108TH CONGRESS 1ST SESSION

S. 1187

To amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to require that ready-to-eat meat or poultry products that are not produced under a scientifically validated program to address Listeria monocytogenes be required to bear a label advising pregnant women and other at-risk consumers of the recommendations of the Department of Agriculture and Food and Drug Administration regarding consumption of ready-to-eat products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

June 4, 2003

Mrs. Clinton introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to require that ready-to-eat meat or poultry products that are not produced under a scientifically validated program to address Listeria monocytogenes be required to bear a label advising pregnant women and other at-risk consumers of the recommendations of the Department of Agriculture and Food and Drug Administration regarding consumption of ready-to-eat products, 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 "At-Risk Consumer
- 3 Protection Through Food Safety Labeling Act".
- 4 SEC. 2. FINDINGS.
- 5 Congress finds that—
- 6 (1) consumption of food contaminated with mi-
- 7 crobial pathogens such as bacteria, parasites, vi-
- 8 ruses, and their toxins causes an estimated
- 9 76,000,000 illnesses, 325,000 hospitalizations, and
- 5,000 deaths each year in the United States;
- 11 (2) Government economists estimate that ill-
- nesses from Campylobacter, Salmonella, E. coli
- O157:H7, E. coli non-O157:H7 STEC, Listeria, and
- Toxoplasma gondii cause \$6,900,000,000 in medical
- 15 costs, lost productivity, and premature death in the
- 16 United States each year;
- 17 (3) in particular, Listeria monocytogenes is the
- cause of 2,500 illnesses and 500 deaths annually,
- 19 with economic costs of \$2,300,000,000;
- 20 (4) people that face relatively higher risks from
- 21 foodborne illness and associated complications in-
- clude the very young, the very old, pregnant women,
- and the immunocompromised, such as persons with
- 24 AIDS and cancer;
- 25 (5) outbreaks of foodborne illness are becoming
- increasingly widespread in both geographic area and

1	duration, making detection and containment dif-
2	ficult;
3	(6) in 1998, following a major listeriosis out-

- (6) in 1998, following a major listeriosis outbreak from deli meats, many ready-to-eat meat and poultry processors established Listeria testing programs, but others have no Listeria testing and control program at all, giving them an unfair advantage in production costs over firms that are taking steps to protect public health;
- (7)(A) in 1989, the Secretary of Agriculture established a performance standard allowing zero tolerance for Listeria monocytogenes that prohibits detectable levels of the pathogen in ready-to-eat meat and poultry products; and
- (B) a performance standard for Listeria monocytogenes of nondetectable levels in ready-to-eat meat products—
 - (i) is appropriate to protect at-risk consumers (including pregnant women) (referred to in this section as "at-risk consumers") from severe health consequences or death from exposure to Listeria monocytogenes; and
 - (ii) is necessary to provide an adequate safety margin for at-risk consumers;

1	(8) in February 2001, the Secretary of Agri-
2	culture proposed regulations establishing perform-
3	ance standards for the production of processed meat
4	and poultry products, including requirements for
5	controlling Listeria monocytogenes, but, in the time
6	since the public comment period closed in September
7	2001, little progress has been made in finalizing the
8	regulation;
9	(9) in 2002, an outbreak of foodborne listeriosis
10	linked to ready-to-eat turkey deli meat in Pennsyl-
11	vania, New York, New Jersey, Delaware, Maryland,
12	Connecticut, and Michigan—
13	(A) sickened 53 persons;
14	(B) killed 8 persons; and
15	(C) caused at least 3 pregnant women to
16	suffer miscarriages or stillbirths;
17	(10) in a March 21, 2003, speech to the North
18	American Meat Processors, Food Safety and Inspec-
19	tion Service Administrator Dr. Gary McKee said the
20	agency's December 2002 directive outlining Listeria
21	testing procedures for agency inspectors is only an
22	interim measure;
23	(11) to ensure the safety of at-risk consumers,
24	ready-to-eat meat and poultry products not produced
25	under a scientifically validated program to address

1	Listeria monocytogenes should be required to bear a
2	label advising at-risk consumers of the Government's
3	recommendations not to consume ready-to-eat meat
4	and poultry products without heating the products
5	until steaming hot; and
6	(12) all data generated through scientifically
7	validated programs to address Listeria
8	monocytogenes should be shared with the Depart-
9	ment of Agriculture and used to improve scientific
10	research regarding the safety of ready-to-eat foods.
11	SEC. 3. READY-TO-EAT MEAT PRODUCTS.
12	(a) In General.—Section 7 of the Federal Meat In-
13	spection Act (21 U.S.C. 607) is amended by adding at
14	the end the following:
15	"(g) Ready-To-Eat Meat Products.—
16	"(1) Definitions.—In this subsection:
17	"(A) AT-RISK CONSUMER.—The term 'at-
18	risk consumer' includes a pregnant woman.
19	"(B) Ready-to-eat meat product.—
20	The term 'ready-to-eat meat product' means a
21	meat product that has been processed so that
22	the meat product may be safely consumed with-
23	out further preparation by the consumer, that
24	is, without cooking or application of some other
25	lethality treatment to destroy pathogens.

1	"(2) Labeling requirement.—Except as
2	provided in paragraph (3) or (4), a ready-to-eat
3	meat product shall bear a label advising consumers
4	that an at-risk consumer—
5	"(A) should not consume the ready-to-eat
6	meat product unless the ready-to-eat meat
7	product is heated until steaming hot; or
8	"(B) should follow such other instructions
9	as the Secretary may prescribe in accordance
10	with health guidelines and recommendations
11	published by the Secretary and the Secretary of
12	Health and Human Services.
13	"(3) Exemptions for producers.—On the
14	motion of the Secretary or on petition of a producer
15	of a ready-to-eat meat product, the Secretary, after
16	notice and opportunity for a public hearing, shall, by
17	regulation applicable to all producers of the ready-
18	to-eat meat product or by order applicable to a par-
19	ticular producer of the ready-to-eat meat product,
20	provide an exemption from the requirement of para-
21	graph (2) if—
22	"(A) in the case of a ready-to-eat meat
23	product that the Secretary determines presents
24	a low risk to at-risk consumers, the producer—

1	"(i) has a scientifically validated pro-
2	gram (as determined by the Secretary) to
3	control Listeria monocytogenes; and
4	"(ii) makes all Listeria control pro-
5	gram records (including the results of any
6	testing of plant environment, food-contact
7	surfaces, or meat product) available for in-
8	spection by the Secretary; or
9	"(B) in the case of any ready-to-eat meat
10	product that the Secretary determines presents
11	a greater risk to at-risk consumers, the pro-
12	ducer of the ready-to-eat meat product has a
13	scientifically valid program to address Listeria
14	monocytogenes under which the producer—
15	"(i) tests food-contact surfaces for
16	Listeria monocytogenes—
17	"(I) at least once every 2 days of
18	production; and
19	$"(\Pi)$ if a food-contact surface
20	tests positive—
21	"(aa) at least 3 times per
22	day until the surface tests nega-
23	tive on 3 consecutive days; or

1	"(bb) in accordance with
2	such other regimen as the Sec-
3	retary may specify;
4	"(ii) tests the plant environment in
5	the ready-to-eat meat processing area for
6	the Listeria species—
7	"(I) at least once every 2 days of
8	production; and
9	"(II) if any part of the plant en-
10	vironment in the ready-to-eat meat
11	processing area tests positive—
12	"(aa) at least 3 times per
13	day until the plant environment
14	tests negative on 3 consecutive
15	days; or
16	"(bb) in accordance with
17	such other regimen as the Sec-
18	retary may specify;
19	"(iii)(I) tests final products for Lis-
20	teria monocytogenes at least 5 times per
21	month to measure the effectiveness of the
22	Listeria control program; and
23	"(II) if any food-contact surface tests
24	positive, conducts daily testing of the meat

1	product from the line found to be positive
2	until the surface tests negative for 3 days;
3	"(iv) makes all control program
4	records (including the results of any test-
5	ing of plant environment, food-contact sur-
6	faces, or meat product) available for in-
7	spection by the Secretary; and
8	"(v) meets any other requirement that
9	the Secretary may specify.
10	"(4) Exemptions for distributors.—On the
11	motion of the Secretary or on petition of a dis-
12	tributor of a ready-to-eat meat product, the Sec-
13	retary, after notice and opportunity for a public
14	hearing, shall, by regulation applicable to all dis-
15	tributors of the ready-to-eat meat product or by
16	order applicable to a particular distributor of the
17	ready-to-eat meat product, provide an exemption
18	from the requirement of paragraph (2) if—
19	"(A) the distributor has purchasing speci-
20	fications incorporating the requirements of
21	paragraph (3); and
22	"(B) the Secretary determines that the
23	suppliers of the distributor are in compliance
24	with paragraph (3).

1 "(5) Reports by the secretary.—Not later 2 than 3 years after the date of enactment of this sec-3 tion, and at least triennially thereafter, the Secretary shall compile and disseminate information 5 from records made available under paragraphs 6 (3)(A)(ii), (3)(B)(iv), and (4) to Federal agencies, 7 universities, and other research institutions and 8 other entities, as appropriate (excluding any such 9 proprietary or confidential information as is pro-10 tected from disclosure), for the purpose of furthering 11 scientific research. 12 13

- "(6) Performance standard.—A performance standard of the Secretary that provides zero tolerance for detectable levels of Listeria monocytogenes in ready-to-eat meats—
 - "(A) shall not be modified to permit any detectable level of Listeria monocytogenes in any ready-to-eat meat product; and
- "(B) shall be based on scientifically validated testing methods for the detection of Listeria monocytogenes, as determined by the Secretary.".
- 23 (b) MISBRANDING.—Section 1(n) of the Federal
 24 Meat Inspection Act (21 U.S.C. 601(n)) is amended—

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1	(1) in paragraph (11), by striking "or" at the
2	end;
3	(2) in paragraph (12), by striking the period at
4	the end and inserting "; or"; and
5	(3) by adding at the end the following:
6	"(13) if it is a ready-to-eat meat product that
7	is required to bear a label under section 7(g), and
8	it does not bear such a label.".
9	SEC. 4. READY-TO-EAT POULTRY PRODUCTS.
10	(a) In General.—Section 8 of the Poultry Products
11	Inspection Act (21 U.S.C. 457) is amended by adding at
12	the end the following:
13	"(e) Ready-To-Eat Poultry Products.—
14	"(1) Definitions.—In this subsection:
15	"(A) AT-RISK CONSUMER.—The term 'at-
16	risk consumer' includes a pregnant woman.
17	"(B) Ready-to-eat poultry prod-
18	UCT.—The term 'ready-to-eat poultry product'
19	means a poultry product that has been proc-
20	essed so that the poultry product may be safely
21	consumed without further preparation by the
22	consumer, that is, without cooking or applica-
23	tion of some other lethality treatment to destroy
24	pathogens.

1	"(2) Labeling requirement.—Except as
2	provided in paragraph (3) or (4), a ready-to-eat
3	poultry product shall bear a label advising con-
4	sumers that an at-risk consumer—
5	"(A) should not consume the ready-to-eat
6	poultry product unless the ready-to-eat poultry
7	product is heated until steaming hot; or
8	"(B) should follow such other instructions
9	as the Secretary may prescribe in accordance
10	with health guidelines and recommendations
11	published by the Secretary and the Secretary of
12	Health and Human Services.
13	"(3) Exemptions for producers.—On the
14	motion of the Secretary or on petition of a producer
15	of a ready-to-eat poultry product, the Secretary,
16	after notice and opportunity for a public hearing,
17	shall, by regulation applicable to all producers of the
18	ready-to-eat poultry product or by order applicable
19	to a particular producer of the ready-to-eat poultry
20	product, provide an exemption from the requirement
21	of paragraph (2) if—
22	"(A) in the case of a ready-to-eat poultry
23	product that the Secretary determines presents
24	a low risk to at-risk consumers, the producer—

1	"(i) has a scientifically validated pro-
2	gram (as determined by the Secretary) to
3	control Listeria monocytogenes; and
4	"(ii) makes all Listeria control pro-
5	gram records (including the results of any
6	testing of plant environment, food-contact
7	surfaces, or poultry product) available for
8	inspection by the Secretary; or
9	"(B) in the case of any ready-to-eat poul-
10	try product that the Secretary determines pre-
11	sents a greater risk to at-risk consumers, the
12	producer of the ready-to-eat poultry product
13	has a scientifically valid program to address
14	Listeria monocytogenes under which the pro-
15	ducer—
16	"(i) tests food-contact surfaces for
17	Listeria monocytogenes—
18	"(I) at least once every 2 days of
19	production; and
20	"(II) if a food-contact surface
21	tests positive—
22	"(aa) at least 3 times per
23	day until the surface tests nega-
24	tive on 3 consecutive days; or

1	"(bb) in accordance with
2	such other regimen as the Sec-
3	retary may specify;
4	"(ii) tests the plant environment in
5	the ready-to-eat poultry processing area for
6	the Listeria species—
7	"(I) at least once every 2 days of
8	production; and
9	"(II) if any part of the plant en-
10	vironment in the ready-to-eat poultry
11	processing area tests positive—
12	"(aa) at least 3 times per
13	day until the plant environment
14	tests negative on 3 consecutive
15	days; or
16	"(bb) in accordance with
17	such other regimen as the Sec-
18	retary may specify;
19	"(iii)(I) tests final products for Lis-
20	teria monocytogenes at least 5 times per
21	month to measure the effectiveness of the
22	Listeria control program; and
23	"(II) if any food-contact surface tests
24	positive, conducts daily testing of the poul-
25	try product from the line found to be posi-

1	tive until the surface tests negative for 3
2	days;
3	"(iv) makes all control program
4	records (including the results of any test-
5	ing of plant environment, food-contact sur-
6	faces, or poultry product) available for in-
7	spection by the Secretary; and
8	"(v) meets any other requirement that
9	the Secretary may specify.
10	"(4) Exemptions for distributors.—On the
11	motion of the Secretary or on petition of a dis-
12	tributor of a ready-to-eat poultry product, the Sec-
13	retary, after notice and opportunity for a public
14	hearing, shall, by regulation applicable to all dis-
15	tributors of the ready-to-eat poultry product or by
16	order applicable to a particular distributor of the
17	ready-to-eat poultry product, provide an exemption
18	from the requirement of paragraph (2) if—
19	"(A) the distributor has purchasing speci-
20	fications incorporating the requirements of
21	paragraph (3); and
22	"(B) the Secretary determines that the
23	suppliers of the distributor are in compliance
24	with paragraph (3).

"(5) Reports by the secretary.—Not later 1 2 than 3 years after the date of enactment of this sec-3 tion, and at least triennially thereafter, the Secretary shall compile and disseminate information 5 from records made available under paragraphs 6 (3)(A)(ii), (3)(B)(iv), and (4) to Federal agencies, 7 universities, and other research institutions and 8 other entities, as appropriate (excluding any such 9 proprietary or confidential information as is pro-10 tected from disclosure), for the purpose of furthering 11 scientific research.

- "(6) Performance Standard.—A performance standard of the Secretary that provides zero tolerance for detectable levels of Listeria monocytogenes in ready-to-eat poultry products—
 - "(A) shall not be modified to permit any detectable level of Listeria monocytogenes in any ready-to-eat poultry product; and
- "(B) shall be based on scientifically validated testing methods for the detection of Listeria monocytogenes, as determined by the Secretary.".
- 23 (b) MISBRANDING.—Section 4(h) of the Poultry 24 Products Inspection Act (21 U.S.C. 453(h)) is amended—

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1	(1) in paragraph (11), by striking "or" at the
2	end;
3	(2) in paragraph (12), by striking the period at
4	the end and inserting "; or"; and
5	(3) by adding at the end the following:
6	"(13) if it is a ready-to-eat poultry product that
7	is required to bear a label under section 8(e), and
8	it does not bear such a label.".

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