Bill no.: HR 4167
Amendment no.:
Date offered: 12/15/05
Disposition: Agreed to by 30 yeas/and 18 nays

109TH CONGRESS
1ST SESSION

# H. R. 4167

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

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 27, 2005

Mr. ROGERS of Michigan (for himself, Mr. TOWNS, Mr. ADERHOLT, Mr. ALEXANDER, Mr. ANDREWS, Mr. BARROW, Mr. BASS, Mr. BEAUPREZ, Mr. BERRY, Mrs. BIGGERT, Mr. BISHOP of Georgia, Mrs. BLACKBURN, Mr. BLUNT, Mr. BOEHLERT, Mr. BOEHNER, Mr. BONILLA, Mr. BONNER, Mr. BOREN, Mr. BOUCHER, Mr. BOUSTANY, Mr. BOYD, Mr. BRADLEY of New Hampshire, Mr. BURGESS, Mr. CALVERT, Mr. CAMP, Mr. CANNON, Mr. CANTOR, Mrs. CAPITO, Mr. CARDOZA, Mr. CARTER, Mr. CHANDLER, Mr. CHOCOLA, Mr. COBLE, Mr. CONAWAY, Mr. CRAMER, Mr. CRENSHAW, Mr. CROWLEY, Mrs. CUBIN, Mr. DAVIS of Illinois, Mr. DAVIS of Kentucky, Mrs. JO ANN DAVIS of Virginia, Mr. DAVIS of Tennessee, Mr. TOM DAVIS of Virginia, Mr. LINCOLN DIAZ-BALART of Florida, Mr. DOOLITTLE, Mr. DOYLE, Mrs. DRAKE, Mr. DUNCAN, Mr. EHLERS, Mr. EMANUEL, Mrs. EMERSON, Mr. ENGLISH of Pennsylvania, Mr. ETHERIDGE, Mr. FERGUSON, Mr. FOLEY, Mr. GALLEGLY, Mr. GERLACH, Mr. GILLMOR, Mr. GINGREY, Mr. GOODE, Mr. GOODLATTE, Mr. GORDON, Ms. GRANGER, Mr. GRAVES, Mr. GREEN of Wisconsin, Mr. HALL, Ms. HART, Mr. HAYES, Mr. HENSARLING, Mr. HERGER, Mr. HIGGINS, Mr. HOEKSTRA, Mr. HULSHOF, Ms. JACKSON-LEE of Texas, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. SAM JOHNSON of Texas, Mr. JOHNSON of Illinois, Mr. JONES of North Carolina, Mrs. KELLY, Mr. KENNEDY of Minnesota, Mr. KINGSTON, Mr. KIRK, Mr. KLINE, Mr. KOLBE, Mr. KUHL of New York, Mr. LAHOOD, Mr. LATHAM, Mr. LATOURETTE, Mr. LEWIS of Georgia, Mr. LEWIS of Kentucky, Mr. LINDER, Mr. LUCAS, Mr. MARCHANT, Mr. MARSHALL, Mr. MATHESON, Mr. MCCOTTER, Mr. MCINTYRE, Miss MCMORRIS, Mr. MEEKS of New York, Mr. MICHAUD, Ms. MILLENDER-MCDONALD, Mr. MOORE of Kansas, Mr. MORAN of Kansas, Mr. MORAN of Virginia, Mrs. MUSGRAVE, Mrs. NORTHUP, Mr. NORWOOD, Mr. NUNES, Mr. ORTIZ, Mr. OSBORNE, Mr. OTTER, Mr. OXLEY, Mr. PEARCE, Mr. PENCE, Mr. PETERSON of Minnesota, Mr. PICKERING, Mr. PITTS, Mr. POMBO, Mr. PORTER, Mr. PRICE of Georgia, Ms. PRYCE of Ohio, Mr. RADANOVICH, Mr. RAMSTAD, Mr. REGULA, Mr. REHBERG, Mr. ROHRABACHER, Mr. ROSS, Mr. ROYCE, Mr. RUPPERSBERGER, Mr. RUSH, Mr. SCHWARZ of Michigan, Mr. SESSIONS,

Mr. SHADEGG, Mr. SHIMKUS, Mr. SHUSTER, Mr. SIMPSON, Mr. SKELTON, Mr. SODREL, Mr. SOUDER, Mr. STRICKLAND, Mr. SULLIVAN, Mr. SWEENEY, Mr. TERRY, Mr. THOMPSON of Mississippi, Mr. TIAHRT, Mr. TIBERI, Mr. UPTON, Mr. WAMP, Mr. WELLER, Mr. WESTMORELAND, Mr. WICKER, Mrs. WILSON of New Mexico, Mr. WILSON of South Carolina, Mr. WYNN, Mr. WHITFIELD, Mr. SHERWOOD, Mr. JEFFERSON, Mr. DAVIS of Alabama, and Mr. MANZULLO) introduced the following bill; which was referred to the Committee on Energy and Commerce

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# A BILL

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

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the "National Uniformity for Food Act of 2005".

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

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

(1) in paragraph (4), by striking "or" at the end;

(2) in paragraph (5), by striking the period and inserting ", or";

(3) by inserting after paragraph (5) the following:

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

(4) by adding at the end the following: "For purposes of paragraph (6) and section 403B, the term 'identical' means that the language under the laws of a State or a political subdivision of a State is substantially the same language as the comparable provision under this Act and that any differences in language do not result in the imposition of materially different requirements. For purposes of paragraph (6), the term 'any requirement for a food' does not refer to provisions of this Act that relate to procedures for Federal action under this Act.".

(b) UNIFORMITY IN FOOD SAFETY WARNING NOTIFICATION REQUIREMENTS.—Chapter IV of such Act (21 U.S.C. 341 et seq.) is amended—

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

(2) by inserting after section 403A the following new section:

**"SEC. 403B. UNIFORMITY IN FOOD SAFETY WARNING NOTIFICATION REQUIREMENTS.**

"(a) UNIFORMITY REQUIREMENT.—

1 "(1) IN GENERAL.—Except as provided in sub-
2 sections (c) and (d), no State or political subdivision
3 of a State may, directly or indirectly, establish or
4 continue in effect under any authority any notifica-
5 tion requirement for a food that provides for a warn-
6 ing concerning the safety of the food, or any compo-
7 nent or package of the food, unless such a notifica-
8 tion requirement has been prescribed under the au-
9 thority of this Act and the State or political subdivi-
10 sion notification requirement is identical to the noti-
11 fication requirement prescribed under the authority
12 of this Act.

13 "(2) DEFINITIONS.—For purposes of paragraph
14 (1)—

15 "(A) the term 'notification requirement' in-
16 cludes any mandatory disclosure requirement
17 relating to the dissemination of information
18 about a food by a manufacturer or distributor
19 of a food in any manner, such as through a
20 label, labeling, poster, public notice, advertising,
21 or any other means of communication, except
22 as provided in paragraph (3);

23 "(B) the term 'warning', used with respect
24 to a food, means any statement, vignette, or
25 other representation that indicates, directly or

1 by implication, that the food presents or may
2 present a hazard to health or safety; and
3 "(C) a reference to a notification require-
4 ment that provides for a warning shall not be
5 construed to refer to any requirement or prohi-
6 bition relating to food safety that does not in-
7 volve a notification requirement.
8 "(3) CONSTRUCTION.—Nothing in this section
9 shall be construed to prohibit a State from con-
10 ducting the State's notification, disclosure, or other
11 dissemination of information, or to prohibit any ac-
12 tion taken relating to a mandatory recall, civil ad-
13 ministrative order, embargo, detention order, or
14 court proceeding involving food adulteration under a
15 State statutory requirement identical to a food adul-
16 teration requirement under this Act.
17 "(b) REVIEW OF EXISTING STATE REQUIRE-
18 MENTS.—
19 "(1) EXISTING STATE REQUIREMENTS; DEFER-
20 RAL.—Any requirement that—
21 "(A)(i) is a State notification requirement
22 that expressly applies to a specified food or food
23 component and that provides for a warning de-
24 scribed in subsection (a) that does not meet the

uniformity requirement specified in subsection (a); or

"(ii) is a State food safety requirement described in section 403A(6) that does not meet the uniformity requirement specified in that paragraph; and

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

"(2) STATE PETITIONS.—With respect to a State notification or food safety requirement that is described in paragraph (1), the State may petition the Secretary for an exemption or a national standard under subsection (c). If a State submits such a petition within 180 days after the date of enactment of the National Uniformity for Food Act of 2005, the notification or food safety requirement shall remain in effect in accordance with subparagraph (C) of paragraph (3), and the time periods and provisions specified in subparagraphs (A) and (B) of such paragraph shall apply in lieu of the time periods and provisions specified in subsection (c)(3) (but not the time periods and provisions specified in subsection (d)(2)).

1 "(3) ACTION ON PETITIONS.—

2 "(A) PUBLICATION.—Not later than 270
3 days after the date of enactment of the Na-
4 tional Uniformity for Food Act of 2005, the
5 Secretary shall publish a notice in the Federal
6 Register concerning any petition submitted
7 under paragraph (2) and shall provide 180 days
8 for public comment on the petition.

9 "(B) TIME PERIODS.—Not later than 360
10 days after the end of the period for public com-
11 ment, the Secretary shall take final agency ac-
12 tion on the petition.

13 "(C) ACTION.—

14 "(i) IN GENERAL.—With respect to a
15 State that submits to the Secretary a peti-
16 tion in accordance with paragraph (2), the
17 notification or food safety requirement in-
18 volved shall remain in effect during the pe-
19 riod beginning on the date of enactment of
20 the National Uniformity for Food Act of
21 2005 and ending on the applicable date
22 under subclause (I) or (II), as follows:

23 "(I) If the petition is denied by
24 the Secretary, the date of such denial.

"(II) If the petition is approved by the Secretary, the effective date of the final rule that is promulgated under subsection (c) to provide an exemption or national standard pursuant to the petition, except that there is no applicable ending date under this subparagraph for a provision of State law that is part of such State requirement in any case in which the final rule does not establish any condition regarding such provision of law.

"(ii) NONCOMPLIANCE OF SECRETARY REGARDING TIMEFRAMES.—

"(I) JUDICIAL REVIEW.—The failure of the Secretary to comply with any requirement of subparagraph (A) or (B) shall constitute final agency action for purposes of judicial review. If the court conducting the review determines that the Secretary has failed to comply with the requirement, the court shall order the Secretary to comply within a period de-

1 termined to be appropriate by the
2 court.
3 "(II) STATUS OF STATE RE-
4 QUIREMENT.—With respect to a State
5 that submits to the Secretary a peti-
6 tion in accordance with paragraph (2),
7 if the Secretary fails to take final
8 agency action on the petition within
9 the period that applies under subpara-
10 graph (B), the notification or food
11 safety requirement involved remains
12 in effect in accordance with clause (i).
13 "(c) EXEMPTIONS AND NATIONAL STANDARDS.—
14 "(1) EXEMPTIONS.—Any State may petition
15 the Secretary to provide by regulation an exemption
16 from section 403A(a)(6) or subsection (a), for a re-
17 quirement of the State or a political subdivision of
18 the State. The Secretary may provide such an ex-
19 emption, under such conditions as the Secretary may
20 impose, for such a requirement that—
21 "(A) protects an important public interest
22 that would otherwise be unprotected, in the ab-
23 sence of the exemption;

1 "(B) would not cause any food to be in
2 violation of any applicable requirement or prohi-
3 bition under Federal law; and
4 "(C) would not unduly burden interstate
5 commerce, balancing the importance of the pub-
6 lic interest of the State or political subdivision
7 against the impact on interstate commerce.
8 "(2) NATIONAL STANDARDS.—Any State may
9 petition the Secretary to establish by regulation a
10 national standard respecting any requirement under
11 this Act or the Fair Packaging and Labeling Act
12 (15 U.S.C. 1451 et seq.) relating to the regulation
13 of a food.
14 "(3) ACTION ON PETITIONS.—
15 "(A) PUBLICATION.—Not later than 30
16 days after receipt of any petition under para-
17 graph (1) or (2), the Secretary shall publish
18 such petition in the Federal Register for public
19 comment during a period specified by the Sec-
20 retary.
21 "(B) TIME PERIODS FOR ACTION.—Not
22 later than 60 days after the end of the period
23 for public comment, the Secretary shall take
24 final agency action on the petition or shall in-
25 form the petitioner, in writing, the reasons that

1 taking the final agency action is not possible,
2 the date by which the final agency action will
3 be taken, and the final agency action that will
4 be taken or is likely to be taken. In every case,
5 the Secretary shall take final agency action on
6 the petition not later than 120 days after the
7 end of the period for public comment.

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

16 "(d) IMMINENT HAZARD AUTHORITY.—

17 "(1) IN GENERAL.—A State may establish a re-
18 quirement that would otherwise violate section
19 403A(a)(6) or subsection (a), if—

20 "(A) the requirement is needed to address
21 an imminent hazard to health that is likely to
22 result in serious adverse health consequences or
23 death;

24 "(B) the State has notified the Secretary
25 about the matter involved and the Secretary

1 has not initiated enforcement action with re-
2 spect to the matter;
3 "(C) a petition is submitted by the State
4 under subsection (c) for an exemption or na-
5 tional standard relating to the requirement not
6 later than 30 days after the date that the State
7 establishes the requirement under this sub-
8 section; and
9 "(D) the State institutes enforcement ac-
10 tion with respect to the matter in compliance
11 with State law within 30 days after the date
12 that the State establishes the requirement
13 under this subsection.
14 "(2) ACTION ON PETITION.—
15 "(A) IN GENERAL.—The Secretary shall
16 take final agency action on any petition sub-
17 mitted under paragraph (1)(C) not later than 7
18 days after the petition is received, and the pro-
19 visions of subsection (c) shall not apply to the
20 petition.
21 "(B) JUDICIAL REVIEW.—The failure of
22 the Secretary to comply with the requirement
23 described in subparagraph (A) shall constitute
24 final agency action for purposes of judicial re-
25 view. If the court conducting the review deter-

1 mines that the Secretary has failed to comply
2 with the requirement, the court shall order the
3 Secretary to comply within a period determined
4 to be appropriate by the court.

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

10 "(e) NO EFFECT ON PRODUCT LIABILITY LAW.—
11 Nothing in this section shall be construed to modify or
12 otherwise affect the product liability law of any State.

13 "(f) NO EFFECT ON IDENTICAL LAW.—Nothing in
14 this section relating to a food shall be construed to prevent
15 a State or political subdivision of a State from estab-
16 lishing, enforcing, or continuing in effect a requirement
17 that is identical to a requirement of this Act, whether or
18 not the Secretary has promulgated a regulation or issued
19 a policy statement relating to the requirement.

20 "(g) NO EFFECT ON CERTAIN STATE LAW.—Noth-
21 ing in this section or section 403A relating to a food shall
22 be construed to prevent a State or political subdivision of
23 a State from establishing, enforcing, or continuing in ef-
24 fect a requirement relating to—

1 "(1) freshness dating, open date labeling, grade
2 labeling, a State inspection stamp, religious dietary
3 labeling, organic or natural designation, returnable
4 bottle labeling, unit pricing, or a statement of geo-
5 graphic origin; or
6 "(2) a consumer advisory relating to food sani-
7 tation that is imposed on a food establishment, or
8 that is recommended by the Secretary, under part
9 3–6 of the Food Code issued by the Food and Drug
10 Administration and referred to in the notice pub-
11 lished at 64 Fed. Reg. 8576 (1999) (or any cor-
12 responding similar provision of such a Code).
13 "(h) DEFINITIONS.—In section 403A and this sec-
14 tion:
15 "(1) The term 'requirement', used with respect
16 to a Federal action or prohibition, means a manda-
17 tory action or prohibition established under this Act
18 or the Fair Packaging and Labeling Act (15 U.S.C.
19 1451 et seq.), as appropriate, or by a regulation
20 issued under or by a court order relating to, this Act
21 or the Fair Packaging and Labeling Act, as appro-
22 priate.
23 "(2) The term 'petition' means a petition sub-
24 mitted in accordance with the provisions of section
25 10.30 of title 21, Code of Federal Regulations, con-

1 taining all data and information relied upon by the
2 petitioner to support an exemption or a national
3 standard.".

4 (c) CONFORMING AMENDMENT.—Section 403A(b) of
5 such Act (21 U.S.C. 343–1(b)) is amended by adding after
6 and below paragraph (3) the following:
7 "The requirements of paragraphs (3) and (4) of section
8 403B(c) shall apply to any such petition, in the same man-
9 ner and to the same extent as the requirements apply to
10 a petition described in section 403B(c).".

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