

Union Calendar No. 475

108TH CONGRESS
2D SESSION

H. R. 2699

[Report No. 108-770]

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

JULY 10, 2003

Mr. BURR (for himself, Mr. GILLMOR, Ms. MCCARTHY of Missouri, Mr. OTTER, Mr. BRADLEY of New Hampshire, Ms. DUNN, Mr. DEAL of Georgia, Mr. PETRI, Mr. THOMPSON of Mississippi, Mr. TERRY, Mr. ISSA, Mr. TOWNS, Mr. BOEHNER, Mr. FOLEY, Mr. SHUSTER, Mr. KOLBE, and Mr. CRENSHAW) introduced the following bill; which was referred to the Committee on Energy and Commerce

OCTOBER 8, 2004

Additional sponsors: Mr. SHAW, Mr. UPTON, Mr. HAYES, Mr. KLINE, Mr. CRAMER, Mr. PETERSON of Minnesota, Mr. COX, Mr. ISAKSON, Mr. CARSON of Oklahoma, Mr. DOOLITTLE, Mr. BOYD, Mr. BEREUTER, Mr. OXLEY, Mr. DEMINT, Mr. HALL, Mr. SCOTT of Georgia, Mr. HERGER, Mr. SHADEGG, Mr. MEEKS of New York, Mr. ROGERS of Michigan, Mr. OSBORNE, Mr. SESSIONS, Mr. PITTS, Mrs. CAPITO, Mr. POMBO, Mr. BLUNT, Mr. KENNEDY of Minnesota, Mr. MCCREERY, Ms. EDDIE BERNICE JOHNSON of Texas, Mr. BURNS, Mr. CANTOR, Mr. DEUTSCH, Mr. GREENWOOD, Mr. STRICKLAND, Mrs. EMERSON, Mr. BERRY, Mr. LINDER, Mr. GOODE, Mr. HASTINGS of Washington, Mr. CAMP, Mr. RUSH, Mr. MOORE, Mr. GREEN of Wisconsin, Mrs. JONES of Ohio, Mr. SHIMKUS, Mr. DAVIS of Alabama, Mr. CUNNINGHAM, Mr. WALDEN of Oregon, Mr. ADERHOLT, Mr. MORAN of Virginia, Mr. ENGLISH, Mr. TIBERI, Mr. BONILLA, Mr. MORAN of Kansas, Ms. GINNY BROWN-WAITE of Florida, Mr. BARTON of Texas, Mr. AKIN, Mr. SOUDER, Mr. SIMPSON, Mr. BURGESS, Mrs. KELLY, Mr. BISHOP of Georgia, Mr. HENSARLING, Mr. GRAVES, Mr. REGULA, Mr. CARTER, Mrs. MUSGRAVE, Mr. QUINN, Mr. LATHAM, Mr. SAM JOHNSON of Texas, Mr. SWEENEY, Mr. MCINTYRE, Mr. ROYCE, Mr. FERGUSON, Mr. PEARCE, Mr. CHOCOLA, Mr. LEWIS of Kentucky, Ms. JACKSON-LEE of Texas, Mr. NORWOOD, Mr.

BONNER, Mr. TIAHRT, Mr. COBLE, Mr. WILSON of South Carolina, Mr. VITTER, Mr. LAHOOD, Mr. LATOURETTE, Ms. GRANGER, Mr. PORTER, Mr. RAMSTAD, Mr. DAVIS of Tennessee, Mr. WICKER, Mr. ROHR-ABACHER, Mr. WELLER, Mr. MCKEON, Mr. GINGREY, Mr. HOUGHTON, Mr. LEWIS of Georgia, Mr. PICKERING, Mr. MICHAUD, Mr. PORTMAN, Mr. EHLERS, Mr. GUTKNECHT, Mr. BOEHLERT, Mr. WYNN, Mr. ROSS, Mr. EMANUEL, Mr. WHITFIELD, Mr. MATHESON, Ms. HARRIS, Mr. COLLINS, Mrs. MYRICK, Mr. CRANE, Mr. RADANOVICH, Mr. WAMP, Mr. HILL, Mr. ALEXANDER, Mr. STENHOLM, Mr. LUCAS of Kentucky, Mr. BUYER, Mr. JOHNSON of Illinois, Mr. CHANDLER, Mr. HOEKSTRA, Mr. NUSSLE, Mr. JOHN, Mr. BROWN of South Carolina, Ms. PRYCE of Ohio, Mr. SULLIVAN, Mr. BASS, Mrs. WILSON of New Mexico, Mr. LAMPSON, Mr. LEACH, Mr. MILLER of Florida, Mr. STEARNS, Mr. GORDON, Mr. ISRAEL, Mr. HEFLEY, Mr. ROGERS of Alabama, Mr. ANDREWS, Mr. DUNCAN, Mr. GOODLATTE, Mrs. BIGGERT, Mr. PENCE, Mr. DAVIS of Illinois, Mr. NETHERCUTT, Mr. CANNON, Mrs. NORTHUP, Mr. MANZULLO, Mr. BISHOP of Utah, Mr. DOOLEY of California, Mrs. BLACKBURN, Mr. GIBBONS, and Mr. LIPINSKI

OCTOBER 8, 2004

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on July 10, 2003]

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 2004”.*

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

2 (a) *NATIONAL UNIFORMITY.*—Section 403A(a) of the
3 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–*
4 *1(a)) is amended—*

5 (1) *in paragraph (4), by striking “or” at the*
6 *end;*

7 (2) *in paragraph (5), by striking the period and*
8 *inserting “, or”;*

9 (3) *by inserting after paragraph (5) the fol-*
10 *lowing:*

11 “*(6) any requirement for a food described in sec-*
12 *tion 402(a)(1), 402(a)(2), 402(a)(6), 402(a)(7),*
13 *402(c), 404, 406, 409, 512, or 721(a), that is not*
14 *identical to the requirement of such section.*”*; and*

15 (4) *by adding at the end the following: “For pur-*
16 *poses of paragraph (6) and section 403B, the term*
17 *‘identical’ means that the language under the laws of*
18 *a State or a political subdivision of a State is sub-*
19 *stantially the same language as the comparable provi-*
20 *sion under this Act and that any differences in lan-*
21 *guage do not result in the imposition of materially*
22 *different requirements. For purposes of paragraph*
23 *(6), the term ‘any requirement for a food’ does not*
24 *refer to provisions of this Act that relate to procedures*
25 *for Federal action under this Act.*”

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

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

6 (2) by inserting after section 403A the following
7 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 notification
18 requirement has been prescribed under the authority
19 of this Act and the State or political subdivision noti-
20 fication requirement is identical to the notification
21 requirement prescribed under the authority of this
22 Act.

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

1 “(A) the term ‘notification requirement’ in-
2 cludes any mandatory disclosure requirement re-
3 lating to the dissemination of information about
4 a food by a manufacturer or distributor of a food
5 in any manner, such as through a label, labeling,
6 poster, public notice, advertising, or any other
7 means of communication, except as provided in
8 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 by
12 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 prohibi-
17 tion relating to food safety that does not involve
18 a notification requirement.

19 “(3) CONSTRUCTION.—Nothing in this section
20 shall be construed to prohibit a State from conducting
21 the State’s notification, disclosure, or other dissemi-
22 nation of information, or to prohibit any action
23 taken relating to a mandatory recall, civil adminis-
24 trative order, embargo, detention order, or court pro-
25 ceeding involving food adulteration under a State

1 *statutory requirement identical to a food adulteration*
2 *requirement under this Act.*

3 “(b) *REVIEW OF EXISTING STATE REQUIREMENTS.*—

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

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

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

16 “(B) *is in effect on the date of enactment of*
17 *the National Uniformity for Food Act of 2004,*
18 *shall remain in effect for 180 days after that date of*
19 *enactment.*

20 “(2) *STATE PETITIONS.*—*With respect to a State*
21 *notification or food safety requirement that is de-*
22 *scribed in paragraph (1), the State may petition the*
23 *Secretary for an exemption or a national standard*
24 *under subsection (c). If a State submits such a peti-*
25 *tion within 180 days after the date of enactment of*

1 *the National Uniformity for Food Act of 2004, the no-*
2 *tification or food safety requirement shall remain in*
3 *effect in accordance with subparagraph (C) of para-*
4 *graph (3), and the time periods and provisions speci-*
5 *fied in subparagraphs (A) and (B) of such paragraph*
6 *shall apply in lieu of the time periods and provisions*
7 *specified in subsection (c)(3) (but not the time periods*
8 *and provisions specified in subsection (d)(2)).*

9 “(3) *ACTION ON PETITIONS.*—

10 “(A) *PUBLICATION.*—*Not later than 270*
11 *days after the date of enactment of the National*
12 *Uniformity for Food Act of 2004, the Secretary*
13 *shall publish a notice in the Federal Register*
14 *concerning any petition submitted under para-*
15 *graph (2) and shall provide 180 days for public*
16 *comment on the petition.*

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

21 “(C) *ACTION.*—

22 “(i) *IN GENERAL.*—*With respect to a*
23 *State that submits to the Secretary a peti-*
24 *tion in accordance with paragraph (2), the*
25 *notification or food safety requirement in-*

1 *olved shall remain in effect during the pe-*
2 *riod beginning on the date of enactment of*
3 *the National Uniformity for Food Act of*
4 *2004 and ending on the applicable date*
5 *under subclause (I) or (II), as follows:*

6 *“(I) If the petition is denied by*
7 *the Secretary, the date of such denial.*

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

20 *“(ii) NONCOMPLIANCE OF SECRETARY*
21 *REGARDING TIMEFRAMES.—*

22 *“(I) JUDICIAL REVIEW.—The fail-*
23 *ure of the Secretary to comply with*
24 *any requirement of subparagraph (A)*
25 *or (B) shall constitute final agency ac-*

1 *tion for purposes of judicial review. If*
2 *the court conducting the review deter-*
3 *mines that the Secretary has failed to*
4 *comply with the requirement, the court*
5 *shall order the Secretary to comply*
6 *within a period determined to be ap-*
7 *propriate by the court.*

8 *“(II) STATUS OF STATE REQUIRE-*
9 *MENT.—With respect to a State that*
10 *submits to the Secretary a petition in*
11 *accordance with paragraph (2), if the*
12 *Secretary fails to take final agency ac-*
13 *tion on the petition within the period*
14 *that applies under subparagraph (B),*
15 *the notification or food safety require-*
16 *ment involved remains in effect in ac-*
17 *cordance with clause (i).*

18 *“(c) EXEMPTIONS AND NATIONAL STANDARDS.—*

19 *“(1) EXEMPTIONS.—Any State may petition the*
20 *Secretary to provide by regulation an exemption from*
21 *section 403A(a)(6) or subsection (a), for a require-*
22 *ment of the State or a political subdivision of the*
23 *State. The Secretary may provide such an exemption,*
24 *under such conditions as the Secretary may impose,*
25 *for such a requirement that—*

1 “(A) protects an important public interest
2 that would otherwise be unprotected, in the ab-
3 sence of the exemption;

4 “(B) would not cause any food to be in vio-
5 lation of any applicable requirement or prohibi-
6 tion under Federal law; and

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

11 “(2) NATIONAL STANDARDS.—Any State may pe-
12 tition the Secretary to establish by regulation a na-
13 tional standard respecting any requirement under
14 this Act or the Fair Packaging and Labeling Act (15
15 U.S.C. 1451 et seq.) relating to the regulation of a
16 food.

17 “(3) ACTION ON PETITIONS.—

18 “(A) PUBLICATION.—Not later than 30
19 days after receipt of any petition under para-
20 graph (1) or (2), the Secretary shall publish such
21 petition in the Federal Register for public com-
22 ment during a period specified by the Secretary.

23 “(B) TIME PERIODS FOR ACTION.—Not
24 later than 60 days after the end of the period for
25 public comment, the Secretary shall take final

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

10 “(4) *JUDICIAL REVIEW.*—The failure of the Sec-
11 retary to comply with any requirement of this sub-
12 section shall constitute final agency action for pur-
13 poses of judicial review. If the court conducting the
14 review determines that the Secretary has failed to
15 comply with the requirement, the court shall order the
16 Secretary to comply within a period determined to be
17 appropriate by the court.

18 “(d) *IMMINENT HAZARD AUTHORITY.*—

19 “(1) *IN GENERAL.*—A State may establish a re-
20 quirement that would otherwise violate section
21 403A(a)(6) or subsection (a), if—

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

1 “(B) *the State has notified the Secretary*
2 *about the matter involved and the Secretary has*
3 *not initiated enforcement action with respect to*
4 *the matter;*

5 “(C) *a petition is submitted by the State*
6 *under subsection (c) for an exemption or na-*
7 *tional standard relating to the requirement not*
8 *later than 30 days after the date that the State*
9 *establishes the requirement under this subsection;*
10 *and*

11 “(D) *the State institutes enforcement action*
12 *with respect to the matter in compliance with*
13 *State law within 30 days after the date that the*
14 *State establishes the requirement under this sub-*
15 *section.*

16 “(2) *ACTION ON PETITION.—*

17 “(A) *IN GENERAL.—The Secretary shall*
18 *take final agency action on any petition sub-*
19 *mitted under paragraph (1)(C) not later than 7*
20 *days after the petition is received, and the provi-*
21 *sions of subsection (c) shall not apply to the peti-*
22 *tion.*

23 “(B) *JUDICIAL REVIEW.—The failure of the*
24 *Secretary to comply with the requirement de-*
25 *scribed in subparagraph (A) shall constitute*

1 *final agency action for purposes of judicial re-*
2 *view. If the court conducting the review deter-*
3 *mines that the Secretary has failed to comply*
4 *with the requirement, the court shall order the*
5 *Secretary to comply within a period determined*
6 *to be appropriate by the court.*

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

12 “(e) *NO EFFECT ON PRODUCT LIABILITY LAW.*—*Noth-*
13 *ing in this section shall be construed to modify or otherwise*
14 *affect the product liability law of any State.*

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

22 “(g) *NO EFFECT ON CERTAIN STATE LAW.*—*Nothing*
23 *in this section or section 403A relating to a food shall be*
24 *construed to prevent a State or political subdivision of a*

1 *State from establishing, enforcing, or continuing in effect*
2 *a requirement relating to—*

3 “(1) *freshness dating, open date labeling, grade*
4 *labeling, a State inspection stamp, religious dietary*
5 *labeling, organic or natural designation, returnable*
6 *bottle labeling, unit pricing, or a statement of geo-*
7 *graphic origin; or*

8 “(2) *a consumer advisory relating to food sanita-*
9 *tion that is imposed on a food establishment, or that*
10 *is recommended by the Secretary, under part 3–6 of*
11 *the Food Code issued by the Food and Drug Adminis-*
12 *tration and referred to in the notice published at 64*
13 *Fed. Reg. 8576 (1999) (or any corresponding similar*
14 *provision of such a Code).*

15 “(h) *DEFINITIONS.—In section 403A and this section:*

16 “(1) *The term ‘requirement’, used with respect to*
17 *a Federal action or prohibition, means a mandatory*
18 *action or prohibition established under this Act or the*
19 *Fair Packaging and Labeling Act (15 U.S.C. 1451 et*
20 *seq.), as appropriate, or by a regulation issued under*
21 *or by a court order relating to, this Act or the Fair*
22 *Packaging and Labeling Act, as appropriate.*

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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