

109<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4167

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## 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 regu-  
14 lation 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:

*Clerk.*

109<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

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