# H. R. 2649

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 26, 2001

Mr. Burr of North Carolina (for himself, Mr. Towns, Mr. Borski, Mr. Scarborough, Mr. Boucher, Mr. Cox, Mr. Kolbe, Mr. Isakson, Mr. Oxley, Mr. Whitfield, Mrs. Emerson, Mr. Sweeney, Mr. Ehrlich, Mr. Goode, Mr. Barton of Texas, Mr. Barcia, Mr. Norwood, Mr. Bishop, Mr. Wynn, Mr. Greenwood, Mr. Lewis of Georgia, Mr. Upton, Mr. Bryant, Mrs. Biggert, Mr. Rush, and Mr. Hall of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

# 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,

#### 1 SECTION 1. SHORT TITLE.

- This Act may be cited as the "National Uniformity
- 3 for Food Act of 2001".
- 4 SEC. 2. NATIONAL UNIFORMITY FOR FOOD.
- 5 (a) NATIONAL UNIFORMITY.—Section 403A(a) of the
- 6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–
- 7 1(a)) is amended—
- 8 (1) in paragraph (4), by striking "or" at the
- 9 end;
- 10 (2) in paragraph (5), by striking the period and
- inserting ", or"; and
- 12 (3) by inserting after paragraph (5) the fol-
- lowing:
- 14 "(6) any requirement for a food described in
- section 402(a)(1), 402(a)(2), 402(a)(6), 402(a)(7),
- 16 402(e), 404, 406, 408, 409, 512, or 721(a), that is
- 17 not identical to the requirement of such section.".
- 18 (b) Uniformity in Food Safety Warning Noti-
- 19 FICATION REQUIREMENTS.—Chapter IV of such Act (21
- 20 U.S.C. 341 et seq.) is amended—
- 21 (1) by redesignating sections 403B and 403C
- as sections 403C and 403D, respectively; and
- 23 (2) by inserting after section 403A the fol-
- lowing new section:

# 1 "SEC. 403B. UNIFORMITY IN FOOD SAFETY WARNING NOTI-

2	FICATION REQUIREMENTS.
3	"(a) Uniformity Requirement.—
4	"(1) In general.—Except as provided in sub-
5	sections (c) and (d), no State or political subdivision
6	of a State may, directly or indirectly, establish or
7	continue in effect under any authority any notifica-
8	tion requirement for a food that provides for a warn-
9	ing concerning the safety of the food, or any compo-
10	nent or package of the food, unless such a notifica-
11	tion requirement has been prescribed under the au-
12	thority of this Act and the State or political subdivi-
13	sion notification requirement is identical to the noti-
14	fication requirement prescribed under the authority
15	of this Act.
16	"(2) Definitions.—For purposes of paragraph
17	(1)—
18	"(A) the term 'notification requirement' in-
19	cludes any mandatory disclosure requirement
20	relating to the dissemination of information
21	about a food by a manufacturer or distributor
22	of a food in any manner, such as through a
23	label, labeling, poster, public notice, advertising,
24	or any other means of communication, except
25	as provided in paragraph (3);

1	"(B) the term 'warning', used with respect
2	to a food, means any statement, vignette, or
3	other representation that indicates, directly or
4	by implication, that the food presents or may
5	present a hazard to health or safety; and
6	"(C) a reference to a notification require-
7	ment that provides for a warning shall not be
8	construed to refer to any requirement or prohi-
9	bition relating to food safety that does not in-
10	volve a notification requirement.
11	"(3) Construction.—Nothing in this section
12	shall be construed to prohibit a State from con-
13	ducting the State's notification, disclosure, or other
14	dissemination of information, or to prohibit any ac-
15	tion taken relating to a mandatory recall or court in-
16	junction involving food adulteration under a State
17	statutory requirement identical to a food adultera-
18	tion requirement under this Act.
19	"(b) REVIEW OF EXISTING STATE REQUIRE-
20	MENTS.—
21	"(1) Existing state requirements; defer-
22	RAL.—Any requirement that—
23	"(A)(i) is a State notification requirement
24	for a food that provides for a warning described
25	in subsection (a) that does not meet the uni-

1	formity	requirement	specified	in	subsection	(a);
2	or					

- "(ii) is a State food safety requirement described in paragraph (6) or (7) of section 403A that does not meet the uniformity requirement specified in that paragraph; and
- 7 "(B) is in effect on the date of enactment 8 of the National Uniformity for Food Act of 9 2001,

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 2001, the notification or food safety requirement shall remain in effect until the Secretary takes all administrative action on the petition pursuant to paragraph (3), and the time periods and provisions specified in paragraph (3) 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).

# "(3) ACTION ON PETITIONS.—

- "(A) Publication.—Not later than 270 days after the date of enactment of the National Uniformity for Food Act of 2001, the Secretary shall publish a notice in the Federal Register concerning any petition submitted under paragraph (2) and shall provide 180 days for public comment on the petition.
- "(B) TIME PERIODS.—Not later than 360 days after the end of the period for public comment, the Secretary shall take final agency action on the petition.
- "(C) Judicial review.—The failure of the Secretary to comply with any requirement of this paragraph 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 determined to be appropriate by the court.
- 24 "(c) Exemptions and National Standards.—

1	"(1) Exemptions.—Any State may petition
2	the Secretary to provide by regulation an exemption
3	from paragraph (6) or (7) of section 403A(a) or
4	subsection (a), for a requirement of the State or a
5	political subdivision of the State. The Secretary may
6	provide such an exemption, under such conditions as
7	the Secretary may impose, for such a requirement
8	that—
9	"(A) protects an important public interest
10	that would otherwise be unprotected, in the ab-
11	sence of the exemption;
12	"(B) would not cause any food to be in
13	violation of any applicable requirement or prohi-
14	bition under Federal law; and
15	"(C) would not unduly burden interstate
16	commerce, balancing the importance of the pub-
17	lic interest of the State or political subdivision
18	against the impact on interstate commerce.
19	"(2) National standards.—Any State may
20	petition the Secretary to establish by regulation a
21	national standard respecting any requirement under
22	this Act or the Fair Packaging and Labeling Act
23	(15 U.S.C. 1451 et seq.) relating to the regulation
24	of a food.
25	"(3) ACTION ON PETITIONS.—

1 "(A) PUBLICATION.—Not later than 30
2 days after receipt of any petition under para3 graph (1) or (2), the Secretary shall publish
4 such petition in the Federal Register for public
5 comment during a period specified by the Sec6 retary.

"(B) Time periods for action.—Not later than 60 days after the end of the period for public comment, the Secretary shall take final agency action on the petition. If the Secretary is unable to take final agency action on the petition during the 60-day period, the Secretary shall inform the petitioner, in writing, the reasons that taking the final agency action is not possible, the date by which the final agency action will be taken, and the final agency action that will be taken or is likely to be taken. In every case, the Secretary shall take final agency action on the petition not later than 120 days after the end of the period for public comment.

"(4) Judicial Review.—The failure of the Secretary to comply with any requirement of this subsection shall constitute final agency action for 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 paragraph
8	(6) or (7) of section 403A(a) 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

that the State establishes the requirement under this subsection.

## "(2) ACTION ON PETITION.—

- "(A) IN GENERAL.—The Secretary shall take final agency action on any petition submitted under paragraph (1)(C) not later than 7 days after the petition is received, and the provisions of subsection (c) shall not apply to the petition.
- "(B) Judicial review.—The failure of the Secretary to comply with the requirement described in subparagraph (A) 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 determined to be appropriate by the court.
- "(3) DURATION.—If a State establishes a requirement in accordance with paragraph (1), the requirement may remain in effect until the Secretary takes final agency action on a petition submitted 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 or section 403A relating to a food shall be
6	construed to prevent a State or political subdivision of a
7	State from establishing, enforcing, or continuing in effect
8	a requirement that is identical to a requirement of this
9	Act, whether or not the Secretary has promulgated a regu-
10	lation or issued a policy statement relating to the require-
11	ment.
12	"(g) No Effect on Certain State Law.—Noth-
13	ing in this section or section 403A relating to a food shall
14	be construed to prevent a State or political subdivision of
15	a State from establishing, enforcing, or continuing in ef-
16	fect a requirement relating to—
17	"(1) freshness dating, open date labeling, grade
18	labeling, a State inspection stamp, religious dietary
19	labeling, organic or natural designation, returnable
20	bottle labeling, unit pricing, or a statement of geo-
21	graphic origin; or
22	"(2) a consumer advisory relating to food sani-
23	tation that is imposed on a food establishment, or
24	that is recommended by the Secretary, under part

3-6 of the Food Code issued by the Food and Drug

- 1 Administration and referred to in the notice pub-
- 2 lished at 64 Fed. Reg. 8576 (1999) (or any cor-
- 3 responding similar provision of such a Code).
- 4 "(h) DEFINITION.—In section 403A and this section,
- 5 the term 'requirement', used with respect to a Federal ac-
- 6 tion or prohibition, means a mandatory action or prohibi-
- 7 tion established under this Act or the Fair Packaging and
- 8 Labeling Act (15 U.S.C. 1451 et seq.), as appropriate, or
- 9 by a regulation issued under or by a court order relating
- 10 to, this Act or the Fair Packaging and Labeling Act, as
- 11 appropriate.".
- 12 (c) Conforming Amendment.—Section 403A(b) of
- 13 such Act (21 U.S.C. 343–1(b)) is amended by adding at
- 14 the end the following:
- 15 "The requirements of paragraphs (3) and (4) of section
- 16 403B(c) shall apply to any such petition, in the same man-
- 17 ner and to the same extent as the requirements apply to
- 18 a petition described in section 403B(c).".

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