

NLWJC - Kagan

DPC - Box 007 - Folder 016

**Consumer Protection - Food Safety
Enforcement Legislation**

URGENT

Cms Protection: Food Safety Enforcement Legislation

Total Pages: _____

LRM ID: ACP164

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Friday, August 29, 1997

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Ronald K. Peterson (for) *Attorney for* Assistant Director for Legislative Reference

OMB CONTACT: Alison C. Perkins
PHONE: (202)395-3857 FAX: (202)395-5691

SUBJECT: HHS Draft Bill on Food Safety Enforcement Enhancement Act

DEADLINE: Noon Tuesday, September 2, 1997

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: The attached draft bill is related to the USDA draft bill entitled the "Meat and Poultry Enforcement Enhancement Act of 1997" circulated on 8/28/97 under LRM #ACP 163.

DISTRIBUTION LIST

AGENCIES:

- 7-AGRICULTURE - Marvin Shapiro - (202) 720-1516
- 25-COMMERCE - Michael A. Levitt - (202) 482-3151
- 61-JUSTICE - Andrew Fois - (202) 514-2141
- 114-STATE - Julia C. Norton - (202) 647-4463
- 118-TREASURY - Richard S. Carro - (202) 622-0650
- 128-US Trade Representative - Fred Montgomery - (202) 395-3475

EOP:

- Jim R. Esquea
- Wendy A. Taylor
- K. Lisa Grove
- Jefferson B. Hill
- Daniel D. Heath
- Adrienne C. Erbach
- Ronald M. Cogswell
- David J. Haun
- Pamula L. Simms
- Donald R. Arbuckle
- Richard J. Turman
- Barry T. Clendenin
- Christopher C. Jennings

A. Kolaian

Sarah A. Bianchi
Joshua Gotbaum
Sally Katzen
T J. Glauthier
James C. Murr
G. E. DeSeve
Toby Donenfeld
Donald H. Gips
Barbara D. Woolley
Phillip Caplan
Jennifer L. Klein
-Jerold R. Mande
Thomas L. Freedman
Elena Kagan
Sylvia M. Mathews

LRM ID: ACP164 SUBJECT: HHS Draft Bill on Food Safety Enforcement Enhancement Act

RESPONSE TO LEGISLATIVE REFERRAL MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:

- (1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter

Please include the LRM number shown above, and the subject shown below.

TO: Alison C. Perkins Phone: 395-3857 Fax: 395-5691
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-6194

FROM: (Date)
(Name)
(Agency)
(Telephone)

The following is the response of our agency to your request for views on the above-captioned subject:

- Concur
No Objection
No Comment
See proposed edits on pages
Other:
FAX RETURN of pages, attached to this response sheet

DRAFT 8/28/97

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for improved public health and food safety through enhanced enforcement.

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

1 **SECTION 1. SHORT TITLE**

2 This Act may be cited as "The Food Safety Enforcement Enhancement Act of
3 1997."

4 **SEC. 2. The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, et seq.) is amended:**

5 (1) by adding after section 413 the following new sections:

6 **NOTIFICATION AND RECALL**

7 "SEC. 414(a) Any person which has a reasonable basis for believing that
8 any article of food is adulterated or misbranded shall immediately notify the
9 Secretary, in such manner and by such means as the Secretary may by regulation
10 prescribe, of the identity and location of such articles.

11 (b)(1) If the Secretary finds, upon such notification or otherwise, that (A)
12 any article of food is adulterated or misbranded and (B) there is a reasonable
13 probability that consumption of such articles presents a threat to public health,
14 as determined by the Secretary, the Secretary shall provide the person with an
15 opportunity to: (i) cease distribution of such articles, (ii) notify all persons
16 producing, manufacturing, packing, processing, preparing, treating, packaging,

1 distributing, or holding such articles, or to which such articles have been
2 distributed, transported or sold, to immediately cease distribution of such articles,
3 (iii) recall such articles, and (iv) provide, in consultation with the Secretary, notice
4 to consumers to whom such articles were, or may have been, distributed. (2) If
5 such person refuses to or does not voluntarily cease distribution, make
6 notification, recall such articles, and provide notice to consumers, within the time
7 and in the manner prescribed by the Secretary, the Secretary shall, by order,
8 require, as the Secretary deems necessary, such person to: (i) immediately cease
9 distribution of such articles, and (ii) immediately notify all persons producing,
10 manufacturing, packing, processing, preparing, treating, packaging, distributing,
11 or holding such articles, or to which such articles have been distributed,
12 transported or sold, to immediately cease distribution of such articles. (3) The
13 Secretary shall, as the Secretary deems necessary, provide notice to consumers to
14 whom such articles were, or may have been, distributed.

15 (c) The Secretary shall provide any person subject to an order under
16 subsection (b) with an opportunity for an informal hearing, to be held as soon as
17 possible but not later than two business days after the issuance of the order, on the
18 actions required by the order and on why the articles that are the subject of the
19 order should not be recalled.

20 (d)(1) If, after providing opportunity for an informal hearing under
21 subsection (c), the Secretary determines that there is a reasonable probability that
22 consumption of the articles that are the subject of an order under subsection (b)

1 presents a threat to public health, the Secretary, as the Secretary deems necessary,
2 may: (i) amend the order to require recall of such articles or other appropriate
3 action, and (ii) specify a timetable in which the recall will occur, require periodic
4 reports to the Secretary describing the progress of the recall, and provide notice to
5 consumers to whom such articles were, or may have been, distributed. (2) If, after
6 such a hearing, the Secretary determines that adequate grounds do not exist to
7 continue the actions required by the order, the Secretary shall vacate the order.

8 (e) The remedies provided in this section shall be in addition to and not
9 exclusive of other remedies that may be available.

10 CIVIL PENALTIES

11 Sec. 415 (a) Any person that violates any provision of section 402 or 403
12 of this Act may be assessed a civil penalty by the Secretary of not more than
13 \$100,000 for each such violation. Each violation and each day during which a
14 violation continues shall be a separate offense. No penalty shall be assessed by
15 the Secretary under this section unless such person is given notice and opportunity
16 for a hearing on the record before the Secretary in accordance with sections 554
17 and 556 of title 5, United States Code. The amount of such civil penalty shall be
18 assessed by the Secretary by written order, taking into account the gravity of the
19 violation, degree of culpability, size and type of business, and any history of prior
20 offenses; and may be reviewed only as provided in subsection (b).

21 (b) An order assessing a civil penalty under subsection (a) shall be final
22 and conclusive unless the person files, within thirty days from the effective date of

1 the order, an application for judicial review in the Court of Appeals of the United
2 States for the circuit in which such person resides or has its principal place of
3 business or in the United States Court of Appeals for the District of Columbia
4 Circuit by filing a notice of appeal in such Court and by simultaneously sending a
5 copy of such notice by certified mail to the Secretary. The Secretary shall
6 promptly file in such Court a certified copy of the record upon which such
7 violation was found and such penalty assessed. The findings of the Secretary
8 shall be set aside only if found to be unsupported by substantial evidence on the
9 record as a whole.

10 (c) If any person fails to pay an assessment of a civil penalty after it has
11 become a final and unappealable order, or after the appropriate Court of Appeals
12 has entered final judgment in favor of the Secretary, the Secretary shall refer the
13 matter to the Attorney General, who shall institute a civil action to recover the
14 amount assessed in an appropriate district court of the United States. In such
15 collection action, the validity and appropriateness of the Secretary's order
16 imposing the civil penalty shall not be subject to review.

17 (d) All penalties collected under authority of this section shall be paid into
18 the Treasury of the United States.

19 (e) Nothing in this Act shall be construed as requiring the Secretary to
20 report for prosecution, or for the institution of libel or injunction proceedings,
21 violations of this Act whenever the Secretary believes that the public interest will
22 be adequately served by assessment of civil penalties.

1 (f) The remedies provided in this section shall be in addition to and not
2 exclusive of other remedies that may be available."

*Consumer protection - food safety enforcement
legislation.*

Total Pages: _____

LRM ID: ACP163

**EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001**

Thursday, August 28, 1997

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below
FROM: Ronald K. Peterson (for) Assistant Director for Legislative Reference
OMB CONTACT: Alison C. Perkins
PHONE: (202)395-3857 FAX: (202)395-5891
SUBJECT: **AGRICULTURE** Draft Bill on Meat and Poultry Enforcement Enhancement Act of 1997
DEADLINE: 10 am Tuesday, September 2, 1997

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: The attached USDA legislative proposal, which has been cleared by OMB for transmittal to Congress, is essentially the same as earlier cleared legislation. We anticipate that USDA will transmit the proposal to Congress by no later than the middle of next week. Please be aware that we will also circulate for comment, probably tomorrow morning, an HHS draft bill that would provide similar authorities, as appropriate, for the FDA.

DISTRIBUTION LIST

AGENCIES:
25-COMMERCE - Michael A. Levitt - (202) 482-3151
52-HHS - Sondra S. Wallace - (202) 690-7760
61-JUSTICE - Andrew Fois - (202) 514-2141

EOP:
Daniel D. Heath
Adrienne C. Erbach
Jim R. Esquea
David J. Haun
Pamula L. Simms
Alicia K. Kolaian
K. Lisa Grove
Donald R. Arbuckle
G. E. DeSeve
Toby Donenfeld
Donald H. Gips
Barbara D. Woolloy

Phillip Caplan
Jennifer L. Klein
Jerold R. Mande
Thomas L. Freedman
Elena Kagan
Sylvia M. Mathews

Honorable Albert Gore
President of the Senate
Washington, D. C. 20510

Dear Mr. President:

In order to protect the public from foodborne illness or death from meat products contaminated with *E. coli* O157:H7, the Department of Agriculture (USDA) has recently initiated the largest food recall in American history. This recall incident highlighted critical gaps in USDA's food safety enforcement authorities. Congressional action is required to provide the additional authorities the Secretary needs to ensure food safety.

Today, I am transmitting to Congress a draft bill to improve public health and food safety by providing USDA with enhanced enforcement powers. This draft bill is an important part of the Clinton Administration's initiative to improve food safety for American consumers. The Administration recommends that the draft bill be promptly enacted.

The draft bill would give the Secretary of Agriculture a more complete range of enforcement tools with which to protect the public health. The bill would amend the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) by adding three new enforcement sections providing for mandatory recall of meat and poultry products, more explicit authority to refuse or withdraw inspection, and the power to assess civil monetary penalties.

Specifically, the bill authorizes the Secretary of Agriculture:

- ◆ to stop the distribution and order the recall of adulterated or misbranded meat and poultry in situations that pose a reasonable probability of a threat to public health;
- ◆ to refuse or withdraw inspection based on any willful or repeated violation of the FMIA or the PPIA; and
- ◆ to impose civil monetary penalties for violations of the FMIA and the PPIA.

Although the recent recall was done at the Department's request, compliance with that request was voluntary. Until the Department has mandatory authority to require the recall of products at any point in the production and distribution chain, establishments and others can refuse to comply. Such mandatory recall authority would enable the Secretary to move more quickly to stop the distribution of adulterated products and to protect the public from food products contaminated with dangerous bacteria like *E. coli* O157:H7.

In addition, this legislation would provide the Secretary the authority to refuse or withdraw inspection when a company has either willfully or repeatedly violated USDA laws or regulations.

Finally, the legislation would give the Secretary the authority to impose civil penalties for violations of the FMIA or the PPIA. Currently, USDA is limited to seeking criminal penalties in the Federal courts. Civil penalty authority will better protect public health and improve food safety by providing a more timely and effective remedy against those who violate USDA meat and poultry laws.

The January 1993 outbreak of *E. coli* O157:H7 in Washington State affected more than 700 people and resulted in four deaths. That outbreak was a tragic reminder of the potential consequences of illness due to foodborne pathogens. Since then, the Clinton Administration has taken aggressive steps to improve food safety, by implementing science-based inspection systems for meat, poultry, and seafood and by expanding foodborne illness surveillance. Additionally, the Administration's Food Safety Initiative contained in the 1998 budget proposes a comprehensive strategy for enhancing food safety. The Administration's efforts over the past four years to improve food safety contributed significantly to the successful containment of the recent outbreak.

The Clinton Administration has made great progress in improving food safety, but more work remains to be done. We look forward to working with Congress to achieve this critical goal.

The Office of Management and Budget advises that there is no objection to the presentation of this proposed legislation from the standpoint of the Administration's program.

A similar letter is being sent to the Speaker of the House.

Sincerely,

DAN GLICKMAN
Secretary

Draft 8/28/97 9am

A BILL

To amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for improved public health and food safety through enhanced enforcement.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the "The Food Safety Enforcement Enhancement Act of 1997."

3 **SEC. 2.** The Federal Meat Inspection Act (21 U.S.C. 601, ~~et seq.~~) is amended:

4 (1) by redesignating section 411 as section 414, and

5 (2) by inserting after section 410 the following new sections:

6 **NOTIFICATION AND RECALL**

7 "SEC. 411 (a) Any person, firm, or corporation which has a reasonable basis for
8 believing that any carcasses, parts thereof, meat, or meat food products are adulterated or
9 misbranded shall immediately notify the Secretary, in such manner and by such means as
10 the Secretary may by regulation prescribe, of the identity and location of such articles.

11 "(b) (1) If the Secretary finds, upon such notification or otherwise, that (A) any
12 carcasses, parts thereof, meat, or meat food products are adulterated or misbranded and
13 (B) there is a reasonable probability that human consumption of such articles presents a
14 threat to public health, as determined by the Secretary, the Secretary shall provide the
15 person, firm, or corporation with an opportunity to: (i) cease distribution of such articles,
16 (ii) notify all persons, firms, and corporations transporting, storing, or distributing such

1 articles, or to which such articles have been transported or sold, to immediately cease
2 distribution of such articles, (iii) recall such articles, and (iv) provide, in consultation with
3 the Secretary, notice to consumers to whom such articles were, or may have been,
4 distributed. (2) If such person, firm, or corporation refuses to or does not voluntarily
5 cease distribution, make notification, recall such articles, and provide notice to
6 consumers, within the time and in the manner prescribed by the Secretary, the Secretary
7 shall, by order, require, as the Secretary deems necessary, such person, firm, or
8 corporation, to: (i) immediately cease distribution of such articles, and (ii) immediately
9 notify all persons, firms, and corporations transporting, storing, or distributing such
10 articles, or to which such articles have been transported or sold, to immediately cease
11 distribution of such articles. (3) The Secretary shall, as the Secretary deems necessary,
12 provide notice to consumers to whom such articles were, or may have been, distributed.

13 "(c) The Secretary shall provide any person, firm, or corporation subject to an
14 order under subsection (b) with an opportunity for an informal hearing, to be held as soon
15 as possible but not later than 48 hours after the issuance of the order, on the actions
16 required by the order and on why the articles that are the subject of the order should not
17 be recalled.

18 "(d) (1) If, after providing opportunity for an informal hearing under subsection
19 (c), the Secretary determines that there is a reasonable probability that human
20 consumption of the articles that are the subject of an order under subsection (b) presents a
21 threat to public health, the Secretary, as the Secretary deems necessary, may: (i) amend
22 the order to require recall of such articles or other appropriate action, and (ii) specify a

1 timetable in which the recall will occur, require periodic reports to the Secretary
2 describing the progress of the recall, and provide notice to consumers to whom such
3 articles were, or may have been, distributed. (2) If, after such a hearing, the Secretary
4 determines that adequate grounds do not exist to continue the actions required by the
5 order, the Secretary shall vacate the order.

6 (e) The remedies provided in this section shall be in addition to and not exclusive
7 of other remedies that may be available.

8 REFUSAL OR WITHDRAWAL OF INSPECTION

9 "SEC. 412 (a) The Secretary may, for such period, or indefinitely, as the Secretary
10 deems necessary to effectuate the purposes of this Act, refuse to provide or withdraw
11 inspection under title I of this Act with respect to any establishment if the Secretary
12 determines, after opportunity for a hearing is accorded to the applicant for, or recipient of,
13 such inspection, that the applicant or recipient, or any person responsibly connected with
14 the applicant or recipient (as defined in section 401), has committed any willful violation
15 of this Act or the regulations promulgated thereunder or repeated violations of this Act or
16 the regulations promulgated thereunder.

17 "(b) The Secretary may deny or suspend inspection under title I of this Act,
18 pending opportunity for an expedited hearing, with respect to an action under subsection
19 (a) to refuse to provide or withdraw inspection, if the Secretary deems such denial or
20 suspension in the public interest to protect the health or welfare of consumers or to assure
21 the safe and effective performance of official duties under this Act.

22 "(c) The determination and order of the Secretary with respect to the refusal or

1 withdrawal of inspection under this section shall be final and conclusive unless the
2 affected applicant for, or recipient of, inspection files application for judicial review
3 within thirty days after the effective date of such order and simultaneously sends a copy
4 of such filing by certified mail to the Secretary. Inspection shall be refused or withdrawn
5 as of the effective date of such order pending any judicial review of such order unless the
6 Secretary directs otherwise. Judicial review of any such order shall be in the United
7 States Court of Appeals for the circuit in which the applicant for, or recipient of,
8 inspection resides or has its principal place of business or in the United States Court of
9 Appeals for the District of Columbia Circuit, and shall be on the record upon which the
10 determination and order are based.

11 "(d) The remedies provided in this section shall be in addition to and not exclusive
12 of other remedies that may be available.

13 CIVIL PENALTIES

14 "SEC. 413 (a) Any person, firm, or corporation that violates any provision of this
15 Act or any regulation or order issued under this Act may be assessed a civil penalty by
16 the Secretary of not more than \$100,000 for each such violation. Each violation and each
17 day during which a violation continues shall be a separate offense. No penalty shall be
18 assessed by the Secretary under this section unless such person, firm, or corporation is
19 given notice and opportunity for a hearing on the record before the Secretary in
20 accordance with sections 554 and 556 of title 5, United States Code. The amount of such
21 civil penalty shall be assessed by the Secretary by written order, taking into account the
22 gravity of the violation, degree of culpability, size and type of business, and any history

1 of prior offenses; and may be reviewed only as provided in subsection (b).

2 "(b) An order assessing a civil penalty under subsection (a) shall be final and
3 conclusive unless the person, firm, or corporation files, within thirty days from the
4 effective date of the order, an application for judicial review in the Court of Appeals of
5 the United States for the circuit in which such person, firm, or corporation resides or has
6 its principal place of business or in the United States Court of Appeals for the District of
7 Columbia Circuit by filing a notice of appeal in such Court and by simultaneously
8 sending a copy of such notice by certified mail to the Secretary. The Secretary shall
9 promptly file in such Court a certified copy of the record upon which such violation was
10 found and such penalty assessed. The findings of the Secretary shall be set aside only if
11 found to be unsupported by substantial evidence on the record as a whole.

12 "(c) If any person, firm, or corporation fails to pay an assessment of a civil penalty
13 after it has become a final and unappealable order, or after the appropriate Court of
14 Appeals has entered final judgment in favor of the Secretary, the Secretary shall refer the
15 matter to the Attorney General, who shall institute a civil action to recover the amount
16 assessed in an appropriate district court of the United States. In such collection action,
17 the validity and appropriateness of the Secretary's order imposing the civil penalty shall
18 not be subject to review.

19 "(d) All penalties collected under authority of this section shall be paid into the
20 Treasury of the United States.

21 "(e) If any person, firm, or corporation fails to pay an assessment of a civil penalty
22 after it has become a final and unappealable order, or after the appropriate Court of

1 **Appeals has entered final judgment in favor of the Secretary, the Secretary may refuse to**
2 **provide inspection to, or suspend inspection from, any such person, firm, or corporation**
3 **until the assessed civil penalty is paid or until otherwise ordered by the Secretary.**

4 **"(f) Nothing in this Act shall be construed as requiring the Secretary to report for**
5 **prosecution, or for the institution of libel or injunction proceedings, violations of this Act**
6 **whenever the Secretary believes that the public interest will be adequately served by**
7 **assessment of civil penalties.**

8 **"(g) The remedies provided in this section shall be in addition to and not**
9 **exclusive of other remedies that may be available."**

10 **SEC. 3. The Poultry Products Inspection Act (21 U.S.C. 451 et seq.) is amended:**

11 **(1) in section 5 © by deleting "and 12-22 of this Act" and inserting in lieu thereof "12-**
12 **22, and 31-33 of this Act", and**

13 **(2) by inserting after section 30 the following new sections:**

14 **NOTIFICATION AND RECALL**

15 **"SEC. 31 (a) Any person which has a reasonable basis for believing that any**
16 **poultry or poultry products are adulterated or misbranded shall immediately notify the**
17 **Secretary, in such manner and by such means as the Secretary may by regulation**
18 **prescribe, of the identity and location of such poultry and poultry products.**

19 **"(b) (1) If the Secretary finds, upon such notification or otherwise, that (A) any**
20 **poultry or poultry products are adulterated or misbranded and (B) there is a reasonable**
21 **probability that human consumption of such poultry or poultry products presents a threat**
22 **to public health, as determined by the Secretary, the Secretary shall provide the person**

1 with an opportunity to: (i) cease distribution of such poultry or poultry products, (ii)
2 notify all persons transporting, storing, or distributing such poultry or poultry products, or
3 to which such poultry or poultry products have been transported or sold, to immediately
4 cease distribution of such poultry or poultry products, (iii) recall such poultry or poultry
5 products, and (iv) provide, in consultation with the Secretary, notice to consumers to
6 whom such poultry and poultry products were, or may have been, distributed. (2) If such
7 person refuses to or does not voluntarily cease distribution, make notification, recall such
8 poultry or poultry products, and provide notice to consumers, within the time and in the
9 manner prescribed by the Secretary, the Secretary shall, by order, require, as the Secretary
10 deems necessary, such person to: (i) immediately cease distribution of such poultry or
11 poultry products, and (ii) immediately notify all persons transporting, storing, or
12 distributing such poultry or poultry products, or to which such poultry or poultry products
13 have been transported or sold, to immediately cease distribution of such poultry or
14 poultry products. (3) The Secretary shall, as the Secretary deems necessary, provide
15 notice to consumers to whom such poultry or poultry products were, or may have been,
16 distributed.

17 "(c) The Secretary shall provide any person subject to an order under subsection
18 (b) with an opportunity for an informal hearing, to be held as soon as possible but not
19 later than 48 hours after the issuance of the order, on the actions required by the order and
20 on why the poultry or poultry products that are the subject of the order should not be
21 recalled.

22 "(d) (1) If, after providing opportunity for an informal hearing under subsection

1 **(c), the Secretary determines that there is a reasonable probability that human**
2 **consumption of the poultry or poultry products that are the subject of an order under**
3 **subsection (b) present a threat to public health, the Secretary, as the Secretary deems**
4 **necessary, may: (i) amend the order to require recall of such poultry or poultry products**
5 **or other appropriate action, and (ii) specify a timetable in which the recall will occur,**
6 **require periodic reports to the Secretary describing the progress of the recall, and provide**
7 **notice to consumers to whom such poultry or poultry products were, or may have been,**
8 **distributed. (2) If, after such a hearing, the Secretary determines that adequate grounds**
9 **do not exist to continue the actions required by the order, the Secretary shall vacate the**
10 **order.**

11 **(e) The remedies provided in this section shall be in addition to and not exclusive**
12 **of other remedies that may be available.**

13 **REFUSAL OR WITHDRAWAL OF INSPECTION**

14 **"SEC. 32 (a) The Secretary may, for such period, or indefinitely, as the Secretary**
15 **deems necessary to effectuate the purposes of this Act, refuse to provide or withdraw**
16 **inspection under this Act if the Secretary determines, after opportunity for a hearing is**
17 **accorded to the applicant for, or recipient of, such inspection, that the applicant or**
18 **recipient, or any person responsibly connected with the applicant or recipient (as defined**
19 **in section 18(a)), has committed any willful violation of this Act or the regulations**
20 **promulgated thereunder or repeated violations of this Act or the regulations promulgated**
21 **thereunder.**

22 **"(b) The Secretary may deny or suspend inspection under this Act, pending**

1 opportunity for an expedited hearing, with respect to an action under subsection (a) to
2 refuse to provide or withdraw inspection, if the Secretary deems such denial or
3 suspension in the public interest in order to protect the health or welfare of consumers or
4 to assure the safe and effective performance of official duties under this Act.

5 "(c) The determination and order of the Secretary with respect to the refusal or
6 withdrawal of inspection under this section shall be final and conclusive unless the
7 affected applicant for, or recipient of, inspection files application for judicial review
8 within thirty days after the effective date of such order and simultaneously sends a copy
9 of such filing by certified mail to the Secretary. Inspection shall be refused or withdrawn
10 as of the effective date of such order pending any judicial review of such order unless the
11 Secretary directs otherwise. Judicial review of any such order shall be in the United
12 States Court of Appeals for the circuit in which the applicant for, or recipient of,
13 inspection resides or has its principal place of business or in the United States Court of
14 Appeals for the District of Columbia Circuit, and shall be on the record upon which the
15 determination and order are based.

16 "(d) The remedies provided in this section shall be in addition to and not exclusive
17 of other remedies that may be available.

18 **CIVIL PENALTIES**

19 "SEC. 33 (a) Any person that violates any provision of this Act or any regulation
20 or order issued under this Act may be assessed a civil penalty by the Secretary of not
21 more than \$100,000 for each such violation. Each violation and each day during which a
22 violation continues shall be a separate offense. No penalty shall be assessed by the

1 Secretary under this section unless such person is given notice and opportunity for a
2 hearing on the record before the Secretary in accordance with sections 554 and 556 of
3 title 5, United States Code. The amount of such civil penalty shall be assessed by the
4 Secretary by written order, taking into account the gravity of the violation, degree of
5 culpability, size and type of business, and any history of prior offenses; and may be
6 reviewed only as provided in subsection (b).

7 "(b) An order assessing a civil penalty under subsection (a) shall be final and
8 conclusive unless the person files, within thirty days from the effective date of the order,
9 an application for judicial review in the Court of Appeals of the United States for the
10 circuit in which such person resides or has its principal place of business or in the United
11 States Court of Appeals for the District of Columbia Circuit by filing a notice of appeal in
12 such Court and by simultaneously sending a copy of such notice by certified mail to the
13 Secretary. The Secretary shall promptly file in such Court a certified copy of the record
14 upon which such violation was found and such penalty assessed. The findings of the
15 Secretary shall be set aside only if found to be unsupported by substantial evidence on the
16 record as a whole.

17 "(c) If any person fails to pay an assessment of a civil penalty after it has become
18 a final and unappealable order, or after the appropriate Court of Appeals has entered final
19 judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney
20 General, who shall institute a civil action to recover the amount assessed in an
21 appropriate district court of the United States. In such collection action, the validity and
22 appropriateness of the Secretary's order imposing the civil penalty shall not be subject to

1 review.

2 "(d) All penalties collected under authority of this section shall be paid into the
3 Treasury of the United States.

4 "(e) If any person fails to pay an assessment of a civil penalty after it has become
5 a final and unappealable order, or after the appropriate Court of Appeals has entered final
6 judgment in favor of the Secretary, the Secretary may refuse to provide inspection to, or
7 suspend inspection from, any such person, firm, or corporation until the assessed civil
8 penalty is paid or until otherwise ordered by the Secretary.

9 "(f) Nothing in this Act shall be construed as requiring the Secretary to report for
10 prosecution or for the institution of libel or injunction proceedings, violations of this Act,
11 whenever the Secretary believes that the public interest will be adequately served by
12 assessment of civil penalties.

13 "(g) The remedies provided in this section shall be in addition to and
14 not exclusive of other remedies that may be available."

Draft 8/28/97, 9 am

SECTION-BY-SECTION-ANALYSIS
FOOD SAFETY ENFORCEMENT ENHANCEMENT ACT OF 1997

Section 1. Section 1 would provide that the Act may be cited as "The Food Safety Enforcement Enhancement Act of 1997".

Section 2. Section 2 would amend the Federal Meat Inspection Act (FMIA) by redesignating the current section 411 as section 414 and adding three new enforcement provisions related to notification and recall of products, the refusal and withdrawal of inspection, and the assessment of civil penalties.

Section 411. Notification and Recall. would require persons, firms, or corporations to notify the Secretary of the identity and location of adulterated and misbranded products. Further, section 411 would provide the Secretary with authority to issue orders to cease distribution of and to recall adulterated and misbranded products if there is a reasonable probability of a threat to public health. Section 411 would provide a mechanism to prevent such articles from reaching consumers.

Section 411(a) would require any person, firm, or corporation which has a reasonable basis for believing that any carcasses, parts of carcasses, meat, or meat food products are adulterated or misbranded to immediately notify the Secretary of the identity and location of such articles. The immediate notification of the identity and location of articles believed to be adulterated or misbranded is necessary to provide the Secretary with the opportunity to limit the distribution of such articles, and possibly avoid human illness. The Secretary would prescribe by regulation the means and manner that notification is to be provided.

Section 411(b) would provide that if the Secretary finds, through notification or otherwise, that (1) any carcasses, parts of carcasses, meat, or meat food products are adulterated or misbranded and (2) there is a reasonable probability that human consumption of such articles presents a threat to public health, the Secretary would provide the persons, firms, or corporations with an opportunity to (1) voluntarily cease distribution of such articles; (2) notify all persons, firms, and corporations transporting, storing, or distributing such articles or to which such articles were transported or sold, to immediately cease distribution of such articles; (3) to recall the articles; and (4) to provide, in consultation with the Secretary, notice to consumers to whom such articles were, or may have been, distributed.

If the person, firm, or corporation refuses to or does not voluntarily cease distribution, make notification, recall the articles, and notify the public, within the time and in the

manner prescribed by the Secretary, the Secretary would issue an order requiring such person, firm, or corporation immediately (1) to cease distribution of the articles and (2) to notify all persons, firms, and corporations transporting or distributing the articles, or to which the articles were transported or sold, to immediately cease distribution. The Secretary shall, as he deems necessary, provide for notice to consumers to whom such articles were, or may have been, distributed.

Section 411(c) would provide for an opportunity for an informal hearing, to be held as soon as possible but not later than 48 hours after the issuance of the order, to allow the affected person, firm, or corporation the opportunity to contest the order. Further, the informal hearing would allow the affected person, firm or corporation an opportunity to present evidence as to why the articles should not be recalled.

Section 411(d) would give the Secretary authority to require recall of the articles if, after opportunity for a hearing under subsection (c), the Secretary continues to find that there is a reasonable probability of a threat to public health. Upon this determination, the Secretary would, as he deems necessary, amend the order to require a recall. The order would specify a timetable for the recall, require periodic reports describing the progress of the recall, and provide for notice to consumers, to whom such articles were or may have been distributed. If, after such hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary would be required to vacate the order.

Section 411(e) would provide that the remedies provided in section 411 are in addition to all other available remedies.

Section 411 would enable the Secretary to better protect the public from receiving products that present a reasonable probability that human consumption of the product presents a threat to public health. Authorized representatives of the Secretary currently have authority to detain products for 20 days that are found outside an official establishment and not in compliance with the FMIA (see section 402 of the FMIA). Under present authority, FSIS must institute an action in the appropriate U.S. District Court in order to get a judicial seizure and condemnation order. The present authority is resource intensive and lengthy. FSIS frequently relies on voluntary recalls by official establishments. This new authority to require recall of certain adulterated or misbranded articles would allow FSIS to protect consumers more effectively and efficiently.

Section 412, Refusal or Withdrawal of Inspection, would provide the Secretary with additional grounds upon which to refuse or withdraw inspection. Section 401 of the FMIA currently

authorizes the Secretary, after opportunity for a hearing, to refuse to provide or to withdraw inspection based upon a determination that the applicant or recipient of inspection is unfit to engage in any business requiring inspection under the FMIA because the applicant, recipient, or anyone responsibly connected with the applicant or recipient, has been convicted in Federal or State court of certain violations of law.

Section 412(a) would provide that the Secretary may refuse to provide or withdraw inspection from an applicant or recipient when it has been determined, after an opportunity for hearing, that the applicant or recipient or any person responsibly connected with the applicant or recipient (as defined in section 401) has committed any willful violation of the requirements of the Act or the regulations promulgated under the Act (one willful violation may result in this section being applied) or repeated violations of the requirements of the Act or the regulations promulgated under the Act. This provision does not require a determination of unfitness, nor is a prior criminal conviction or civil or administrative order or determination required.

Section 412(b) would authorize the Secretary to deny or suspend inspection, pending an opportunity for an expedited hearing, with respect to an action under section 412(a) to refuse to provide or withdraw inspection, if the Secretary deems such denial or suspension in the public interest in order to protect the health or welfare of consumers or to assure the safe and effective performance of official duties under the Act. The Secretary would have the authority to take immediate action against a violator if such action is deemed in the public health or to assure the safe and effective performance of official duties under the Act. The denial or suspension would be effective upon service of the complaint or other such notice.

Section 412(c) would provide that the determination and order of the Secretary is final and conclusive unless the affected person, firm, or corporation files for judicial review within thirty days after the effective date of the order. Unless the Secretary directs otherwise, inspection would be refused or withdrawn as of the effective date of the order, pending judicial review of the order. The United States Court of Appeals for the circuit in which the applicant for, or recipient of, inspection resides or has its principal place of business and the United States Court of Appeals for the District of Columbia Circuit would have jurisdiction. Judicial review would be on the record upon which the determination and order are based.

Section 412(d) would provide that the remedies provided in section 412 are in addition to all other available remedies.

Section 413, Civil Penalties, would authorize the Secretary to assess civil monetary penalties for violations of any

provision of the Act, the regulations promulgated under the Act, or any order issued under new section 411 of the Act.

Section 413(a) would authorize the Secretary to impose civil penalties of not more than \$100,000 for each violation against any person, firm or corporation which violates any provision of the Act, the regulations under the Act, or any order issued under the Act. Each violation and each day would be a separate offense subject to civil penalties. These penalties would be assessed after the person, firm, or corporation has received notice and an opportunity for a hearing on the record in accordance with 5 U.S.C. 554 and 556. The sanction would be based upon the gravity of the violation, degree of culpability, size and type of business, and any history of prior offenses.

Criminal sanctions are vital in ensuring the enforcement of the FMIA, but are not enough. Criminal prosecution can be a lengthy and cumbersome process in an overburdened judicial system. Civil monetary penalties, on the other hand, can be imposed administratively, ensuring a timely and effective resolution. Moreover, a monetary penalty is more tangible than a distant and lengthy legal process that may or may not be instituted and may or may not lead to a conviction. The proposed civil penalty amount is reasonable and will deter potential violators. Civil penalties would therefore be an effective enforcement tool.

Section 413(b) would provide that orders of the Secretary assessing a civil penalty may be reviewed in the U.S. Court of Appeals for the circuit in which the party resides or has its principal place of business or in the U.S. Court of Appeals for the District of Columbia Circuit by filing a notice of appeal within thirty days from the date of such order and by simultaneously sending a copy of such notice by certified mail to the Secretary. The findings of the Secretary would be set aside only if found to be unsupported by substantial evidence on the record as a whole.

Section 413(c) would provide that failure to pay the civil penalty after the order assessing the penalty has become final and unappealable or after the appropriate Court of Appeals has entered final judgement in favor of the Secretary shall result in the Secretary referring the matter to the Attorney General who shall institute a civil action to recover the assessed penalty. The validity of the Secretary's order would not be reviewable in such a collection action.

Section 413(d) would require that the civil penalties collected under section 413 be paid into the U.S. Treasury.

Section 413(e) would provide that the Secretary may refuse to provide inspection to, or suspend inspection from any person, firm, or corporation that fails to pay an assessment of a civil

5

penalty after it has become a final and unappealable order, or after the appropriate Court of Appeals has entered final judgment in favor of the Secretary.

Section 413(f) would provide that nothing in the Act shall require the Secretary to report for criminal prosecution or for the institution of libel or injunction proceedings violations of the Act when the Secretary believes that the public interest will be adequately served by the assessment of civil penalties.

Section 413(g) would provide that the remedies provided in section 413 are in addition to all other available remedies.

Section 1. Section 3 would amend section 5(c) the Poultry Products Inspection Act (PPIA) by substituting sections 12-22, and 31-33 of this Act for the reference to sections 12-22. Section 5(c) of the PPIA requires that the Secretary designate any State whose poultry products inspection requirements with respect to transactions wholly within such State are not at least equal to those of sections 1-4, 6-10, and 12-22 of the PPIA. This section would provide that sections 1-4, 6-10, 12-22, and 31-33 would apply to such intrastate transactions and no poultry or poultry products could be sold unless inspected for wholesomeness and passed by inspectors of the Food Safety and Inspection Service (FSIS).

Section 3 of the bill would add at the end of the PPIA three new enforcement provisions related to notification and recall of products, the refusal and withdrawal of inspection, and the assessment of civil penalties.

Section 31, Notification and Recall, would require persons (as defined in Section 4(j)) to notify the Secretary of the identity and location of adulterated and misbranded products. Further, section 31 would provide the Secretary with authority to issue orders to cease distribution of and orders to recall adulterated and misbranded products if there is a reasonable probability of a threat to public health. Section 31 would provide a mechanism to prevent such articles from reaching consumers.

Section 31(a) would require any person which has a reasonable basis for believing that any adulterated or misbranded, immediately to notify the Secretary of the identity and location of such articles. The immediate notification of the identity and location of articles believed to be adulterated or misbranded is necessary to provide the Secretary with the opportunity to limit the distribution of such articles, and possibly avoid human illness. The Secretary would prescribe by

regulation the means and manner that notification is to be provided.

Section 31(b) would provide that if the Secretary finds, through notification or otherwise, that (1) any poultry or poultry products are adulterated or misbranded, and (2) there is a reasonable probability that human consumption of such poultry or poultry products presents a threat to public health, the Secretary would provide the appropriate person with an opportunity to (1) voluntarily cease distribution of such poultry or poultry products; (2) notify all persons transporting, storing, or distributing such poultry or poultry products or to which such poultry or poultry products were transported or sold to immediately cease distribution of such articles; (3) to recall the poultry or poultry products; and (4) to provide, in consultation with the Secretary notice, to consumers to whom such articles were, or may have been, distributed.

If the person refuses to or does not voluntarily cease distribution, make notification, recall the articles, and notify the public, within the time and in the manner prescribed by the Secretary, the Secretary would issue an order requiring the person immediately (1) to cease distribution of the poultry or poultry products and (2) to notify all persons transporting or distributing the poultry or poultry products, or to which the poultry or poultry products were transported or sold, to immediately cease distribution. The Secretary shall, as he deems necessary, provide for notice to consumers to whom such articles were, or may have been, distributed.

Section 31(c) would provide for opportunity for an informal hearing, to be held as soon as possible but not later than 48 hours after the issuance of the order, to allow the affected person the opportunity to contest the order. Further, the informal hearing would allow the affected person an opportunity to present evidence as to why the articles should not be recalled.

Section 31(d) would give the Secretary authority to require recall of the articles if, after opportunity for a hearing under subsection (c), the Secretary continues to find that there is a reasonable probability of a threat to public health. Upon this determination, the Secretary would, as he deems necessary, amend the order to require a recall. The order would specify a timetable for the recall, require periodic reports describing the progress of the recall, and provide for notice to consumers, to whom such articles were or may have been distributed. If, after such hearing, the Secretary determines that adequate grounds do not exist to continue the actions required by the order, the Secretary would be required to vacate the order.

Section 31(e) would provide that the remedies provided in section 31 are in addition to all other available remedies.

Section 31 would enable the Secretary to better protect the public from receiving products that present a reasonable probability that human consumption of the products presents a threat to public health. Authorized representatives of the Secretary currently have authority to detain products for 20 days that are found outside an official establishment and not in compliance with the PPIA (see section 19 of the PPIA). Under present authority, FSIS must institute an action in the appropriate U.S. District Court in order to get a judicial seizure and condemnation order. The present authority is resource intensive and lengthy. FSIS frequently relies on voluntary recalls by official establishments. This new authority to require recall of certain adulterated or misbranded articles would allow FSIS to protect consumers more effectively and efficiently.

Section 32, Refusal or Withdrawal of Inspection, would provide the Secretary with additional grounds upon which to refuse or withdraw inspection. Section 18 of the PPIA currently authorizes the Secretary, among other things, to refuse to provide or to withdraw inspection, after opportunity for a hearing, based upon a determination that the applicant or recipient of inspection is unfit to engage in any business requiring inspection under the PPIA because the applicant or recipient (or anyone responsibly connected with the applicant or recipient) has been convicted in a Federal or State court of certain violations of law.

Section 32(a) would provide that the Secretary may refuse to provide or withdraw inspection from an applicant or recipient when it has been determined, after an opportunity for hearing, that the applicant or recipient or any person responsibly connected with the applicant or recipient (as defined in section 18(a)) has had committed any willful violation of the requirements of Act or the regulations promulgated under the Act (one willful violation may result in this section being applied) or repeated violations of the requirements the Act or the regulations promulgated under the Act. This provision does not require a determination of unfitness, nor is a prior criminal conviction or civil or administrative order or determination required.

Section 32(b) would authorize the Secretary to deny or suspend inspection, pending an opportunity for an expedited hearing, with respect to an action under section 32(a) to refuse to provide or withdraw inspection, if the Secretary deems such denial or suspension in the public interest in order to protect the health or welfare of consumers or to assure the safe and effective performance of official duties under the Act. The Secretary would have the authority to take immediate action against a violator if such action is deemed necessary to protect the public health or to assure the safe and effective performance

of official duties under the Act. The denial or suspension would be effective upon service of the complaint or other such notice.

Section 32(c) would provide that the determination and order of the Secretary is final and conclusive unless the affected person files for judicial review within thirty days after the effective date of the order. Unless the Secretary directs otherwise, inspection would be refused or withdrawn as of the effective date of the order, pending judicial review of the order. The United States Court of Appeals for the circuit in which the applicant for, or recipient of, inspection resides or has its principal place of business and the United States Court of Appeals for the District of Columbia Circuit would have jurisdiction. Judicial review would be on the record upon which the determination and order are based.

Section 32(d) would provide that the remedies provided in section 31 are in addition to all other available remedies.

Section 33 Civil Penalties, would authorize the Secretary to assess civil monetary penalties for violations of any provision of the Act, the regulations promulgated under the Act, or any order issued under new section 31 of the Act.

Section 33(a) would authorize the Secretary to impose civil penalties of not more than \$100,000 for each violation against any person who violates any provision of the Act, regulations under the Act, or any order issued under the Act. Each violation and each day would be a separate offense subject to civil penalties. These penalties shall be assessed after the person has received notice and an opportunity for a hearing on the record in accordance with 5 U.S.C. 554 and 556. The sanction would be based upon the gravity of the violation, degree of culpability, size and type of business of the person, and any history of prior offenses.

Criminal sanctions are vital in ensuring the enforcement of the PPIA, but are not enough. Criminal prosecution can be a lengthy and cumbersome process in an overburdened judicial system. Civil monetary penalties, on the other hand, can be imposed administratively, ensuring a timely and effective resolution. Moreover, a monetary penalty is more tangible than a distant and lengthy legal process that may or may not be instituted and may or may not lead to a conviction. The proposed civil penalty amount is reasonable and will deter potential violators. Civil penalties could therefore be an effective enforcement tool.

Section 33(b) would provide that orders of the Secretary assessing a civil penalty may be reviewed in the U.S. Court of Appeals for the circuit in which the person resides or has its principal place of business or in the U.S. Court of Appeals for the District of Columbia Circuit by filing a notice of appeal

within thirty days from the date of such order and by simultaneously sending a copy of such notice by certified mail to the Secretary. The findings of the Secretary would be set aside only if found to be unsupported by substantial evidence on the record as a whole.

Section 33(c) would provide that failure to pay the civil penalty after the order assessing the penalty has become final and unappealable or after the appropriate Court of Appeals has entered final judgment in favor of the Secretary shall result in the Secretary referring the matter to the Attorney General who shall institute a civil action to recover the assessed penalty. The validity of the Secretary's order would not be reviewable in such a collection action.

Section 33(d) would require that the civil penalties collected under section 33 shall be paid into the U.S. Treasury.

Section 33(e) would provide that the Secretary may refuse to provide inspection to, or suspend inspection from any person that fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate Court of Appeals has entered final judgment in favor of the Secretary.

Section 33(f) would provide that nothing in the Act shall require the Secretary to report for criminal prosecution or for the institution of libel or injunction proceedings violations of the Act when the Secretary believes that the public interest will be adequately served by the assessment of civil penalties.

Section 33(g) would provide that the remedies provided in section 33 are in addition to all other available remedies.

Consumer protection - food safety
enforcement legislation

DRAFT

DRAFT

Honorable Albert Gore
President of the Senate
Washington, D. C. 20510

Dear Mr. President:

The Department of Agriculture (USDA) has recently been involved in the largest food recall in American history in order to protect the American public from food borne illness or death from meat products contaminated with *E. coli* O157:H7. While successful in containing the number of illness caused by the contaminated product, the incident highlighted critical gaps in USDA's food safety enforcement regime. Congressional action is required to fill those gaps.

Today, I am transmitting to Congress a draft bill to improve public health and food safety by providing USDA with enhanced enforcement powers. This draft bill is an important part of the Clinton Administration's initiative to improve food safety for American consumers. The Administration recommends that the draft bill be promptly enacted.

The draft bill would give the Secretary of Agriculture a more complete range of enforcement tools with which to protect the public health. Section 2 of the bill would amend the Federal Meat Inspection Act (FMIA) and section 3 of the Poultry Products Inspection Act (PPIA) by providing three new enforcement provisions related to notification and recall of meat, meat products, poultry, and poultry products, the refusal and withdrawal of inspection, and the assessment of civil monetary penalties.

Specifically, the Secretary of Agriculture would be:

- ◆ authorized to stop the distribution and order the recall of adulterated or misbranded meat and poultry in situations that pose a reasonable probability of a threat to public health;
- ◆ provided with the ability to refuse or withdraw inspection based on any willful or repeated violation of the FMIA, the PPIA, or the Federal meat and poultry inspection regulations; and
- ◆ authorized to impose civil monetary penalties for violations of the FMIA and the PPIA.

The recent recall highlighted the need for this legislation. The recall was voluntary and was done at the Department's request. However, it is possible that establishments could, in the future, refuse to comply with the Department's request for a recall. Moreover, voluntary recalls often occur less quickly than desirable from a public health perspective because of the lack of mandatory recall authority. Mandatory recall authority would give the Secretary the ability to move much more quickly to stop the distribution of adulterated products and protect the public from food products containing dangerous bacteria like *E. coli* O157:H7.

In addition, the legislation would provide the Secretary with the authority to refuse inspection when a company has either wilfully or repeatedly violated USDA laws and

regulations. This authority would allow the Secretary to move much more quickly than current authorities provide to close down establishments operating unsafely, thus providing further protection of the public health.

Finally, the legislation would give the Secretary the ability to impose civil penalties for violations of USDA food safety laws and regulations. Currently, USDA must pursue a lengthy legal process to obtain criminal penalties. In addition, because they must be brought in Federal court, many potential actions are not brought to trial. The establishment of a civil penalty regime will better protect public health and improve food safety by providing a more timely and effective remedy against those who violate USDA food safety laws and regulations.

These three amendments would give the Department a full array of enforcement tools with which to protect public health. In addition to their importance from a food safety perspective, however, I also want to point out that the Department is committed to the fair and proper enforcement of these provisions, which also provide aggrieved parties with opportunities for administrative hearings and judicial review if they disagree with the Department's actions under these provisions.

The January 1993 outbreak of *E. coli* O157:H7 in Washington State affected more than 700 people and resulted in four deaths. The outbreak was an acute reminder of the risk of food borne illness due to pathogens. Since then, the Clinton Administration has taken a number of significant actions to improve food safety, including new, science-based inspection systems for meat, poultry, and seafood, expanded food borne illness surveillance, and the Administration's Food Safety Initiative contained in the 1998 budget. We believe that the Administration's investments over the past four years to improve the Nation's food safety infrastructure were a critical reason why this recent outbreak, which has resulted in at least 16 illnesses and no known deaths, was successfully contained.

Still, there is more work to be done to protect American families and improve food safety. We look forward to working with Congress to achieve this critical goal.

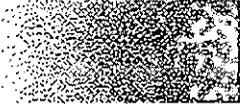
The Office of Management and Budget advises that there is no objection to the presentation of this proposed legislation from the standpoint of the Administration's program.

A similar letter is being sent to the Speaker of the House.

Sincerely,

DAN GLICKMAN
Secretary

consumer pro - food safety enforcement legislation



Jerold R. Mande

08/27/97 06:18:32 PM

Record Type: Record

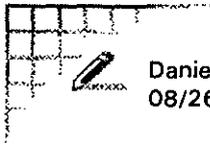
To: Elena Kagan/OPD/EOP
cc: Thomas L. Freedman/OPD/EOP, Elizabeth Dye/OPD/EOP
Subject: Food safety legislation

Elena --

As you know, in the wake of the Hudson hamburger outbreak, USDA is seeking to have the White House send legislation to the Hill on Friday that would provide additional enforcement authorities to USDA (e.g., recall, civil money). I know Secretary Glickman is hot to move on this, but I do not believe this is the right response to the Hudson outbreak. First, any legislation should not single out USDA, but should apply to CDC and FDA as well. As we have seen repeatedly during our work on the President's Food Safety Initiative one of the biggest food safety problems we have is the poor coordination between USDA, FDA, and CDC. Some public health experts have begun criticizing the poor coordination among our science and regulatory agencies on Hudson, and Hudson may prove to be a better example of poor coordination than of an effective response. Sending up USDA-only legislation reinforces that point. Second, recall authority and money penalties may not be as important as record inspection authority. We should take the time to get the right answer. When you have a minute, I would like to discuss this with you, but in the mean time I would urge you to support telling USDA to hold off.

FYI..CBS Evening News will run a piece tonight about an E. coli O157:H7 outbreak in alfalfa sprouts in Michigan and Virginia that occurred over the same time period as Hudson, presented a greater public health threat, and received no public attention. It may imply that USDA overreacted and FDA underreacted

cons protection - food safety
enforcement legislation



Daniel D. Heath
08/26/97 06:00:01 PM

Record Type: Record

To: See the distribution list at the bottom of this message
cc: See the distribution list at the bottom of this message
Subject: Food Safety Plan

OMB is working with USDA to generate a planning response to the recent Hudson Foods meat recall. Within the next two days we expect to have draft legislation circulated to you for comments through OMB's standard LRD process.

At this point, Secretary Glickman favors a simple request for increased authority for dealing with tainted food crises, including recalls and levying of civil penalties. Other suggestions for a comprehensive Administration plan include a broader pathogen reduction approach, such as the Administration proposed in 1994, and increased authorities for FDA as well as USDA. If you have thoughts about the strategy or coordination of the Administration's response to the food safety issues raised by the recent events, please feel free to discuss them with TJ Glauthier at OMB (x54561). Comments on the legislation proper should be directed to LRD.

Please let me know of any others who should be included in these reviews.

Message Sent To:

Sylvia M. Mathews/WHO/EOP
Elena Kagan/OPD/EOP
Thomas L. Freedman/OPD/EOP
Jerold R. Mande/OSTP/EOP
Jennifer L. Klein/OPD/EOP
Phillip Caplan/WHO/EOP
Barbara D. Woolley/WHO/EOP
Donald H. Gips/OVP @ OVP
Toby Donenfeld/OVP @ OVP
Donald R. Arbuckle/OMB/EOP
K. Lisa Grove/OMB/EOP
Ronald K. Peterson/OMB/EOP
Alison C. Perkins/OMB/EOP

Message Copied To:

G. E. DeSeve/OMB/EOP
T J. Glauthier/OMB/EOP
Ronald M. Cogswell/OMB/EOP
Mark A. Weatherly/OMB/EOP
Adrienne C. Erbach/OMB/EOP
Alecia Ward/OMB/EOP
Jim R. Esquea/OMB/EOP