph are available to the Adminis-
14 trator, the person submitting the petition may,
15 in lieu of submitting the information or data,
16 cite the availability of the information or data.

17 “(3) ACTIONS ON PETITIONS.—

18 “(A) NOTICE.—

19 “(i) IN GENERAL.—Within 45 days of
20 the filing of a petition under paragraph (1)
21 for the establishment of a tolerance or an
22 exemption, the Administrator shall deter-
23 mine if the petition complies with the re-
24 quirements of paragraph (2). If the Ad-
25 ministrator determines that the petition

1 complies with such requirements, the Ad-
2 ministrator shall publish a notice of the fil-
3 ing of the petition. If the Administrator
4 determines that the petition does not com-
5 ply with such requirements, the Adminis-
6 trator shall notify the petitioner of such
7 determination.

8 “(ii) CONTENTS.—A notice published
9 under this subparagraph shall—

10 “(I) announce the availability of
11 a complete description of the analyt-
12 ical methods available to the Adminis-
13 trator for the detection and measure-
14 ment of the pesticide chemical residue
15 with respect to which the petition is
16 filed;

17 “(II) include the summary re-
18 quired by paragraph (2)(A)(i); and

19 “(III) provide at least 30 days
20 for comments on the petition.

21 “(B) ACTION.—The Administrator shall,
22 within 270 days of the publication of a notice
23 under subparagraph (A) with respect to a peti-
24 tion, and after giving due consideration to the
25 petition, any comments on the petition, and any

1 other information available to the Adminis-
2 trator—

3 “(i) issue a final regulation in accord-
4 ance with the petition establishing a toler-
5 ance or exemption for the pesticide chemi-
6 cal residue;

7 “(ii) issue a proposed regulation es-
8 tablishing a tolerance or exemption for the
9 pesticide chemical residue, which tolerance
10 or exemption is different from the toler-
11 ance or exemption requested in the peti-
12 tion; or

13 “(iii) issue an order denying the peti-
14 tion.

15 “(C) MODIFICATION OR REVOCATION.—

16 “(i) NOTICE.—Within 45 days of the
17 filing of a petition under paragraph (1) for
18 the modification or revocation of a toler-
19 ance or exemption, the Administrator shall
20 publish a notice of the filing of the peti-
21 tion. Such notice shall contain the full peti-
22 tion or a summary of the petition and shall
23 provide at least 30 days for comments on
24 the petition.

1 “(ii) ACTION.—The Administrator
2 shall, within 270 days of the publication of
3 the notice under subparagraph (A) and
4 after giving due consideration to the peti-
5 tion, any comments on the petition, and
6 any other information available to the Ad-
7 ministrator—

8 “(I) issue a final regulation in
9 accordance with the petition modify-
10 ing or revoking a tolerance or exemp-
11 tion for the pesticide chemical residue;

12 “(II) issue a proposed regulation
13 modifying or revoking a tolerance or
14 exemption for the pesticide chemical
15 residue, which tolerance or exemption
16 is different from the modification or
17 revocation requested in the petition;
18 or

19 “(III) issue an order denying the
20 petition.

21 “(D) COMMENTS AND FINAL REGULA-
22 TIONS.—If the Administrator issues a proposed
23 regulation under subparagraph (B)(ii) or
24 (C)(ii)(II), the Administrator shall allow at
25 least 30 days for comments on such proposed

1 regulations. The Administrator shall issue a
2 final decision within 180 days of the date of the
3 publication of the proposed regulations.

4 “(E) PRIORITIES.—The Administrator
5 shall give priority to petitions for the establish-
6 ment of a tolerance for a pesticide chemical res-
7 idue that appears to pose a significantly lower
8 risk to human health from dietary exposure
9 than pesticide chemical residues that have toler-
10 ances in effect for the same or similar uses.

11 “(4) ACTION ON THE INITIATIVE BY THE AD-
12 MINISTRATOR.—

13 “(A) GENERAL RULE.—The Administrator
14 may, on the initiative of the Administrator,
15 issue a final regulation establishing, modifying,
16 or revoking a tolerance or exemption for a pes-
17 ticide chemical residue.

18 “(B) NOTICE.—Before issuing a final reg-
19 ulation under subparagraph (A), the Adminis-
20 trator shall issue a notice of proposed rule-
21 making and provide a period of not less than 30
22 days for public comment on the proposed regu-
23 lation unless the Administrator finds that it
24 would be contrary to the public interest to issue
25 the notice and provide the period and states the

1 reasons for the finding in the notice of the final
2 regulation.

3 “(5) EFFECTIVE DATE.—

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

8 “(B) DELAY.—

9 “(i) GENERAL RULE.—If a regulation
10 issued under paragraph (3) or (4) revokes
11 or modifies a tolerance for a pesticide
12 chemical residue or revokes an exemption
13 for a pesticide chemical residue, the Ad-
14 ministrators may, in accordance with clause
15 (ii), delay the effective date of the regula-
16 tion to permit the tolerance or exemption
17 to remain in effect at the level in effect im-
18 mediately before such regulation is issued
19 only—

20 “(I) for foods that, on the date of
21 the publication of the regulation, con-
22 tain such pesticide chemical residue in
23 an amount that is not more than the
24 amount that could legally be applied

1 on the date the Administrator acted
2 under paragraph (3) or (4); and

3 “(II) if dietary exposure to the
4 pesticide chemical residue in or on the
5 foods described in subclause (I) meets
6 the negligible risk standard prescribed
7 by subsection (b)(2) during the period
8 of delay of the effective date.

9 “(ii) PERIOD OF DELAY.—If the Ad-
10 ministrator finds that delay of the effective
11 date of such a revocation or modification is
12 consistent with the public health, the Ad-
13 ministrator may delay such date under
14 clause (i), for each type of food that con-
15 tains such pesticide chemical residue, for
16 the period that is required for such food to
17 be sold to consumers in the course of the
18 usual practice for persons engaged in the
19 production, processing, transportation,
20 storage, and distribution of the type of
21 food.

22 “(I) SPECIAL DATA REQUIREMENTS.—

23 “(1) DETERMINATION OF INADEQUATE DATA.—

24 The Administrator shall take the action described in
25 paragraph (2) if a tolerance or exemption is in effect

1 for a pesticide chemical residue and the Adminis-
2 trator determines that data contained in the peti-
3 tion, which had been submitted, under subsection
4 (k)(1) for establishment of the tolerance or exemp-
5 tion, or under this section, before the date of the en-
6 actment of the Pesticide Food Safety Act of 1994,
7 are not adequate to support the continuation of such
8 tolerance or exemption because—

9 “(A) based on the data contained in the
10 petition and other data available to the Admin-
11 istrator, the Administrator determines that die-
12 tary exposure to such pesticide chemical residue
13 may present a risk to human health that is
14 greater than the standard prescribed by sub-
15 section (b)(2) or (j)(2); or

16 “(B) the data contained in the petition are
17 insufficient to determine if the tolerance or ex-
18 emption meets the requirements of subsection
19 (b)(2) or (j)(2) or the requirements of sub-
20 section (k)(2).

21 “(2) ACTION BY ADMINISTRATOR.—When the
22 Administrator makes the determination described in
23 paragraph (1) with respect to a tolerance or exemp-
24 tion for a pesticide chemical residue, the Adminis-
25 trator shall—

1 “(A) within 30 days of a determination
2 under paragraph (1)(A), initiate an action
3 under subsection (k)(4) to modify or revoke the
4 tolerance or exemption so that the tolerance or
5 exemption meets the standard prescribed by
6 subsection (b)(2) or (j)(2), and within 1 year of
7 such determination issue a final regulation to
8 complete such action; and

9 “(B) within 30 days of the date of a deter-
10 mination under paragraph (1)(B), require the
11 submission of data to support—

12 “(i) the existing tolerance or exemp-
13 tion; or

14 “(ii) a new tolerance or exemption for
15 such residue,

16 that meets the standard prescribed by sub-
17 section (b)(2) or (k)(2).

18 “(3) SUBMISSION OF REQUIRED DATA.—When
19 the Administrator requires the submission of data
20 under paragraph (2)(B), the Administrator shall
21 publish an order—

22 “(A) requiring one or more interested per-
23 sons to notify the Administrator that such per-
24 son will submit the required data;

1 “(B) describing the type of data required
2 to be submitted;

3 “(C) describing the reports required to be
4 made during and after the collection of the
5 data; and

6 “(D) establishing deadlines for the actions
7 described in subparagraphs (A) and (C).

8 “(4) DEADLINES.—

9 “(A) GENERAL RULE.—Except as provided
10 in subparagraphs (B) and (C), if an order is is-
11 sued under paragraph (3) with respect to a tol-
12 erance or exemption and a deadline in the order
13 is not met, the tolerance or exemption is re-
14 voked, effective 45 days after the date the dead-
15 line is not met. Immediately after such deadline
16 is not met, the Administrator shall publish a
17 notice of the revocation.

18 “(B) EXTENSION REQUEST.—

19 “(i) REQUEST.—Any person may re-
20 quest the Administrator to issue an order
21 to extend the deadline established under
22 paragraph (3)(D) before expiration of the
23 deadline.

1 “(ii) GRANT OF REQUEST.—The Ad-
2 ministrators may grant such a request only
3 if—

4 “(I) the person submitting the
5 request notified the Administrator
6 pursuant to paragraph (3)(A) in com-
7 pliance with the deadline established
8 under paragraph (3)(C); and

9 “(II) the Administrator finds
10 that extraordinary circumstances be-
11 yond the control of such person pre-
12 vented such person from submitting
13 the required data.

14 “(iii) EXTENSION.—If the Adminis-
15 trator issues an order extending a dead-
16 line—

17 “(I) the Administrator may ex-
18 tend the deadline for a period no
19 longer than such time as is necessary
20 for such person to submit the data;
21 and

22 “(II) the Administrator shall es-
23 tablish a new deadline in accordance
24 with paragraph (3)(D).

1 “(C) DELAY.—If a tolerance or exemption
2 is revoked under subparagraph (A), the Admin-
3 istrator may delay the effective date of the rev-
4 ocation in accordance with subsection (k)(5)(B).

5 “(5) EVALUATION OF DATA.—Within 90 days
6 of the date of the receipt of data under paragraph
7 (3), the Administrator shall evaluate such data and
8 determine whether action is required under sub-
9 section (k)(4) with respect to the tolerance or ex-
10 emption for the pesticide chemical residue for which
11 the data were submitted so that such tolerance
12 meets the negligible risk standard prescribed under
13 subsection (b)(2) or (j)(2). If the Administrator de-
14 termines that action under subsection (k)(4) is re-
15 quired, the Administrator shall complete such action
16 within 1 year of the date of such determination.

17 “(m) CONFIDENTIALITY OF DATA.—

18 “(1) GENERAL RULE.—Data submitted to the
19 Administrator in support of a petition under sub-
20 section (k)(1), which data have not previously been
21 made available to the public without restriction,
22 shall, upon request of the petitioner, be considered
23 as entitled to confidential treatment by the Adminis-
24 trator until publication of a regulation or order
25 under subsection (k)(3) in response to the petition

1 unless disclosure of such data is required by sub-
2 section (k)(3)(A)(ii)(II) or (n) or is allowed by para-
3 graph (2).

4 “(2) DISCLOSURE.—Data that are entitled to
5 confidential treatment under paragraph (1) until
6 publication of a regulation or order under subsection
7 (k)(3) may be revealed to—

8 “(A) either House of Congress or any com-
9 mittee or subcommittee of such House to the
10 extent of matter within the jurisdiction of the
11 committee or subcommittee;

12 “(B) any officer or employee of the United
13 States in connection with the official duties of
14 such officer or employee under any law for the
15 protection of health or the environment or for
16 specific law enforcement purposes;

17 “(C) any officer or employee of a State in
18 connection with the official duties of such offi-
19 cer or employee under any law of the State for
20 the protection of health or the environment or
21 for specific law enforcement purposes; or

22 “(D) contractors with the United States
23 authorized by the Administrator to examine
24 such data in the carrying out of contracts under

1 such statutes under such security requirements
2 as the Administrator may provide.

3 “(n) ACCESS TO DATA IN SUPPORT OF PETITION.—

4 “(1) GENERAL RULE.—

5 “(A) PUBLIC ACCESS.—If data in support
6 of a petition are submitted to the Adminis-
7 trator, the Administrator, before acting on such
8 petition, shall provide, in accordance with this
9 subsection, public access to health and safety
10 data that are submitted or cited in support of
11 such petition.

12 “(B) REQUEST.—To obtain access to such
13 data, a person shall, not later than 30 days
14 after the publication under subsection (k)(3)(A)
15 of a notice of the filing of a petition, send by
16 certified mail to the Administrator and to the
17 petitioner a request for such access and the af-
18 firmation required by paragraph (2).

19 “(C) GRANT OF REQUEST.—The Adminis-
20 trator shall grant such request unless, within
21 15 days after the receipt by the Administrator
22 of such request and affirmation, the petitioner
23 submits to the Administrator an objection to
24 the request asserting that the affirmation is in-
25 accurate and other reasons for the objection.

1 “(D) OBJECTION.—If an objection to a re-
2 quest is submitted to the Administrator within
3 such 15-day period, the Administrator shall de-
4 termine whether to grant the request within 5
5 days after the receipt of the objection. If the
6 Administrator determines to grant the request,
7 access shall not be permitted until 5 days after
8 the petitioner making the objection has been
9 notified that access has been granted.

10 “(E) DENIAL OF REQUEST.—If access to
11 data is denied, comments on the petition for
12 which such data were submitted or cited shall
13 be filed within 30 days after the decision of the
14 Administrator denying access.

15 “(2) RESTRICTION.—

16 “(A) AFFIRMATION.—Data referred to in
17 paragraph (1) may be made available only to a
18 person who provides an affirmation (and such
19 supporting evidence as the Administrator may
20 require) that—

21 “(i) states that the person is not en-
22 gaged in, and is neither employed by, nor
23 acting (directly or indirectly) on behalf of,
24 any other person, or affiliate of a person,

1 engaged in, the production, sale, or dis-
2 tribution of a pesticide chemical;

3 “(ii) identifies any business, employer,
4 or other person, if any, on whose behalf
5 the person is requesting access to the data;
6 and

7 “(iii) states that the person will not
8 intentionally or recklessly violate this sub-
9 section.

10 “(B) AFFILIATE.—For purposes of this
11 paragraph, an affiliate of a person is a person
12 who directly or indirectly, through one or more
13 intermediates, controls or is controlled by or is
14 under common control with the other person.

15 “(C) FRAUD.—Section 1001 of title 18,
16 United States Code, shall apply to an affirma-
17 tion made under this paragraph.

18 “(3) COMMENTS.—

19 “(A) GENERAL RULE.—Data supporting a
20 petition may be made available under para-
21 graph (1) to a person only for the purpose of
22 permitting the person to comment to the Ad-
23 ministrator on such petition. Such comments
24 may reasonably quote data submitted to the
25 Administrator. No person, including the Admin-

1 istrator, may make such comments public be-
2 fore the decision of the Administrator on the
3 petition for which such data were submitted or
4 after such decision if the petition is denied.

5 “(B) RESTRICTIONS.—A person who ob-
6 tains data (directly or indirectly) under para-
7 graph (1) may not publish, copy, or transfer the
8 data to any other person to obtain approval to
9 sell, manufacture, or distribute a pesticide
10 chemical anywhere in the world.

11 “(4) PROCEDURE.—

12 “(A) IN GENERAL.—Data made available
13 under paragraph (1) may be examined at an of-
14 fice of the Environmental Protection Agency or
15 an appropriate State agency under the condi-
16 tions prescribed by this subsection and may not
17 be removed from such office.

18 “(B) RECORD.—The Administrator shall
19 maintain a record of the persons who inspect
20 data. A copy of such record shall be sent on re-
21 quest to the person who submitted the data.

22 “(C) BASIS FOR COMMENTS.—Once access
23 to data supporting a petition is granted, the
24 data may be examined and notes may be taken
25 for use in developing comments on the petition.

1 Such comments on the petition shall be filed
2 within 60 days after the decision of the Admin-
3 istrator granting access, unless the comment
4 period is extended by the Administrator for an
5 additional 30 days for good cause.

6 “(o) ACCESS TO DATA AFTER DECISION.—When the
7 Administrator takes final action on a petition submitted
8 under subsection (k)(1) or on the initiative of the Adminis-
9 trator under subsection (k)(4), the Administrator shall
10 make available to the public the administrative record of
11 the decision, including the data relied upon for the deci-
12 sion.

13 “(p) EXISTING PESTICIDE CHEMICAL RESIDUES.—

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

22 “(2) PESTICIDE CHEMICAL RESIDUES UNDER
23 REGULATIONS.—Regulations establishing tolerances
24 for pesticide chemical residues under this section
25 and section 409 or exemptions for pesticide chemical

1 residues under this section on or before the date of
2 the enactment of this section shall be deemed to be
3 tolerances or exemptions issued under this section
4 and shall be subject to modification or revocation
5 under subsection (k) or (l).

6 “(3) GENERALLY RECOGNIZED AS SAFE PES-
7 TICIDE CHEMICAL RESIDUES.—

8 “(A) GENERAL RULE.—Pesticide chemical
9 residues that, on the day before the date of the
10 enactment of the Pesticide Food Safety Act of
11 1994, do not have tolerances or exemptions
12 from tolerances under this section because the
13 residues are generally recognized as safe under
14 this section or section 409 shall, until the expi-
15 ration of the period prescribed by subparagraph
16 (C), not be considered unsafe under section
17 402(a)(2)(B) solely because the chemicals do
18 not have such a tolerance or exemption.

19 “(B) LIST.—Not later than 90 days after
20 the date of the enactment of such Act, the Ad-
21 ministrator shall—

22 “(i) publish a list of all pesticide
23 chemical residues that the Administrator
24 has determined are generally recognized,
25 on the day before the date of the enact-

1 ment of such Act, as safe under this sec-
2 tion or section 409; and

3 “(ii) require, by regulation, that any
4 person who, before the date of the enact-
5 ment of such Act, distributed in commerce
6 as a pesticide chemical, a pesticide chemi-
7 cal that is not on the list described in
8 clause (i), and that such person deter-
9 mined is generally recognized as safe under
10 this section or section 409, shall—

11 “(I) report to the Administrator
12 the identity of such pesticide chemical;
13 and

14 “(II) report to the Administrator
15 the data that supports the claim that
16 the pesticide chemical is so safe.

17 “(C) DETERMINATION OF THE ADMINIS-
18 TRATOR.—Not later than 270 days after such
19 date, the Administrator shall determine if each
20 pesticide chemical reported to the Adminis-
21 trator in accordance with subparagraph (B)(ii)
22 is generally recognized as safe. If the Adminis-
23 trator determines, by order, that such pesticide
24 chemical is generally recognized as safe, the
25 residue of such pesticide chemical shall be con-

1 sidered a pesticide chemical residue subject to
2 an exemption under this section, which exemp-
3 tion shall be subject to modification or revoca-
4 tion under subsection (k) or (l).

5 “(q) FOOD AND DRUG ADMINISTRATION MONITOR-
6 ING OF PESTICIDE CHEMICAL RESIDUES.—

7 “(1) SAMPLING.—The Secretary shall conduct
8 surveillance and compliance sampling of food for
9 pesticide chemical residues to determine if the pes-
10 ticide chemical residues are in compliance with this
11 section. In carrying out this paragraph, the Sec-
12 retary shall give priority to foods that contain pes-
13 ticide chemical residues included in a notice under
14 paragraph (2).

15 “(2) NOTIFICATION.—The Administrator shall
16 notify the Secretary of the pesticide chemical resi-
17 dues that the Administrator determines, in the ad-
18 ministration of this section—

19 “(A) are above the standard prescribed by
20 subsection (b)(2); or

21 “(B) are not above such standard but that
22 may under certain circumstances reach or ex-
23 ceed such standard.

24 “(r) FEES.—The Administrator shall by regulation
25 require the payment of such fees as will in the aggregate,

1 in the judgment of the Administrator, be sufficient over
2 a reasonable term to provide, equip, and maintain an ade-
3 quate service for the performance of the functions of the
4 Administrator under this section. Under such regulations,
5 the performance of the services or other functions of the
6 Administrator under this section may be conditioned upon
7 the payment of such fees. Such regulations may further
8 provide that the continuation in effect of a tolerance or
9 exemption shall be conditioned upon the payment of an
10 annual fee and for waiver or refund of fees in whole or
11 in part when, in the judgment of the Administrator, such
12 waiver or refund is equitable and not contrary to the pur-
13 poses of this subsection.

14 “(s) JUDICIAL REVIEW.—

15 “(1) REVIEW.—Any person (including a person
16 without an economic interest) who may be adversely
17 affected by a final regulation or order issued under
18 subsection (k)(3), (k)(4), (l)(4), or (i)(3) may obtain
19 judicial review of such regulation or order by filing
20 a petition requesting that the regulation or order be
21 set aside in whole or in part in the United States
22 Court of Appeals for the circuit in which such per-
23 son resides or has its principal place of business, or
24 in the United States Court of Appeals for the Dis-
25 trict of Columbia Circuit, within 60 days after publi-

1 cation of the regulation or order under such sub-
2 section.

3 “(2) REVIEW OF DATA.—

4 “(A) IN GENERAL.—Any person (including
5 a person without an economic interest) may ob-
6 tain judicial review, of the adequacy of the data
7 made available by the Administrator under sub-
8 section (o) to support the issuance of a toler-
9 ance or exemption for a pesticide chemical resi-
10 due, by filing a petition for the review of the
11 data in the United States Court of Appeals for
12 the circuit in which such person resides or has
13 its principal place of business, or in the United
14 States Court of Appeals for the District of Co-
15 lumbia Circuit.

16 “(B) SCOPE OF REVIEW.—Review in a pro-
17 ceeding initiated under this paragraph shall be
18 limited to whether the data under review are
19 adequate to demonstrate that the tolerance or
20 exemption supported by such data meets the
21 standards required by subsection (b)(2) or
22 (j)(2) and interpreted by the guidelines issued
23 under subsection (b)(3) or (j)(3). Unless the
24 court determines that such data are adequate,

1 the court shall revoke the tolerance or exemp-
2 tion supported by such data.

3 “(C) BURDEN OF PROOF.—In any such
4 proceeding the Administrator shall have the
5 burden of proof on all issues.

6 “(3) COURT RESPONSIBILITY.—In any action
7 seeking judicial review of actions under this section,
8 the court shall have the principal responsibility for
9 deciding issues of law.

10 “(4) ATTORNEY FEES.—Any petitioner who
11 prevails in a proceeding brought under this section
12 shall be entitled to recover reasonable attorney fees
13 and expenses (including expert witness fees).

14 “(t) DEFINITIONS.—For purposes of this section, the
15 terms ‘modify’ and ‘modification’ mean the lowering of a
16 tolerance for a pesticide chemical residue.”.

17 (b) CONFORMING AMENDMENT.—Section 303 (21
18 U.S.C. 333) is amended by adding at the end the follow-
19 ing:

20 “(g) A person who violates a tolerance established
21 under section 408(b)(2) for a food at the time the food
22 is purchased at retail shall not be subject to any penalty
23 under this section.”.

1 **SEC. 4. EVALUATION OF EXISTING PESTICIDE CHEMICAL**
2 **RESIDUE TOLERANCES AND EXEMPTIONS.**

3 (a) EVALUATION.—Within 1 year of the date of the
4 enactment of this Act, the Administrator of the Environ-
5 mental Protection Agency shall, for each pesticide chemi-
6 cal residue that has a tolerance or exemption in effect
7 under the Federal Food, Drug, and Cosmetic Act, evaluate
8 all available data with respect to the safety of such pes-
9 ticide chemical residue and the nature and amount of such
10 residue remaining in or on foods and determine if—

11 (1) the tolerance or exemption meets the re-
12 quirements of subsection (b)(2) or (j)(2) of section
13 408 of such Act;

14 (2) the tolerance or exemption does not meet
15 such requirements; or

16 (3) the data are insufficient to determine if the
17 tolerance or exemption meets such requirements.

18 (b) SUFFICIENT DATA.—

19 (1) ACCEPTABLE RISK.—If, with respect to any
20 pesticide chemical residue that is evaluated under
21 subsection (a), the Administrator finds that data for
22 the pesticide chemical residue are sufficient to deter-
23 mine that the tolerance or exemption for the pes-
24 ticide chemical residue meets the standard under
25 section 408(b)(2) or 408(j)(2) of such Act, the Ad-
26 ministrator shall publish such finding.

1 (2) UNACCEPTABLE RISK.—If, with respect to
2 any pesticide chemical residue that is evaluated
3 under subsection (a), the Administrator finds that
4 data for the pesticide chemical residue are sufficient
5 to determine that the tolerance or exemption for the
6 pesticide chemical residue does not meet the stand-
7 ard under section 408(b)(2) or 408(j)(2) of such
8 Act, the Administrator shall, within 1 year of the
9 date of such finding, modify or revoke the tolerance.

10 (3) INSUFFICIENT DATA.—

11 (A) GENERAL RULE.—

12 (i) SUBMISSION OF DATA.—If, with
13 respect to any pesticide chemical residue
14 that is evaluated under subsection (a), the
15 Administrator determines that the data are
16 insufficient to determine whether the toler-
17 ance or exemption meets the requirements
18 of section 408(b)(2) or 408(j)(2) of such
19 Act, the Administrator shall establish a
20 schedule for the submission of data in ac-
21 cordance with the requirements of sections
22 408(g), 408(h), 408(l)(2)(B), and
23 408(l)(3) of such Act, which data shall be
24 the basis for a determination by the Ad-
25 ministrator as to whether the tolerance or

1 exemption meets the standard prescribed
2 by section 408(b)(2) or 408(j)(2) of such
3 Act.

4 (ii) DETERMINATIONS.—The Adminis-
5 trator shall—

6 (I) within 2 years of the date of
7 the enactment of this Act, make such
8 a determination respecting a tolerance
9 or exemption meeting a standard
10 under section 408 of such Act for at
11 least 30 percent of the tolerances or
12 exemptions in effect for pesticide
13 chemical residues in existence on such
14 date;

15 (II) within 4 years of the date of
16 the enactment of this Act, make such
17 a determination for at least 60 per-
18 cent of the tolerances or exemptions
19 in effect for pesticide chemical resi-
20 dues in existence on such date;

21 (III) within 6 years of the date of
22 the enactment of this Act, make such
23 a determination for at least 90 per-
24 cent of the tolerances or exemptions

1 in effect for pesticide chemical resi-
2 dues in existence on such date; and

3 (IV) within 7 years of the date of
4 the enactment of this Act, make such
5 a determination for 100 percent of the
6 tolerances or exemptions in effect for
7 pesticide chemical residues in exist-
8 ence on such date.

9 (iii) DEADLINES.—Section 408(l)(4)
10 of such Act shall apply to the deadlines es-
11 tablished by such schedule.

12 (B) PRIORITIES.—In establishing such
13 schedule, the Administrator shall give priority
14 to the consideration of any pesticide chemical
15 residue for which there is reason to believe that
16 the tolerance or exemption in effect for such
17 residue may present a risk greater than the
18 negligible risk standard prescribed by section
19 408(b)(2) or 408(j)(2) of such Act.

20 (C) ACTION BY THE ADMINISTRATOR.—If
21 the Administrator determines under subpara-
22 graph (A) that a tolerance or exemption does
23 not meet the standard under section 408(b)(2)
24 or 408(j)(2) of such Act after the submission of
25 data in accordance with the schedule prescribed

1 by such subparagraph, the Administrator shall
2 take the action described in section
3 408(l)(2)(A) of such Act with respect to such
4 tolerance or exemption.

5 **SEC. 5. REVIEW OF EXISTING METHODS OF ANALYSIS.**

6 (a) DETERMINATION.—Within 180 days of the date
7 of the enactment of this Act, the Administrator of the En-
8 vironmental Protection Agency shall determine, for each
9 method of detecting and measuring levels of pesticide
10 chemical residues, whether the requirements of section
11 408(b)(2)(G) of the Federal Food, Drug, and Cosmetic
12 Act have been met.

13 (b) NOTICE.—The Administrator shall issue a notice
14 identifying each pesticide chemical for which there is such
15 a method that does not meet such requirements. Any such
16 method that does not meet such requirements shall be re-
17 vised so that the method meets such requirements within
18 3 years of the date of the issuance of the notice.

19 (c) REVOCATION.—If upon the expiration of such 3-
20 year period, a method does not meet such requirements,
21 then any tolerance or exemption in effect for the pesticide
22 chemical residue subject to such method shall be consid-
23 ered revoked.

1 **SEC. 6. FEES.**

2 The Administrator of the Environmental Protection
3 Agency shall by regulation require the payment of such
4 fees as will in the aggregate, in the judgment of the Ad-
5 ministrator, be sufficient over a reasonable term to pro-
6 vide, equip, and maintain an adequate service for the per-
7 formance of the functions of the Administrator under this
8 section and sections 4 and 5 of this Act.

9 **SEC. 7. GENERAL DEFINITIONS.**

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

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

15 (2) **DIETARY EXPOSURE.**—The term “dietary
16 exposure” means dietary exposure as determined
17 under section 408(b)(2)(C) of the Federal Food,
18 Drug, and Cosmetic Act.

19 (3) **EXEMPTION.**—The term “exemption”
20 means an exemption from the requirement for a tol-
21 erance under section 408 of the Federal Food, Drug,
22 and Cosmetic Act.

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HR 4091 SC—2

HR 4091 SC—3

HR 4091 SC—4

HR 4091 SC—5