

NLWJC - Kagan

DPC - Box 008 - Folder 001

**Consumer Protection - Food Safety
Fruits & Vegetables [2]**

Crisis pro - food safety -
fruits + vegs

White House News Report

- (1)
- Who's going to carry it?
 - Why w/ any leadership?
 - What strategy in place?
 - Introduced this yr?



How do I explain this to my constituents?
(How help me this year.)

(2)

Calls

Monday, November 03, 1997 8:19:00 AM
 She called Saturday re: charter school conference and wants you to call her over the weekend on her cell phone 321-9090
 Norma Cantu Planned
 Education
 11/3/97 8:19 AM
 205-9953

Monday, November 03, 1997 8:20:00 AM
 Called Sunday morning
 Cliff Kellog Planned
 Treasury
 11/3/97 8:20 AM
 h 332-1463

Monday, November 03, 1997 8:21:00 AM
 Please call as soon as possible re: POTUS reaction to assault weapons
 Chuck Ruff Planned
 Counsel's Office
 11/3/97 8:21 AM
 62832

Monday, November 03, 1997 8:33:00 AM
 Please call; he will be here Nov. 19-20 and wants to have dinner; his work # is 404-639-2082
 Todd Planned
 11/3/97 8:33 AM
 h 404-881-6862

Monday, November 03, 1997 9:03:00 AM
 Returning your call
 Richard Tarplin Planned
 HHS
 11/3/97 9:03 AM
 690-7627

Monday, November 03, 1997 9:46:00 AM
 Please call re: Congr. Eshoo
 Dave Carlin Planned
 USDA
 11/3/97 9:46 AM
 720-7095

Monday, November 03, 1997 10:40:00 AM
 Please call
 John Leibowitz Planned
 11/3/97 10:40 AM
 224-3406

Monday, November 03, 1997 12:57:00 PM
 Please call
 Lin Liu Planned
 President's Initiative on Race
 11/3/97 12:57 PM
 51045

Monday, November 03, 1997 2:19:00 PM
 Please call
 Maria Echaveste Planned
 Public Liaison
 11/3/97 2:19 PM
 66594

Monday, November 03, 1997 3:17:00 PM
 Please call
 Debby Kilmore Planned
 Governor Chile's Office
 11/3/97 3:17 PM
 624-5885

Monday, November 03, 1997 3:18:00 PM
 He will call you back
 Bill Schultz Planned
 FDA
 11/3/97 3:18 PM
 301-827-3370

Monday, November 03, 1997 3:59:00 PM
 Please call re food safety
 Chris Colon Planned
 Congressman Gephardt
 11/3/97 3:59 PM
 226-0815

Monday, November 03, 1997 5:41:00 PM
 Returning your call
 John Petersen Planned
 LA Times
 11/3/97 5:41 PM
 861-9290

unrevisited
 we've gotten calls
 right party - - Barron - Health
 - Palmer - Commerce
 - Strupch

*Haven't yet talked to
 Dingell + Waxman*

new pro -
- food safety -
fruits & veg

Decent chance - 10 prominent
Demo; Landed Eggs

Approach Dingen
most amir/
most puvahel

Schedule for sending it up?

interested / get advice



If not -> Baranu
(he wants to introduce)

Palme } also called
Styphel }

Should call Policy
[Stage may be interested
Eggs

Senti - Abolish to ^ f.s. event

*hus pro - food safety -
p-units treps*

Total Pages: 5

LRM ID: RJP164

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

Monday, November 3, 1997

LEGISLATIVE REFERRAL MEMORANDUM

URGENT

TO: Legislative Liaison Officer - See Distribution below
 FROM: *Janet R. Forsgren*
 Janet R. Forsgren (for) Assistant Director for Legislative Reference
 OMB CONTACT: Robert J. Pellicci
 PHONE: (202)395-4871 FAX: (202)395-6148
 SUBJECT: REVISED HHS Draft Bill on Safety of Imported Food Act of 1997
 DEADLINE: 4:00 P.M. Tuesday, November 4, 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: HHS advises that the attached draft bill reflects its understanding of the agreements reached on Friday, October 31st in meetings with USTR, State, and USDA. The White House would like to transmit the draft bill to Congress on Wednesday, November 5th. **DEADLINE IS FIRM.**

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LRM ID: RJP164
1997

SUBJECT: REVISED HHS Draft Bill on Safety of Imported Food Act of

**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: Robert J. Pellicci Phone: 395-4871 Fax: 395-6148
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

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

The Honorable Newt Gingrich
Speaker of the House
of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

Enclosed for the consideration of the Congress is the Administration's draft bill, the "Safety of Imported Food Act of 1997."

The purpose of the bill is to add to existing safeguards in the Federal Food, Drug, and Cosmetic Act, and thus enhance the Secretary's ability to prevent the importation of potentially unsafe food, in a manner consistent with U.S. trade agreements. The bill would amend the Act to provide that food imported into the United States will be considered adulterated if it has not been prepared, packed, and held under a system or conditions, or subject to measures, that meet the requirements of the Act or otherwise achieve the level of protection required for foods produced domestically. The bill authorizes the Secretary to consider, in determining whether such requirements or level have been achieved, whether the Food and Drug Administration (FDA) has requested, but been denied, access in order to conduct an inspection of the location or establishment where a food was prepared, packed, or held.

Under current law, FDA has authority to deny importation of foods that appear to be adulterated (section 801 of the Act). Under the bill, foods that do not adhere to the criteria of the new legislation could be denied entry under FDA's current authority to prevent the importation of foods that appear to be adulterated. Current seizure authority under the Act (section 304 of the Act) could also be used to deal with such foods.

This proposal will improve FDA's ability to ensure that food imported into the United States affords a level of safety comparable to that for domestically produced foods, and is part of a broader Administration initiative to enhance the safety of the food supply.

We recommend that the Congress give the draft bill its prompt and favorable consideration.

The Office of Management and Budget has advised that there is no

The Honorable Newt Gingrich - Page 2

objection to the transmittal of this draft legislation from the standpoint of the Administration's program.

Sincerely,

Donna E. Shalala

Enclosure

DRAFT:clcopf/OCC/FDA:10-31-97:C:\files\imports\billnew.031)
A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for improved safety of imported foods.

1 *Be it enacted by the Senate and the House of Representatives of the United States of*
2 *America in Congress assembled, That this Act may be cited as the "Safety of Imported Food Act*
3 *of 1997".*

4 **SEC. 2. CRITERIA FOR DEEMING IMPORTED FOOD ADULTERATED.**

5 (a) **AMENDMENT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.--**

6 (a) Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by
7 adding at the end the following new subsection:

8 "(h) If it is a food offered for import into the United States that has not been prepared,
9 packed, and held under a system or conditions, or subject to measures, that meet the requirements
10 of this Act or that otherwise achieve the level of protection required, as determined by the
11 Secretary, for such food prepared, packed, or held in the United States. In determining whether a
12 system, conditions, or measures meet the requirements of this Act or otherwise achieve the level
13 of protection required, the Secretary may consider whether an officer or employee duly designated
14 by the Secretary has requested, and has been refused, access to the establishment or location
15 where such food was prepared, packed, or held for the purpose of inspection (including sample
16 collection), testing, or other relevant procedures, at a reasonable time and in a reasonable manner,
17 and may refuse the importation of such food from such establishment or location on the basis of
18 such refusal and other relevant factors."

19 (b) **IMPLEMENTATION OF AUTHORITY.--**

20 (1) **PLAN.**--The Secretary shall develop a plan for the initial implementation of
21 the authority under section 402(h) of the Federal Food, Drug, and Cosmetic Act, as added
22 by subsection (a), and shall carry out the authority of such subsection consistent with such
23 plan.

Liz Meece
Dave Costin

cons pro -
food safety -
fruits & vegs

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+ may when the importation
of food from such states
on that basis
+ any other relevant
factors

cus pro -
 food safety -
 fruits & veps

DRAFT:clcopp/OCC/FDA:October 22, 1997:12:00noon
 (C:\files\imports\billnew.022)

A BILL

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 10 or location where such food was prepared, packed, or held for the purpose of inspection
 11 (including sample collection), testing, or other relevant procedures, at a reasonable time and in a
 12 reasonable manner; or

13 **"(2)** If it is a food offered for import into the United States that has not been prepared,
 14 packed, and held under a system or conditions, or subject to measures, that meet the requirements
 15 of this Act or that otherwise achieve the ~~standards~~² of protection required under this Act, as
 16 determined by the Secretary, for such food prepared, packed, or held in the United States.

17 **(b) IMPLEMENTATION OF AUTHORITY.--**

18 **(1) PLAN.--**The Secretary shall develop a plan for the initial implementation of
 19 the authority under section 402(h)(2) of the Federal Food, Drug, and Cosmetic Act, as
 20 added by subsection (a), and shall carry out the authority of such subsection consistent
 21 with such plan.

cus pro -
food safety -
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NOTES FOR FOOD SAFETY

CONCERNS

I. Scenario 1: If foreign producer doesn't allow inspection, then FDA doesn't allow in US. H1

Problem: is this "least restrictive." No according to USTR

Problem: "equal treatment." Here we prosecute if no inspection, under new law foreign goods we would be banned. (We can throw someone domestically in jail?) Query, What is the showing in court, according to FDA domestically it is just no inspection.

Problem: "Irrational regulations" banned by GATT, need science. FDA USDA already has principles, but uses licenses.

II. Scenario 2: If no foreign regulatory system, then FDA version would allow no produce in. Says we should have equivalent system.

-- Solution: should just seek to achieve protection achieved under U.S.

Can work this out.

USTR feels we didn't vet fairly.

III. USTR says take mandatory inspection (domestic or foreign) into account in deciding equivalence.

Hypo: Mexico has a equal system, but a plan doesn't allow US inspectors. FDA bans import from that plant, USTR says take into account....

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10/22/96

FOOD CHEMICAL NEWS



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FDA import inspections and recall authority proposals unlikely to see action this year

Don't hold your breath waiting for congressional legislation to boost FDA's regulatory authority over imported foods. The legislation will not be sent to Congress before January, an FDA official told *Food Chemical News*.

Last month, President Clinton called for legislation authorizing FDA to block all food imports from a trading partner based on results of one violative inspection (See *Food Chemical News*, Oct. 20, Page 17). The directive also called for adding FDA inspectors to cover foreign establishments in an effort to stem potential contamination before imports arrive in the U.S.

Because it is so late in the congressional session, there is no need to get FDA's suggested language to Congress in a hurry, the agency official said. Also, crafting the legislation is a more intricate process than FDA is accustomed to, because it is a trade issue involving many other players, such as the U.S. Trade Representative, State Department and White House, he added.

Work is progressing on the legislation, and the agency may have something to discuss more publicly in a few weeks, although that timing remains unclear. Further, funding for added import inspectors will be requested for fiscal year 1999. That money will be part of Clinton's next budget request, which Congress will not address until early next year. At that time, a legislative proposal will be needed so that congressional members may know what Clinton wants. "The money would be useless without legislation," the FDA official explained.



Agency work on the budget proposal has temporarily stalled progress on a bill to give FDA mandatory recall authority in the U.S. That legislation also is of no urgency, because "we can get recalls accomplished simply by jawboning companies," the official commented.

(See *Import proposals*, Page 20)

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state law standards, including the requirement to test for *E. coli* and an obligation to warn Foodmaker of the existence of *E. coli* in the product, Judge Horowitz ruled.

The judge ruled that Foodmaker had failed to demonstrate that the collective negligence of Vons — while possibly a contributing factor in the incident — was a "substantial factor" in bringing about the illnesses. Vons had argued that it could not be held liable for committing acts that federal law did not prohibit.

The judge also found that neither USDA's Food Safety and Inspection Service nor federal law required testing for *E. coli* or any other pathogens and did not require any biological testing on finished patties. The law further did not require companies to warn that pathogens might be present in the meat. The judge ruled that the "requirements" that Foodmaker said Vons should have adhered to under their state causes of action were preempted because they are "in addition to, or different" than those required under federal law that existed at the time of the outbreak. "Vons has no liability for negligence per se," the judge wrote.

Jeremy Russell at the National Meat Association, who provided *Food Chemical News* with the court documents, said that the judge's decision to allow the Federal Meat Inspection Act to override state laws is a good thing. "It is better to have a federal law for the whole industry rather than state laws that differ from state to state," he said.

While acknowledging that industry is generally relieved that the Jack-in-the-Box case is finally closed, Russell said the ruling does not have a significant impact on today's manufacturing practices, because laws have changed so much since the 1993 outbreak.

(Import proposals, continued from Page 3)

Elsewhere, USDA is pursuing expanded recall authority, as well as power to levy civil penalties and enhanced authority to withdraw inspectors. Because their sister agency is slightly ahead in discussing recall powers with Congress, FDA officials will have the luxury of observing how

USDA's proposals are received before they take their case to Capitol Hill.

Numerous staffers at FDA's Center for Food Safety and Applied Nutrition expressed strong interest in knowing the status of the legislative proposals. Many said they expected to have seen proposed legislation by now.

Senate Labor Committee staffers, who handle FDA authorizing legislation, expressed surprise that they had not heard anything from the White House on the import regulation proposal. "Usually we would get a letter or something announcing the effort and maybe seeking a response from [Chairman James] Jeffords (R-Vt.), but this time, nothing," one staffer said, quipping that the process is unfolding in the White House's "usual prompt manner. Maybe we'll see something in a year or two."

Interstate Milk Shippers Reject Resolution 5 procedures at stormy Chicago conference

The National Conference on Interstate Milk Shipments defeated a proposed 1997 procedures document that would have codified the hotly debated NCIMS Resolution 5. The action occurred at a special session held Oct. 15-19 in Chicago.

Resolution 5, initially passed by NCIMS in 1993, created a committee to address the conference's desire to reexamine all of its previously passed policies. However, the phrase "Resolution 5" came to refer to a group of changes to U.S. milk inspection programs. The changes were lauded as "science-based" by Resolution 5 supporters and as "deregulation" by its foes.

The Resolution 5 Committee recommendations included changing FDA check ratings to "state field audits," instituting voluntary HACCP for all interstate milk shippers, and removing punitive waiting periods — before the resumption of operations — following certain public health violations. Proposal 402 at the Chicago conference, which amended NCIMS's Procedures-Governing the Federal-State Cooperative Program, reflected the Resolution 5 Committee's agenda.

Although FDA has supported Resolution 5 in principle, the agency's unease about certain the procedures document became increasing in Chicago. FDA Milk Safety Branch Chief Smucker noted that "some elements of the p may not be compatible with the mission stat and goals" of the Resolution 5 Committee.

"Our number one goal ... is to ensure product," Smucker explained. "FDA supports incorporation of HACCP programs into the [pasteurized milk ordinance] and the Grade A milk safety program comments made before voting began, FDA field programs director Carl Reynolds added FDA, while "not opposed to change," was a "science-based and transparent" system.

Worries over state audits prompt

FDA's trepidation surfaced when Proposal 402 came to a delegate vote; the proposal would reinstate "check ratings" in place of Resolution 5's "state field audits" in the Procedures document. "We have supported the field audit concept," Smucker told the delegates, "[but] we feel would need to be adjusted in some areas." The proposal stopped short of threatening a "nonconcurrent" position on any aspect of the Resolution 5 and merely emphasized the importance of health considerations.

Supporting Proposal 429, Louisiana delegate Richard Graham noted that the switch to state audits would put his state "in the position to respond to problems when there's not the ... to protect the consuming public with the assurances they need that their milk supply is safe. To remove that oversight would water down what we've done and could compromise the integrity of the conference."

But Kentucky delegate David Klee defended the field audit: "If we are dependent on FDA to enforce our program, we are saying that we have no program in the interim." Klee's proposal won the day, as Proposal 429 fell four votes short of the two-thirds majority needed to approve proposals that would change the Resolution 5 Procedures draft. Proposal 430 also failed. Proposals 418 and 443 were passed as amendments to the 1997 Procedures document.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE GENERAL COUNSEL
FOOD AND DRUG DIVISION
5600 FISHERS LANE, GCF-1
ROCKVILLE, MD 20857

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- food safety -
fruits & vgs

for Sue
Allen

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3 NUMBER OF PAGES (including coversheet)

456-7028

TO: Kevin Brosch
Office of the General Counsel/USDA

Facsimile Telephone Number: 202-690-2091 Voice Telephone Number: 202-720-2940

FROM: Catherine L. Copp
Office of the General Counsel/FDA

Facsimile Telephone Number: 301-443-0739 Voice Telephone Number: 301-827-1178

DATE: October 17, 1997

MESSAGE: Attached are two redrafts of the food imports legislative proposal — one a red-lined version and one a "clean" draft. FDA will meet internally to discuss this revision first thing Monday morning. If you have any further reactions/ideas, please let me know. Thanks.

This transmission is from a Xerox 7020 telecopier. If you do not receive a legible document, or do not receive all of the pages, please telephone /us immediately at the voice number above.

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9 ~~duly designated by the Secretary has requested, and has been refused, access to the~~
10 ~~establishment or location where such food was prepared, packed, or held for the purpose of~~
11 ~~inspection (including sample collection), testing, or other relevant procedures, at a reasonable~~
12 ~~time and in a reasonable manner.~~

13 ~~-----"(2) If it is a food offered for import into the United States, unless such food has~~
14 ~~been prepared, packed, and held under a system or conditions, or subject to measures, that meet~~
15 ~~the requirements of this Act and implementing regulations or otherwise achieve the level of~~
16 ~~protection required, at the time such food is offered for import, the Secretary~~
17 ~~for such food prepared, packed, or held in the United States. Those persons who seek to~~
18 ~~introduce the food into commerce in the United States shall be required to demonstrate~~
19 ~~objectively that the system, conditions, or measures in the exporting country relevant to such~~
20 ~~food meet the requirements of this Act or otherwise achieve the appropriate level of protection.~~

21 ~~and the Secretary shall have the authority to require such persons to demonstrate~~

22 ~~otherwise achieve the level of protection required in the United States, or to require an officer~~

1 or employee duly designated by the Secretary has requested, and has been refused, access to the
2 establishment or location where such food was prepared, packed, or held for the purpose of
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DRAFT:clcopp/OCC/FDA:October 17, 1997:2:00pm
(C:\files\fdsafe\billnew.017)

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22 plan.

cons pro -
food safety -
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Congress of the United States

Washington, DC 20515

September 24, 1997

Tam -

Could you please
draft a response to
this? Emphasize
our initiative, of course.
Thanks.

EJ

The Honorable William Jefferson Clinton
1600 Pennsylvania Ave., N.W.
Washington, DC 20500

Dear Mr. President:

We urge you to give serious consideration to remedying the inadequate food safety provisions in the North American Free Trade Agreement (NAFTA). Because of your commitment to ensuring the safety of our nation's food supply, we expect that you will not agree to fast track authority that does not contain adequate food safety protections. Current fast track proposals do not address these concerns.

SEP 25 PM 5:35

In an effort to increase trade with Mexico, NAFTA limited border inspections of food and allowed Mexican trucks to enter the U.S. with limited inspection.

These lax inspection practices contributed to a sharp increase in food imports from Mexico: imports of Mexican fruit have increased 45%, and vegetable imports have risen 31%. More than 70% of these imports are carried into the U.S. on trucks. The General Accounting Office (GAO) recently found that 99% of Mexican trucks enter the U.S. without any inspection.

These provisions in NAFTA have resulted in imports of fruits and vegetables contaminated with diseases and unhealthy pesticides. We were alarmed earlier this year when 179 Michigan school children contracted hepatitis after eating tainted Mexican strawberries. In order to prevent similar incidents in the future, we urge you to take the following action:

- o Renegotiate the provisions in NAFTA that relate to border inspections and food safety, and ensure that any fast track authority include strong food safety protections.
- o Increase the funding for border inspections or, alternatively, limit the increasing rate of food imports to ensure the safety of our food supply.
- o Begin an aggressive program to label all food stuffs -- including fresh and frozen fruits, vegetables and meats -- with their country of origin.

We look forward to working with you on these vital public health issues.

Sincerely,

Paul Snyah

Shirley Brown

~~no (mon)~~

Loel Blagovesh

Patsy T. Munk

Blert Weyler

Paul Khayrati

John Sanders

Marianne Smith

Bob Wedgwood

J. L. Fisher

Mike Dege

Bert Ascroft

Paul Dwyer

John Smith

William J. Coyne

Bob Bourke

John

Errol Haller

Steve Johnson

Lawrence

Guy Z. Costello

Dillon Spink

Ted Strickland

Jack Lee

Frank Palmer, Jr.

Eric McKinn

Bobby Clark

Robert Bell

Cole E. Gilder

Max Foss

George E. Brown, Jr.

Martin O. Pals

Eliot L. Engel

Al Johnson

Margaret Waters

Livia V. Gutierrez

Walter D. Dineen

Tom Allen

Melvin L. Watt

Jules Carson

John W. Oliver

Adam Smith

Jim McSweeney

Sonny Brown

Robert F. Kennedy

Mark Foley

John F. Trump

Henry R. Lujan

Vic Fazio

Colin Powell

Gary Miller

James L. Clavester

John Longenecker

Matthew L. Martinez

Elizabeth Duce

Pat Turner

Ron Kent

James Masera

Q. Q. Q.

Marcy Kaptun

Paul E. Brown

Tom H. Mahony

Bruce E. Vento

Pete Fitz

William D. Delahunt

Paul Blum

Lynn S. Davis

Paul Lamb

Jim Davis

John Teterace

Pete Starb

Dennis Keenick

Henry A. Wexler

Sam Jeph

Jack Metcalf

Neil Abernethy

Ed Kennedy

Carolyn McCarty

Marty Mah

Ann V. Cochran

Jim Barcia

Tom A. Coburn

Sam W. Johnson

Congress of the United States
House of Representatives
Washington, DC 20515

September 23, 1997

SEP 25 PM5:36

The Honorable Bill Clinton
The White House
Washington, D.C. 20500

Dear Mr. President:

We, the members of the Florida congressional delegation, are writing to express our problem in supporting the renewal of fast track authority.

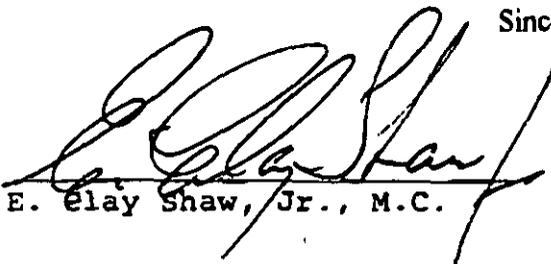
While we support free trade, we are hesitant to support fast track legislation in light of the fact that existing agreements regarding Florida fresh fruit and vegetable commodities have not been fully enforced. For example, in the recent past, tomatoes from Mexico were dumped in this country below cost in elevated surging quantities. And because current safeguards were not effective, Florida's tomato industry was severely damaged.

Furthermore, it is our understanding that not one Florida orange has been exported to Mexico since the passage of NAFTA. This situation demonstrates the inherent unfairness against Florida produce by the Mexican government.

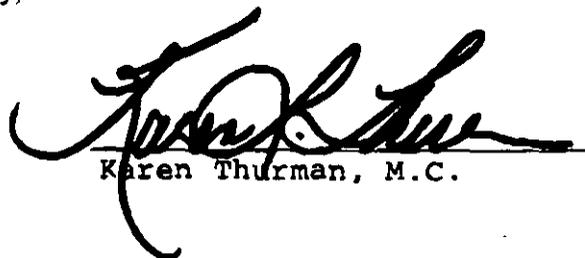
We understand that expanding free trade is crucial to continue growing America's economy. However, we are reluctant to support renewing fast track authority for agreements with other nations when promises made in the past to fairly treat Florida produce have gone largely unfulfilled. Therefore, we believe the existing foreign trade inequities concerning Florida agriculture should be addressed and resolved before fast track authority is renewed.

Thank you for your consideration of our views.

Sincerely,



E. Elay Shaw, Jr., M.C.



Karen Thurman, M.C.

The Honorable Bill Clinton -- Page 2

Carrie P. Meek

Carrie Meek, M.C.

Bill Young

C.W. "Bill" Young, M.C.

Bill McCollum

Bill McCollum, M.C.

Mike Belirakis

Michael Bilirakis, M.C.

Porter Goss

Porter Goss, M.C.

Ileana Ros-Lehtinen

Ileana Ros-Lehtinen, M.C.

Tillie Fowler

Tillie Fowler, M.C.

Corrine Brown

Corrine Brown, M.C.

Mark Foley

Mark Foley, M.C.

Alcee Hastings

Alcee Hastings, M.C.

Peter Deutsch

Peter Deutsch, M.C.

John Mica

John Mica, M.C.

Charles Canady

Charles Canady, M.C.

Joe Scarborough

Joe Scarborough, M.C.

F. Allen Boyd, Jr.

F. Allen Boyd, Jr., M.C.

Robert Wexler

Robert Wexler, M.C.

David Weldon

David Weldon, M.C.

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OFFICE OF THE SECRETARY
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH
OFFICE OF PUBLIC HEALTH AND SCIENCE, EXECUTIVE OFFICE
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 701H, 703H or 709H
Washington, D.C. 20201
Phone No: (202) 690-5605
Fax No: (202) 690-7425

FAX TRANSMITTAL COVER SHEET

TO: KAGW

Date: 10/17/97

FAX NO: _____

PHONE NO. _____

SUBJECT: _____

FROM: HAL THOMPSON Voice 202-205-0677 ART LAWRENCE Voice 202-690-7439
JIM O'HARA Voice 202-690-7694 MARY ANN SYPERT Voice 202-690-5605
SHEILA NORRIS Voice 202-690-6561 OTHER: _____

Number of pages including cover sheet: _____

MESSAGE: _____

- PER OUR CONVERSATION
- PER YOUR REQUEST
- FOR YOUR INFORMATION
- PLEASE REVIEW AND APPROVE FOR SIGNATURE
- YOUR REQUEST IS APPROVED
- MORE INFORMATION IS NEEDED
- PLEASE SIGN AND RETURN
- PLEASE PROVIDE THE FOLLOWING:

Have a Active and Healthy Day!

IF TRANSMITTAL PROBLEMS, CALL MARY ANN ON 202-690-5605.

DRAFT: October 6, 1997:1:30 PM

NOT CLEARED
By No. CIRCUMSTANCES

Section 402 of the Federal Food, Drug, and Cosmetic Act would be amended by adding at the end thereof, the following new subsection (h):

(h)(1) If it is a food offered for import into the United States,

(A) and an officer or employee duly designated by the Secretary has requested, and has been refused, access to the establishment or location where such food was prepared, packed, or held to conduct an inspection (including sample collection), testing, or other relevant procedures, at a reasonable time and in a reasonable manner.

(B) unless such food has been prepared, packed and held under a system or conditions, or subject to measures, that achieve the level of protection required, at the time such food is offered for import, for food prepared, packed, or held in the United States. Those persons who seek to introduce the food into commerce in the United States shall be required to demonstrate objectively that the system, conditions, or measures in the exporting country relevant to such food achieve the appropriate level of protection.

(2) The Secretary shall develop a plan for implementing this subsection, including the review of the systems, conditions, and measures subject to this section.

(3) The Secretary shall implement the authority of this section consistent with the plan developed by subsection (2).

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UCI-10-1997 10.14 10:11 - AGRICULTURE

FROM: DADS, J.

P. 1/6

690-4322 Sec. DANKL -
395-9597

105 HHS 177
42142

Total Pages: 6

LRM ID: RJP148

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

Friday, October 10, 1997

LEGISLATIVE REFERRAL MEMORANDUM



TO: Legislative Liaison Officer - See Distribution below
FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Robert J. Pallicci
PHONE: (202)395-4871 FAX: (202)395-6145

SUBJECT: HHS Draft Bill on Safety of Imported Food Act of 1997

DEADLINE: 10:00 A.M. Wednesday, October 15, 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 HHS draft bill is designed to implement a recently announced Presidential initiative. DEADLINE IS FIRM.

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- 128-US Trade Representative - Fred Montgomery - (202) 395-3475

① title

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- Janet R. Forsgren
- Alison Perley

OCT-10-1997 10:12 TO:7 - AGRICULTURE

FROM:DADE, J.

P. 3/6

The Honorable Newt Gingrich
Speaker of the House
OF Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

Enclosed for the consideration of the Congress is the Administration's draft bill, the "Safety of Imported Food Act of 1997."

The purpose of the bill is to add to existing safeguards in the Federal Food, Drug, and Cosmetic Act, and thus enhance the Secretary's ability to prevent the importation of unsafe food, in a manner consistent with United States trade agreements. The bill would amend the Act to provide that food imported into the United States will be considered adulterated if (1) those seeking to import the food cannot demonstrate that it has been prepared, packed, and held under a system or conditions, or subject to measures, that meet the requirements of the Act or otherwise achieve the level of protection required by the Act for foods produced domestically, or (2) the Food and Drug Administration (FDA) has been refused reasonable access to inspect the establishment or location where such food was prepared, packed, or held.

This legislation would place the burden of establishing that food meets United States safety standards on those seeking to introduce food into the United States. Those persons would be required to demonstrate that such food met the criteria described in clause (1) above. The Department of Agriculture already has similar authority for meat and poultry products and applies it to imports from many countries.

Under current law, the FDA has authority to refuse the importation of foods that appear to be adulterated. However, FDA does not have the resources to examine every entry of food. Furthermore, current border inspection capability for foods is being strained by the increasing volume of products and reduced resources available for sampling and analysis. With this new legislation, foods failing either of the criteria described above could be denied entry under FDA's current authority to prevent the importation of foods that appear to be adulterated (section 801 of the Act).

The Honorable Newt Gingrich - Page 2

This proposal will enhance FDA's ability to ensure that food imported into the United States affords a level of safety comparable to that for domestically produced foods.

We recommend that the Congress give the draft bill its prompt and favorable consideration.

The Office of Management and Budget has advised that there is no objection to the transmittal of this draft legislation from the standpoint of the Administration's program.

Sincerely,

Donna R. Shalala

Enclosure

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for improved safety of imported foods.

1 *Be it enacted by the Senate and the House of Representatives of the United States of*
2 *America in Congress assembled, That this Act may be cited as the "Safety of Imported Food Act*
3 *of 1997".*

SEC. 2. CRITERIA FOR DETERMINING IMPORTED FOOD ADULTERATED.**(a) AMENDMENT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.--**

5
6 (a) Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by
7 adding at the end the following new subsection:

8 "(h)(1) If it is a food offered for import into the United States, and an officer or employee
9 duly designated by the Secretary has requested, and has been refused, access to the
10 establishment or location where such food was prepared, packed, or held for the purpose of
11 inspection (including sample collection), testing, or other relevant procedures, at a reasonable
12 time and in a reasonable manner.

13 "(2) If it is a food offered for import into the United States, unless such food has been
14 prepared, packed, and held under a system or conditions, or subject to measures, that meet the
15 requirements of this Act and implementing regulations or otherwise achieve the level of
16 protection required, at the time such food is offered for import, for food prepared, packed, or held
17 in the United States. Those persons who seek to introduce the food into commerce in the United
18 States shall be required to demonstrate objectively that the system, conditions, or measures in the
19 exporting country relevant to such food meet the requirements of this Act or otherwise achieve
20 the appropriate level of protection."

(b) IMPLEMENTATION OF AUTHORITY.--

21
22 (1) PLAN.--The Secretary shall develop a plan for the initial implementation of
23 the authority under section 402(h)(2) of the Federal Food, Drug, and Cosmetic Act, as

10/15/97 15:06 FAX 202 456 5581

DOMESTIC POLICY COL

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2

- 1 added by subsection (a), and shall carry out the authority of such subsection consistent
- 2 with such plan.

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FAST TRACK AND AGRICULTURE

Trade Agreements and Food Safety

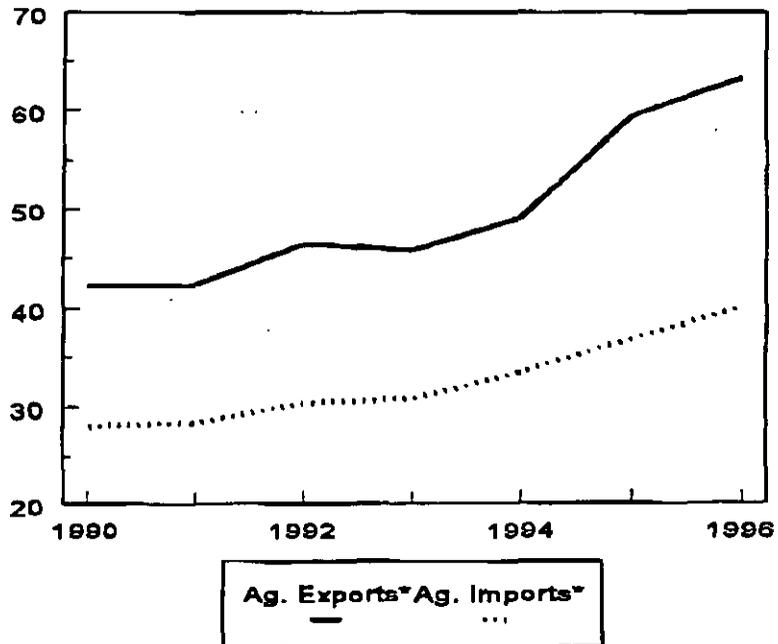
The United States has the world's highest safety standards and is the undisputed leader internationally in assuring its consumers of a safe, diversified and abundant food supply. Trade agreements such as the NAFTA and Uruguay Round Agreement did not strip U.S. regulatory bodies of their authority to protect U.S. consumers. Imports may only gain access to the U.S. market if the exporting country as a whole or specified individual products demonstrate equivalent high standards for public health, as well as animal and plant health.

Our regulatory agencies have a strong track record in assuring that imported foods are held to the same high food safety standards applied to domestic product. In negotiating both the NAFTA and the Uruguay Round Agreements, the United States made certain that provisions were included to guarantee the our sovereign right to protect human, animal and plant health. These same provisions can and will be included in any future trade agreements.

WHY TRADE MATTERS

Globalization of production and increased trade is a fact in both food and non-food sectors. Agriculture is one of the few U.S. industries that consistently shows a trade surplus, and has done so since 1960. Modern technology is enabling even greater latitude for trade in agricultural products due to better product preparation and handling and more efficient, affordable transportation. As a result, U.S. strength in the agricultural sector supports over 1 million jobs. Furthermore, agricultural imports augment consumer choice and make it possible for Americans to include healthy fruits and vegetables in their diets throughout the year.

U.S. Agricultural Exports Outpace Imports
(Billions of dollars)



*Does not include forest products
Source: USDA/FAS/ITP/FSTS

THE FACTS

- The United States regulatory network assures U.S. consumers of a safe food supply through a systems approach involving pre-market approval of products, implementation of Hazard Analysis and Critical Control Point principles, and statistical-based sampling and inspection programs for both domestically produced and imported product.
- Food safety standards that apply to domestically produced foods also apply to imported foods. For example, the U.S. standards, or "tolerances," for permissible levels of pesticide residues in domestic foods also apply to imported foods.
- The President's Food Safety Initiative announced earlier this year includes many activities to strengthen the programs already in place to help ensure the safety of both domestic and imported foods.
- As announced last summer by President Clinton, surveillance and sentinel site activities designed to detect foodborne illness at its earliest stages are being enhanced as part of the Administration's Food Safety Initiative.
- The further development of an early warning system by Federal, State and local governments to help provide earlier detection of foodborne illness will allow the U.S. regulatory network to respond more effectively to identify and contain future incidents, whether they involve domestic or imported food products.

ENSURING FOOD SAFETY: HOW IT IS ACHIEVED

The U.S. applies a **broad system-based approach** to ensure that the highest standards of human, animal and plant health are achieved. Safety means assuring that U.S. farmers and ranchers are protected from the threat of debilitating animal and plant diseases and pests so that abundant supplies of safe raw agricultural goods can be provided to domestic industries. It also means assuring that the final retail products are safe via a system that includes -- (1) pre-market assessment and approval, (2) production monitoring and adoption of HACCP systems, and (3) statistical sampling and inspection of raw and processed food products.

- Pre-Market Approval and Assessment: The most effective way to avoid introducing unsafe food products into the domestic market is to evaluate the potential for risk and prohibit the entry into the U.S. of those products which present a significant risk to human, animal or plant health. Several U.S. regulatory agencies play a role in monitoring every link in the food chain, including the movement of diseased plants and animals; the use of feed supplements and pesticides; and the safety of food additives and packaging. U.S. agricultural production capacity is further safeguarded by the use of programs to ensure that genetic materials (foundation seed, male animal health, semen and embryos) do not pass along harmful diseases or pests.

Imported products face the same scrutiny as domestic products. U.S. authorities review an export country's regulatory and production infrastructure to determine its ability to meet U.S.

standards. Depending on such reviews, U.S. authorities may then disqualify a country completely, approve only selected production facilities, or require specific products to be subjected to strict sampling protocols (100% sampling rates) to assure that the imported product is safe.

- **Production Monitoring and Auxiliary Measures:** If a product is allowed to enter the U.S. market, numerous checks are established to ensure compliance with the overall food and agricultural production safety objectives. For example, with respect to pesticides, veterinary drugs, feed and food additives, safeguards are in place to ensure only limited uses within specified tolerances. Crop protection pesticides and fungicides may only be used on specific crops during precise growth stages. Animal health drug use must observe not only dosage but also abstention requirements sufficiently prior to slaughter.

Safety rules also apply to material, equipment and processes utilized in gathering, storing and processing agricultural food and fiber products. Traditionally, methods in the food sector relied on basic hygiene principles and time-honored processing advancements, such as cooking times and temperatures, low-acid canning methods or vacuum packing. The implementation of Hazard Analysis Critical Control Point (HACCP) systems will significantly increase food safety guarantees.

- **Statistical Sampling and Inspection:** FDA, FSIS, and APHIS each maintain a comprehensive import inspection system which involves the tracking and monitoring of each trading partner's compliance history. One-hundred percent of imports are subject to reviews prior to entry into the country. The screening determines if the product, manufacturer, shipper and country of origin have consistently met U.S. standards. The assistance of tracking systems allows sampling and reinspection to be targeted at products which pose a significant risk. In order to ensure U.S. food safety is protected as imports continue to grow, FDA and USDA have devoted increased resources for inspection.

TRADE AGREEMENTS FOSTER TRANSPARENCY AND PROMOTE HIGHER FOOD SAFETY STANDARDS INTERNATIONALLY

United States representatives hold leadership positions in every major international organization charged with ensuring the safety of food produced and consumed around the world and they use these leadership positions to promote the adoption of international food safety measures that maintain high levels of protection for human, animal and plant health.

- The United States is an active participant in the Sanitary and Phytosanitary Committee of the World Trade Organization (WTO), which addresses a variety of food safety issues. U.S. participation ensures that our food standards are promoted and not compromised in the interest of facilitating trade.
- The United States is active in all committees of the Codex Alimentarius Commission (CAC), the international food standard-setting forum established in 1962, under the auspices of the World Health Organization (WHO). U.S. involvement in CAC activities ensures that our

views on critical food safety issues will be reflected in the development of all international food standards. The U.S. currently holds the chairmanships of both the CAC committees on Food Hygiene and Residues of Veterinary Drugs in Foods. The Food Hygiene Committee is now developing strong new food safety guidelines based on systems of preventive measures, including our own HACCP system.

- In addition, U.S. food safety officials frequently meet with their foreign counterparts to evaluate and discuss emerging food safety issues. These bilateral meetings, which often occur independent of any specific trade agreement or commission, are effective in developing programs to control microbiological contaminants in food.

STRONGER COUNTRY OF ORIGIN FOOD LABELING CAN NOT GUARANTEE SAFE FOOD SUPPLIES

Federal, state and local governments cooperate together to ensure that all food offered to U.S. consumers is wholesome and safe, and that consumers are fairly and adequately informed about the product. Product labeling is a critical link for assuring individual consumer safety, particularly for reasons of allergenicity or other dietary concerns.

Contrary to the opinion of those who support it, country of origin labeling does not address the issue of food safety. If a food product is not safe, it should be prohibited from entering this country. Country of origin labels will not help consumers determine on their own if a product is safe.

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- fruits & vegs

**JOSHUA
GOTBAUM**

09/30/97 06:13:36 PM



Record Type: Non-Record

To: Elena Kagan/OPD/EOP
cc:
Subject: International Food Safety

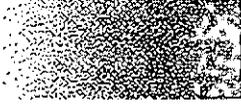
Since I haven't been able to talk with you after trying four times, I'm resorting to email.

Our understanding on this issue was that we agreed in Erskine's office that there would be an announcement and that it would include the promise of an increased international force, but that the specific amount would be determined in the FY99 budget process. This is why I was surprised when you called last night and asked for an amount. I said I would see what we could do, but also would check whether a specific budget amount was part of the agreement. I then checked with Frank and Jack, who said that deferring the particular amount until the budget was also their understanding.

We know you would like to name a number now, but don't think that was part of the deal and would have trouble agreeing on what the right amount would be. As you probably know, all we have from FDA is a very hastily-prepared, half-baked request for \$28 million (up from \$15m a week or so earlier). It doesn't prioritize countries or products and FDA is quick to admit that if there was a chance they'd have to take part or all out of existing resources they would ask for much less.

Please call or page me. If you and Bruce still feel the need for a specific budget amount, that needs to be discussed with Frank and Jack and agreed by Erskine.

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- food safety -
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Jerold R. Mande

09/30/97 04:36:09 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Thomas L. Freedman/OPD/EOP, Mary L. Smith/OPD/EOP

Subject: Food safety.

Here is what I've learned about the lines of attack trade foes are likely to try:

1. Requiring foreign countries have "equivalent" systems rather than the same systems. One way we could bypass this debate is by insisting upon the same safety standard.
2. The guidance we are directing the Secretaries to issue will be voluntary when it should be mandatory.
3. We should be calling for country-of-origin labeling.
4. Fast-track has language that specifically forbids inclusion of food-safety and environment standards for the next 8 years.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Rockville MD 20857

March 31, 1993

MEMORANDUM TO THE SECRETARY

THROUGH: DS _____
COS _____
ES _____
Acting ASH _____

SUBJECT: Food Safety Initiative--DECISION

PURPOSE

During the recent budget briefings, I mentioned the urgent need for a comprehensive Federal policy for food safety. This memorandum is intended to explain that concept in more detail, and to recommend that the Department embark upon such an initiative as soon as possible.

INTRODUCTION

The Food and Drug Administration is the lead food safety agency within the Federal government, through its enforcement of the broad food safety provisions of the Food, Drug, and Cosmetic Act of 1938. Although Theodore Roosevelt spurred passage of the first Federal food law in 1906, that law was "updated" in 1938 to form the current food statute, whose provisions have remained essentially unchanged since enactment.

The food supply, however, has changed dramatically since 1938. Food technology has become "high tech;" food processing operations are increasingly large scale and centralized; and market-driven innovations in product formulation, processing and packaging have vastly increased the sheer number of food products FDA regulates. Food consumption patterns are also different, with, for example, the great increase in restaurant consumption.

¹Of course, there are other significant agencies involved in food safety--USDA regulates meat and poultry, CDC carries out the Federal government's epidemiological surveillance, EPA approves pesticides for use on food crops, and the National Marine Fisheries Services oversees seafood in conjunction with FDA.

²The Pure Food and Drug Act created FDA's forerunner in the Agriculture Department to regulate most foods; the Meat Inspection Act gave authority over meat and poultry to another part of USDA. FDA was given its current name in 1930 and transferred to HHS' predecessor department in 1940.

Page 2 - The Secretary

Accompanying these changes in food processing and consumption has been a rise in foodborne illnesses, caused by many factors (e.g., new pathogens, changes in food handling, increased transport of food over long distances, environmental pollution and increased use of chemicals that can contaminate foods). Finally, unlike in the pre-World War II era, many foods are today imported from other countries, whose food safety standards are in some cases inadequate to ensure that foods are protected from contamination.

In the years since the Act's passage, food safety has been a potent issue in this country. In the 1950s there was great public concern about pesticide and food additive use, culminating in amendments to the Food, Drug and Cosmetic Act authorizing FDA to set limits on pesticides and to approve food additives (and leading the Eisenhower Administration to double FDA's staff). Publication in 1962 of Rachel Carson's bestseller Silent Spring generated great consumer anxiety about pesticides, and prompted the Kennedy Administration to again increase FDA's size.

Throughout the 1970s and 80s there were periodic public scares about food contaminations. Many have been "false alarms" (such as the Alar in apples incident) that have obscured the very real threats to food, usually caused by microbiological agents that take advantage of inadequate quality control procedures.

Despite the many years of growth and change in the food supply, the statutory structure for ensuring food safety has remained essentially unchanged since 1938. Over the years piecemeal amendments have been made to solve individual problems, creating a patchwork of statutory directions. We believe it is now time to prepare the food supply for the 21st century by modernizing our food safety legislation and the regulatory system.

THE SCOPE OF THE FOOD SAFETY HAZARDS

The term "food safety" has been used generically for years to cover a number of problems and challenges related to food and health. It includes, for both domestically-produced and imported foods, issues such as the following:

- o Foodborne biological hazards such as salmonella in eggs, Listeria in dairy products, cholera in shellfish, E. coli in meat, and many other pathogens that threaten health;
- o Chemical contaminants, such as heavy metals and pesticides (both those registered by EPA for agricultural use and ones of public health concern that are persistent environmental contaminants, e.g., lead);
- o Natural contaminants, such as aflatoxin, a carcinogen that is often found in grain and peanuts;

Page 3 - The Secretary

- o Drug residues in animal products for human consumption, such as antibiotics in milk or meat;
- o New foods made using biotechnology that will change the nature of food we consume in the years ahead;
- o New food components, such as the "fake fat," Olestra, that we are now reviewing for marketing approval, that will have major impacts on dietary practices if approved.
- o Improper consumer preparation of foods, which is the most common cause of foodborne illness (such as chopping salad ingredients on a cutting board after using the board to prepare raw chicken); and
- o New food processing and packaging techniques that will make substantial contributions to food storage and consumer convenience, yet will also challenge both the food industry and FDA scientists to understand their possible effects upon health (e.g., the effects of microwaving on food packaging).

THE COSTS OF FAILURE TO SOLVE THE PROBLEM

As well meaning as attempts in recent years have been to address the food safety dilemma, there remains much room for improvement. The public continues to have high expectations for the performance of food safety regulatory agencies and the U.S. continues to face a significant public health threat from foodborne illness. Witness, for example:

- o CDC estimates that over 9,000 people die each year from foodborne illness, caused principally by microbiological contamination (although least often from commercially processed foods).
- o A recent study by FDA's Center for Food Safety and Applied Nutrition estimated that there are at least 24 million, and perhaps as many as 81 million, cases of foodborne illness per year.
- o The health care costs associated with foodborne illness are enormous. One estimate of the annual costs associated with one common pathogenic illness, salmonellosis, is about \$2 billion, and total costs of foodborne illnesses are probably well over \$10 billion per year.

¹ Because disease from foodborne sources is generally preventable, any resources spent on prevention-related research, surveillance and public education would be only a fraction of the cost otherwise borne by the economy when disease occurs.

Page 4 - The Secretary

- o USDA is now reporting to us about 6,000 cases each year of improper drug residues in meat and poultry (USDA regulates the meat; FDA regulates the use of drugs in food-producing animals). This has been exacerbated by greater concentrations of producers in recent years, which has led to more extensive spread of disease and drug use in herds and flocks.
- o The safety of fish and other seafood is increasingly questioned by consumer groups and Congress, and calls have been made to move seafood regulation to USDA. [The safety of meat is also being questioned, and there are calls to transfer meat regulation to FDA or an independent food agency.] Also, new drug residue concerns in seafood are emerging from the rapid growth in aquaculture (in which farm-raised fish are given drugs with their feed).
- o Imports of foods from other countries are growing rapidly, now up to over 2 million "entries" per year, posing an ever-increasing challenge to our ability to ensure that those foods are safe and wholesome. In fact, we can only inspect under 10 percent of food imports and, of those inspected, thousands must be "detained" as being in violation of our standards.
- o The cumulative effect of years of exposure to pesticides and other chemical contaminants is uncertain, but public concern about those food contaminants has remained high for a generation.
- o Hardly a month goes by in which there is not a public scare over the latest contaminant in food -- Alar in apples, aldicarb in watermelon, ED0C in flour, PCBs in fish, lead in ceramicware, cholera in shellfish, dioxin in food packaging, salmonella in eggs, Listeria in cheese, and more (many of which are not true health problems, but are perceived as such by the public). The E. coli incident in Washington state is only the latest in a long series.
- o There are enormous inefficiencies in the current food protection system. For one example, FDA, USDA, and state agencies duplicate efforts in some areas. For another, FDA wastes resources attacking problems with antiquated enforcement authority (for example, having to go to a U.S. Attorney to seek judicial seizure of a contaminated food when most agencies could merely detain it administratively).
- o Although our principal concern should be public health, you should know that the United States has an annual export surplus of \$8 billion, and foreign buyers are increasingly asking for government "certification" that U.S. foodstuffs are safe.

Page 5 -- The Secretary

WHAT IS NEEDED TO SOLVE THE PROBLEM

Years of experience with foodborne public health threats and with regulation of the food supply, as well as numerous public and private reports on food safety, have suggested that there are additional steps that may be appropriate to adequately ensure the safety of our Nation's food supply, including:

- 1) A Uniform National System of Food Safety Assurance - We need to design a system under which the food industry subscribes to a comprehensive food safety assurance program to improve both efficiency and effectiveness, which would govern the handling, processing, transportation, and preparation of food, and that would focus on the areas where we know food is most likely to become contaminated or otherwise threatened (e.g., adequate refrigeration in holding and shipment; adequate protection from chemical contaminants, pests, and pathogens; and adequate handling and cooking during processing). If implemented, this should comprise a coordinated regulatory framework encompassing the states, HHS, USDA, and other agencies concerned about food safety.
- 2) Authority to Protect the Public - FDA lacks many of the modern enforcement tools available to virtually all other Federal regulatory agencies. For example, the agency is not authorized to detain a contaminated product, cannot require food firms to register, lacks explicit authority to inspect the records of a food processor, and cannot order a recall of a product known to pose a health threat.
- 3) Inspection and Sampling - While the food industry has grown enormously in recent years, and imported foods have increased substantially, FDA's inspectional resources have been reduced. We do not have the resources to inspect many food processing facilities regularly (on average, every eight years), and inspect only a tiny fraction of imported foods. In addition, FDA has lacked the resources to take a proactive role in the growing internationalization of food commerce, to ensure that food imports are safer at the source.
- 4) Other Needs - There is great need for additional research into the nature and biological action of pathogens, for better analytical methods to test for the presence of chemical and biological contaminants, and for more training for the state, local, and Federal inspectors who are charged with identifying such threats.

Page 6 -- The Secretary

THE FOOD SAFETY INITIATIVE

Despite the years of public disagreement about how to resolve the food safety problems, I believe that the basis for a new program exists that can have an enormously beneficial impact on health with little or no additional taxpayer funding. The program would involve three principal elements to strengthen FDA's role in improving food safety. These elements can be summarized as follows:

Regulations to Ensure Quality Control

We should promulgate new regulations that would require food producers, processors, transporters and retailers to prepare plans for controlling hazards within their operations. These regulations would be based on the proven concept of "HACCP"--Hazard Analysis Critical Control Points--which focuses on critical points in food processing that might permit food to become contaminated. The regulations could be tailored to each segment of industry, yet be national in scope to ensure consistent, uniform protection of the food supply. We believe we can build strong industry support for a broad HACCP program. In fact, we are working now with the National Fisheries Institute (the seafood industry trade association) on a mandatory HACCP program for seafood processors that will greatly improve seafood safety.

New Statutory Authority to Control Food Hazards

We should seek new authorities to ensure safe food handling and preparation, for example:

- to require food producers and handlers to register their facilities, so that we know where food is being produced and held, and by whom;
- to authorize FDA to require that all food producers, transporters, and retailers establish and maintain a comprehensive program to ensure the safety of the foods they handle--thus enabling FDA to positively certify their products for domestic and international commerce;
- to authorize FDA to refuse entry to food imports where the food safety inspection system of the originating country is not equivalent to the U.S. system and the food handler has not registered with FDA, does not have a HACCP program, or has refused FDA access to inspect the manufacturing facility;
- to permit an inspector to review a food producer's processing records;

Page 7 -- The Secretary

- to authorize FDA inspectors to detain a suspect food until its safety can be determined;
- to allow FDA to order the recall of a food found to be hazardous to health;
- to give FDA the flexibility to seek punishment for offenders short of criminal action, that is, to impose civil penalties as an intermediate deterrent; and
- to authorize the collection of user fees for some of FDA's food safety efforts, as described below.

Increased Resources to Protect the Food Supply

The level of effort to protect the food supply has simply not kept pace with the increasing size and complexity of the food industry and food imports. Indeed, as one comparison, USDA has 9000 employees devoted to the inspection of meat and poultry, while FDA has 770 for the entire rest of the food supply. We need to increase domestic inspections, import coverage, overseas inspections and standard setting, and other related activities such as HACCP development, research, and methods development. We are now examining those needs in detail so as to arrive at estimates of their likely costs.

HOW CAN FOOD SAFETY IMPROVEMENTS BE FUNDED?

I am keenly aware of the limitations on new funding for any Federal program. However, I believe we can develop a strategy that accomplishes our goals without seeking new appropriations.

First, there are areas of food protection that are appropriate for user fees. Last year the drug industry agreed to support user fees for increased FDA resources for drug reviews. That program promises to significantly reduce the time it takes to get new therapies on the market. In the food safety area, there are three sources of user fees that I recommend we consider--import examination, export certification, and establishment registration. Imposing an import fee merely requires that foreign importers pay for FDA to ensure that their foods are of sufficient quality to enter the United States. Export certification is a service provided to American exporters that provides a significant benefit to those exporters, by certifying to foreign governments that an American food export would be of acceptable quality in this country. Establishment registration fees would support the costs of registering a food processing facility with the FDA. We believe all of these fees can be designed to generate sufficient funds without creating an undue burden on food production or international trade.

Page 8 -- The Secretary

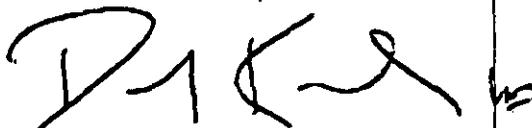
In addition to funding, we may be able to greatly enhance the use of existing resources with more modern inspection and enforcement powers. Also, the states have food safety programs, and it should be possible to design programs in which Federal and state officials ensure against duplication of effort while also improving coverage of the food supply.

Finally, USDA has substantial numbers of employees nationwide involved in all aspects of food production and marketing--not only meat inspection, but also insect control, land management on farms, grading of agricultural products, and other agriculture related activities. I recommend that we approach Secretary Espy about factoring joint HHS-USDA food safety protections into his comprehensive review of USDA's organization and mission, and that we explore ways of better coordinating HHS' and USDA's food safety activities. Indeed, Mr. Espy has said that meat and poultry safety--using the HACCP principles we are recommending--is high on his list of priorities. The Centers for Disease Control should be a part of any such discussions, as their role in epidemiological surveillance and disease prevention is an important part of protecting the public from unsafe foods.

RECOMMENDATION

I believe that food safety reform is essential to carrying out FDA's mission of protecting the food supply and the public health. It will have the ancillary benefits of strengthening the integrity (and thus competitiveness) of American agricultural exports and of lowering health care costs. Accordingly, I recommend that you announce, in consultation with Secretary Espy, that the Administration will initiate a comprehensive overhaul of the food safety assurance program--a program that will include new regulations requiring quality assurance programs based on the HACCP concept, new legislation to strengthen FDA's enforcement authorities, and statutory authority to assess user fees to fund the new food safety program.

Dr. Lee and I are available to discuss these recommendations with you at your convenience.



David A. Kessler, M.D.
Commissioner of Food and Drugs

DECISION

Announce and implement a new food safety initiative as proposed.

Concur _____ Nonconcur _____ Date _____

discuss pro -
food safety -
fruits + vege

Q&A on the Safety of Imported Food
September 29, 1997

Q: Is increased international trade going to introduce added risk to the U.S. food supply as today's New York Times article indicated?

A: No. Food on U.S. grocery shelves produced either in the U.S. or overseas are both extremely safe. In fact, our nation's food supply today is probably the safest it has ever been, but we are working to make it even safer.

As was reported last week, the President will be sending legislation to Congress that will go a long way to filling the remaining gaps in our food safety system. The legislation will authorize the FDA to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the U.S. The President will also provide the necessary funds in his FY99 budget to enable FDA to expand dramatically its international inspection force so that it can make good use of this new authority.

In addition, the President has asked the Secretaries of Health and Human Services and Agriculture to take additional steps to improve the safety of both imported and domestic fruits and vegetables. Specifically, he has asked the Secretaries to issue within one year guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those, foreign and domestic, seeking to sell produce in the U.S. market.

These efforts all build on the Clinton Administration's long-term commitment to strengthening our food safety system. With the help of the Vice-President's National Performance Review, we have fundamentally improved the way we ensure the safety of meat, poultry, and seafood. We have also put in place important new protections against the risks of pesticides in our food, especially for our children. And we are hopeful Congress will provide the \$43 million the President requested in his FY98 budget to improve food safety.

Q: Why hasn't the Administration acted sooner? Are these steps being taken now only because of the Administration's interest in passing fast-track legislation?

A: No, we are taking these steps now because they are the natural next steps in the President's long-term efforts to ensure the safety of the nation's food supply.

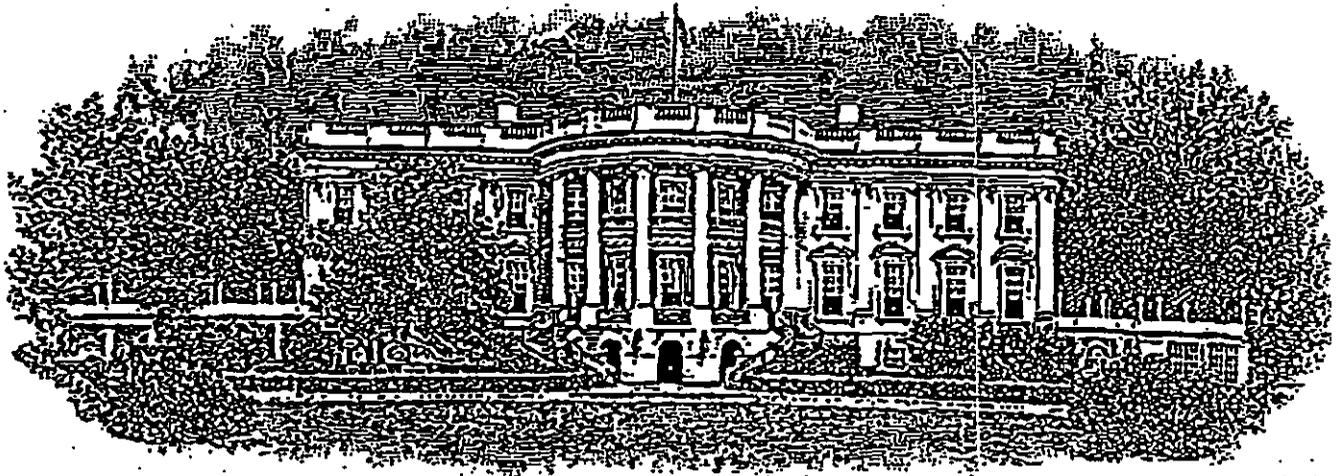
One of the first challenges we faced after taking office in 1993 was an outbreak of *E. coli* in hamburger in the northwest. We recommended replacing our old system of responding

to problems only after they occur with a new system to prevent problems before they occur. That system, which we are putting in place for meat, poultry, and seafood is greatly increasing our ability to make sure food is safe.

In January, we announced several additional steps to improve the safety of our food. The President asked Congress to add \$43 million to our food safety budget to fund a nationwide early-warning system for foodborne illness, increase seafood safety inspections, and expand food-safety research, training, and education. We are hopeful Congress will provide the funds we requested and beginning next month we will be using that money to further reduce the incidence of foodborne illness.

This new initiative is the natural next step. With significant measures already taken to ensure the safety of meat, poultry, and seafood, we are now directing our efforts to the produce consumed by Americans.

The White House ^{fruits/vegs}



DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Laura Emmett / Elena

FAX NUMBER: _____

TELEPHONE NUMBER: _____

FROM: _____

TELEPHONE NUMBER: _____

PAGES (INCLUDING COVER): _____

COMMENTS: USDA Talking Points

Key Points and Messages

General Background:

Fruits and vegetables are safe and a key part of a healthful diet. This includes both domestic and imported foods.

A number of foodborne illness outbreaks linked to fruits and vegetables have occurred recently. But food safety experts do not know where or how the contamination occurs i.e. on the farm, during transportation or distribution, at grocery stores, in households or restaurants.

The data does not support making a conclusion that imports are either more or less safe than domestic product. This initiative is about making both domestic and imported product even safer.

1. Direct FDA and USDA to work cooperatively with constituents to develop Good Agricultural and Good Manufacturing Practices Guidance.

This is NOT about FDA going onto farms or regulating what farmers do on their farms. This is about government and producers working cooperatively to improve food safety by developing VOLUNTARY guidelines for producers to follow.

Many producer groups have taken a leadership role in this effort and have been developing such guidance for their members. We applaud their leadership and want to work with them to expand on their effort.

Agriculture issues vary by crop and by region. Practices will reflect that. Not a one-size fits all approach.

2. Direct USDA and FDA to work with constituents to develop outreach and educational effort to encourage producers to adopt these practices.

USDA works with a vast network of agencies that are grassroots-based and can and do work effectively and cooperatively with farmers to encourage the adoption of these new practices. Such as land-grant institutions, extension service, soil and water conservation districts.

Not a regulatory scheme imposed by Washington. Grassroots program to encourage farmers to adopt these practices.

3. Direct USDA and FDA to Evaluate Potential for Food Safety Problems in Exporting Countries (Assessing agricultural production, transportation, and processing practices in these countries)

USDA and FDA will develop profiles of exporting countries. They will evaluate the food production, transportation, and handling practices.

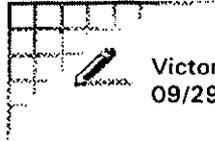
7. Report Back to WH with Additional Actions

Additional actions are needed to build on this initiative. For example, we may need to take action to address food safety concerns regarding transportation and handling of fruits and vegetables.

There are also likely to be additional actions to build on the progress we have made in the 1998 Administration initiative. For example, we may need to further expand the FoodNet sentinel site program, or we may need to continue to expand our educational and outreach efforts to improve awareness of food safety at the retail or restaurant level, for example.

Legislation: Imports must meet U.S. safety standards. The legislation will make clear that they must continue to meet those standards.

CMS pro - food safety -
fruits + vegs



Victoria Radd
09/29/97 07:07:13 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:

Subject: Congressional Food Safety Letter

Last week, about 75 House members sent a letter to the President about NAFTA and food safety. Legislative Affairs is tracking down the letter -- and will send to you for a draft response. The response should follow closely on the official announcement of our initiative, don't you agree? When are you planning to announce?

V.

cons pro - food safety/
fruits + veps

To Elana/Tom:

Re: request for info on growth of produce imports, here's what USDA has:

Fresh fruit imports from other countries has increased by an average of about 9% per year in recent years. Fresh vegetable imports have increased by an average of 21% in recent years.
[Recent years are the period 1992-96.]

Re: the earlier data on the percentage of total fresh vegetables consumed in this country, USDA has informed us that they misread the data that concluded that 22% was imported. They tell us now that it's 12%. They confirm that the fresh fruit # is still 38%.

Bill Hubbard

Date: 9/25

FAX



Health Division



Office of Management and Budget
Executive Office of the President
Washington, D.C. 20503

To: *Mac Reed*
Fax:
Phone:

From: *Jim Engler / Richard Turman*

Number of Pages (not including cover): *2*

Subject: *Attached are the edits to the food safety document.*

Please call if there are any problems with this transmission:

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Health & Human Services Unit	202/395-4925
Health Programs & Services Branch	202/395-4926
Health Financing Branch	202/395-4930

Fax Numbers:

Health Division (Front Office)	202/395-3910
Health Division (Room 7001)	202/395-7640

[Someone should check
with HHS &
FDA,
especially
P. 2]

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
SECRETARY OF AGRICULTURE

SUBJECT: Initiative to Safeguard Imported Fruits and Vegetables

During my Administration, we have taken significant steps to strengthen our entire food safety system, including expanded research, education, and surveillance activities. We also have put into place enhanced safety standards relating particularly to meat, poultry, and seafood products. These measures have greatly improved the safety of the nation's food supply and reduced the incidence of foodborne illness.

We need to build on these efforts, and today I ask you to do so by focusing on the safety of fruits and vegetables, and particularly those imported from foreign countries. Last year, 38 percent of the fruit and 22 percent of the vegetables consumed by Americans came from overseas. We must ensure that these fruits and vegetables are produced under safety systems equivalent to those existing in the United States. At the same time as we upgrade our own domestic standards.

I plan to ask Congress to enact
As you know, I am introducing legislation in Congress that will help accomplish this task. This legislation will authorize the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the United States. This authority, which is equivalent to power the USDA now has to halt the importation of meat and poultry, will enable the FDA to prevent the importation of potentially unsafe foreign produce. In addition, I will ask Congress for an increase in FDA funding in Fiscal Year 1999 to allow the agency to expand dramatically its international inspection force. With this greatly increased ability to inspect food safety conditions abroad, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

also work to expand FDA's

At the same time, I direct you to take administrative actions that will better ensure the safety of fruits and vegetables coming from abroad, while continuing to improve the safety of domestic produce. You should accelerate whatever food safety research is necessary to support these actions.

First, I direct the Secretary of Health and Human Services, in consultation with the Secretary of Agriculture, to report back to me within 90 days with a plan on how to improve the use of existing and projected resources to monitor agricultural and manufacturing practices abroad, assist foreign countries to improve those practices, and prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. I especially urge you to consider the best ways to target inspection and testing resources toward those foreign areas where problems are especially likely to occur.

Second, I direct the Secretary of Health and Human Services, in consultation with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue

within one year guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should deal with such matters as sanitation, worker health, and water use, and should take into account differences in both crops and regions. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those, foreign and domestic, seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities regarding these new safety standards.

These steps, taken together and in coordination with the legislation I will send to Congress, will ensure to the fullest extent possible the safety of fruits and vegetables for all Americans. I will also direct the Administrator of the Environmental Protection Agency and the Secretary of Labor to provide you with assistance in achieving this goal.



U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

Telephone (202) 720-3631 Fax (202) 720-5437

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PLEASE DELIVER TO: Elena

FAX NUMBER: () _____ PHONE NUMBER: () _____

FROM:

Euz

My last edit. I promise.
"partnership" with IFCS
instead of consultation.

Thanks.

MESSAGE: _____

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
SECRETARY OF AGRICULTURE

SUBJECT: suggested Initiative to ~~Safeguard Imported~~ *Improve the Safety of Domestic Imported* Fruits and Vegetables

During my Administration, we have taken significant steps to strengthen our entire food safety system, including expanded research, education, and surveillance activities. We also have put into place enhanced safety standards relating particularly to meat, poultry, and seafood products. These measures are greatly improving the safety of the nation's food supply.

We need to build on these efforts, and today I ask you to do so by focusing on the safety of fruits and vegetables, and particularly those imported from foreign countries. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas. We must ensure that these fruits and vegetables are produced under safety systems equivalent to those existing in the United States, at the same time that we upgrade our own domestic standards.

must add

As you know, I am introducing legislation in Congress that will help accomplish this task. This legislation will authorize the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the United States. This authority, which is equivalent to authority the USDA now has to halt the importation of meat and poultry, will enable the FDA to prevent the importation of potentially unsafe foreign produce. In addition, I will provide the necessary funds in my Fiscal Year 1999 budget to enable the FDA to expand dramatically its international inspection force. With this greatly increased ability to inspect food safety conditions abroad, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

At the same time, I direct you to take administrative actions that will better ensure the safety of fruits and vegetables coming from abroad, while continuing to improve the safety of domestic produce. You should accelerate whatever food safety research is necessary to support these actions.

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and the

new edit → partnership

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Fruits and vegetables are safe and are an essential part of healthy diet. However, we need to take strong action to make them even safer, including...

must
add
delete

fruits and vegetables. This guidance should ~~also take into account differences in both crops and regions and should address potential food safety problems throughout the food distribution and marketing system.~~ By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those, foreign and domestic, seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities.

X

These steps, taken together and in coordination with the legislation I will send to Congress, will ensure to the fullest extent possible the safety of fruits and vegetables for all Americans. I will also direct the Administrator of the Environmental Protection Agency and the Secretary of Labor to provide you with assistance in achieving this goal.

Elena -

I really think these edits must be made to the text to help with domestic producers, especially with the interplay of "standards" and "guidance".

The title change is suggested ~~and the~~

~~and the~~

~~and the~~

Thanks for your help.

Elena

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES
SECRETARY OF AGRICULTURE

SUBJECT: Suggested Initiative to ~~Safeguard~~ ^{Improve the Safety of Domestic and Imported} Fruits and Vegetables

During my Administration, we have taken significant steps to strengthen our entire food safety system, including expanded research, education, and surveillance activities. We also have put into place enhanced safety standards relating particularly to meat, poultry, and seafood products. These measures are greatly improving the safety of the nation's food supply.

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than even safer, including

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X

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U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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 - JOHN GIBSON, SPECIAL ASSISTANT
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 - KOFI DEGRAFT-JOHNSON, EXECUTIVE ASSISTANT
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 - PAUL DRAZEK, SPECIAL ASSISTANT FOR POLICY
 - ANNE KENNEDY, SPECIAL ASSISTANT FOR POLICY
 - ERIC OLSEN, SPECIAL ASSISTANT FOR POLICY
 - JANET POTTS, COUNSEL TO THE SECRETARY

MESSAGE: Yet Another Edt. I think
this is necessary to quell domestic
produce concerns.

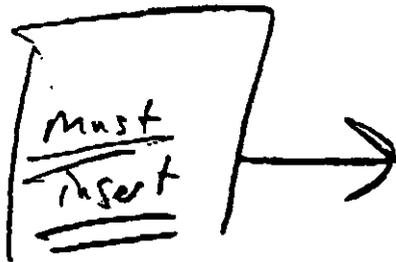
h

09/25/97 14:28

003

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~~also~~
~~the~~ ~~and~~ ~~should~~
~~and~~ address
potential food safety
problems throughout
the food distribution
and marketing system.

The New York Times

cus pro -
- food safety -
fruits + vegs

WASHINGTON NEWS BUREAU

FACSIMILE TRANSMITTAL SHEET

TO: <u>ELENA KAGAN</u>	FROM: <u>Jeff Gerth</u>
COMPANY:	DATE: <u>9/26</u>
FAX NUMBER:	TOTAL NO. OF PAGES INCLUDING COVER: <u>9</u>

URGENT FOR REVIEW PLEASE COMMENT PLEASE REPLY

PLEASE CALL 202-862-0324 WITH ANY TRANSMISSION PROBLEMS

NOTES/COMMENTS:

as discussed

*Special Issue***Foodborne Disease Control:
A Transnational Challenge**

F. K. Käferstein, Y. Motarjemi, and D. W. Bettcher
World Health Organization, Geneva, Switzerland

*"Disease knows no boundaries and
borders are porous to disease."⁽¹⁾*

In the globalized political economy of the late 20th century, increasing social, political, and economic interdependence is occurring as a result of the rapid movement of people, images, values, and financial transactions across national borders. Another consequence of the increase in transnational trade, travel, and migration is the greater risk of cross-border transmission of infectious diseases. As the world becomes more interconnected, diseases spread more rapidly and effectively. With more than one million people crossing international borders every day, and with the globalization of food production, manufacturing, and marketing, the risk of infectious disease transmission is greater. Economic globalization has also increased the need for governmental budget austerity, and consequent national preparedness has been eroded. The emergence of new infectious diseases, as well as the reemergence of old ones, thus represents a crucial transnational policy issue. These problems cannot be resolved by national governments alone; they require international cooperation. This article analyzes the role of foodborne disease surveillance programs, nationally and internationally, in the control of foodborne diseases.

In the past two to three decades, public health authorities in industrialized countries have been faced with an increasing number of food safety problems. In 1983, a Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Safety concluded that illness due to contaminated food was perhaps the most widespread health problem in the contemporary world and an important cause of reduced economic productivity (2). More recent data from industrialized countries indicate that annually up to 10% or more of the population may have a foodborne disease. The situation is equally serious in developing countries, where infant diarrhea causes many illnesses and deaths. In addition to known foodborne diseases, public health communities are being challenged by the emergence of new or newly recognized types of foodborne illnesses, often with serious and chronic health consequences. Certain popula-

tions (e.g., pregnant women, the elderly, infants and children, immunocompromised persons, and the undernourished) are particularly vulnerable. In economic terms, foodborne illnesses are very costly for industry, health services, and society as a whole.

Many factors have contributed to the increase in foodborne disease. Industrialization, leading to increased wealth and urbanization, has revolutionized the food supply system, resulting in mass production and an explosive increase in the number of food service establishments and food outlets. Mass production, environmental factors, and inadequate knowledge on the part of food handlers have contributed to increased contamination of primary foodstuffs.

The increase in international trade has increased the risk for cross-border transmission of infectious diseases. The globalization of food (and feed) trade, facilitated by the liberalization of world trade, while offering many benefits and opportunities, also presents new risks (3). Food, a major trade commodity, is also an important

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vehicle for transmission of infectious diseases. Because food production, manufacturing, and marketing are now global, infectious agents can be disseminated from the original point of processing and packaging to locations thousands of miles away. This multinational approach to food production and distribution and the progressive opening up of world markets have allowed the international food trade to flourish. The value of food trade, U.S. \$266 billion in 1994, was more than 300% greater than it was 20 years ago and continues to grow rapidly (4).

The globalization of foodborne diseases also results from increased travel. International travel is more accessible today. The World Tourism Organization estimates world tourist arrivals at 567 million in 1995, and this figure is expected to rise to 660 million by the year 2000. Over the past 200 years, the average distance traveled and the speed of travel have increased by 1,000% while incubation times of microorganisms have not changed. As a result, a person can be exposed to a foodborne illness in one country and expose others to the infection in a location thousands of miles from the original source of the infection (5). Depending on their destination, travelers are estimated to run a 20% to 50% risk of contracting a foodborne illness.

As international trade and travel increase, foodborne disease outbreaks of the same origin are more likely to occur in different parts of the globe. Food safety in the late 20th century represents a transnational challenge requiring enhanced levels of international cooperation in setting standards and regulations and in strengthening surveillance systems. Effective food safety programs, built on a clear understanding of the epidemiology of foodborne disease, must be developed and implemented. The globalization of the world's economy has been accompanied by intense economic competition and increased pressure on governments to downsize. Public sector austerity has reduced disease surveillance in many countries (6). For example, in Great Britain, the failure to maintain public health infrastructures has, in the words of the British Medical Association, resulted in "Britain returning to the 19th century in terms of public health, with problems such as dirty water, contaminated food, and old infectious diseases reemerging" (7). Failing a reversal of this trend, public health authorities and health services may be overwhelmed in the near future by outbreaks

or epidemics of foodborne diseases. The 1991 epidemic of cholera in Peru and the 1996 outbreak of *Escherichia coli* O157 in Japan demonstrate how one single foodborne disease epidemic or outbreak may disrupt the functioning of a health-care system.

Epidemiologic surveillance of foodborne illness is fundamental to the planning of food safety programs and the development of a strategy for prevention and control. There are different methods of surveillance: death registrations and hospital discharges; disease notification; laboratory-confirmed cases; sentinel surveillance; surveillance of investigated outbreaks; population-based surveillance; and case-control studies of sporadic cases (8). This article examines the role of foodborne disease surveillance programs, nationally and internationally, in the control and prevention of foodborne disease.

Foodborne Disease Awareness of Public Health Authorities

Data on the incidence of foodborne illnesses collected through notifications, laboratory confirmations, and sentinel or population-based studies can provide a measure of the magnitude of the foodborne disease problems, their economic consequences, and over the years, an indication of the trend. Although several weaknesses are associated with the collection of such data—particularly those collected through notification and laboratory confirmations (since they represent only the tip of the iceberg)—they can nevertheless be useful in raising the awareness of public health authorities about the importance of food safety.

Surveillance data collected in some industrialized countries confirm that foodborne diseases constitute one of the most widespread health problems and that they have increased over the last two or three decades (Figures 1-4). Part of the increase may be attributable to recent improvements in information reporting and collection systems, improved diagnoses, or greater publicity and concern about food safety in general. However, a real increase of foodborne disease incidence is not disputed. First, the increase has been steady and cannot be explained by a one-time improvement in the surveillance system. Second, increases have been observed in different countries, including those with no improvement in reporting and surveillance

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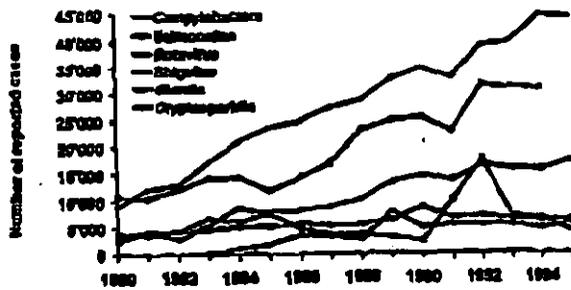


Figure 1. Laboratory reports of gastrointestinal infections in England and Wales.

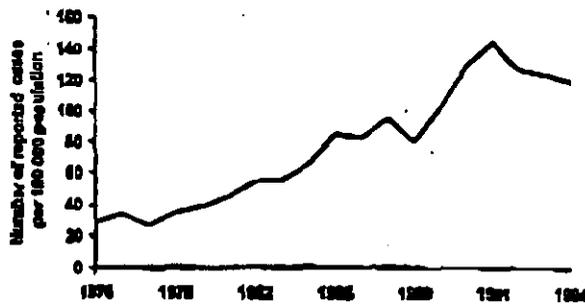


Figure 2. Incidence of foodborne diseases in Venezuela.

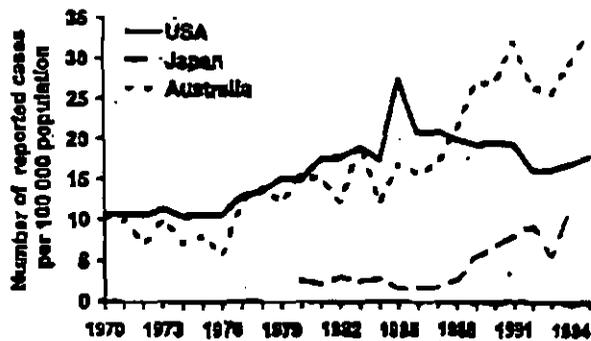


Figure 3. Incidence of salmonellosis in the United States, Japan, and Australia.

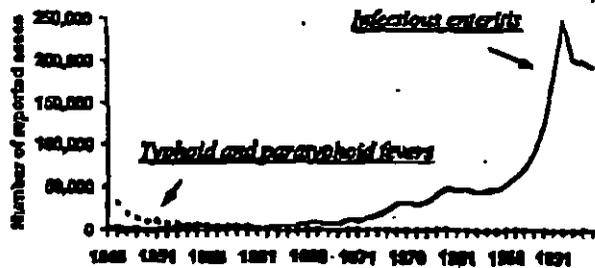


Figure 4. Incidence of infectious enteritis and typhoid and paratyphoid fevers in Germany.

programs. The general increase, as demonstrated by the results of surveillance data, has led many public health authorities to take stringent regulatory and educational measures to improve food safety, with some successful results (9). For instance, in the United States, active surveillance of foodborne listeriosis has led to concerted efforts by industry and government to prevent the disease. As a consequence, the number of cases and deaths has decreased by 44% and 48%, respectively (10).

Public health authorities must be aware of the magnitude and trend of foodborne illness so that necessary resources can be mobilized to improve food safety programs. Lack of reliable epidemiologic data in many parts of the world has impeded the recognition of the public health importance of food safety and consequently the emphasis on food safety programs.

Early Detection Of Foodborne Disease Outbreaks

Surveillance of foodborne diseases plays an important role in the early detection of foodborne disease outbreaks and their control. Early identification of the source of the outbreak is becoming increasingly important as countries move towards industrialization. Increased mass production means outbreaks can change from being small and confined to a family to large, affecting hundreds or even thousands of people (Table).

Rapid investigation of foodborne disease outbreaks is crucial to prevent them from taking on massive proportions. In the 1993 French outbreak of listeriosis due to potted minced pork (affecting 39 persons and causing eight miscarriages and one death), public health authorities traced its source within 1 week and thus prevented the outbreak from spreading by

Table. Examples of large foodborne disease outbreaks

Country	Year	Disease	No. cases
United Kingdom	1986	Salmonellosis	1,000
United States	1985	Salmonellosis	>168,000
United States	1998	Salmonellosis	224,000
China	1988	Hepatitis A	>310,000
Germany	1993	Salmonellosis	1,000
Australia	1991	Norwalk-like agent	>3,050
United States	1992-93	E. coli O157 infection	>500
Japan	1996	E. coli O157 infection	>8,000

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removing the implicated food product from the market and informing the group at risk about its unsafe nature (11). In an outbreak of botulism in the United Kingdom traced to hazelnut yogurt, the source was identified within 9 days, and the product was withdrawn from the market (12).

Because of global food distribution and worldwide travel, an international exchange of information on foodborne disease incidences and outbreaks and the foods involved is extremely important to identify international clusters originating from a common source. For instance, Salm-Net, a network for the international surveillance of human salmonellosis, has demonstrated the value of such an interactive international collaboration. Individual countries with apparently isolated outbreaks can feed their information into the network and ascertain whether the outbreak is confined to their country or is of wider international importance. The identification and investigation of several international outbreaks have been simplified by the Salm-Net network (13).

Food, the Transmission of Diseases, and the Identification of Associated Risk Factors

Information collected through investigation of foodborne disease outbreaks or case-control studies of sporadic cases provides a better understanding of the role of food in the transmission of communicable diseases and in the identification of risk factors leading to disease. Epidemiologic data from foodborne disease surveillance can provide public health authorities with important information about the types of food implicated in outbreaks; populations at risk; practices that lead to contamination, growth, and survival of foodborne pathogens; and places where foods are often mishandled. Such data are essential for designing effective intervention programs. Such programs in industrialized countries, for example, have demonstrated the relatively greater prevalence and incidence of foodborne diseases of microbial origin over those of chemical origin and the role of food handlers in the transmission of diseases; they have identified campylobacteriosis and salmonellosis (particularly infections caused by *Salmonella enteritidis*) as the leading foodborne diseases. The emergence of other diseases, such as infections due to *E. coli* O157 and *Listeria monocytogenes*—often with serious sequelae—

has been pinpointed as a major public health problem. These surveillance programs have also alerted public health authorities to the foods most often implicated and the major risk factors in food preparation.

Because of the lack of epidemiologic data, the role of food in the transmission of diseases has been poorly acknowledged, particularly in developing countries. Diarrheal diseases in infants and children and diseases such as shigellosis and cholera have been perceived as being water-borne for many years. For instance, after the cholera epidemic in Peru (where epidemiologic investigations implicated, among other foods, seafood, and an embargo was placed on trade in foodstuffs), the role that food plays in the transmission of the disease began to be fully recognized.

Increased trade in food, international travel and migration, and economic and technologic development have changed dietary habits. New foods, food preparations, and dietary habits are introduced into different regions, and as a consequence, foodborne diseases are emerging or reemerging. Dietary habits are also changing as a result of nutritional recommendations and campaigns or may be influenced by food policy, production systems, or environmental changes that lead to increased access to certain foods. These changes in dietary habits influence the epidemiology of foodborne illnesses and contribute to the emergence of foodborne diseases. In the United States, public information campaigns promote an increased consumption of fruits and vegetables. To meet the increased demand, these products have to be imported on a seasonal basis. At certain times of the year, more than 75% of the fresh fruits and vegetables available in grocery stores and restaurants are imported (14). Epidemiologic data have shown that, partly as a consequence of the increased consumption of fruits and vegetables, the proportion of foodborne disease outbreaks has doubled (15).

Data collected through foodborne disease surveillance programs permit the monitoring of changes in the epidemiology of foodborne diseases and the identification of new pathogens and new dietary or food preparation habits that may present a health risk. The data can also determine if existing programs need to be readjusted to ensure that the food safety program is adequate and relevant.

A method used in recent years to complement

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epidemiologic data in identifying risky practices and behavior is the Hazard Analysis and Critical Control Points system (HACCP). Application of HACCP to food preparation permits the identification of practices that may be potentially hazardous and need to be modified or those that are critical for ensuring the safety of foods and require specific monitoring. However, the first principle of HACCP—to conduct a hazard analysis—calls for epidemiologic data on foodborne diseases, as the process involves an appraisal of the possibility of hazards and the severity of their effects; the qualitative and quantitative evaluation of the presence of hazards; the survival and multiplication of microorganisms of concern; the production or persistence of toxins, chemicals, or physical agents in foods; and, conditions leading to the above.

As demonstrated in the decision tree for hazard analysis (Figure 5) (16), access to information would be difficult without epidemiologic surveillance of foodborne diseases. Simi-

larly, epidemiologic data are also needed to develop sampling plans of food, as demonstrated in the decision tree for *Listeria monocytogenes* sampling plans of foods (Figure 6) (17).

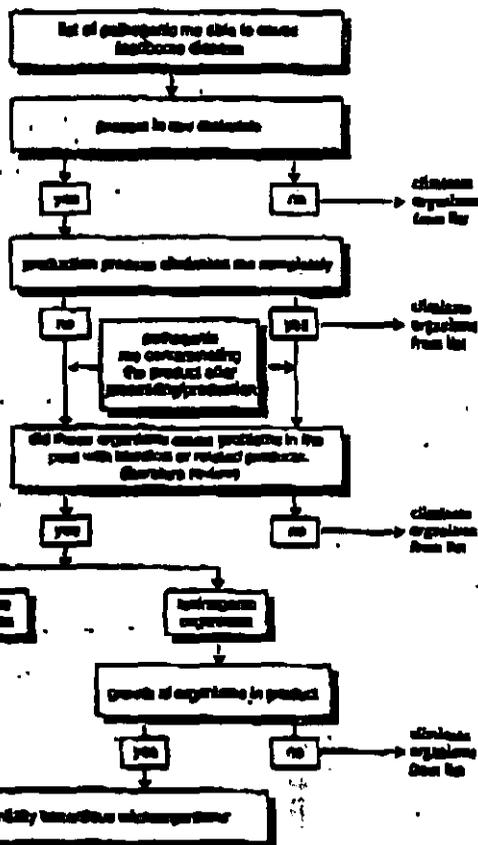


Figure 5. Hazard identification: identification of potentially hazardous microorganisms (16).

Listeria monocytogenes sampling plans of foods (which did not receive an in-pack listericidal treatment) when no HACCP data are available

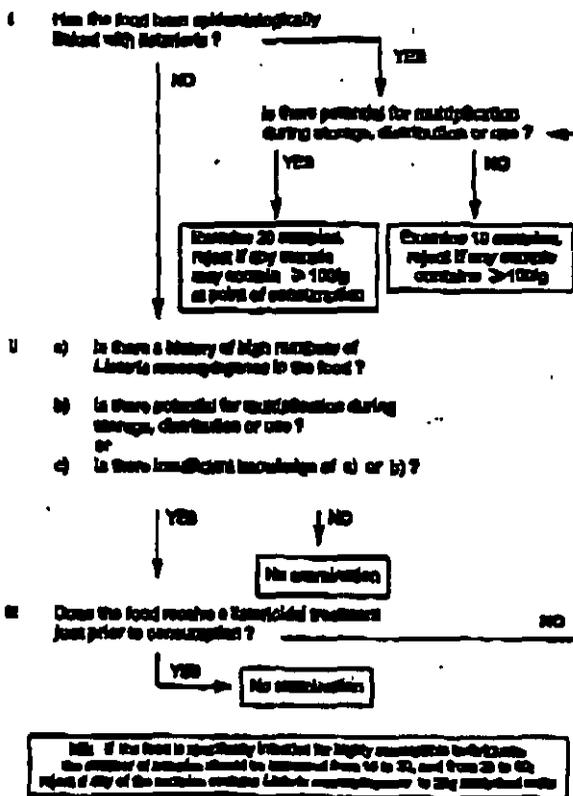


Figure 6. *Listeria monocytogenes* sampling plans of foods that did not receive an in-pack listericidal treatment (17).

Planning and Evaluating the Effectiveness of Food Safety Programs

The collection of epidemiologic data is important in planning interventions and setting priorities. Countries with scarce resources, facing an abundant number of foodborne diseases and food safety problems, need to prioritize food safety issues. Epidemiologic data provide a basis for identifying foodborne diseases, groups at risk, or even priority points in the food chain.

Evaluating the effectiveness and impact of an

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intervention is an important element of any plan. Data collected through disease notification or sentinel studies permit an evaluation of the effectiveness of interventions and their impact on health, and if necessary, the adjustment of a program to improve its efficacy and impact. Data on the rising incidence of foodborne illnesses in many countries demonstrate that present prevention strategies, mainly based on regulatory measures, are inadequate and emphasize the need for additional measures (e.g., additional regulatory initiatives and health education about food safety).

Risk Assessment and International Food Standards

The movement of ever-increasing quantities of food across borders has resulted in a transnationalization of disease risk (18). Therefore, the globalization of food trade and the open access to foreign markets need to be accompanied by effective means of health protection for populations. In the food sector, international regulatory instruments need to be integrated with strengthened surveillance and monitoring.

As a result of the Uruguay Round of Multilateral Trade Negotiations and the increased liberalization of trade facilitated by this agreement, concern about the safety of imported food has grown. However, provisions in the Agreement on the Application of Sanitary and Phytosanitary Measures, which entered into force with the establishment of the World Trade Organization on January 1 1995, are designed to address these concerns: according to the work of the Codex Alimentarius Commission, its standards, guidelines, and recommendations, are recognized as the reference for national food safety requirements. Countries that are members of the World Trade Organization may no longer be able to reject foods that meet Codex standards, guidelines, and recommendations without providing justification.

Moreover, the increased volume of the global food trade underscores the need for sound epidemiologic information and international risk assessment. In this regard, Article 5 of the Sanitary and Phytosanitary Measures agreement explicitly requires World Trade Organization members to conduct scientific and consistent risk assessments. Furthermore, the World Health Organization has recommended that the application of the HACCP system at every stage

of the food chain represents an effective approach for governments to meet the terms outlined in the agreement (19).

Another issue receiving more attention from regulatory agencies and underlined during the Food and Agriculture Organization/World Health Organization Conference on Food Standards, Chemicals in Food, and Food Trade (1991), is the scientific basis of the Codex standards. The Conference recommended that the Codex, in its norm-setting work on health and safety, place greater emphasis on risk assessment (20). Epidemiologic data on foodborne diseases have an important role in risk assessment. One example is assessing the risk of contracting listeriosis associated with different levels of *Listeria monocytogenes* in smoked fish and meat products (11). However, the need for risk assessment as the basis for setting standards has shown a great gap in knowledge about foodborne pathogens and their relation to human illness (21-23). To address the national/transnational risks caused by foodborne diseases, this gap must be narrowed.

Risk Assessment Approach

Risk assessment is defined as a scientifically based process that has the following steps: 1) Hazard Identification—The identification of biologic, chemical, and physical agents present in a particular food or group of foods that can cause illness. 2) Hazard characterization—The qualitative or quantitative evaluation of the nature of the illness associated with biologic, chemical, and physical agents that may be present in food. For chemical agents, a dose-response assessment should be performed. For biologic or physical agents, a dose-response assessment should be performed if the data are obtainable. 3) Exposure assessment—The qualitative or quantitative evaluation of the likely intake of biologic, chemical, and physical agents in food as well as exposures from other sources. 4) Risk characterization—The qualitative or quantitative estimation, including uncertainties, of the probability of and severity of known or potential illness in a given population on the basis of hazard identification, hazard characterization, and exposure assessment.

In many cases, data are not available to support a quantitative risk assessment of biologic hazards. We discuss next the types of challenges that make quantitative risk assessment difficult

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for pathogenic organisms associated with food and the role of epidemiologic surveillance.

Hazard Identification

Because only some foodborne disease outbreaks are adequately investigated and have the etiologic agents identified, many foodborne pathogens remain unidentified. Most of the available epidemiologic data are furnished by industrialized countries, while the situation in developing countries is largely unknown. The epidemiologic database must be extended to include information from developing countries. However, investigation and surveillance systems in developing countries need to be strengthened before the database can expand.

Hazard Characterization

For many foodborne pathogens, dose-response data are limited or nonexistent. Information on which dose-response estimates can be based is difficult to obtain and may be inaccurate for various reasons: host susceptibility to pathogens is highly variable, attack rates from a specific pathogen may vary widely, virulence of a pathogenic species is highly variable, pathogenicity is subject to genetic variation resulting from frequent mutation, antagonism from other bacteria in foods or the digestive system may influence pathogenicity, and foods may modulate the ability of bacteria to infect or otherwise affect the host.

Exposure Assessment

An exposure assessment will give an estimate of either the number of pathogenic organisms or the level of toxins consumed in food. Although the levels of chemical agents in food may change only slightly due to processing, the population of bacterial agents is dynamic and may increase or decrease dramatically. Changes in populations of bacteria are affected by complex interactions of these factors: ecology of the bacterial pathogen; processing, packaging, and storing of food; preparation steps, such as cooking, which may inactivate bacterial agents; and cultural factors relating to consumers.

In addition, for some of the emerging foodborne pathogens, the sources of exposure are still not fully understood. Information on foodborne disease outbreaks provides an opportunity to learn about the types of foods that may harbor the pathogen.

Risk Characterization

Characterizing the risk associated with biologic pathogens depends on information gained in the previous steps. Risk characterization will result in a qualitative or quantitative estimate of the potential for adverse effects from a particular pathogen on a specific population. Whether a quantitative risk assessment approach is possible and appropriate for characterization of risks associated with foodborne pathogens is not known. Thus, the qualitative approach to characterizing risk may be the only alternative.

International Travel

International travel and migration are contributing factors in the spread of foodborne diseases in some countries. For instance, 80% to 90% of the incidence of salmonellosis in Scandinavian countries is attributed to international travel. Surveillance of travel-related foodborne diseases provides a mechanism for appreciating the relative prevalence of foodborne diseases in various countries. It also provides a basis for informing physicians and health services about unfamiliar diseases contracted by travelers returning from distant places. In this way, advice on precautionary measures can also be given to travelers. The only foodborne disease now covered by the International Health Regulations is cholera, which is reported to the World Health Organization. Since the purpose of these regulations is to help provide maximum security against the international spread of diseases with a minimum of interference with world traffic (i.e., trade and travel) (24), it is timely to consider whether the regulations should cover additional foodborne diseases.

Conclusion

The globalization of the risks associated with foodborne illness, specifically increased international travel and trade in food, has resulted in greater interdependence in terms of food safety. Therefore, internationally agreed upon food safety standards and other types of agreements are becoming increasingly important in addressing the complex transnational challenge of foodborne disease control. Epidemiologic data provide a common ground for reaching international consensus on food safety issues.

As Morris Potter has said, "If one recognizes

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that ensuring food safety is inherently uncertain, foodborne illnesses become opportunities to learn rather than failures to predict. Foodborne disease will occur, and we must be prepared to react quickly to reduce the risk of new foodborne hazards" (26).

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GAO

United States General Accounting Office

Report to the Chairman, Human Resources and Intergovernmental Relations Subcommittee, Committee on Government Operations, House of Representatives

September 1994

FOOD SAFETY

Changes Needed to Minimize Unsafe Chemicals in Food



Appendix V
Comments From the Food and Drug
Administration

Recommendation

In addition, we believe that the Congress should consider the feasibility of requiring that all food eligible for import to the United States--not just meat and poultry--be produced under equivalent food safety systems.

FDA Comment

While this is a recommendation to the Congress that does not require FDA comment or concurrence, we would like to point out that it would be virtually impossible to impose on other countries. Field-grown crops such as fruits and vegetables present totally different challenges from slaughter operations, which generally are done at a central location that can be continuously inspected. Neither the U.S. nor any other country is likely to have the resources to monitor food production in the way that a slaughter operation can be monitored. Furthermore, the Congress has not imposed such a system upon the domestic producers. Insofar as FDA's requirements are concerned, imported products are required to meet the same safety standards that are required of domestic products.

Technical Comments

In addition to the above, FDA has the following technical comments:

1. Overall: The report commingles all substances under the general word, "chemicals." This needs to be corrected. It is confusing and often worded incorrectly with respect to at least some of the specific residues that may occur, i.e., pesticides, environmental contaminants, animal drugs, industrial chemicals, etc. All are treated differently by the specific statutes and therefore, must be treated differently by the agencies.
2. Page 2, line 8: Change to read, "...for and used in various aspects of food production."
3. Page 2, line 9 and throughout the report: Technically, the term "residues" refers to residual chemicals present after intentional application, e.g., pesticides and drugs. Environmental contaminants are not "residues", but should be called "food borne chemical contaminants." This is more than a technicality. The residues and chemical contaminants are specifically treated differently under the statutes in recognition that some are preventable and others are not. This very important distinction is lost throughout the report.

*
comment 4.
comment 2.
comment 5.
comment 6.

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Appendix V
Comments From the Food and Drug
Administration

See comment 6.

Now on p. 2.
See comment 7.

Now on p. 2.
See comment 8.

See comment 9.

Now on p. 3.
See comment 10.

See comment 10.

Now on p. 4.

See comment 11.

Now on p. 4.
See comment 12.

4. Page 2, line 25: Change to read, "...considered illegal only..."
5. Page 3, line 14: The Environmental Protection Agency does not monitor foods for "residues" of any kind. Please delete them from the list.
6. Page 3, line 36: The statement as written is true for drugs, pesticides, and food additives. It is not true for environmental contaminants or industrial chemicals.
7. Page 3, lines 49 through 51: If we correctly read the intent of this statement, it is speculative and not substantiated by the rest of the report. Is there documentation to support this contention? If so, it should be cited in the report. Another reading of the sentence could be that the existence of risks from chemicals in food is questionable? Is this the intended meaning? Perhaps the appropriate term is "unacceptable risk".
8. Page 4, lines 88-92: It should be noted that some, if not most, of the industrial chemicals have a very small (even vanishingly small) potential for entering the food supply.
9. Page 4, lines 97-98: No system will ever be able to guarantee that it can "...detect and prevent all contaminated food products from entering the food supply..." It should be noted that the food producers have the primary responsibility for producing safe food. The Federal programs act as checks to determine whether the producers are meeting their obligations and to impose corrective action when necessary.
10. Page 5, lines 108-110: The report should acknowledge that FDA has led the effort to institute the HACCP program in food-producing operations. Some such programs have been in place for quite some time, and others are being initiated, e.g., seafood HACCP and possibly all food products.
11. Page 5, lines 130-131: Item (?) is not true with respect to FDA's pesticide residue monitoring program. The statement should be qualified to indicate specifically which import programs are being indicted.
12. Page 10, second paragraph: This paragraph needs to be re-written. As we state above, pesticides, animal drugs, and food additives, by definition in the governing statutes, are not correctly categorized as chemical contaminants. Only chemicals that are not intentionally added to foods are called "chemical contaminants." Over tolerance residues of pesticides or animal drugs are technically called as "illegal" or "non-permitted." The second sentence of the

4

*curr pro-food safety -
- fruits & veg*

Date: 9/23/97

FAX



Health Division



Office of Management and Budget
Executive Office of the President
Washington, D.C. 20503

To: *Elena Kagan*
Fax: *62878*
Phone:

From: *Jim ESQUEA*

Number of Pages (not including cover): *2*

Subject: *Attached are some general descriptions of the
FDA food safety proposal & possible ways to fund
them. We are still working on getting numbers
that would reflect current authority activities.*

Please call if there are any problems with this transmission:

Health Division (Front Office)	202/395-4922
Health & Human Services Unit	202/395-4925
Health Programs & Services Branch	202/395-4926
Health Financing Branch	202/395-4930

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if you have any
questions.*

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Health Division (Front Office)	202/395-3910
Health Division (Room 7001)	202/395-7840

Jim Esquea

54371

Proposals For Budget Offset Mechanisms

Option 1. Reprogramming Within FDA Appropriations

- **FDA can reallocate funds within their total FDA budget appropriations to fund this program. No offset will be needed for this, but it is unlikely Congressional appropriators will grant such a reauthorization.**

Option 2. Budget Amendment for FY 1998

- **The Administration can send up a budget amendment for FY 1998 requesting additional funds for this initiative. An offset would need to be provided.**

Option 3. Budget Supplement for FY 1997

- **The Administration can send up a budget supplement request for FY 1997 to fund this initiative now. An offset would be required.**

FDA Food Safety Proposals

Proposal for Fresh Fruit & Vegetable HACCP

- The FDA proposal will require the development of new regulations regarding good agricultural and manufacturing practices guidance for fresh fruits and vegetables. These regulations would ultimately lead to the development of mandatory Hazard Analysis Critical Control Points procedures for fresh fruits and vegetables.

Authority: Current Rulemaking Process

Proposal for Improved Import Food Inspections

- The FDA proposal would require that no food be imported into the U.S. unless it is produced under a food safety system ensuring the same level of protection as provided by the U.S. system. This proposal would require the addition of 100 food import inspectors. These inspectors would visit/inspect foreign food plants.
- FDA currently has about five inspectors making foreign inspections.

Authority: This proposal would require authorizing legislation. Currently foreign food manufacturers allow FDA to inspect their operations only on a voluntary basis.

Food Safety Initiative FDA Proposal for Resources			
	FY 1998	FY 1999	TOTAL
TOTAL, Inspections & Research	15.7	12.3	28
FTEs	128	98	222

conspro - food safety - fruits + vegs

FDA inspects 2-3% of imports

.02% inspect on microbial levels - sample/labouring

Have auth to look at it all; don't have any resources.

Domestic produce - inspect plants (on average - once every 5-7 yrs for
inputs we look at when it appears at border.
even less - most done on processed foods.

Wolke

NYT: ^① meat + poultry need equiv syst overseas.

plant has to look same -

country has to have equiv syst of inspection
we send inspectors to make sure they
have equiv systs - ref. scheme.

additional checks on
similar that approach
products entering into
to respective country.

* Equivalency approach -
could req equiv fd safety systs

- sanitation
- water used for treatment
- who health
- privies etc.

some of this set by
states for domestic
raw produce

have to establish national standards
for domestic
farms to do this
very politically sensitive

Raw fruits + vegs
Frozen stuff
Milk + cheese

Harris systems - new on meat/poultry and sea food.

Voluntary approach - incentives - seals of approval

just starting fruit juices.
will take decades to get whole
thing here.

* seals of approval - incentive program.

where have national standards? (p 1, 2, 6)

Records access authority.

P. asks FDA to speed up HARIP on fruits + vege.

- purity of water
- presence of feces

for products in this country too

→ Start writing NPRM

establish program that can then be enhanced over time

USDA - work w/ producers to meet

HARIP guidelines

- research that will enable ag. practices ~~and~~ coordinated w/ FDA

← foreign ed. actions gen w/ FDA.

Rahim

What are they doing?
Who does it impact?
What does it mean?

✓ 301-P27-3370 - FDA - Bill Schultz
~~6018~~ ~~Tony Plante~~
256

2+ for Central High issues

DC vaccines
vacc testing
MDS
AZT testing
need safety - Human Foods
wellfare

✓ Jim O'Hara 610-7677
Cunice W. 219-6611

Hasap system -

Haz Analysis. Critical Control Point
control point in process going
to safety of products
points ~~to~~ where risk. to human
health risk.

Identify these steps; put in place
a syst of controls to ensure
that no such health risks
enter into process.

Need to assign
HACCP plans - Buy
analytical
monitoring

need resources
to implement
HACCP

also intercept &
some products as
burden.

~~For inspection~~

Plans has to keep detailed
records in rel to these
control points.

Focus on prevention

Not cop-on-heat inspection →

preventive system - make sure controls
are in place

hold other countries responsible

Clus pro -
food safety -
fruits + vege

Initiative to Improve the Safety of Imported and Domestic Fruits and Vegetables

Today President Clinton announced an initiative to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States, as well as to upgrade our own domestic standards. The President stated that he will ask Congress to enact legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, and other food products produced in countries that do not meet U.S. food safety requirements. The President also directed the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) to work cooperatively with the agricultural community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

Enhanced FDA Oversight for Imported Foods. The President announced that he will send legislation to Congress that will require the FDA to halt imports of fruits, vegetables, and other food products from any foreign country with food safety systems and standards that are not on par with those of the United States. The legislation also will require the FDA to halt imports from countries or facilities that do not allow FDA inspections to occur. This legislation -- comparable to existing law that requires the USDA to halt the importation of meat and poultry from such countries -- will enable the FDA to prevent the importation of potentially unsafe foreign produce. The President also committed to providing the necessary funds in his Fiscal Year 1999 budget to enable the FDA to expand dramatically its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to make effective use of its new authority.

Development of Guidance on Good Agricultural and Manufacturing Practices. The President directed the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and close cooperation with the agricultural community, to develop guidance on good agricultural practices and good manufacturing practices within one year. This guidance will take into account differences in both crops and regions and will address potential food safety problems throughout the food production and distribution system such as sanitation, worker health, and water quality. The guidance -- the first-ever specific safety standards for fruits and vegetables -- will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, the President also directed the FDA and USDA to develop coordinated outreach and educational activities.

Improvement of Monitoring and Inspection Activities Abroad. In addition to committing to substantial additional resources to expand the FDA's international food inspection force, the President directed the Secretaries of Health and Human Services and Agriculture to report within 90 days with a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve these practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock and border. The President urged consideration of ways to target inspection and testing toward those areas where problems are most likely to occur.

A Record of Improving Food Safety. The President's announcement builds on a strong record of food safety initiatives ensuring that Americans eat the safest food possible. The Administration has put into place improved safety standards for meat, poultry, and seafood products, and has begun the process of developing enhanced safety standards for fruit and vegetable juices. The Administration also has expanded research, education, and surveillance activities throughout the food safety system.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE
WASHINGTON, D.C. 20508

September 30, 1997

cons pro -
food safety -
fruits & vegs

MEMORANDUM FOR ELENA KAGAN

FROM: Peter Scher

SUBJECT: Food Safety Initiative

As you know, USTR cleared on the draft legislative proposal that would give FDA additional authorities. However, we have received draft copies of Q&A's and talking points on the initiative (dated September 29, 1997) that we understand will be used later this week as part of the roll-out plan on this initiative. We are concerned that some statements in these documents may signal that we are going to take actions in violation of our international obligations by immediately halting imported foods. In order to alleviate any concerns, and to signal that we will implement this initiative in accordance with our international rights and obligations, we suggest the following language changes to the text:

Q&A on the Safety of Imported Food, September 29, 1997

A. "No. Food on U.S. grocery shelves...to make it even safer." Please consider also adding at the end of this paragraph: "Available FDA data do not indicate a greater risk of food borne illness from imported produce when compared to domestic produce."

"As we reported last week, the President will be sending legislation to Congress that will go a long way to filling the remaining gaps in our food safety system. The legislation will include authority to ensure that imported fruits, vegetables, and other food remains on par with U.S. food safety requirements. The President will also provide the necessary funds in the FY99 budget to enable FDA to expand dramatically its international inspection capabilities so that it can make good use of this new authority."

Talking Points on Initiative to Ensure the Safety of Imported Fruits and Vegetables

First bullet: "The President will announce next week a major initiative to ensure the safety of fruits and vegetables consumed by the American public, including those coming from foreign countries."

Third bullet: "Secondly, the President will propose legislation to give the FDA authority to restrict any food imports that do not meet U.S. food safety requirements. The USDA already has this authority for meat and poultry products. This legislation will give the FDA the same

456-
2530

authority over fruits, vegetables and other food products, to ensure that all food consumed in the U.S. meets the same high standards.

Fourth bullet: "Third, the President will call for an increase in FDA funding in FY99 to allow the FDA to expand dramatically its domestic and international inspection capabilities." The budget request will enable the FDA to deploy inspectors, when appropriate, in foreign countries which export fruits and vegetables to the U.S.

Food Safety Q&A

Q. Are foreign fruits and vegetables less safe than domestic foods?

A. Available FDA data do not indicate a greater risk of food borne illness from imported produce when compared to domestic produce. The President's initiative is designed to take the extra step to ensure that all produce marketed in the U.S. -- both domestic and imported -- meets our high food safety requirements.

I'll be out of the office this afternoon. If you or your staff have any questions about this, please contact John Ellis at 395-9476 or Audrae Erickson at 395-9560.

Country of Origin Labeling

On the issue of country-of-origin labeling, USTR and USDA staff will be meeting with Senator Daschle's staff at 3:00 today to discuss this issue.

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fruits + vgs



Jerold R. Mande

09/30/97 04:36:09 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Thomas L. Freedman/OPD/EOP, Mary L. Smith/OPD/EOP

Subject: Food safety.

Here is what I've learned about the lines of attack trade foes are likely to try:

1. Requiring foreign countries have "equivalent" systems rather than the same systems. One way we could bypass this debate is by insisting upon the same safety standard.
2. The guidance we are directing the Secretaries to issue will be voluntary when it should be mandatory.
3. We should be calling for country-of-origin labeling.
4. Fast-track has language that specifically forbids inclusion of food-safety and environment standards for the next 8 years.

720-3801

862-0345

ens pro / food safety /
fruits & vefs

235 FDA inspectors

International inspectors - fewer
Min 5

At-look 235

Proposal - 40-10
cranes

atlock

38% of fruit consumed in US
is imp

~~20%~~ 20% of veg.

Carol Foreman / Safe Food Coalition
202-822-8060

Caroline Smith-Dewaal
202-332-9110 x366
Center for Science in The Pub Int

Mark Silbergeld
Cornell Univ
202-462-6262

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fruits + vegg

Elena--

Per our discussion last night, our statute contains an affirmative requirement, not simply an authorization. I am attaching it FYI.

Second, Secretary Glickman is talking to the House Democratic Caucus lunch today about fast track. He and Secretary Herman are representing the Administration. Reps. Gephardt and Bonior are also talking.

Sec. Glickman is going to specifically include food safety in his talking points in addition to agriculture.

Eric

21 § 620

FOOD AND DRUGS

FOOD AND DRUGS

§ 620. Imports

(a) Adulteration or misbranding prohibition; compliance with inspection, building construction standards, and other provisions; humane methods of slaughter; treatment as domestic articles subject to this chapter and food, drug, and cosmetic provisions; marking and labeling; personal consumption exemption

No carcasses, parts of carcasses, meat or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines which are capable of use as human food, shall be imported into the United States if such articles are adulterated or misbranded and unless they comply with all the inspection, building construction standards, and all other provisions of this chapter and regulations issued thereunder applicable to such articles in commerce within the United States. No such carcasses, parts of carcasses, meat or meat food products shall be imported into the United States unless the livestock from which they were produced was slaughtered and handled in connection with slaughter in accordance with the Act of August 27, 1958 (72 Stat. 822; 7 U.S.C. 1901-1906). All such imported articles shall, upon entry into the United States, be deemed and treated as domestic articles subject to the other provisions of this chapter and the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 301 et seq.) Provided, That they shall be marked and labeled as required by such regulations for imported articles: Provided further, That nothing in this section shall apply to any individual who purchases meat or meat products outside the United States for his own consumption except that the total amount of such meat or meat products shall not exceed fifty pounds.

[See main volume for text of (b) to (d)]

e) Reports to Congress

Not later than March 1 of each year the Secretary shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a comprehensive and detailed written report with respect to the administration of this section during the immediately preceding calendar year. Such report shall include, but shall not be limited to the following:

(1)(A) A certification by the Secretary that foreign plants exporting carcasses or meat or meat products referred to in subsection (a) of this section have complied with requirements that achieve a level of sanitary protection equivalent to that achieved under United States requirements with regard to all inspection, building construction standards, and all other provisions of this chapter and regulations issued under this chapter.

(B) The Secretary may treat as equivalent to a United States requirement a requirement described in subparagraph (A) if the exporting country provides the Secretary with scientific evidence or other information, in accordance with risk assessment methodologies determined appropriate by the Secretary, to demonstrate that the requirement achieves the level of sanitary protection achieved under the United States requirement. For the purposes of this subsection, the term "sanitary protection" means protection to safeguard public health.

(C) The Secretary may—

(i) determine, on a scientific basis, that a requirement of an exporting country does not achieve the level of protection that the Secretary considers appropriate; and

(ii) provide the basis for the determination to the exporting country in writing on request.

(2) The names and locations of plants authorized or permitted to have imported into the United States therefrom carcasses or meat or meat products referred to in subsection (a) of this section.

(3) The number of inspectors employed by the Department of Agriculture in the calendar year concerned who were assigned to inspect plants referred to in paragraph (e)(2) hereof and the frequency with which each such plant was inspected by such inspectors.

(4) The number of inspectors, licensed by each country from which any imports subject to the provisions of this section were imported who were assigned, during the calendar year concerned, to inspect such imports and the facilities in which such imports were handled and the frequency and effectiveness of such inspections.

(5) The total volume of this subsection (a) of this calendar year concerning volume of each major volume and a detailed report appropriate standard

(6) The name of of meat articles from this section.

(f) Inspection and other

Notwithstanding any and meat food product capable of use as human subject to the inspection applied to products that do not meet such The Secretary shall inspections for such of testing of internal organs by the exporting country from United States shall country maintains a with the United States article shall be permit Secretary has not his certifications and a country involved is ensure compliance with consideration of any of any such certificate establishments to a meeting such United

(g) Administration order violation

The Secretary in goats, horses, mule antibiotic banned consumption. No equines into the U the Secretary.

(h) Reciprocal

(1) As used in:

(A) The cattle, sheep as human food

(B) The quality, species articles.

(2) On request Means of the H Forestry or the Secretary, the foreign country States that are be substantiated

(3) If the paragraph (2)

OPTIONAL FORM NO. 10 (7-84) FAX TRANSMITTAL From: [Handwritten Name] To: [Handwritten Name] Date: [Handwritten Date] 1998-101 GENERAL SERVICES ADMINISTRATION

AND DRUGS

FOOD AND DRUGS

21 § 620

(5) The total volume of carcasses or meat or meat products referred to in subsection (a) of this section which was imported into the United States during the calendar year concerned from each country, including a separate itemization of the volume of each major category of such imports from each country during such year, and a detailed report of rejections of plants and products because of failure to meet appropriate standards prescribed by this chapter.

(6) The name of each foreign country that applies standards for the importation of meat articles from the United States that are described in subsection (h)(3) of this section.

(d) Inspection and other standards; applicability, enforcement, etc.; certifications

Notwithstanding any other provision of law, all carcasses, parts of carcasses, meat, and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, capable of use as human food, offered for importation into the United States shall be subject to the inspection, sanitary, quality, species verification, and residue standards applied to products produced in the United States. Any such imported meat articles that do not meet such standards shall not be permitted entry into the United States.

The Secretary shall enforce this provision through (1) the imposition of random inspections for such species verification and for residues; and (2) random sampling and testing of internal organs and fat of the carcasses for residues at the point of slaughter by the exporting country in accordance with methods approved by the Secretary. Each foreign country from which such meat articles are offered for importation into the United States shall obtain a certification issued by the Secretary stating that the country maintains a program using reliable analytical methods to ensure compliance with the United States standards for residues in such meat articles. No such meat article shall be permitted entry into the United States from a country for which the Secretary has not issued such certification. The Secretary shall periodically review such certifications and shall revoke any certification if the Secretary determines that the country involved is not maintaining a program that uses reliable analytical methods to ensure compliance with United States standards for residues in such meat articles. The consideration of any application for a certification under this subsection and the review of any such certification, by the Secretary, shall include the inspection of individual establishments to ensure that the inspection program of the foreign country involved is meeting such United States standards.

(g) Administration of animal drugs or antibiotics; terms and conditions; entry order violations

The Secretary may prescribe terms and conditions under which cattle, sheep, swine, goats, horses, mules, and other equines that have been administered an animal drug or antibiotic banned for use in the United States may be imported for slaughter and human consumption. No person shall enter cattle, sheep, swine, goats, horses, mules, and other equines into the United States in violation of any order issued under this subsection by the Secretary.

(h) Reciprocal meat inspection requirement

(1) As used in this subsection:

(A) The term "meat articles" means carcasses, meat and meat food products of cattle, sheep, swine, goats, horses, mules, or other equines, that are capable of use as human food.

(B) The term "standards" means inspection, building construction, sanitary, quality, species verification, residues, and other standards that are applicable to meat articles.

(2) On request of the Committee on Agriculture or the Committee on Ways and Means of the House of Representatives or the Committee on Agriculture, Nutrition, and Forestry or the Committee on Finance of the Senate, or at the initiative of the Secretary, the Secretary shall, as soon as practicable, determine whether a particular foreign country applies standards for the importation of meat articles from the United States that are not related to public health concerns about end-product quality that can be substantiated by reliable analytical methods.

(3) If the Secretary determines that a foreign country applies standards described in paragraph (2)—

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option exemption

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CMS Pro - food safety - fruits + veps

204

(B) US plans new controls on fruit, vegetable imports, aide says

By Richard Cowan, Bridge News
Knight-Ridder/Tribune Business News

Washington--Sep 29--The Clinton administration is likely to soon unveil proposals for new federal controls on imported fruits and vegetables, the White House said today. The move would be in response to rising food safety concerns with imported foods and well-publicized outbreaks of illnesses linked to foreign-grown fruits and vegetables.

no lab

"Later this week we'll have some things to say" about new regulations on imported fruits and vegetables, as well as the handling of domestic products, White House Press Secretary Michael McCurry said today.

Fruit and vegetable imports have been on the rise in recent years, as have illnesses associated with eating imported strawberries, basil and other produce. End

Bridge News, Tel: (202) 383-6173

Send comments to Internet address: news@bridge.com

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Elena -

This clip raises the national treatment issue we have discussed. It ~~implies~~ ^{states} that we are going to impose regulations on imports. To do that, we must also impose regulations on domestic products, which we are not doing. It leaves us open to

criticisms that we are inflating what the initiative is U.S. vs U.S. imports, and suspicion domestically that we really do intend to impose regulations. We need to be careful. Plus, we don't have data that says imports are worse than domestic product.

which we heard on the 14/1

Eric

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Views on Draft 28M FDA Food Safety Proposal

1. Within the Total -- FDA believes that if they have to 'eat' any of the costs of this proposal in FY99, they don't want to do it at all. Per Food Center staff and Bob Byrd. **Our staff view --** Worth pressing back on, and helps argue for a smaller number/range in FY99.

2. 80 countries instantly. We are in no countries now. We have roughly 700 inspectors/investigators/analysts today, 500 of which focus on domestic producers and 200 of which focus on imports. 160 countries send us food. FDA believes there are 50-60 developing countries that send us problem food, and 30-40 developed countries that do -- for a total of 80-100 problem countries. HHS has not cross-checked which countries send us the foods that are among the 15 food groups most at risk, but will do so. **Our staff view --** start in FY99 with some number of countries, growing over two years to 50-55 countries (1/3 of the 160 total instead of the 1/2 that FDA proposes).] ← why?

3. Cost/FTE -- FDA fully-loaded the costs to 110,000, based on a FY99 estimate of salaries and benefits of 74K/person, and adding in overhead, rent, utilities, travel, etc. This is just a bit high, since some of those costs are fixed, not variable, so we shaved it to 100,000 per for the professionals. FDA agreed that some portion of the 'support' staff are clerical (they estimated 10%!), so we have reduced the per-FTE costs for support staff from 100,000 per to 90,000 per.

4. Professional/Support ratio: FDA said they used general rules of thumb for the ratios of investigators/scientists to support personnel, varying from 1.2 to 1.5:1. We assumed the professionals could ALL be supported by a uniform ratio of 1.5:1.

5. Total proposals:

	FDA	Alternative
1. FTE		
Professional	120	86
Support	86	58
total	206	144
2. \$	28.4M	17.7M

6. Bottom Line -- we suggest using a range of 10-15 in 99, with the program phasing in to something like our \$18 million figure in FY2000, since to actually start a program from scratch to go from 0 countries to 50-55 will be awfully ambitious.

Assumptions:	FTE - 110,000 1.2:1 ratio of prof/support staff 80 countries			AR FTE - 100,000 & 90,000 1.5:1 Prof/support ratio 50-55 countries			SAVINGS Under Alternative
	FTE	Cost per FDA	Cost	FTE	Cost per FDA	Cost	
1. Foreign eval.							
A. Evaluate 80 countries							
Investigators	80	110,000	6,600,000	40	100,000	4,000,000	
Support	40	110,000	4,400,000	27	90,000	2,430,000	
subtotal	<u>100</u>			<u>67</u>			
Travel			2,200,000			1,500,000	
SUBTOTAL, A			13,200,000			7,930,000	5,270,000
B. Guidance/QAPS							
FTE, including support	11	110,000	1,210,000	9	90,000	810,000	400,000
	7	110,000	770,000	6	90,000	540,000	230,000
C. Collection/analysis							
2 Investigators, 10 analyst	12	110,000	1,320,000	9	100,000	900,000	
10 support	10	110,000	1,100,000	6	90,000	540,000	
subtotal			<u>2,420,000</u>			<u>1,440,000</u>	980,000
D. Screening							
13 investigators	13	110,000	1,430,000	10	100,000	1,000,000	
10 support	10	110,000	1,100,000	7	90,000	630,000	
subtotal			<u>2,530,000</u>			<u>1,630,000</u>	900,000
2. Leg. Proposals							
10 investigators	10	110,000	1,100,000	8	100,000	800,000	
8 support	8	110,000	880,000	6	90,000	450,000	
subtotal			<u>1,980,000</u>			<u>1,250,000</u>	730,000
Travel			500,000			400,000	100,000
SUBTOTAL, 2			2,480,000			1,650,000	830,000
3. Tech development							
Scientists	14	110,000	1,540,000	10	110,000	1,100,000	
support	11	110,000	1,210,000	7	90,000	630,000	
subtotal			<u>2,750,000</u>			<u>1,730,000</u>	1,020,000
Contracts			3,000,000			2,000,000	1,000,000
SUBTOTAL, 3			5,750,000			3,730,000	2,020,000
TOTALS			28,360,000			17,730,000	10,630,000
Professional Staff	120			86			
Support	86			58			
subtotal	<u>206</u>			<u>144</u>			

countries
160 that export f+v.

to do inspect full country all - ~~USA~~

FDA -
150,000 per person 200 inspectors = 2.8m.
(inspect + support staff)

Comp -
74 in total -
scale occurs.

Supporting military ??

15m - hit every country once every 3 yrs -
10-15 m. - 1st yr.
(ramp up)
by 3rd yr at 18

could ramp up.

65-75,000
per inspector

75,000

× 200

15,000

All FDA - new 700 inspectors

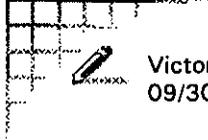
500 dom.

200 at border

2 internationally.

How does 200 compare to USDA?

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fruits + vegs



Victoria Radd
09/30/97 11:47:10 AM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:

Subject: Q&A on NAFTA & UR Impact on Imported Food -Forwarded

FYI from USTR.

V.

----- Forwarded by Victoria Radd/WHO/EOP on 09/30/97 11:44 AM -----



jziegler @ ustr.gov
09/30/97 10:52:00 AM

Record Type: Record

To: victoria radd

cc:

Subject: Q&A on NAFTA & UR Impact on Imported Food -Forwarded

The attached paper is interesting in underscoring two points: The increase in U.S. food imports is not related to recent trade agreements (UR or Nafta) but is driven by consumer demand; and while that growth has been substantial since 1993 (53%) this is a systems and resources issue as to inspections (exactly how the Administration is handling it), not a trade issue.

Is Sec. Glickman responding to the Gerth article? If so information in the attached should be included in the response letter. I'll be on the Hill for the next couple of hours, please reach Chris in my office if you need immediate information. Please advise. jz

Trade Liberalization and U.S. Imports of Fresh Fruits and Vegetables

Question: What impact have the NAFTA and Uruguay Round had on U.S. imports of fresh fruits and vegetables?

Answer: The NAFTA and Uruguay Round have had a negligible impact on U.S. imports of fresh fruits and vegetables. Prior to these agreements, U.S. import tariffs on fresh fruits and vegetables were relatively low. The United States market was open to imports, and the tariff reductions called for in NAFTA and the Uruguay Round were very small. Other factors such as currency fluctuations, weather conditions, and consumer demand in the United States account for nearly all of the rise in fresh fruit and vegetable imports.

For those few commodities where U.S. protection was high--imports of cantaloupe from Mexico were 25% prior to the NAFTA for example--long phase in periods for tariff reductions and the fact that we are just four years into NAFTA have meant that today's import protection remains relatively high.

In Secretary Glickman's report to the Congress on the *Effects of the NAFTA on Agriculture and the Rural Economy*, USDA concluded that:

- Although U.S. agricultural imports from the NAFTA partners grew from \$7.3 billion in 1993 to \$10.5 billion in 1996, U.S. agricultural imports from Mexico and Canada were only about 3 to 5 percent higher, respectively, in 1996 than they would have been without the agreement.
- For U.S. imports of winter vegetables, only a small increase in imports can be attributed directly to the NAFTA tariff changes. NAFTA tariff reductions on U.S. imports of winter tomatoes from Mexico have been very small, less than 1.5 percent on an ad valorem basis. The peso crisis in Mexico, technological shifts in tomato production, and unusual weather in Florida were far more important than the NAFTA tariff reductions.
- Because Mexico's tariffs on agricultural imports from the United States were much higher than U.S. tariffs on agricultural imports from Mexico, Mexican tariffs have been reduced substantially more than U.S. tariffs.

Background

U.S. total imports of fresh fruits and vegetables (excluding bananas) were \$2.95 billion in 1996, up 53 percent from the \$1.93 billion imported in 1993 (the year before NAFTA began).

ews pro -
food safety -
fruits & vegs

Congress of the United States

Washington, DC 20515

September 24, 1997

Chris Walker
legis effort
Tom -

The Honorable William Jefferson Clinton
1600 Pennsylvania Ave., N.W.
Washington, DC 20500

Could you please
send a response to
this? Emphasize
our initiative, of course
Thanks.

EJen

Dear Mr. President:

We urge you to give serious consideration to remedying the inadequate food safety provisions in the North American Free Trade Agreement (NAFTA). Because of your commitment to ensuring the safety of our nation's food supply, we expect that you will not agree to fast track authority that does not contain adequate food safety protections. Current fast track proposals do not address these concerns.

SEP 25 PM 5:35

In an effort to increase trade with Mexico, NAFTA limited border inspections of food and allowed Mexican trucks to enter the U.S. with limited inspection.

These lax inspection practices contributed to a sharp increase in food imports from Mexico: imports of Mexican fruit have increased 45%, and vegetable imports have risen 31%. More than 70% of these imports are carried into the U.S. on trucks. The General Accounting Office (GAO) recently found that 99% of Mexican trucks enter the U.S. without any inspection.

These provisions in NAFTA have resulted in imports of fruits and vegetables contaminated with diseases and unhealthy pesticides. We were alarmed earlier this year when 179 Michigan school children contracted hepatitis after eating tainted Mexican strawberries. In order to prevent similar incidents in the future, we urge you to take the following action:

- o Renegotiate the provisions in NAFTA that relate to border inspections and food safety, and ensure that any fast track authority include strong food safety protections.
- o Increase the funding for border inspections or, alternatively, limit the increasing rate of food imports to ensure the safety of our food supply.
- o Begin an aggressive program to label all food stuffs -- including fresh and frozen fruits, vegetables and meats -- with their country of origin.

We look forward to working with you on these vital public health issues.

Sincerely,

Paul Senek

Shirrod Brown

~~no (17-04)~~

Paul Blagovitch

Pat T. Mink

Robert Wexler

Paul H. Kanjir

John Sweeney

Maureen Donohue

Bob W. Dugan

J. Robert

Mike DeLo

Bill Pascregg

Paul D. By

Bill Smith

William J. Coyne

Bob Boudin

John

Errol Haller

Steve Rothman

Lawrence

Jay J. Costello

William G. Smith

Ted Strickland

Jack L. Lee

Frank Palmer, Jr.

Eric McKinn

Bobby Z. Clark

Robert W. Bell

Carl E. Gildea

Max F. Fox

George E. Brown, Jr.

Martin O. Pals

Eric L. Enger

H. Johnson

Maple Waters

Lisa V. Gutierrez

Wanda D. Dwyer

Tom Allen

William L. Watt

Julia Carson

John W. Oliver

Alan Smith

Jim McSweeney

Sammy Davis

Robert F. Kennedy

Mark Foley

John F. Trump

Henry R. Latta

Vic Fazio

Ellen DeLoach

Cass Miller

James L. Christy

John Longenecker

Matthew G. Martiney

Robert D. Muse

Pat Lerner

Ron Klatt

Thomas Casca

Q. Q. Q.

Marcy Kaptur

Paul E. Brown

Tom H. M. King

Bruce E. Veale

Pete at 7⁰⁰

William D. Delahunt

Paul E. King

Lynn S. Lewis

Paul Lander

Jim Davis

John J. Lerner

Pete Starb

Dennis Keenick

Henry A. W. W.

Sam Jeph

Jack Metcalf

Neil Abernethy

John Hendry

Carolyn M. Carley

Marty Mah

Ann V. Cochran

Jim Barcia

Tom A. Colman

Tom W. Johnson

Sammy L. Davis

Tom

Tom Lantos

Tom Kind

Congress of the United States
House of Representatives
Washington, DC 20515

September 23, 1997

SEP 25 PM 5:36

The Honorable Bill Clinton
The White House
Washington, D.C. 20500

Dear Mr. President:

We, the members of the Florida congressional delegation, are writing to express our problem in supporting the renewal of fast track authority.

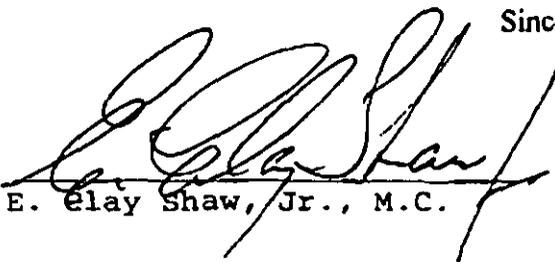
While we support free trade, we are hesitant to support fast track legislation in light of the fact that existing agreements regarding Florida fresh fruit and vegetable commodities have not been fully enforced. For example, in the recent past, tomatoes from Mexico were dumped in this country below cost in elevated surging quantities. And because current safeguards were not effective, Florida's tomato industry was severely damaged.

Furthermore, it is our understanding that not one Florida orange has been exported to Mexico since the passage of NAFTA. This situation demonstrates the inherent unfairness against Florida produce by the Mexican government.

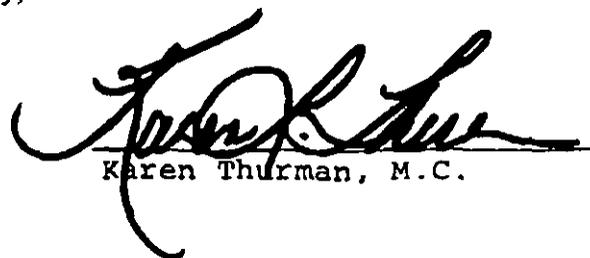
We understand that expanding free trade is crucial to continue growing America's economy. However, we are reluctant to support renewing fast track authority for agreements with other nations when promises made in the past to fairly treat Florida produce have gone largely unfulfilled. Therefore, we believe the existing foreign trade inequities concerning Florida agriculture should be addressed and resolved before fast track authority is renewed.

Thank you for your consideration of our views.

Sincerely,



E. Elay Shaw, Jr., M.C.



Karen Thurman, M.C.

The Honorable Bill Clinton -- Page 2

Carrie P. Meek

Carrie Meek, M.C.

Bill Young

C.W. "Bill" Young, M.C.

Bill McCollum

Bill McCollum, M.C.

Mike Bilirakis

Michael Bilirakis, M.C.

Porter Goss

Porter Goss, M.C.

Ileana Ros-Lehtinen

Ileana Ros-Lehtinen, M.C.

Tillie Fowler

Tillie Fowler, M.C.

Corrine Brown

Corrine Brown, M.C.

Mark Foley

Mark Foley, M.C.

Alcee Hastings

Alcee Hastings, M.C.

Peter Deutsch

Peter Deutsch, M.C.

John Mica

John Mica, M.C.

Charles Canady

Charles Canady, M.C.

Joe Scarborough

Joe Scarborough, M.C.

F. Allen Boyd, Jr.

F. Allen Boyd, Jr., M.C.

Robert Wexler

Robert Wexler, M.C.

David Weldon

David Weldon, M.C.

cons pro - food safety -
fruits/veg

THE WHITE HOUSE
WASHINGTON

October 1, 1997

FOOD SAFETY EVENT

DATE: October 2, 1997
LOCATION: Oval Office
BRIEFING TIME: 10:30 am - 11:00 am
EVENT TIME: 11:10 am - 11:30 am
FROM: Bruce Reed

I. PURPOSE

To launch an initiative to improve the safety of fruits and vegetables, especially those imported from foreign countries.

II. BACKGROUND

To demonstrate your commitment to food safety, you will be announcing a new food safety initiative, which was leaked to several papers last week. Your announcement of the initiative follows charges by some in Congress that Fast Track will endanger food safety by increasing imports of food products. It also follows publication of a recent article in the New York Times suggesting that the FDA is currently unable to ensure the safety of imported fruits and vegetables.

Your new initiative includes the following elements:

New Legislation to Enhance FDA Oversight for Imported Foods. To ensure that imported fruits and vegetables are as safe as those produced in the United States, you will be proposing legislation that requires the FDA to halt imports of fruits, vegetables, and other food products produced in countries that do not meet U.S. food safety standards. Existing law requires the USDA to halt imports of meat and poultry from such countries, but the FDA currently has neither the responsibility nor the authority to do so. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas.

To enable the FDA to make effective use of this proposed authority, you also will commit to providing the necessary funds in your FY 1999 budget to enable the FDA to expand dramatically its international food inspection force.

Executive Memorandum. You will sign an Executive Memorandum that directs the FDA

and the USDA to work cooperatively to issue guidance within one year for good agricultural and manufacturing practices for fruits and vegetables. To ensure that this first-ever safety guidance has the greatest effect, the FDA and USDA will develop outreach and educational activities.

In addition, you will direct the Secretaries of HHS and USDA to report back to you within 90 days with a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve these practices when necessary, and to prevent the importation of unsafe produce, including detecting unsafe food at the dock and border.

This initiative builds on your prior actions on food safety -- including a new early warning system to detect outbreaks of food borne illness as quickly as possible and enhanced safety standards for meat, poultry, and seafood products.

III. PARTICIPANTS

- The Vice President
- Secretary Shalala
- FDA Administrator Friedman
- Richard Rominger, USDA Deputy Secretary of USDA
- Cathie Woteki, USDA Under Secretary for Food Safety
- Carol Tucker Foreman, President, Safe Food Coalition
- Caroline Smith Dewaal, Center for Science in the Public Interest
- Nancy Donley, Safe Tables Our Priority
- Tom Stenzel, President, United Fresh Fruit and Vegetables Association
- C. Manley Molpus, President, Grocery Manufacturers Association
- Anita Brown, Trade Consultant, Western Growers Association

IV. PRESS PLAN

Pool Press.

V. SEQUENCE OF EVENTS

- The Vice President will make welcoming remarks and introduce you.
- You will make remarks at the podium and then sign the Executive Memorandum at your desk. You will then have the option of taking questions from the pool.

VI. REMARKS

Remarks provided by June Shih in Speechwriting.

Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables

Today President Clinton announced an initiative to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States, as well as to upgrade our own domestic standards. The President stated that he will ask Congress to enact legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, and other food products produced in countries that do not meet U.S. food safety requirements. The President also directed the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) to work cooperatively with the agricultural community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

Enhanced FDA Oversight for Imported Foods. The President announced that he will send legislation to Congress that will require the FDA to halt imports of fruits, vegetables, and other food products from any foreign country with food safety systems and standards that are not on par with those of the United States. The legislation also will require the FDA to halt imports from countries or facilities that do not allow FDA inspections to occur. This legislation -- comparable to existing law that requires the USDA to halt the importation of meat and poultry from such countries -- will enable the FDA to prevent the importation of potentially unsafe foreign produce. The President also committed to providing the necessary funds in his Fiscal Year 1999 budget to enable the FDA to expand dramatically its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to make effective use of its new authority.

Development of Guidance on Good Agricultural and Manufacturing Practices. The President directed the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and close cooperation with the agricultural community, to develop guidance on good agricultural practices and good manufacturing practices within one year. This guidance will take into account differences in both crops and regions and will address potential food safety problems throughout the food production and distribution system such as sanitation, worker health, and water quality. The guidance -- the first-ever specific safety standards for fruits and vegetables -- will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, the President also directed the FDA and USDA to develop coordinated outreach and educational activities.

Improvement of Monitoring and Inspection Activities Abroad. In addition to committing to substantial additional resources to expand the FDA's international food inspection force, the President directed the Secretaries of Health and Human Services and Agriculture to report within 90 days with a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve these practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock and border. The President urged consideration of ways to target inspection and testing toward those areas where problems are most likely to occur.

A Record of Improving Food Safety. The President's announcement builds on a strong record of food safety initiatives ensuring that Americans eat the safest food possible. The Administration has put into place improved safety standards for meat, poultry, and seafood products, and has begun the process of developing enhanced safety standards for fruit and vegetable juices. The Administration also has expanded research, education, and surveillance activities throughout the food safety system.

Clinton Administration Accomplishments In Improving Food Safety

- * October, 1997. President announces new initiative to enhance FDA oversight over imported foods and develop guidance on good agricultural and manufacturing practices for fruits and vegetables.
- * May, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply -- "Food Safety from Farm to Table" -- detailing a \$43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.
- * January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop food borne disease outbreaks quickly and to improve prevention systems further.
- * August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.
- * August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.
- * July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.
- * December, 1995. Administration issues new rules to ensure seafood safety. Utilizes HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.
- * 1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.
- * 1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

Q&A for Presidential Initiative to Improve the Safety of Imported Fruits and Vegetables
October 2, 1997

Q: What is the President proposing?

A: The President is proposing legislative and executive actions that will further improve the safety of fresh fruits and vegetables, especially those imported into the U.S. The legislation will require the FDA to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the U.S. The President will back up this legislation by providing the necessary funds in his FY99 budget to enable FDA to expand dramatically its international food inspection force so that it can make good use of this new authority.

In addition, the President has asked the Secretaries of Health and Human Services and Agriculture to take additional steps to improve the safety of both imported and domestic fruits and vegetables. Specifically, he has asked the Secretaries to issue within one year guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those, foreign and domestic, seeking to sell produce in the U.S. market.

Finally, the President has asked for a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve those practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border.

These efforts all build on the Clinton Administration's long-term commitment to strengthening our food safety system. With the help of the Vice-President's National Performance Review, we have fundamentally improved the way we ensure the safety of meat, poultry, and seafood. We have also put in place important new protections against the risks of pesticides in our food, especially for our children. And we are hopeful Congress will provide the \$43 million the President requested in his FY98 budget to improve food safety.

Q: Why is the President proposing these actions?

A: There have been dramatic changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round, increasing to as many as 50 in the summer. Today, no matter where you live in the United States, the chances are that there are 400 or more items in the produce section and they are there all year round. Last year, 38 percent of the fruit and 12 percent of the vegetables Americans ate were imported.

We have changed as well. Americans are eating more fresh fruits and vegetables than ever before, and our nation's health experts tell us we will live longer, better quality lives as a result. Our environment is also changing. We are finding "new" exotic bugs such as cyclospora and *E. coli O157:H7* on our food that once were not there.

We must ensure that these changes do not increase the risk to American consumers of foodborne illnesses. Although raw produce -- including that imported from foreign countries -- is now safe, experts have suggested ways to make further improvements, and the President's actions today accord with their recommendations.

Q: But aren't these actions just a response to the negative news articles of recent days that have pointed out the shortcomings in the inspection of imported produce?

A: No. We couldn't possibly have developed these initiatives following the publication of those articles. The Department of Health and Human Services have been laying the groundwork for this initiative for over a year. We knew that some reporters were making inquiries about this issue, and those inquiries may have accelerated the final part of the policy development process. But that process has been underway for some time, and this same initiative would have been announced with or without those articles.

Q: Why has the Administration waited until now to take these steps? [An article published today reveals that today's actions were suggested by Commissioner Kessler years ago, but that no action was taken. Why has it taken so long to act?]

A: No one can tackle everything at once, and the President's food safety initiatives have addressed priority items in the way best calculated to ensure their achievement. One of the first challenges the President faced after taking office was an outbreak of E. Coli in hamburger in the northwest. The President responded by putting in place a new system to ensure the safety of meat, poultry, and seafood products. With this process now underway, the FDA in 1995 began to investigate the problem of pathogens in fresh produce and develop proposed approaches for preventing foodborne illnesses from these food products.

Q: Are these actions meant to provide political cover with respect to the food safety issue because it has become a part of the Fast Track trade debate?

A: No. Again, the policy development process that led to this initiative began in 1995. This is a part of the President's food safety agenda -- his longstanding commitment to ensuring that Americans' food supply is the safest in the world. It does not relate to Fast Track.

Q: What makes you think this new legislation can be effective? Do you seriously think you are going to be able to put FDA inspectors in every country abroad?

A: Our proposed legislation would give the FDA the same kind of responsibility that the USDA already has for meat and poultry. The USDA system has worked very well to ensure that countries with inferior safety standards can't import their meat and poultry. We see no reason why the FDA can't run a similarly effective system that inspects food safety system and standards abroad and prevents imports from countries that do not provide the protections that the U.S. does.

Of course, making good use of this authority will take additional resources, so that FDA can dramatically expand its international food inspection force. Although the President will not announce a specific dollar figure until publication of his FY 99 budget, he has committed to investing the resources to ensure that FDA can make good use of this new authority.

Q: Doesn't this legislation impose trade barriers to food imports at a time when you are saying you want to lower them? Wouldn't we object if another country tried to keep out our food products on this basis?

A: This legislation is completely consistent with free trade principles and all our treaty obligations. We have no obligation to open our borders to imports that pose a greater risk than domestic products to American consumers. As long as we are not imposing any greater requirements on foreign countries -- as long as we are only holding them to our standards -- we are acting consistently with our trade policy.

There aren't many countries in the world with higher safety standards than the U.S., so not many countries would be in a position to halt our imports on this basis. If we did, we would not and could not object.

Q: Are you saying that imported produce is unsafe?

A: There is no data indicating that imported fruits and vegetables are more unsafe than domestic products. But some recent outbreaks of foodborne illness have been traced back to imports and it is important that foreign fruits and vegetables be held to the same safety standards as American products. The steps we are taking today are adding additional layers of protection. We are making sure that there are no gaps in our food safety system -- that high safety standards apply to imported as well as domestic food, and to fruits and vegetables as well as to meat, poultry, and seafood.

Q: Since HACCP has been successful for meat, poultry, and seafood, why don't you require HACCP for fresh fruits and vegetables? Why are you only doing good agricultural and manufacturing practices?

A: HACCP is a science-based approach for identifying and controlling hazards in food

production. We need better scientific data before we can develop HACCP for fresh fruits and vegetables. The Administration's plan is to develop and issue guidance that will help companies interpret existing safety requirements for fruits and vegetables, and that will lead to the science needed for HACCP. The agency is contemplating guidance on basic, common-sense sanitation and employee practices in the form of Good Agricultural Practices (GAPs) for farms and Good Manufacturing Practices (GMPs) applicable for those who sort, wash, and otherwise handle fresh fruits and vegetables.

Q: Aren't these guidelines only voluntary? If so, what effect will they have?

A: The Good Agricultural and Manufacturing Practices will be what is called "interpretive guidance." It will help companies interpret and follow existing, very broadly written safety requirements for fruits and vegetables by spelling out specific practices involving such matters as sanitation, worker health, and water quality. The guidance does not itself have legal force. But it tells growers, processors, and others what the FDA looks to when it enforces existing safety standards. There is no doubt that such guidance -- especially when it is developed, as it will be, in concert with the agricultural community -- will improve safety standards.

Q: Will foreign countries have to comply with Good Agricultural and manufacturing

WHITE HOUSE STAFFING MEMORANDUM

*cons pno/ food safety -
Fruits/vegs*

DATE: 10/1/97

ACTION/CONCURRENCE/COMMENT DUE BY: 10/2/97 8:00 AM

SUBJECT: Remarks on Food Safety

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input checked="" type="checkbox"/>	<input type="checkbox"/>	McCURRY	<input type="checkbox"/>	<input checked="" type="checkbox"/>
BOWLES	<input checked="" type="checkbox"/>	<input type="checkbox"/>	McGINTY	<input checked="" type="checkbox"/>	<input type="checkbox"/>
McLARTY	<input type="checkbox"/>	<input type="checkbox"/>	NASH	<input type="checkbox"/>	<input type="checkbox"/>
PODESTA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RADD	<input type="checkbox"/>	<input type="checkbox"/>
MATHEWS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	REED	<input checked="" type="checkbox"/>	<input type="checkbox"/>
RAINES	<input type="checkbox"/>	<input type="checkbox"/>	RUFF	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BLUMENTHAL	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SMITH	<input type="checkbox"/>	<input type="checkbox"/>
BERGER	<input type="checkbox"/>	<input type="checkbox"/>	SOSNIK	<input type="checkbox"/>	<input type="checkbox"/>
ECHAVESTE	<input type="checkbox"/>	<input type="checkbox"/>	SPERLING	<input type="checkbox"/>	<input type="checkbox"/>
EMANUEL	<input checked="" type="checkbox"/>	<input type="checkbox"/>	STREETT	<input type="checkbox"/>	<input type="checkbox"/>
GIBBONS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	TARULLO	<input checked="" type="checkbox"/>	<input type="checkbox"/>
HILLEY	<input checked="" type="checkbox"/>	<input type="checkbox"/>	VERVEER	<input type="checkbox"/>	<input type="checkbox"/>
IBARRA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	WALDMAN	<input checked="" type="checkbox"/>	<input type="checkbox"/>
KLAIN	<input type="checkbox"/>	<input type="checkbox"/>	YELLEN	<input type="checkbox"/>	<input type="checkbox"/>
LEWIS	<input checked="" type="checkbox"/>	<input type="checkbox"/>	BEGALA	<input checked="" type="checkbox"/>	<input type="checkbox"/>
LINDSEY	<input type="checkbox"/>	<input type="checkbox"/>	<u>Elena Kagana</u> → <input checked="" type="checkbox"/>		
MARSHALL	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>

REMARKS: Comments to June Shik (6-5640)

RESPONSE:

**PRESIDENT WILLIAM J. CLINTON
REMARKS ON FOOD SAFETY REGULATIONS
OVAL OFFICE
OCTOBER 2, 1997**

At the beginning of this century, our government made a fundamental promise to our people: We committed ourselves to making sure that the world's most bountiful food supply would always be the world's safest. And from the day I took office five years ago, I have worked very hard not only to honor this promise, but to make our food supply even safer.

We have put in place new rigorous safety standards for meat, poultry, and seafood products, throwing out archaic and ineffective inspection methods that had been left untouched for nearly a century. We have required slaughterhouses to test for deadly E. Coli and salmonella bacteria before shipping their products to our stores. We have begun developing new safety standards for fruit and vegetable juices. And we have brought a host of federal agencies together to boost food safety research, education, and surveillance efforts across the country. In doing so, we are using the world's best science to help prevent food contamination tragedies before they happen, to make sure that our food supply is the safest it can be.

Today, our food supply remains the world's safest. But we know we cannot rest on our accomplishments. We must do more. We must make sure that increased trade never diminishes the safety of our food. Today, I want to tell you the new steps we are taking to ensure that our fruits and vegetables -- including those imported from other countries -- meet the highest health and safety standards.

First, I am asking Congress to give the Food and Drug Administration the power to ban the importation of fruits, vegetables and other foods from countries whose food safety precautions do not meet American standards. This new law would be similar to the USDA's current policy of keeping meats and poultry from countries with unacceptable food safety systems out of our stores. Also, in my next budget, I will provide extra funding to strengthen the FDA's international food inspection force.

With these efforts, we can make sure that no fruits and vegetables cross our borders, enter our ports or reach our dinner tables without meeting the same, strict safety standards as those grown in America. Our food safety system is the strongest in the world. And that's how it's going to stay.

I am also directing the Secretary of Health and Human Services, the Department of Agriculture to work together, in close cooperation with the agricultural community, to develop rigorous safety standards for growing, processing, shipping and selling fruits and vegetables. The standards should address issues such as sanitation, worker health, water use, problems in the distribution and marketing system, regional and crop variations.

I am asking Secretaries Shalala and Glickman to report back to me within 90 days with a complete schedule for developing these standards within a year, as well as a comprehensive plan

to improve the monitoring of food safety systems abroad, help foreign countries upgrade their safety precautions, and toughen food inspections at the border.

Being a parent is perhaps the toughest job in the world. Our parents deserve the peace of mind that comes from knowing that the food they set before their children will nourish and strengthen their bodies, not make them sick. With today's new actions, we can help make their jobs that much easier.