

109TH CONGRESS
2D SESSION

S. 3128

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

IN THE SENATE OF THE UNITED STATES

MAY 25, 2006

Mr. BURR (for himself, Mr. NELSON of Nebraska, and Mr. ROBERTS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 2006”.

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

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

1 (1) in subsection (a)(4), by striking “or” at the
2 end;

3 (2) in subsection (a)(5), by striking the period
4 and inserting “, or”;

5 (3) in subsection (a), by inserting after para-
6 graph (5) the following:

7 “(6) any requirement for a food described in
8 section 402(a)(1), 402(a)(2), 402(a)(6), 402(a)(7),
9 402(c), 404, 406, 409, 512, or 721(a), that is not
10 identical to the requirement of such section.”; and

11 (4) by adding at the end the following:

12 “(c)(1) For purposes of subsection (a)(6) and section
13 403B, the term ‘identical’ means that the language under
14 the laws of a State or a political subdivision of a State
15 is substantially the same language as the comparable pro-
16 vision under this Act and that any differences in language
17 do not result in the imposition of materially different re-
18 quirements. For purposes of subsection (a)(6), the term
19 ‘any requirement for a food’ does not refer to provisions
20 of this Act that relate to procedures for Federal action
21 under this Act.

22 “(2) For purposes of subsection (a)(6), a State or
23 political subdivision of a State may enforce a State law
24 that contains a requirement that is identical to a require-
25 ment in a section of Federal law referred to in subsection

1 (a)(6) if the Secretary has promulgated a regulation or
2 adopted a final guidance relating to the requirement and
3 the State applies the State requirement in a manner that
4 conforms to the regulation or guidance.

5 “(3) If the Secretary has not promulgated a regula-
6 tion or adopted final guidance relating to a requirement
7 in a section of Federal law referred to in subsection (a)(6),
8 a State or political subdivision of a State may enforce a
9 policy, such as a State regulation or an administrative de-
10 cision, that is based on a State law that contains a require-
11 ment that is identical to a requirement in a section of Fed-
12 eral law referred to in subsection (a)(6).

13 “(4) If the Secretary has considered a proposal for
14 a regulation or final guidance relating to a requirement
15 in a section of Federal law referred to in subsection (a)(6)
16 and has, after soliciting public comment, made a deter-
17 mination not to promulgate such regulation or adopt such
18 guidance, which determination is published in the Federal
19 Register, a State or political subdivision of a State may
20 not enforce any requirements in State law that are policies
21 rejected by the Secretary through such determination.”.

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

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

3 (2) by inserting after section 403A the fol-
4 lowing new section:

5 **“SEC. 403B. UNIFORMITY IN FOOD SAFETY WARNING NOTI-
6 FICATION REQUIREMENTS.**

7 “(a) UNIFORMITY REQUIREMENT.—

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

20 “(2) DEFINITIONS.—For purposes of paragraph
21 (1)—

22 “(A) the term ‘notification requirement’ in-
23 cludes any mandatory disclosure requirement
24 relating to the dissemination of information
25 about a food by a manufacturer or distributor

1 of a food in any manner, such as through a
2 label, labeling, poster, public notice, advertising,
3 or any other means of communication, except
4 as provided in paragraph (3);

5 “(B) the term ‘warning’, used with respect
6 to a food, means any statement, vignette, or
7 other representation that indicates, directly or
8 by implication, that the food presents or may
9 present a hazard to health or safety; and

10 “(C) a reference to a notification require-
11 ment that provides for a warning shall not be
12 construed to refer to any requirement or prohi-
13 bition relating to food safety that does not in-
14 volve a notification requirement.

15 “(3) CONSTRUCTION.—Nothing in this section
16 shall be construed to prohibit a State from con-
17 ducting the State’s notification, disclosure, or other
18 dissemination of information, or to prohibit any ac-
19 tion taken relating to an inspection, mandatory re-
20 call, civil administrative order, embargo, detention
21 order, or court proceeding involving food adultera-
22 tion under a State statutory requirement identical to
23 a food adulteration requirement under this Act.

24 “(b) REVIEW OF EXISTING STATE REQUIRE-
25 MENTS.—

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

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

9 “(ii) is a State food safety requirement de-
10 scribed in section 403A(a)(6) that does not
11 meet the uniformity requirement specified in
12 that paragraph; and

13 “(B) is in effect on the date of enactment
14 of the National Uniformity for Food Act of
15 2006, shall remain in effect for 180 days after
16 that date of enactment.

17 “(2) STATE PETITIONS.—With respect to a
18 State notification or food safety requirement that is
19 described in paragraph (1), the State may petition
20 the Secretary for an exemption or a national stand-
21 ard under subsection (c). If a State submits such a
22 petition within 180 days after the date of enactment
23 of the National Uniformity for Food Act of 2006,
24 the notification or food safety requirement shall re-
25 main in effect in accordance with subparagraph (C)

1 of paragraph (3), and the time periods and provi-
2 sions specified in subparagraphs (A) and (B) of such
3 paragraph shall apply in lieu of the time periods and
4 provisions specified in subsection (c)(3) (but not the
5 time periods and provisions specified in subsection
6 (d)(2)).

7 “(3) ACTION ON PETITIONS.—

8 “(A) PUBLICATION.—Not later than 270
9 days after the date of enactment of the Na-
10 tional Uniformity for Food Act of 2006, the
11 Secretary shall publish a notice in the Federal
12 Register concerning any petition submitted
13 under paragraph (2) and shall provide 180 days
14 for public comment on the petition.

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

19 “(C) ACTION.—

20 “(i) IN GENERAL.—With respect to a
21 State that submits to the Secretary a peti-
22 tion in accordance with paragraph (2), the
23 notification or food safety requirement in-
24 volved shall remain in effect during the pe-
25 riod beginning on the date of enactment of

1 the National Uniformity for Food Act of
2 2006 and ending on the applicable date
3 under subclause (I) or (II), as follows:

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

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

18 “(ii) NONCOMPLIANCE OF SECRETARY
19 REGARDING TIMEFRAMES.—

20 “(I) JUDICIAL REVIEW.—The
21 failure of the Secretary to comply
22 with any requirement of subparagraph
23 (A) or (B) shall constitute final agen-
24 cy action for purposes of judicial re-
25 view. If the court conducting the re-

1 view determines that the Secretary
2 has failed to comply with the require-
3 ment, the court shall order the Sec-
4 retary to comply within a period de-
5 termined to be appropriate by the
6 court.

7 “(II) STATUS OF STATE RE-
8 QUIREMENT.—With respect to a State
9 that submits to the Secretary a peti-
10 tion in accordance with paragraph (2),
11 if the Secretary fails to take final
12 agency action on the petition within
13 the period that applies under subpara-
14 graph (B), the notification or food
15 safety requirement involved remains
16 in effect in accordance with clause (i).

17 “(c) EXEMPTIONS AND NATIONAL STANDARDS.—

18 “(1) EXEMPTIONS.—Any State may petition
19 the Secretary to provide by regulation an exemption
20 from section 403A(a)(6) or subsection (a), for a re-
21 quirement of the State or a political subdivision of
22 the State. The Secretary may provide such an ex-
23 emption, under such conditions as the Secretary may
24 impose, 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
5 violation of any applicable requirement or prohi-
6 bition 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
12 petition the Secretary to establish by regulation a
13 national 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
16 of a 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
21 such petition in the Federal Register for public
22 comment during a period specified by the Sec-
23 retary.

24 “(B) TIME PERIODS FOR ACTION.—Not
25 later than 60 days after the end of the period

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

11 “(C) EXPEDITED CONSIDERATION.—The
12 Secretary shall expedite the consideration of
13 any petition under paragraphs (1) or (2) that
14 involves a request for a notification requirement
15 for a food that provides a warning where the
16 health effect to be addressed by the warning re-
17 lates to cancer or reproductive or birth defects
18 or is intended to provide information that will
19 allow parents or guardians to understand, mon-
20 itor, or limit a child’s exposure to cancer-caus-
21 ing agents or reproductive or developmental
22 toxins or will allow pregnant women to under-
23 stand, monitor, or limit their exposure to fetal
24 development toxins.

1 “(4) JUDICIAL REVIEW.—The failure of the
2 Secretary to comply with any requirement of this
3 subsection shall constitute final agency action for
4 purposes of judicial review. If the court conducting
5 the review determines that the Secretary has failed
6 to comply with the requirement, the court shall
7 order the Secretary to comply within a period deter-
8 mined to be appropriate by the court.

9 “(d) IMMINENT HAZARD AUTHORITY.—

10 “(1) IN GENERAL.—A State may establish a re-
11 quirement that would otherwise violate section
12 403A(a)(6) or subsection (a), if—

13 “(A) the requirement is needed to address
14 an imminent hazard to health that is likely to
15 result in serious adverse health consequences or
16 death;

17 “(B) the State has notified the Secretary
18 about the matter involved and the Secretary
19 has not initiated enforcement action with re-
20 spect to the matter;

21 “(C) a petition is submitted by the State
22 under subsection (c) for an exemption or na-
23 tional standard relating to the requirement not
24 later than 30 days after the date that the State

1 establishes the requirement under this sub-
2 section; and

3 “(D) the State institutes enforcement ac-
4 tion with respect to the matter in compliance
5 with State law within 30 days after the date
6 that the State establishes the requirement
7 under this subsection.

8 “(2) ACTION ON PETITION.—

9 “(A) IN GENERAL.—The Secretary shall
10 take final agency action on any petition sub-
11 mitted under paragraph (1)(C) not later than 7
12 days after the petition is received, and the pro-
13 visions of subsection (c) shall not apply to the
14 petition.

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

24 “(3) DURATION.—If a State establishes a re-
25 quirement in accordance with paragraph (1), the re-

1 requirement may remain in effect until the Secretary
2 takes final agency action on a petition submitted
3 under paragraph (1)(C).

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

7 “(f) NO EFFECT ON CERTAIN STATE LAW.—Nothing
8 in this section or section 403A relating to a food shall
9 be construed to prevent a State or political subdivision of
10 a State from establishing, enforcing, or continuing in ef-
11 fect a requirement relating to—

12 “(1) freshness dating, open date labeling, grade
13 labeling, a State inspection stamp, religious dietary
14 labeling, organic or natural designation, returnable
15 bottle labeling, unit pricing, a statement of geo-
16 graphic origin, or dietary supplements; or

17 “(2) a consumer advisory relating to food sani-
18 tation that is imposed on a food establishment, or
19 that is recommended by the Secretary, under part
20 3–6 of the Food Code issued by the Food and Drug
21 Administration and referred to in the notice pub-
22 lished at 64 Fed. Reg. 8576 (1999) (or any cor-
23 responding similar provision of such a Code).

24 “(g) DEFINITIONS.—In section 403A and this sec-
25 tion:

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

9 “(2) The term ‘petition’ means a petition sub-
10 mitted in accordance with the provisions of section
11 10.30 of title 21, Code of Federal Regulations, con-
12 taining all data and information relied upon by the
13 petitioner to support an exemption or a national
14 standard.”.

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

18 “The requirements of paragraphs (3) and (4) of sec-
19 tion 403B(c) shall apply to any such petition, in the same
20 manner and to the same extent as the requirements apply
21 to a petition described in section 403B(c).”.

22 **SEC. 3. CONDITIONS.**

23 The amendments made by this Act take effect only
24 if the Secretary of Health and Human Services certifies
25 to the Congress, after consultation with the Secretary of

1 Homeland Security, that the implementation of such
2 amendments will pose no additional risk to the public
3 health or safety from terrorists attacks relating to the food
4 supply.

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