

109TH CONGRESS
2^D SESSION

H. R. 4167

IN THE SENATE OF THE UNITED STATES

MARCH 9, 2006

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to provide for uniform food safety warning notification requirements, and for other purposes.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “National Uniformity
3 for Food Act of 2005”.

4 **SEC. 2. NATIONAL UNIFORMITY FOR FOOD.**

5 (a) NATIONAL UNIFORMITY.—Section 403A of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–
7 1) is amended—

8 (1) in subsection (a)(4), by striking “or” at the
9 end;

10 (2) in subsection (a)(5), by striking the period
11 and inserting “, or”;

12 (3) in subsection (a), by inserting after para-
13 graph (5) the following:

14 “(6) any requirement for a food described in
15 section 402(a)(1), 402(a)(2), 402(a)(6), 402(a)(7),
16 402(c), 404, 406, 409, 512, or 721(a), that is not
17 identical to the requirement of such section.”; and

18 (4) by adding at the end the following:

19 “(c)(1) For purposes of subsection (a)(6) and section
20 403B, the term ‘identical’ means that the language under
21 the laws of a State or a political subdivision of a State
22 is substantially the same language as the comparable pro-
23 vision under this Act and that any differences in language
24 do not result in the imposition of materially different re-
25 quirements. For purposes of subsection (a)(6), the term
26 ‘any requirement for a food’ does not refer to provisions

1 of this Act that relate to procedures for Federal action
2 under this Act.

3 “(2) For purposes of subsection (a)(6), a State or
4 political subdivision of a State may enforce a State law
5 that contains a requirement that is identical to a require-
6 ment in a section of Federal law referred to in subsection
7 (a)(6) if—

8 “(A) the Secretary has promulgated a regula-
9 tion or adopted a final guidance relating to the re-
10 quirement and the State applies the State require-
11 ment in a manner that conforms to the regulation
12 or guidance; or

13 “(B) the Secretary has not promulgated a regula-
14 tion or adopted a final guidance relating to the re-
15 quirement, except that if the Secretary has consid-
16 ered a proposal for a regulation or final guidance re-
17 lating to the requirement and has, after soliciting
18 public comment, made a determination not to pro-
19 mulgate such regulation or adopt such guidance,
20 which determination is published in the Federal
21 Register, the State may not enforce any require-
22 ments in State law that are policies rejected by the
23 Secretary through such determination.”.

1 (b) UNIFORMITY IN FOOD SAFETY WARNING NOTI-
2 FICATION REQUIREMENTS.—Chapter IV of such Act (21
3 U.S.C. 341 et seq.) is amended—

4 (1) by redesignating sections 403B and 403C
5 as sections 403C and 403D, respectively; and

6 (2) by inserting after section 403A the fol-
7 lowing new section:

8 **“SEC. 403B. UNIFORMITY IN FOOD SAFETY WARNING NOTI-
9 FICATION REQUIREMENTS.**

10 **“(a) UNIFORMITY REQUIREMENT.—**

11 **“(1) IN GENERAL.—**Except as provided in sub-
12 sections (c) and (d), no State or political subdivision
13 of a State may, directly or indirectly, establish or
14 continue in effect under any authority any notifica-
15 tion requirement for a food that provides for a warn-
16 ing concerning the safety of the food, or any compo-
17 nent or package of the food, unless such a notifica-
18 tion requirement has been prescribed under the au-
19 thority of this Act and the State or political subdivi-
20 sion notification requirement is identical to the noti-
21 fication requirement prescribed under the authority
22 of this Act.

23 **“(2) DEFINITIONS.—**For purposes of paragraph
24 (1)—

1 “(A) the term ‘notification requirement’ in-
2 cludes any mandatory disclosure requirement
3 relating to the dissemination of information
4 about a food by a manufacturer or distributor
5 of a food in any manner, such as through a
6 label, labeling, poster, public notice, advertising,
7 or any other means of communication, except
8 as provided in paragraph (3);

9 “(B) the term ‘warning’, used with respect
10 to a food, means any statement, vignette, or
11 other representation that indicates, directly or
12 by implication, that the food presents or may
13 present a hazard to health or safety; and

14 “(C) a reference to a notification require-
15 ment that provides for a warning shall not be
16 construed to refer to any requirement or prohi-
17 bition relating to food safety that does not in-
18 volve a notification requirement.

19 “(3) CONSTRUCTION.—Nothing in this section
20 shall be construed to prohibit a State from con-
21 ducting the State’s notification, disclosure, or other
22 dissemination of information, or to prohibit any ac-
23 tion taken relating to a mandatory recall, civil ad-
24 ministrative order, embargo, detention order, or
25 court proceeding involving food adulteration under a

1 State statutory requirement identical to a food adul-
2 teration requirement under this Act.

3 “(b) REVIEW OF EXISTING STATE REQUIRE-
4 MENTS.—

5 “(1) EXISTING STATE REQUIREMENTS; DEFER-
6 RAL.—Any requirement that—

7 “(A)(i) is a State notification requirement
8 that expressly applies to a specified food or food
9 component and that provides for a warning de-
10 scribed in subsection (a) that does not meet the
11 uniformity requirement specified in subsection
12 (a); or

13 “(ii) is a State food safety requirement de-
14 scribed in section 403A(6) that does not meet
15 the uniformity requirement specified in that
16 paragraph; and

17 “(B) is in effect on the date of enactment
18 of the National Uniformity for Food Act of
19 2005, shall remain in effect for 180 days after
20 that date of enactment.

21 “(2) STATE PETITIONS.—With respect to a
22 State notification or food safety requirement that is
23 described in paragraph (1), the State may petition
24 the Secretary for an exemption or a national stand-
25 ard under subsection (c). If a State submits such a

1 petition within 180 days after the date of enactment
2 of the National Uniformity for Food Act of 2005,
3 the notification or food safety requirement shall re-
4 main in effect in accordance with subparagraph (C)
5 of paragraph (3), and the time periods and provi-
6 sions specified in subparagraphs (A) and (B) of such
7 paragraph shall apply in lieu of the time periods and
8 provisions specified in subsection (c)(3) (but not the
9 time periods and provisions specified in subsection
10 (d)(2)).

11 “(3) ACTION ON PETITIONS.—

12 “(A) PUBLICATION.—Not later than 270
13 days after the date of enactment of the Na-
14 tional Uniformity for Food Act of 2005, the
15 Secretary shall publish a notice in the Federal
16 Register concerning any petition submitted
17 under paragraph (2) and shall provide 180 days
18 for public comment on the petition.

19 “(B) TIME PERIODS.—Not later than 360
20 days after the end of the period for public com-
21 ment, the Secretary shall take final agency ac-
22 tion on the petition.

23 “(C) ACTION.—

24 “(i) IN GENERAL.—With respect to a
25 State that submits to the Secretary a peti-

1 tion in accordance with paragraph (2), the
2 notification or food safety requirement in-
3 volved shall remain in effect during the pe-
4 riod beginning on the date of enactment of
5 the National Uniformity for Food Act of
6 2005 and ending on the applicable date
7 under subclause (I) or (II), as follows:

8 “(I) If the petition is denied by
9 the Secretary, the date of such denial.

10 “(II) If the petition is approved
11 by the Secretary, the effective date of
12 the final rule that is promulgated
13 under subsection (c) to provide an ex-
14 emption or national standard pursu-
15 ant to the petition, except that there
16 is no applicable ending date under
17 this subparagraph for a provision of
18 State law that is part of such State
19 requirement in any case in which the
20 final rule does not establish any con-
21 dition regarding such provision of law.

22 “(ii) NONCOMPLIANCE OF SECRETARY
23 REGARDING TIMEFRAMES.—

24 “(I) JUDICIAL REVIEW.—The
25 failure of the Secretary to comply

1 with any requirement of subparagraph
2 (A) or (B) shall constitute final agen-
3 cy action for purposes of judicial re-
4 view. If the court conducting the re-
5 view determines that the Secretary
6 has failed to comply with the require-
7 ment, the court shall order the Sec-
8 retary to comply within a period de-
9 termined to be appropriate by the
10 court.

11 “(II) STATUS OF STATE RE-
12 QUIREMENT.—With respect to a State
13 that submits to the Secretary a peti-
14 tion in accordance with paragraph (2),
15 if the Secretary fails to take final
16 agency action on the petition within
17 the period that applies under subpara-
18 graph (B), the notification or food
19 safety requirement involved remains
20 in effect in accordance with clause (i).

21 “(c) EXEMPTIONS AND NATIONAL STANDARDS.—

22 “(1) EXEMPTIONS.—Any State may petition
23 the Secretary to provide by regulation an exemption
24 from section 403A(a)(6) or subsection (a), for a re-
25 quirement of the State or a political subdivision of

1 the State. The Secretary may provide such an ex-
2 emption, under such conditions as the Secretary may
3 impose, for such a requirement that—

4 “(A) protects an important public interest
5 that would otherwise be unprotected, in the ab-
6 sence of the exemption;

7 “(B) would not cause any food to be in
8 violation of any applicable requirement or prohi-
9 bition under Federal law; and

10 “(C) would not unduly burden interstate
11 commerce, balancing the importance of the pub-
12 lic interest of the State or political subdivision
13 against the impact on interstate commerce.

14 “(2) NATIONAL STANDARDS.—Any State may
15 petition the Secretary to establish by regulation a
16 national standard respecting any requirement under
17 this Act or the Fair Packaging and Labeling Act
18 (15 U.S.C. 1451 et seq.) relating to the regulation
19 of a food.

20 “(3) ACTION ON PETITIONS.—

21 “(A) PUBLICATION.—Not later than 30
22 days after receipt of any petition under para-
23 graph (1) or (2), the Secretary shall publish
24 such petition in the Federal Register for public

1 comment during a period specified by the Sec-
2 retary.

3 “(B) TIME PERIODS FOR ACTION.—Not
4 later than 60 days after the end of the period
5 for public comment, the Secretary shall take
6 final agency action on the petition or shall in-
7 form the petitioner, in writing, the reasons that
8 taking the final agency action is not possible,
9 the date by which the final agency action will
10 be taken, and the final agency action that will
11 be taken or is likely to be taken. In every case,
12 the Secretary shall take final agency action on
13 the petition not later than 120 days after the
14 end of the period for public comment.

15 “(C) EXPEDITED CONSIDERATION.—The
16 Secretary shall expedite the consideration of
17 any petition under paragraphs (1) or (2) that
18 involves a request for a notification requirement
19 for a food that provides a warning where the
20 health effect to be addressed by the warning re-
21 lates to cancer or reproductive or birth defects
22 or is intended to provide information that will
23 allow parents or guardians to understand, mon-
24 itor, or limit a child’s exposure to cancer-caus-

1 ing agents or reproductive or developmental
2 toxins.

3 “(4) JUDICIAL REVIEW.—The failure of the
4 Secretary to comply with any requirement of this
5 subsection shall constitute final agency action for
6 purposes of judicial review. If the court conducting
7 the review determines that the Secretary has failed
8 to comply with the requirement, the court shall
9 order the Secretary to comply within a period deter-
10 mined to be appropriate by the court.

11 “(d) IMMINENT HAZARD AUTHORITY.—

12 “(1) IN GENERAL.—A State may establish a re-
13 quirement that would otherwise violate section
14 403A(a)(6) or subsection (a), if—

15 “(A) the requirement is needed to address
16 an imminent hazard to health that is likely to
17 result in serious adverse health consequences or
18 death;

19 “(B) the State has notified the Secretary
20 about the matter involved and the Secretary
21 has not initiated enforcement action with re-
22 spect to the matter;

23 “(C) a petition is submitted by the State
24 under subsection (c) for an exemption or na-
25 tional standard relating to the requirement not

1 later than 30 days after the date that the State
2 establishes the requirement under this sub-
3 section; and

4 “(D) the State institutes enforcement ac-
5 tion with respect to the matter in compliance
6 with State law within 30 days after the date
7 that the State establishes the requirement
8 under this subsection.

9 “(2) ACTION ON PETITION.—

10 “(A) IN GENERAL.—The Secretary shall
11 take final agency action on any petition sub-
12 mitted under paragraph (1)(C) not later than 7
13 days after the petition is received, and the pro-
14 visions of subsection (e) shall not apply to the
15 petition.

16 “(B) JUDICIAL REVIEW.—The failure of
17 the Secretary to comply with the requirement
18 described in subparagraph (A) shall constitute
19 final agency action for purposes of judicial re-
20 view. If the court conducting the review deter-
21 mines that the Secretary has failed to comply
22 with the requirement, the court shall order the
23 Secretary to comply within a period determined
24 to be appropriate by the court.

1 “(3) DURATION.—If a State establishes a re-
2 quirement in accordance with paragraph (1), the re-
3 quirement may remain in effect until the Secretary
4 takes final agency action on a petition submitted
5 under paragraph (1)(C).

6 “(e) NO EFFECT ON PRODUCT LIABILITY LAW.—
7 Nothing in this section shall be construed to modify or
8 otherwise affect the product liability law of any State.

9 “(f) NO EFFECT ON CERTAIN STATE LAW.—Nothing
10 in this section or section 403A relating to a food shall
11 be construed to prevent a State or political subdivision of
12 a State from establishing, enforcing, or continuing in ef-
13 fect a requirement relating to—

14 “(1) freshness dating, open date labeling, grade
15 labeling, a State inspection stamp, religious dietary
16 labeling, organic or natural designation, returnable
17 bottle labeling, unit pricing, a statement of geo-
18 graphic origin, or dietary supplements; or

19 “(2) a consumer advisory relating to food sani-
20 tation that is imposed on a food establishment, or
21 that is recommended by the Secretary, under part
22 3–6 of the Food Code issued by the Food and Drug
23 Administration and referred to in the notice pub-
24 lished at 64 Fed. Reg. 8576 (1999) (or any cor-
25 responding similar provision of such a Code).

1 “(g) DEFINITIONS.—In section 403A and this sec-
2 tion:

3 “(1) The term ‘requirement’, used with respect
4 to a Federal action or prohibition, means a manda-
5 tory action or prohibition established under this Act
6 or the Fair Packaging and Labeling Act (15 U.S.C.
7 1451 et seq.), as appropriate, or by a regulation
8 issued under or by a court order relating to, this Act
9 or the Fair Packaging and Labeling Act, as appro-
10 priate.

11 “(2) The term ‘petition’ means a petition sub-
12 mitted in accordance with the provisions of section
13 10.30 of title 21, Code of Federal Regulations, con-
14 taining all data and information relied upon by the
15 petitioner to support an exemption or a national
16 standard.”.

17 (c) CONFORMING AMENDMENT.—Section 403A(b) of
18 such Act (21 U.S.C. 343–1(b)) is amended by adding after
19 and below paragraph (3) the following:

20 “The requirements of paragraphs (3) and (4) of section
21 403B(c) shall apply to any such petition, in the same man-
22 ner and to the same extent as the requirements apply to
23 a petition described in section 403B(c).”.

1 **SEC. 3. CONDITIONS.**

2 The amendments made by this Act take effect only
3 if the Secretary of Health and Human Services certifies
4 to the Congress, after consultation with the Secretary of
5 Homeland Security, that the implementation of such
6 amendments will pose no additional risk to the public
7 health or safety from terrorists attacks relating to the food
8 supply.

9 **SEC. 4. ENSURING ADEQUATE INFORMATION FOR INFANTS,**
10 **CHILDREN, AND WOMEN OF CHILD-BEARING**
11 **AGE.**

12 Nothing in this Act or the amendments made by this
13 Act shall have any effect upon a State law, regulation,
14 proposition or other action that establishes a notification
15 requirement regarding the presence or potential effects of
16 mercury in fish and shellfish.

 Passed the House of Representatives March 8,
2006.

Attest:

KAREN L. HAAS,

Clerk.