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Food Safety

1999 CFSAN PROGRAM PRIORITIES

Center for Food Safety and Applied Nutrition
Food and Drug Administration

January 1999

OFFICE OF SENATOR BARBARA A. MIKULSKI
UNITED STATES SENATE
709 HART SENATE OFFICE BUILDING
WASHINGTON, D.C. 20510-2003

FAX TRANSMITTAL FORM

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7962

(ADDITIONAL INFORMATION):

THE FOLLOWING

Here is #231 w/
the latest changes
that reg. couns. is making

?
Coling
Fool
Call

Liz

Please, strike line 15, p. 2 through line 7, p. 3 and substitute:

(1) (d)(1) Subject to paragraphs 2 and 3 of this subsection, any food offered for import into the United States shall be prepared (including produced), packed, and held under a system or conditions, or subject to measures, that meet the requirements of this Act or that otherwise achieve the level of public health protection for such food prepared, packed, and held in the United States. Consistent with section 492 of the Trade Agreement Act of 1979 (19 U.S.C. 2578a), the Secretary shall make, where appropriate, equivalence determinations described in that section relating to sanitary or phytosanitary measures (including systems and conditions) that apply to the preparation, packing, and holding of food offered for import into the United States.

Continue with line 8, p. 3.

Thank you

(2) p: 3 1. 23 strike "may" +
subst. "shall"

(3) Collins, Mikulski, Kennedy, Abraham, Snowe

106TH CONGRESS
1ST SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and
referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to
improve the safety of imported food, 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 "Imported Food Safety
5 Improvement Act".

1 **TITLE I—IMPROVEMENTS TO**
2 **THE FOOD SAFETY IMPORT**
3 **SYSTEM**

4 **SEC. 101. EQUIVALENCE AUTHORITY TO PROTECT THE**
5 **PUBLIC HEALTH FROM CONTAMINATED IM-**
6 **PORTED FOODS.**

7 (a) EQUIVALENCE DETERMINATIONS, AND MEAS-
8 URES, SYSTEMS, AND CONDITIONS TO ACHIEVE PUBLIC
9 HEALTH PROTECTION.—Section 801 of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

11 (1) by redesignating subsections (d), (e), and
12 (f) as subsections (f), (g), and (h), respectively; and

13 (2) by inserting after subsection (c) the follow-
14 ing:

15 *Subject to P(2) + (3) of this subg,*
Any
“(d)(1)(A) No person shall import a food or offer a

16 *shall be* food for import into the United States unless the food has

17 been prepared (including produced), packed, and held

18 under a system or conditions, or subject to measures, that

19 meet the requirements of this Act or that otherwise

20 achieve the level of public health protection for such food

21 prepared, packed, and held in the United States. In deter-

22 mining whether the food meets the requirements of this

23 subparagraph, the Secretary shall consider whether a de-

24 termination described in subparagraph (B) has been made

25 that relates to the food.

1 “(R) Consistent with section 492 of the Trade Agree-
2 ments Act of 1979 (19 U.S.C. 2578a), the Secretary shall
3 make, where appropriate, equivalence determinations de-
4 scribed in that section relating to sanitary or
5 phytosanitary measures (including systems and condi-
6 tions) that apply to the preparation, packing, and holding
7 of food offered for import into the United States.

8 “(2) In carrying out this subsection, the Secretary
9 shall conduct systematic evaluations of the systems, condi-
10 tions, and measures in foreign countries that apply to the
11 preparation, packing, and holding of food offered for im-
12 port into the United States.

13 “(3) The Secretary shall develop a plan for the imple-
14 mentation of the authority under this subsection within
15 2 years after the date of enactment of the Imported Food
16 Safety Improvement Act. In developing the plan, the Sec-
17 retary shall provide an opportunity for, and take into con-
18 sideration, public comment on a proposed plan.”.

19 (b) GENERAL AUTHORITY.—Section 801 of the Fed-
20 eral Food, Drug, and Cosmetic Act (21 U.S.C. 381), as
21 amended in subsection (a), is further amended by insert-
22 ing after subsection (d) the following:

23 “(e)(1)(A) The Secretary *shall* establish a system, for
24 use by the Secretary of the Treasury, to deny the entry
25 of any food offered for import into the United States if

1 the Secretary of Health and Human Services makes and
2 publishes—

3 “(i) a written determination that the food—

4 “(I) has been associated with repeated and
5 separate outbreaks of foodborne disease or has
6 been repeatedly determined by the Secretary to
7 be adulterated within the meaning of section
8 402;

9 “(II) presents a reasonable probability of
10 causing serious adverse health consequences or
11 death; and

12 “(III) is likely, without systemic interven-
13 tion or changes, to cause disease or be adulter-
14 ated again; or

15 “(ii) an emergency written determination that
16 the food has been strongly associated with a single
17 outbreak of foodborne disease that has caused seri-
18 ous adverse health consequences or death.

19 “(B)(i) The Secretary shall make a determination de-
20 scribed in subparagraph (A) with respect to—

21 “(I) a food from a specific producer, manufac-
22 turer, or transporter; or

23 “(II) a food from a specific growing area or
24 country;

25 that meets the criteria described in subparagraph (A).

1 “(ii) Only the food from the specific producer, manu-
2 facturer, transporter, growing area, or country for which
3 the Secretary makes the determination shall be subject to
4 denial of entry under this subsection.

5 “(C) The denial of entry of any food under this para-
6 graph shall be done in a manner consistent with bilateral,
7 regional, and multilateral trade agreements and the rights
8 and obligations of the United States under the agree-
9 ments.

10 “(D)(i) Before making any written determination
11 under subparagraph (A)(i), the Secretary shall consider
12 written comments, on a proposed determination, made by
13 any party affected by the proposed determination and any
14 remedial actions taken to address the findings made in
15 the proposed determination. In making the written deter-
16 mination, the Secretary may modify or rescind the pro-
17 posed determination in accordance with such comments.

18 “(ii)(I) The Secretary may immediately issue an
19 emergency written determination under subparagraph
20 (A)(ii) without first considering comments on a proposed
21 determination.

22 “(II) Within 30 days after the issuance of the emer-
23 gency determination, the Secretary shall consider written
24 comments on the determination that are made by a party
25 described in clause (i) and received within the 30-day pe-

1 riod. The Secretary may affirm, modify, or rescind the
2 emergency determination in accordance with the com-
3 ments.

4 “(III) The emergency determination shall be in ef-
5 fect—

6 “(aa) for the 30-day period; or

7 “(bb) if the Secretary affirms or modifies the
8 determination, until the Secretary rescinds the de-
9 termination.

10 “(2)(A) The food initially denied entry under para-
11 graph (1) may be imported into the United States if the
12 Secretary finds that—

13 “(i) the written determination made under
14 paragraph (1) no longer justifies the denial of entry
15 of the food; or

16 “(ii) evidence of remedial action submitted from
17 the producer, manufacturer, transporter, specific
18 growing area, or country for which the Secretary
19 made the written determination under paragraph (1)
20 addresses the determination.

21 “(B)(i) The Secretary shall take action on evidence
22 submitted under subparagraph (A)(ii) within 90 days after
23 the date of the submission of the evidence.

24 “(ii) The Secretary’s action may include—

25 “(I) lifting the denial of entry of the food; or

1 “(II) continuing to deny entry of the food while
2 requesting additional information or specific reme-
3 dial action from the producer, manufacturer, trans-
4 porter, specific growing area, or country.

5 “(iii) If the Secretary does not take action on evi-
6 dence submitted under subparagraph (A)(ii) within 90
7 days after the date of submission, effective on the 91st
8 day after the date of submission, the food initially denied
9 entry under paragraph (1) may be imported into the Unit-
10 ed States.

11 “(3) The Secretary shall by regulation establish cri-
12 teria and procedures for the system described in para-
13 graph (1). The Secretary may by regulation modify those
14 criteria and procedures, as the Secretary determines ap-
15 propriate.”.

16 (c) TECHNICAL AND CONFORMING AMENDMENTS.—

17 (1) Section 351(h) of the Public Health Service
18 Act (42 U.S.C. 262(h)) is amended by striking “sec-
19 tion 801(e)(1) of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 381(e))” and inserting “sec-
21 tion 801(g)(1) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 381(g)(1))”.

23 (2) Section 301 of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 331) is amended—