107TH CONGRESS
2D 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Seafood Safety Enforcement Act''.

SEC. 2. FINDINGS

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

is administered to humans only in life-threatening situations when less toxic drugs are not effective.

(b) Because of these human health impacts, chloramphenicol and similar drugs are not approved for use in food-producing animals in the United States. However, other countries have been found to use these drugs in the aquaculture of shrimp and other seafood, including Thailand, Vietnam, and China.

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

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

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

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

(g) Imports of seafood from nations that utilize substances banned in the United States pose potential threats to United States consumers. Denial of entry to contaminated shrimp and other products to the European Union and Canada will likely redirect imports to the United States of contaminated products turned away from these countries.

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

SEC. 3. CONTAMINATED SEAFOOD.

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

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

530.41(a) of title 21, Code of Federal Regulations, or (5) such article is seafood originating from an exporter or country that the Secretary has identified in guidance as a likely source of articles subject to refusal of admission under clause (4) of this sentence, then such article shall be refused admission, except as provided in subsection (c) of this section and, with respect to articles subject to clause (5) of this sentence, except as provided in subsection (b) of this section.'';

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

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

''(b)(1) Notwithstanding clause (5) of the third sentence in subsection (a) of this section, the Secretary may permit individual shipments of seafood originating in a country or from an exporter listed in guidance to be admitted into the United States if evidence acceptable to the Secretary is presented that the seafood in that shipment does not bear or contain a substance listed in section 530.41(a) of title 21, Code of Federal Regulations.

''(2) The Secretary may remove a country or exporter listed in guidance under clause (5) of the third sentence of subsection (a) of this section only if the country or exporter has shown to the satisfaction of the Secretary that

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

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

(a) ISSUANCE OF GUIDANCE.—Upon a determination by the Secretary of Health and Human Services that, based on information acceptable to the Secretary, an exporter or country appears to be a source of articles subject to refusal under section 801(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)(4)), the Secretary shall issue guidance described in section 801(a)(5) of that Act.

(b) DETERMINATION CRITERIA.—In making the determination described in subsection (a), or any determination under section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), the Secretary may consider—

(1) the detection of substances described in section 801(a)(4) of that Act by the Secretary;

(2) the detection of such substances by a person commissioned to carry out examinations and investigations under section 702(a) of that Act;

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

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

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

(c) ANNUAL REPORT.—The Secretary shall provide a report within 30 days after the end of each fiscal year to the Senate Committee on Health, Education, Labor, and Pensions and the House of Representatives Committee on Energy and Commerce setting forth the names of all countries and exporters for which the guidance described in subsection (a) was issued during that fiscal year.

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

SEC. 5. ISSUANCE OF TOLERANCES.

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

stances listed in section 530.41(a) of title 21, Code of Federal Regulations, then the Secretary shall notify the Senate Committee on Health, Education, Labor, and Pensions and the House of Representatives Committee on Energy and Commerce before issuing that tolerance. The Secretary shall include in the notification a draft of any changes in Federal statute law that may be necessary.

SEC. 6. CONFORMING AMENDMENTS.

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

(1) striking ''subsection (b)'' in subsection (d), as redesignated by section 2(2) of this Act, and inserting ''subsection (c)'';

(2) striking ''subsection (e)'' in paragraph (1) of subsection (g), as redesignated by section 2(2) of this Act, and inserting ''subsection (f)'';

(3) striking ''section 801(a)'' in paragraph (1)(A)(i) of subsection (h), as redesignated by section 2(2) of this Act, and inserting ''subsection (a) of this section'';

(4) striking ''section 801(a)'' in paragraph (1)(A)(ii) of subsection (h), as redesignated by section 2(2) of this Act, and inserting ''subsection (a) of this section'';

(5) striking ''section 801(d)(1);'' in paragraph (1)(A)(iii) of subsection (h), as redesignated by section 2(2) of this Act, and inserting ''subsection (e)(1) of this section;''.

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

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

(8) striking ''Subsection (b)'' in subsection (m), as redesignated by section 2(2) of this Act, and inserting ''Subsection (c)''; and

(9) striking ''Subsection (b)'' in paragraph (2)(B)(i) of subsection (n), as redesignated by section 2(2) of this Act, and inserting ''Subsection (c)''.

○