

107TH CONGRESS
2^D SESSION

S. 2759

To protect the health and safety of American consumers under the Federal Food, Drug, and Cosmetic Act from seafood contaminated by certain substances.

IN THE SENATE OF THE UNITED STATES

JULY 18, 2002

Mr. HOLLINGS (for himself, Mr. LOTT, and Mr. BREAUX) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To protect the health and safety of American consumers under the Federal Food, Drug, and Cosmetic Act from seafood contaminated by certain substances.

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 “Seafood Safety En-
5 forcement Act”.

6 **SEC. 2. FINDINGS**

7 (a) Chloramphenicol, a potent antibiotic, can cause
8 severe toxic effects in humans, including hypo-aplastic
9 anemia, which is usually irreversible and fatal. The drug

1 is administered to humans only in life-threatening situa-
2 tions when less toxic drugs are not effective.

3 (b) Because of these human health impacts, chlor-
4 amphenicol and similar drugs are not approved for use
5 in food-producing animals in the United States. However,
6 other countries have been found to use these drugs in the
7 aquaculture of shrimp and other seafood, including Thai-
8 land, Vietnam, and China.

9 (c) The majority of shrimp consumed by the United
10 States is imported. The nation imports 400,000 metric
11 tons of shrimp annually, and the percentage of shrimp im-
12 ports rises each year. Thailand and Vietnam are the top
13 two exporters of shrimp to the United States, and China
14 is the fifth largest exporter of shrimp to the United States.

15 (d) Upon detection of chloramphenicol in certain
16 shipments of seafood from China and other nations, in
17 2002 the European Union and Canada severely restricted
18 imports of shrimp and other food from these nations.

19 (e) The United States Food and Drug Administration
20 inspects only 2 percent of all seafood imports into the
21 United States and utilizes a testing procedure that cannot
22 detect the presence of chloramphenicol below 1 part per
23 billion. The European Union and Canada use testing pro-
24 tocols that can detect such substances to 0.3 parts per
25 billion.

1 (f) While Food and Drug Administration import test-
2 ing did not detect chloramphenicol in shrimp imported
3 from these nations in 2002, independent testing per-
4 formed by the state of Louisiana detected chloramphenicol
5 at a level of over 2 parts per billion in crawfish imported
6 from China.

7 (g) Imports of seafood from nations that utilize sub-
8 stances banned in the United States pose potential threats
9 to United States consumers. Denial of entry to contami-
10 nated shrimp and other products to the European Union
11 and Canada will likely redirect imports to the United
12 States of contaminated products turned away from these
13 countries.

14 (h) Immediate and focused actions must be taken by
15 the Federal government to improve enforcement of food
16 import restrictions of seafood imports in order to protect
17 United States consumers and ensure safety of the food
18 supply.

19 **SEC. 3. CONTAMINATED SEAFOOD.**

20 Section 801 of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 381) is amended by—

22 (1) striking all of the text in the third sentence
23 of subsection (a) after “section 505,” and inserting
24 “or (4) such article is seafood that appears to bear
25 or contain one or more substances listed in section

1 530.41(a) of title 21, Code of Federal Regulations,
2 or (5) such article is seafood originating from an ex-
3 porter or country that the Secretary has identified
4 in guidance as a likely source of articles subject to
5 refusal of admission under clause (4) of this sen-
6 tence, then such article shall be refused admission,
7 except as provided in subsection (c) of this section
8 and, with respect to articles subject to clause (5) of
9 this sentence, except as provided in subsection (b) of
10 this section.”;

11 (2) redesignating subsections (b) through (n) as
12 subsections (c) through (o), respectively; and

13 (3) inserting after subsection (a) the following:

14 “(b)(1) Notwithstanding clause (5) of the third sen-
15 tence in subsection (a) of this section, the Secretary may
16 permit individual shipments of seafood originating in a
17 country or from an exporter listed in guidance to be ad-
18 mitted into the United States if evidence acceptable to the
19 Secretary is presented that the seafood in that shipment
20 does not bear or contain a substance listed in section
21 530.41(a) of title 21, Code of Federal Regulations.

22 “(2) The Secretary may remove a country or exporter
23 listed in guidance under clause (5) of the third sentence
24 of subsection (a) of this section only if the country or ex-
25 porter has shown to the satisfaction of the Secretary that

1 each substance at issue is no longer sold for use in, being
2 used in, or being used in a manner that could contaminate
3 food-producing animals in the country at issue.”.

4 **SEC. 4. GUIDANCE FOR REFUSING ENTRY OF SEAFOOD**
5 **FROM A COUNTRY OR EXPORTER.**

6 (a) ISSUANCE OF GUIDANCE.—Upon a determination
7 by the Secretary of Health and Human Services that,
8 based on information acceptable to the Secretary, an ex-
9 porter or country appears to be a source of articles subject
10 to refusal under section 801(a)(4) of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 381(a)(4)), the Sec-
12 retary shall issue guidance described in section 801(a)(5)
13 of that Act.

14 (b) DETERMINATION CRITERIA.—In making the de-
15 termination described in subsection (a), or any determina-
16 tion under section 801(a) of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 381(a)), the Secretary may
18 consider—

19 (1) the detection of substances described in sec-
20 tion 801(a)(4) of that Act by the Secretary;

21 (2) the detection of such substances by a person
22 commissioned to carry out examinations and inves-
23 tigations under section 702(a) of that Act;

24 (3) findings from an inspection under section
25 704 of that Act;

1 (4) the detection by other importing countries
2 of such substances in shipments of seafood that
3 originate from such country or exporter; and

4 (5) other evidence or information as determined
5 by the Secretary.

6 (c) ANNUAL REPORT.—The Secretary shall provide
7 a report within 30 days after the end of each fiscal year
8 to the Senate Committee on Health, Education, Labor,
9 and Pensions and the House of Representatives Com-
10 mittee on Energy and Commerce setting forth the names
11 of all countries and exporters for which the guidance de-
12 scribed in subsection (a) was issued during that fiscal
13 year.

14 (d) RULE OF CONSTRUCTION.—Nothing in this Act,
15 and no amendment made by this Act, shall be construed
16 to limit the existing authority of the Secretary of Health
17 and Human Services or the Secretary of the Treasury to
18 consider any information or to refuse admission of any
19 article under section 801(a) of the Federal Food, Drug,
20 and Cosmetic Act (21 U.S.C. 381(a)).

21 **SEC. 5. ISSUANCE OF TOLERANCES.**

22 If, after the date of enactment of this Act, the Sec-
23 retary of Health and Human Services intends to issue a
24 tolerance under section 512(b) of the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 360b(b)) for any of the sub-

1 stances listed in section 530.41(a) of title 21, Code of Fed-
2 eral Regulations, then the Secretary shall notify the Sen-
3 ate Committee on Health, Education, Labor, and Pensions
4 and the House of Representatives Committee on Energy
5 and Commerce before issuing that tolerance. The Sec-
6 retary shall include in the notification a draft of any
7 changes in Federal statute law that may be necessary.

8 **SEC. 6. CONFORMING AMENDMENTS.**

9 Section 801 of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 381), as amended by subsection (a), is
11 amended by—

12 (1) striking “subsection (b)” in subsection (d),
13 as redesignated by section 2(2) of this Act, and in-
14 serting “subsection (c)”;

15 (2) striking “subsection (e)” in paragraph (1)
16 of subsection (g), as redesignated by section 2(2) of
17 this Act, and inserting “subsection (f)”;

18 (3) striking “section 801(a)” in paragraph
19 (1)(A)(i) of subsection (h), as redesignated by sec-
20 tion 2(2) of this Act, and inserting “subsection (a)
21 of this section”;

22 (4) striking “section 801(a)” in paragraph
23 (1)(A)(ii) of subsection (h), as redesignated by sec-
24 tion 2(2) of this Act, and inserting “subsection (a)
25 of this section”;

1 (5) striking “section 801(d)(1);” in paragraph
2 (1)(A)(iii) of subsection (h), as redesignated by sec-
3 tion 2(2) of this Act, and inserting “subsection
4 (e)(1) of this section;”.

5 (6) striking “Subsection (b)” in paragraph (2)
6 of subsection (k), as redesignated by section 2(2) of
7 this Act, and inserting “Subsection (c)”;

8 (7) striking “Subsection (b)” in paragraph (1)
9 of subsection (l), as redesignated by section 2(2) of
10 this Act, and inserting “Subsection (c)”;

11 (8) striking “Subsection (b)” in subsection (m),
12 as redesignated by section 2(2) of this Act, and in-
13 serting “Subsection (c)”;

14 (9) striking “Subsection (b)” in paragraph
15 (2)(B)(i) of subsection (n), as redesignated by sec-
16 tion 2(2) of this Act, and inserting “Subsection (c)”.

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