

Union Calendar No. 208

109TH CONGRESS
2^D SESSION

H. R. 4167

[Report No. 109-379]

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

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

FEBRUARY 28, 2006

Additional sponsors: Mr. BARRETT of South Carolina, Mr. OWENS, Mr. SCOTT of Georgia, Mr. SIMMONS, Mr. HEFLEY, Mr. FORD, Mr. COOPER, Mrs. JOHNSON of Connecticut, Mr. HASTINGS of Washington, Ms. GINNY BROWN-WAITE of Florida, Mr. BISHOP of Utah, Mr. LOBIONDO, Mr. SHAW, Mr. MURPHY, Mr. WALDEN of Oregon, Mr. MCHENRY, Mr. PLATTS, Mr. RYAN of Wisconsin, Mrs. MYRICK, Mr. COLE of Oklahoma, Ms. BEAN, Ms. ROS-LEHTINEN, Mr. PETRI, Ms. FOXX, Mr. JINDAL, Mr. AKIN, Mr. MCCAUL of Texas, Mr. PETERSON of Pennsylvania, Mr. INGLES of South Carolina, Mr. MILLER of Florida, Mr. GUTKNECHT, Mr. TANCREDO, Mr. SALAZAR, Mr. MACK, Mr. HOBSON, Ms. HARRIS, Mr. KELLER, Mr. SHAYS, Mr. BOOZMAN, Mr. MELANCON, Mr. TAYLOR of Mississippi, Mr. LIPINSKI, Mr. CLAY, Mrs. JONES of Ohio, Mr. REYNOLDS, Mr. KANJORSKI, Mr. STEARNS, Mr. SAXTON, Mr. REICHERT, Mr. MCHUGH, Mrs. MILLER of Michigan, Mr. KING of Iowa, Mr. RYUN of Kansas, Mr. NUSSLE, Mr. JENKINS, Mr. ISRAEL, Mr. COSTELLO, Mr. WELDON of Pennsylvania, Mr. POE, Ms. HERSETH, Mr. MCCRERY, Mr. FORBES, Mrs. SCHMIDT, Mr. COSTA, Mr. HOLDEN, Mr. BUTTERFIELD, Mr. BROWN of South Carolina, and Mr. DEAL of Georgia

FEBRUARY 28, 2006

Committed to the Committee of the Whole House on the State of the Union
and ordered to be printed

A BILL

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,*

3 **SECTION 1. SHORT TITLE.**

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

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

7 (a) NATIONAL UNIFORMITY.—Section 403A(a) of the
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–
9 1(a)) is amended—

10 (1) in paragraph (4), by striking “or” at the
11 end;

12 (2) in paragraph (5), by striking the period and
13 inserting “, or”;

14 (3) by inserting after paragraph (5) the fol-
15 lowing:

16 “(6) any requirement for a food described in
17 section 402(a)(1), 402(a)(2), 402(a)(6), 402(a)(7),
18 402(c), 404, 406, 409, 512, or 721(a), that is not
19 identical to the requirement of such section.”; and

20 (4) by adding at the end the following: “For
21 purposes of paragraph (6) and section 403B, the
22 term ‘identical’ means that the language under the
23 laws of a State or a political subdivision of a State
24 is substantially the same language as the comparable
25 provision under this Act and that any differences in

1 language do not result in the imposition of materi-
2 ally different requirements. For purposes of para-
3 graph (6), the term ‘any requirement for a food’
4 does not refer to provisions of this Act that relate
5 to procedures for Federal action under this Act.”.

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

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

11 (2) by inserting after section 403A the fol-
12 lowing new section:

13 **“SEC. 403B. UNIFORMITY IN FOOD SAFETY WARNING NOTI-
14 FICATION REQUIREMENTS.**

15 **“(a) UNIFORMITY REQUIREMENT.—**

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

1 fication requirement prescribed under the authority
2 of this Act.

3 “(2) DEFINITIONS.—For purposes of paragraph
4 (1)—

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

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

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

23 “(3) CONSTRUCTION.—Nothing in this section
24 shall be construed to prohibit a State from con-
25 ducting the State’s notification, disclosure, or other

1 dissemination of information, or to prohibit any ac-
2 tion taken relating to a mandatory recall, civil ad-
3 ministrative order, embargo, detention order, or
4 court proceeding involving food adulteration under a
5 State statutory requirement identical to a food adul-
6 teration requirement under this Act.

7 “(b) REVIEW OF EXISTING STATE REQUIRE-
8 MENTS.—

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

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

17 “(ii) is a State food safety requirement de-
18 scribed in section 403A(6) that does not meet
19 the uniformity requirement specified in that
20 paragraph; and

21 “(B) is in effect on the date of enactment
22 of the National Uniformity for Food Act of
23 2005, shall remain in effect for 180 days after
24 that date of enactment.

1 “(2) STATE PETITIONS.—With respect to a
2 State notification or food safety requirement that is
3 described in paragraph (1), the State may petition
4 the Secretary for an exemption or a national stand-
5 ard under subsection (c). If a State submits such a
6 petition within 180 days after the date of enactment
7 of the National Uniformity for Food Act of 2005,
8 the notification or food safety requirement shall re-
9 main in effect in accordance with subparagraph (C)
10 of paragraph (3), and the time periods and provi-
11 sions specified in subparagraphs (A) and (B) of such
12 paragraph shall apply in lieu of the time periods and
13 provisions specified in subsection (c)(3) (but not the
14 time periods and provisions specified in subsection
15 (d)(2)).

16 “(3) ACTION ON PETITIONS.—

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

24 “(B) TIME PERIODS.—Not later than 360
25 days after the end of the period for public com-

1 ment, the Secretary shall take final agency ac-
2 tion on the petition.

3 “(C) ACTION.—

4 “(i) IN GENERAL.—With respect to a
5 State that submits to the Secretary a peti-
6 tion in accordance with paragraph (2), the
7 notification or food safety requirement in-
8 volved shall remain in effect during the pe-
9 riod beginning on the date of enactment of
10 the National Uniformity for Food Act of
11 2005 and ending on the applicable date
12 under subclause (I) or (II), as follows:

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

15 “(II) If the petition is approved
16 by the Secretary, the effective date of
17 the final rule that is promulgated
18 under subsection (c) to provide an ex-
19 emption or national standard pursu-
20 ant to the petition, except that there
21 is no applicable ending date under
22 this subparagraph for a provision of
23 State law that is part of such State
24 requirement in any case in which the

1 final rule does not establish any con-
2 dition regarding such provision of law.

3 “(ii) NONCOMPLIANCE OF SECRETARY
4 REGARDING TIMEFRAMES.—

5 “(I) JUDICIAL REVIEW.—The
6 failure of the Secretary to comply
7 with any requirement of subparagraph
8 (A) or (B) shall constitute final agen-
9 cy action for purposes of judicial re-
10 view. If the court conducting the re-
11 view determines that the Secretary
12 has failed to comply with the require-
13 ment, the court shall order the Sec-
14 retary to comply within a period de-
15 termined to be appropriate by the
16 court.

17 “(II) STATUS OF STATE RE-
18 QUIREMENT.—With respect to a State
19 that submits to the Secretary a peti-
20 tion in accordance with paragraph (2),
21 if the Secretary fails to take final
22 agency action on the petition within
23 the period that applies under subpara-
24 graph (B), the notification or food

1 safety requirement involved remains
2 in effect in accordance with clause (i).

3 “(c) EXEMPTIONS AND NATIONAL STANDARDS.—

4 “(1) EXEMPTIONS.—Any State may petition
5 the Secretary to provide by regulation an exemption
6 from section 403A(a)(6) or subsection (a), for a re-
7 quirement of the State or a political subdivision of
8 the State. The Secretary may provide such an ex-
9 emption, under such conditions as the Secretary may
10 impose, for such a requirement that—

11 “(A) protects an important public interest
12 that would otherwise be unprotected, in the ab-
13 sence of the exemption;

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

17 “(C) would not unduly burden interstate
18 commerce, balancing the importance of the pub-
19 lic interest of the State or political subdivision
20 against the impact on interstate commerce.

21 “(2) NATIONAL STANDARDS.—Any State may
22 petition the Secretary to establish by regulation a
23 national standard respecting any requirement under
24 this Act or the Fair Packaging and Labeling Act

1 (15 U.S.C. 1451 et seq.) relating to the regulation
2 of a food.

3 “(3) ACTION ON PETITIONS.—

4 “(A) PUBLICATION.—Not later than 30
5 days after receipt of any petition under para-
6 graph (1) or (2), the Secretary shall publish
7 such petition in the Federal Register for public
8 comment during a period specified by the Sec-
9 retary.

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

22 “(4) JUDICIAL REVIEW.—The failure of the
23 Secretary to comply with any requirement of this
24 subsection shall constitute final agency action for
25 purposes of judicial review. If the court conducting

1 the review determines that the Secretary has failed
2 to comply with the requirement, the court shall
3 order the Secretary to comply within a period deter-
4 mined to be appropriate by the court.

5 “(d) IMMINENT HAZARD AUTHORITY.—

6 “(1) IN GENERAL.—A State may establish a re-
7 quirement that would otherwise violate section
8 403A(a)(6) or subsection (a), if—

9 “(A) the requirement is needed to address
10 an imminent hazard to health that is likely to
11 result in serious adverse health consequences or
12 death;

13 “(B) the State has notified the Secretary
14 about the matter involved and the Secretary
15 has not initiated enforcement action with re-
16 spect to the matter;

17 “(C) a petition is submitted by the State
18 under subsection (c) for an exemption or na-
19 tional standard relating to the requirement not
20 later than 30 days after the date that the State
21 establishes the requirement under this sub-
22 section; and

23 “(D) the State institutes enforcement ac-
24 tion with respect to the matter in compliance
25 with State law within 30 days after the date

1 that the State establishes the requirement
2 under this subsection.

3 “(2) ACTION ON PETITION.—

4 “(A) IN GENERAL.—The Secretary shall
5 take final agency action on any petition sub-
6 mitted under paragraph (1)(C) not later than 7
7 days after the petition is received, and the pro-
8 visions of subsection (e) shall not apply to the
9 petition.

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

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

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

4 “(f) NO EFFECT ON IDENTICAL LAW.—Nothing in
5 this section relating to a food shall be construed to prevent
6 a State or political subdivision of a State from estab-
7 lishing, enforcing, or continuing in effect a requirement
8 that is identical to a requirement of this Act, whether or
9 not the Secretary has promulgated a regulation or issued
10 a policy statement relating to the requirement.

11 “(g) NO EFFECT ON CERTAIN STATE LAW.—Noth-
12 ing in this section or section 403A relating to a food shall
13 be construed to prevent a State or political subdivision of
14 a State from establishing, enforcing, or continuing in ef-
15 fect a requirement relating to—

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

21 “(2) a consumer advisory relating to food sani-
22 tation that is imposed on a food establishment, or
23 that is recommended by the Secretary, under part
24 3–6 of the Food Code issued by the Food and Drug
25 Administration and referred to in the notice pub-

1 lished at 64 Fed. Reg. 8576 (1999) (or any cor-
2 responding similar provision of such a Code).

3 “(h) DEFINITIONS.—In section 403A and this sec-
4 tion:

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

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

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

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

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