

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 2, 1997

REMARKS BY THE PRESIDENT
ON FOOD SAFETY REGULATIONS

The Rose Garden

10:59 A.M. EDT

THE PRESIDENT: Thank you, Mr. Vice President, Secretary Shalala, Deputy Secretary Rominger, Cathie Woteki, Dr. Friedman, all the representatives of the groups that have helped us come to this day.

Our government made a fundamental promise to the American people of a bountiful and safe food supply way back at the beginning of this century. It is a promise that we have had to renew our commitment to periodically over the years, and a promise that needed a lot of work when I became President. From the day I took office, I worked very hard to honor that commitment, to make our food supply -- the world's safest -- even safer.

In 1993, the Vice President's national performance review recommended an overhaul of our food safety procedures so that we could use the best scientific technology available in inspection methods, to make sure that we had put in the best preventive controls to keep our food supply the world's safest.

Since then, we have taken major steps. We first put in place rigorous new safety standards for seafood, meat and poultry products, throwing out archaic and ineffective methods of inspection that had not been updated for nearly a century. We've required slaughterhouses to test for deadly E. Coli and salmonella bacteria. We've begun developing new safety standards for fruit and vegetable juices. We've strengthened our system of guaranteeing that our drinking water will remain safe, and improved public health protections for pesticide uses on food. And we brought a host of federal agencies together to boost food safety research, education and surveillance efforts around our nation. In so doing, we're using the world's best science to help prevent food contamination tragedies before they happen, to make sure our supply of food is as safe as it can be.

Today, our food supply remains the world's safest, but we can't rest on those accomplishments. We have to do more. At the time when Americans are eating more and more food from around the globe, we must spare no effort to ensure the safety of our food supply from whatever source.

Today, I want to tell you the new steps we're taking to ensure that our fruits and vegetables, including those imported from other countries, meet the highest health and safety standards. First, I'm asking Congress to give the Food and Drug Administration the power and the obligation to ban the importation of fruits, vegetables and other foods from countries whose safety precautions do not meet American standards. This new law would be similar to a law that already requires the United States Department of Agriculture to keep meat and poultry from countries with inferior food safety systems out of our stores.

In my next budget, I will provide enough funds to ensure that the FDA can fully implement this new legislation by dramatically expanding its international food inspection force. With these

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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 standards as those grown here in America. Our food safety system is the strongest in the world, and that's how it's going to stay.

I'm also directing the Secretary of Health and Human Services and the Secretary of Agriculture to work together in close cooperation with the agricultural community to develop the first-ever specific safety standards for the growing, processing, shipping and selling of fruits and vegetables. These standards will address potential food safety problems throughout the production and distribution system, and they'll improve the sanitation and safety practices of all those seeking to sell produce in the United States market.

I'm asking Secretary Shalala and Glickman to report back to me within 90 days with a complete schedule for developing these standards within a year. I'll also ask them to submit a comprehensive plan to improve the monitoring of food safety programs abroad, to 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 the food they set before their children is safe. With today's new actions, we can help make their jobs much easier.

And, again, let me thank all of those who were involved in this effort as I sign this order. Thank you very much.

(The order is signed.)

THE PRESIDENT: Thanks. (Applause.)

Q Mr. President, will you be using the line item veto

THE PRESIDENT: Excuse me?

Q Will you be using the line item veto on any of the appropriations bills that you've just passed -- that you've just signed?

THE PRESIDENT: Well, let me say, I have received only -- I've received one memorandum for my staff on one bill. And that came in late last night, so I haven't read it. But I will consider it -- as the bills come in, I will ask for a review of the potential uses by specific bill and make judgments as we go along. I have nothing to report at this time, because I have received only one memorandum and I haven't read it.

Q What about the census, sir? Do you have any concerns concerning the Commerce bill and the particular ways that the money will be used for the census?

THE PRESIDENT: Well, my feeling is that we ought to do the census as well as we can. I don't think this is a complicated issue. The National Science Foundation has recommended this statistical sampling method. The man who did President Bush's census says that it's the only way to get the most accurate count. I just want to do whatever the Census Bureau believes, the full-time professionals, believe is the most accurate thing to do.

I think that's a heavy constitutional responsibility we have, to conduct a census that is as accurate as possible based on what the professionals say. This ought to be a professional, not a political judgment. And that's the position I will take throughout.

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Q Mr. President, did the Democratic Party send money to the states because of federal election law restrictions?

Q Mr. President, there are fresh fruit and vegetables producers that are saying --

THE PRESIDENT: Well, wait a minute. I'll take both of them. Go ahead first.

Q There are fresh fruit and vegetable producers that are saying that you're acting with this action as the world food police and that your actions here today are unwarranted and that's going to complicate the trade environment.

THE PRESIDENT: Well, I hope it doesn't complicate the trade environment. But, you know, it seems to me that we have no higher responsibility than to protect the health and safety of our citizens, and everyone who has been following all of your reporting over the last four or five years knows that we have had continuing challenges in food safety. We have millions of people who get sick every year. And we're not trying to unfairly target foreign producers of food into our market; we don't ask them to meet any standards we don't meet. And indeed, if you look at the actions of this administration over the last four years, when we started, I think you can make a compelling case that we started working on things that were problems coming out of the American market first. So I just don't think that's right.

I don't want it to complicate the trade environment, but I'm not interested in trade in things that will make the American people sick.

Q Mr. President, did the Democratic National Committee send money to the states in order to get around the federal spending limits that went along with accepting federal money for the national campaign, sir?

THE PRESIDENT: It's my understanding that everything the Democratic National Committee did had the prior approval of the lawyers. If they cleared it all in advance, then it was perfectly legal. And when this issue was raised about a year ago, the exact issue, I believe that that was clarified at that time. I'm sure that they had legal advice that they followed, and I believe the Republicans said that they did some of the same things and also had prior legal clearance.

Q Mr. Clinton, do you think that Mrs. Reno -- she's been advised to go forward with the 90-day investigation into the fundraising calls of the Vice President -- and perhaps Mr. Gore would like to comment, too --

THE PRESIDENT: I think that --

Q -- do you feel that the 90-day investigation would be helpful?

THE PRESIDENT: Well, if you read the statute, she can consider certain things in the 90-day period that are not permitted in the 30-day period. But I think this is a legal question and it should be done based on an independent legal review with no pressure from the outside, from me or from anyone else. And that's the way I intend to keep it, at least on my part.

Thank you.

END

11:09 A.M. EDT

THE WHITE HOUSE
Office of the Press Secretary

Handwritten signature/initials

For Immediate Release

October 2, 1997

October 2, 1997

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

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

American consumers today enjoy the safest food supply in the world, and I am proud of my Administration's record in this area. We have taken significant steps to ensure that we maintain the safest food possible. We have put in place improved safety standards for meat, poultry, and seafood products, and we have begun the process of developing enhanced safety standards for fruit and vegetable juices. We have also expanded research, education, and surveillance activities through coordinated efforts of all agencies involved in food safety issues. Together, these measures will greatly improve 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. Although the produce Americans eat is very safe, we can and must do even better, especially at a time when Americans are eating more fruits and vegetables from all over the world. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas. We must ensure that fruits and vegetables coming from abroad are as safe as those produced in the United States, especially as we upgrade our own domestic standards.

To help accomplish this task, I plan to send to the Congress proposed legislation that will require 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 legislation, which will be similar to existing law requiring 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. My Fiscal Year 1999 budget will provide the necessary funds 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 determine when to halt the importation of fruits and vegetables from foreign countries.

Today, I hereby direct two administrative actions that will better ensure the safety of fruits and vegetables coming from abroad, while continuing to improve the safety of domestic produce.

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First, I direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue within 1 year from the date of this memorandum, guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should address ways to prevent potential sources of contamination, should take into account differences in both crops and regions, and should address food safety issues throughout the food production and distribution 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 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.

Second, I direct the Secretary of Health and Human Services and the Secretary of Agriculture, to report back to me within 90 days from the date of this memorandum with a status report and complete schedule for the good agricultural and manufacturing practices, and 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. I especially urge you to consider the best ways to target inspection and testing toward those areas where problems are most likely to occur.

In addition to taking these actions, you should accelerate whatever food safety research is necessary to support them. You should also call upon the Environmental Protection Agency, the Department of Labor, and other agencies as necessary to provide you with assistance in achieving this goal. These steps, taken together and in coordination with the proposed legislation I will send to the Congress, will improve the safety of fruits and vegetables for all Americans.

WILLIAM J. CLINTON

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THE WHITE HOUSE

Office of the Press Secretary

Food Safety

For Immediate Release

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In addition to taking these actions, you should accelerate whatever food safety research is necessary to support them. You should also call upon the Environmental Protection Agency, the Department of Labor, and other agencies as necessary to provide you with assistance in achieving this goal. These steps, taken together and in coordination with the proposed legislation I will send to the Congress, will improve the safety of fruits and vegetables for all Americans.

WILLIAM J. CLINTON

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OFFICE OF SENATOR BARBARA A. MIKULSKI
UNITED STATES SENATE
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WASHINGTON, D.C. 20510-2003

FAX TRANSMITTAL FORM

DATE: 3-3-98

PAGE(S) (INCLUDING THIS FORM)

IS/ARE FOR: Mary Smith

FROM: Laura Chapin 224-0574

IF THIS TRANSMITTAL IS INCOMPLETE, PLEASE CALL (202) 224-4654

(ADDITIONAL INFORMATION):

THE FOLLOWING

19 pp + cover
More paper than you've ever
wanted - I included the background
article from the Post.

Hope the charts are legible -
they're dark blue & yellow (TV
colors) in real life, with red
stop signs.

BARBARA A. MIKULSKI
MARYLAND

COMMITTEES:
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LABOR AND HUMAN RESOURCES

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United States Senate

WASHINGTON, DC 20510-2003

February 10, 1998

Dear Colleague:

I am writing to invite you to join me in cosponsoring the **Safety of Imported Food Act**. This legislation, a major component of the Administration's food safety initiative, amends the Federal Food, Drug and Cosmetic Act to provide for improved safety of imported foods.

Thousands of food-related deaths and millions of food-related illnesses occur each year in the United States alone. These numbers are expected to rise in the coming years. In addition to the health consequences, the financial costs of these illnesses are staggering -- over \$3 billion each year is spent in hospital costs alone.

The percentage of imported food in the country has almost doubled in the past decade. Almost 40% of fruits consumed in the U.S. are imported from foreign countries. It is imperative that those charged with ensuring the safety of our food are given the tools necessary to prevent the importation of unsafe food.

This bill gives the FDA authority to exclude food items from the United States that were produced under a system, or subject to controls or conditions that do not meet the U.S. level of protection. The bill would amend current law 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 otherwise achieve the level of protection required for foods produced domestically. In determining whether such requirements have been achieved, the bill authorizes the Secretary to consider whether the FDA has requested, but been denied, access to inspect a facility where a food was prepared, packed or held. The World Trade Organization agreements allow WTO members, including the U.S., to set individual levels of protection and to exclude imported food that does not meet those standards. This legislation explicitly endows FDA with this authority.

Please join me in sponsoring this important legislation which ensures the safety of the imported foods we all consume. For more information, or to cosponsor this legislation, please contact Bonnie Kirkland in my office at x47962.

Sincerely,



Barbara A. Mikulski
United States Senator

105TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Ms. MIKULSKI introduced the following bill; which was read twice and referred
to the Committee on _____

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 House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Safety of Imported
5 Food Act of 1998".

6 **SEC. 2. CRITERIA FOR DEEMING IMPORTED FOOD ADUL-**
7 **TERATED.**

8 (a) AMENDMENT TO THE FEDERAL FOOD, DRUG,
9 AND COSMETIC ACT.—Section 402 of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 342) is amended by
11 adding at the end the following:

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

19 (b) IMPLEMENTATION OF AUTHORITY; PLAN.—The
20 Secretary of Health and Human Services shall develop a
21 plan for the initial implementation of the authority under
22 section 402(h) of the Federal Food, Drug, and Cosmetic
23 Act, as added by subsection (a), and shall carry out the
24 authority of such section consistent with such plan.

KEY STATISTICS ON FOODBORNE ILLNESS IN THE UNITED STATES

- **DISEASE/DEATH STATISTICS:** Up to 9,000 food-related deaths and up to 33 million illnesses are estimated to occur each year (these numbers may actually be much higher—50-100 times higher)
- **ECONOMIC IMPACT OF FOODBORNE ILLNESS:** Hospitalization costs are estimated at over \$3 billion per year—with costs for lost productivity estimated at several billion dollars
- **FOOD POISONING MAY CAUSE MORE THAN VOMITING AND DIARRHEA, INCLUDING:**
 - spontaneous abortion
 - birth defects, including mental retardation
 - chronic reactive arthritis
 - Guillain-Barre' syndrome (including life-threatening paralysis)
 - HUS (a highly fatal disease in children causing kidney failure)

• **FDA'S RESPONSIBILITIES ARE ENORMOUS, AND GROWING...**

FDA-regulated products account for about two-thirds of consumer spending on food, including nearly \$430 billion worth of food products, made by 60,000 U.S. manufacturers, warehouses, and distributors

More than 1.6 million food products are imported into the U.S. each year—and that number is growing

• **...BUT FDA'S RESOURCES HAVE DECLINED OVER THE LAST DECADE**

FDA food inspections have fallen from 21,000 in 1981 to 5,000 in 1996.

FDA inspects the average plant about once every 10 years.

Imports have almost doubled in the last 5 years—the number of inspectors has remained the same.

Product recalls for life-threatening microbial contamination have increased almost five-fold since 1988—and today inspectors are finding more hazardous conditions in the plants they inspect.

THE WHITE HOUSE

WASHINGTON

October 2, 1997

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We need to build on these efforts, and today I ask you to do so by focusing on the safety of fruits and vegetables. Although the produce Americans eat is very safe, we can and must do even better, especially at a time when Americans are eating more fruits and vegetables from all over the world. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas. We must ensure that fruits and vegetables coming from abroad are as safe as those produced in the United States, especially as we upgrade our own domestic standards.

To help accomplish this task, I plan to send to the Congress proposed legislation that will require 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 legislation, which will be similar to existing law requiring 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. My Fiscal Year 1999 budget will provide the necessary funds 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 determine when to halt the importation of fruits and vegetables from foreign countries.

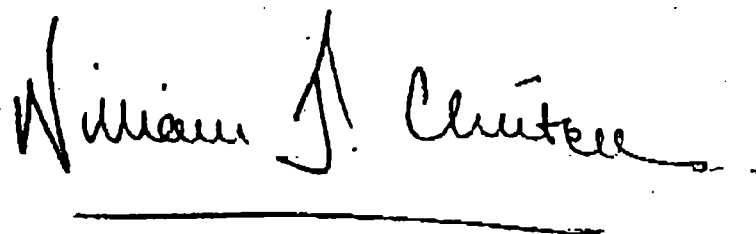
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11/14/97 14:19

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

FOR IMMEDIATE RELEASE
November 14, 1997

CONTACT: Lewis Roth/Eshoo
(202) 225-8104
Ted Loud/Pallone
(202) 225-4671 5-9665

Eshoo and Pallone Move To Boost Imported Food Safety

Washington, D.C.—Rep. Anna Eshoo (D-CA) has introduced legislation to give the Food and Drug Administration (FDA) authority to stop the importation of food that has not been prepared, packed, and held under conditions that meet U.S. safety requirements. Last year, 38% of the fruit and 12% of the vegetables consumed by Americans came from overseas. The initiative was developed with the cooperation of the FDA and comes after she prodded the Clinton Administration to implement its promise to expand the nation's food safety program to include foreign fruits and vegetables. President Clinton announced his intent to seek such FDA authority at an October 2nd press conference held at the White House.

Rep. Frank Pallone, Jr. (D-NJ) is the principle cosponsor of the legislation. Pallone has been working with the Administration on new and strengthened enforcement tools, including notification and recall provisions, that will improve the ability of the FDA to protect consumers.

Both Eshoo and Pallone are members of the House Commerce Committee, which has jurisdiction over the FDA.

"America must be able to maintain the safety of our food supply as more foreign fruits and vegetables enter our market, particularly goods from tropical climates," said Rep. Eshoo. "We shouldn't compromise the standards of what we put on our tables and feed our families. The legislation I've introduced will give FDA inspectors the leverage they need to go into other countries and guarantee that if foreign produce crosses our borders, it's as safe as any food grown and processed in the U.S.A."

"The issue is very prominently in the public eye because of some recent cases of contaminated food products, which I think gives us some needed momentum and public support to take action now," Pallone said. "While consumption of imported produce continues to increase, inspections of imported food are actually decreasing. We need to be able to regulate fruits and vegetables coming from other countries, particularly those countries with a bad track record in terms of food handling."

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14:19

Finally, the President directed the Department of Health and Human Services and the Agriculture Department to develop a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries in improving these practices where necessary, and to prevent the importation of unsafe produce, including the detection of unsafe food at docks and the border. The President's FY99 budget request will include the necessary funds for the FDA to expand dramatically its international food inspection force.

19TH STORY of Level 1 printed in FULL format.

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July 08, 1997, Tuesday, Final Edition



SECTION: HEALTH; Pg. Z10

LENGTH: 2989 words

HEADLINE: Forbidding Fruit; How Safe is Our Produce?

BYLINE: Sandra G. Boodman

BODY:

Of all the foods that harbor germs that can make people sick, fruits and vegetables have long been regarded as risk-free.

Not anymore.

In the past several years public health officials have investigated a spate of outbreaks of produce-associated illness. Hepatitis A virus contaminated batches of frozen strawberries imported from Mexico that were served to schoolchildren in Michigan. In the past year, salmonella invaded bean sprouts in the Midwest and earlier had been found on cantaloupes and alfalfa sprouts. *Escherichia coli* 0157:H7, an untreatable infection usually associated with undercooked hamburger, tainted lettuce in Connecticut. And shigella, a waterborne parasite, was found on scallions.

Last month Food and Drug Administration officials warned people suffering from diarrhea who had recently eaten fresh raspberries to seek medical treatment and to be tested for *Cyclospora cayetanensis*, an unusual waterborne parasite found in Nepal, Haiti, Peru and other developing countries.

So far this year, more than 1,300 cases of cyclospora infection have been reported, according to the federal Centers for Disease Control and Prevention (CDC). Symptoms include severe, prolonged diarrhea, considerable weight loss, vomiting, chills and fatigue. Most cases appear to have been caused by Guatemalan raspberries, CDC officials said.

Some cases have been local. In Maryland, health officials investigated two small outbreaks involving eight people that were traced to two private dinner parties in Montgomery County in early May. On both occasions, fresh raspberries were served for dessert.

In addition, lettuce appears to have been the culprit in at least 72 cases of cyclosporiasis reported since April. Two outbreaks that sickened 27 people have been linked to mesclun lettuce that was served in two Florida restaurants last spring. Some of the lettuce was grown in the United States and some in Peru, where cyclospora is endemic. CDC officials say that a mixed green salad served on a Miami-based cruise ship appears to be responsible for at least 45 cases of an illness consistent with cyclospora infection; that outbreak is still being investigated.

The Washington Post, July 08, 1997

Unlike E. coli 0157, which has killed five children in the United States since 1992, no deaths have been attributed to cyclospora infection, and the illness can be successfully treated with sulfa drugs.

That does not mean that cyclospora infection is trivial, public health officials caution. "Cyclospora is a serious public health problem," said David Portesi, an epidemiologist with the Maryland Department of Health. "We're not talking about a 24-hour bug here, but something that can disable you for 30 days or more with serious diarrhea and dehydration."

So far, most of the concern has centered on Guatemalan raspberries. Officials at the FDA say the parasite has not been conclusively linked to fresh raspberries grown in any country but Guatemala, nor has it been found in frozen raspberries.

The current outbreak is especially frustrating for public health officials because they confronted a similar epidemic last year and thought they had devised a system to prevent the problem. Last summer 1,465 cases of cyclospora infection were reported to the CDC; most were linked to Guatemalan raspberries. Tracking the source of that outbreak was complicated by an erroneous announcement by officials in Texas that California strawberries were to blame. At the time, some health officials suggested that raspberries, 20 percent of which are imported from Guatemala, were a safe alternative.

American health officials had thought that a recurrence had been prevented when inspectors for the FDA and CDC worked with growers to improve sanitation practices on farms in Guatemala, which began growing raspberries in 1987.

Even though raspberry imports from Guatemala have been suspended since May 28, Barbara Herwalt, a medical epidemiologist for the CDC who headed last year's cyclospora investigation and is tracking this year's epidemic, expects new cases may continue to surface for several weeks because the lag time between infection and diagnosis averages about four weeks.

The FDA, which is charged with overseeing the safety of much of the nation's food supply, has scheduled a meeting in Washington on July 23 to review scientific information about cyclospora. FDA deputy commissioner Mary Pendergast said that the agency is expected to decide shortly whether to permit Guatemala to resume raspberry shipments in the fall.

The problems with fresh produce come as a growing number of Americans are heeding the federal government's exhortations to eat five servings of fruits or vegetables every day to cut their risk of developing cancer or heart disease. While cases of produce-associated illness are rare, public health officials say they appear to be increasing.

"What we do know is that we've got a lot of fruits and vegetables imported from countries where we're warned not to eat them [raw] or to drink the water," said Caroline Smith DeWaal, director of food safety for the Center for Science in the Public Interest, a Washington-based consumer advocacy group. "The question is, why is it safe to eat it when it's imported?"

Traveler's Diarrhea -- at Home

In the past decade the quantity of produce imported from Mexico, Central America and other Third World countries has increased dramatically. A recent editorial in the New England Journal of Medicine by Michael T. Osterholm, chief epidemiologist for the state of Minnesota, notes that in some seasons as much as 70 percent of produce sold in this country is grown elsewhere, often in developing countries where travelers are routinely warned to be careful about what they eat.

"One no longer needs to leave home to contract traveler's diarrhea caused by an exotic agent," Osterholm wrote, warning that the globalization of the nation's food supply has "led to a new range of problems for the gastrointestinal tract."

Those warnings were echoed in a report to President Clinton on food safety released in May by the Environmental Protection Agency and the Departments of Agriculture and Health and Human Services. The report notes that the annual number of food inspections conducted by the FDA has plummeted since 1981 from 21,000 to 5,000, chiefly as a result of budget cuts.

According to the report, a plant regulated by the FDA is inspected only about once every 10 years. And while there has been a dramatic increase in the number of imported foods sold to American consumers -- 2.2 million shipments were received last year compared to 1.5 million five years ago -- inspections have dropped by 50 percent since 1992. Currently only about 1 or 2 of every 100 shipments of imported food is inspected.

"Given the limited inspection coverage," the report states, "FDA is finding an increasing number of problems -- the number of products recalled for life-threatening microbial contamination has increased almost five-fold since 1988."

Food-borne illnesses are among the most underreported maladies, according to the CDC. About 100,000 cases and 9,000 deaths are reported annually, but CDC officials believe that the actual toll is exponentially higher: They estimate that the annual case count is between 6.5 million and 33 million. In a recent article about the 1996 cyclospora outbreak in the New England Journal of Medicine, Herwalt and her colleagues noted that only about 1 to 5 percent of infections caused by salmonella, a much more recognizable and easily diagnosed malady, are reported to the CDC annually.

Parasite Packs a Big Punch

The problem with cyclospora is not limited to imported fruits and vegetables, health officials say. The first mass outbreak of cyclospora infection was reported in 1990 at a Chicago hospital dormitory; 21 people were sickened by contaminated tap water.

Yet because cyclospora is an "emerging pathogen" -- a disease-causing germ that was first identified in Papua New Guinea, in 1979 -- little is known about the one-celled parasite and many problems remain detecting and tracking it.

There is no way to test for cyclospora in food or water; stool testing is the only method and, as Herwalt notes, the bug is hard to detect and may require

multiple samples. Not everyone exposed to cyclospora gets sick. The amount necessary to cause illness appears to be small. Herwalt said some of those who contracted cyclosporiasis last summer told epidemiologists that they ate only one raspberry.

A routine stool culture does not test for cyclospora; it must be specially requested by a physician, many of whom have never heard of the infection. In addition, many commercial laboratories cannot or do not test for the parasite. Cyclospora is resistant to disinfectants; chlorination does not kill it. Scientists don't yet know what temperature or how much time is necessary to kill the parasite by freezing or cooking.

Washing, although always advised to remove dirt and pesticides, does not appear to be sufficient to kill cyclospora on raspberries, possibly because the germ hides in the fruit's numerous crevices. And health officials say that many people do not wash raspberries because the fruit is so delicate.

Tracking outbreaks of the illness is complicated by its long incubation period and by the lack of a uniform national system of surveillance. Unlike other food-borne illnesses, some of which develop within a few hours or days, it takes on average a week for symptoms of cyclospora infection to show up. By that time, most people have forgotten what they ate and the packaging vital to tracing has been discarded by a store or restaurant.

Unlike E. coli 0157 and many other food-borne infections that can be transmitted from person to person, cyclospora does not appear to be contagious. And even for those who do not receive treatment, or who cannot take sulfa drugs, the illness appears to be self-limiting; it may wax and wane, but it will go away after several months without any treatment.

The CDC reports that 22 people were hospitalized last summer, mostly for treatment of severe dehydration. The infection is more serious in elderly patients, children and in those with malfunctioning immune systems, such as cancer or AIDS patients.

Jeffrey Foran, a chemical toxicologist with the International Life Sciences Institute, a nonprofit Washington-based research group that studies, among other issues, food safety, contracted the infection last May along with 11 of his co-workers after eating raspberries at a staff lunch.

"This was much worse" than other bouts of food-borne illness he has suffered, said Foran, a frequent traveler. Foran said he lost 12 pounds in three weeks. "This was a long, drawn-out illness."

Searching for the Elusive Source

Last fall, officials from the CDC and the FDA went to Guatemala to inspect raspberry farms to determine how the contamination occurred and why it was associated with the spring crop but not with berries grown in the fall.

Because the outbreak coincided with the rainy season -- which occurs in May when many Guatemalans report suffering from a gastrointestinal illness known as mal de Mayo -- health officials theorized that the parasite had somehow contaminated water used in berry production -- for irrigation; mixed with a pesticide that was sprayed on the fruit; or used by workers to clean equipment

and to wash their hands. Another theory under investigation is that the berries were contaminated by the seasonal migration of wild birds.

The farms were reinspected last fall, after a U.S. contractor helped growers improve their water systems. Based on the results of those inspections, health officials classified them as low-, medium- or high-risk. Only low-risk farms were allowed to ship berries to the United States during the rainy season, Pendergast said. Medium-risk farms "couldn't ship during the bad core weeks we were most worried about," she added, and high-risk farms were barred from the U.S. market.

This year, Pendergast noted, the first cases of cyclospora were reported from berries harvested in March, long before the May rainy season, which this year occurred even later than usual.

The CDC and FDA have been baffled that the infection apparently has not involved berries grown in other Central American nations, such as Costa Rica.

To CSPI's Caroline Smith DeWaal the emergence of cyclosporiasis underscores the need for better inspection of food, especially imported food.

"The more we ship food around the globe, the more we're subject to food hazards not in our environment," she said. "How can we verify that foreign countries are living up to our food safety standards? We have no enforcement capability. There is no good trade reason to expose American consumers to large quantities of contaminated food."

To the FDA's Pendergast, the issue lies not in improved inspections in the United States but in raising standards within countries that export food here.

"We never have enough inspectors," Pendergast said. "But having said that, this isn't the solution in the long run. We have to have a system in place in the country of origin."

Increasingly health officials are considering a third option: irradiation, a method of sterilization. After it is packaged, food is run through a machine that resembles an airport conveyer belt on which luggage is inspected. As food moves down the belt, it passes through a chamber lined with impenetrable concrete walls and is bombarded with ionizing radiation in the form of gamma rays or from electron beams. Irradiation has been approved by the FDA for use on poultry and is widely used on medical equipment. The process kills many bacteria, parasites, molds and fungi but leaves no residual radiation on the product itself.

In his editorial in the New England Journal, Osterholm wrote that "the time has come to use irradiation . . . [which] provides the greatest likelihood of substantially reducing bacterial and parasitic causes of food-borne disease associated with numerous foods, including fresh fruits and vegetables. . . . This may be the most crucial lesson to be learned from the story of cyclosporiasis and imported raspberries."

But Osterholm notes that the food industry, fearing protests by environmental groups and mistrust by consumers, has been reluctant to embrace the expensive technology.

"The other problem," Osterholm added in an interview, "is that we in public health have not done a good job of pushing it."

CSPI's Caroline Smith DeWaal said that her group has misgivings about irradiation, not because of safety concerns, but because of the expense and uncertainties surrounding the new technology. "We're not in the camp that says it makes your food glow in the dark," she said. But irradiation, she added, is "no magic bullet" and would do nothing to combat viruses, such as the hepatitis A that contaminated the frozen strawberries served in the school lunch program. And it would do nothing to kill *E. coli* 0157 or cyclospora on lettuce, a product too fragile to survive irradiation.

"We believe irradiation is a technique of last resort, and we don't think we're there yet," DeWaal said. "We would advocate looking to on-farm controls first."

Simple Steps to Reduce the Risk of Contamination From Produce

Food-borne illnesses increase in the summer months and typically peak in July. Health officials say that the seasonality reflects a combination of factors: increased consumption of produce that may not have been washed, substandard food storage practices and higher temperatures in which many bacteria thrive.

The chances of contracting an illness from fresh produce can be greatly reduced by simple measures. Among them:

Use cool running water to wash fruits and vegetables. Running water has an abrasive effect that soaking does not and may remove harmful germs from the crevices of berries. Discard the outer leaves of lettuce, which are more likely to harbor dirt or bacteria. Peel carrots, don't just scrub them.

Wash the outside of melons before cutting them. Some cases of salmonella have been traced to unwashed cantaloupe rind that was spread to the fruit when the melon was cut.

Wash your hands before preparing food. More than 97 percent of food-borne illnesses are preventable and result from human error. Contamination with human or animal feces is one of the most frequent causes of food-borne illness and is often the result of inadequate hand-washing -- or none at all -- by those preparing food.

Promptly refrigerate cut produce. Even though fresh fruits and vegetables are far less likely than cheese or meat to become a breeding ground for harmful organisms, proper storage is important.

When in doubt, don't eat it. If the skin of a fruit or vegetable is broken, throw it out. Organisms may have invaded the interior, beyond the reach of washing.

Avoid cross-contaminating produce with raw meat or poultry. Wash hands, knives, plates and cutting boards after handling raw meat or poultry and before handling produce or other items. Wash cutting boards in the dishwasher, or with

soap and hot water.

Wash pre-packaged salad mix and vegetables. It is hard to know how well or if they have been washed. The mesclun lettuce that caused an outbreak of cyclosporiasis in Florida last spring was not washed by the Tallahassee restaurant that served it, Florida health officials said, because workers thought the salad mix had been washed.

Don't eschew fruits and vegetables out of fear of produce-associated illness. They're too important to a healthy diet. If you're worried about being served unwashed produce in a restaurant or at a party, eat it at home.

Sources: Centers for Disease Control and Prevention, Center for Science in the Public Interest, Florida Dept. of Health, United Fresh Fruit and Vegetable Association

GRAPHIC: Photo, max hirshfeld; Photo, max hirshfeld

LANGUAGE: ENGLISH

LOAD-DATE: July 08, 1997

SAFETY OF IMPORTED FOOD ACT OF 1998
"FREE TRADE FOR SAFE FOOD"

--SEN. MIKULSKI



Importation of food PRODUCED in
unsanitary conditions



Importation of food from countries that
deny FDA INSPECTION



Importation of food that does not meet
the U.S. level of PROTECTIONS

Every Year

- 38% of fruits consumed in the U.S. are imported
 - 12% of the vegetables consumed are imported
 - As many as 33 million illnesses are caused by contaminated meat, poultry, & produce
 - Over \$3 billion is spent in hospitalization due to food borne illness
-
-

Least Wanted Foodborne Pathogens



E. Coli O157:H7

A bacterium that can produce a deadly toxin; Sources: meat, especially undercooked or raw hamburger, raw milk and produce



Listeria monocytogenes

Causes listeriosis, a serious disease for pregnant women, newborns and adults with a weakened immune system; Sources: soil and water. It has been found in improperly processed dairy products including soft cheeses as well as in raw and undercooked meat, in poultry and seafood, and in produce



Salmonella

Responsible for millions of cases of foodborne illness a year; Sources: raw and undercooked eggs, undercooked poultry and meat, dairy products, seafood, fruits and vegetables



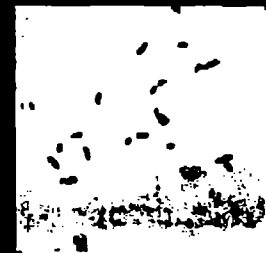
Staphylococcus aureus

Causes staph infection; Sources: cooked foods high in protein (e.g. cooked ham, salads, bakery products, dairy products)



Shigella

Causes an estimated 300,000 cases of dysentery; Sources: salads, milk and dairy products, and produce



Yersinia enterocolitica

Causes yersiniosis, a disease characterized by diarrhea and/or vomiting; Sources: pork, dairy products, and produce



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV 13 1997

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

Dear Mr. President:

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 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) could also be used to deal with such foods.

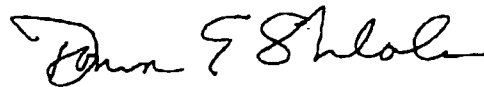
The Honorable Albert Gore, Jr. - Page 2

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

Sincerely,

A handwritten signature in dark ink, appearing to read "Donna E. Shalala". The signature is fluid and cursive, with the first name "Donna" and last name "Shalala" clearly distinguishable.

Donna E. Shalala

Enclosure

BARBARA A. MIKULSKI
MARYLAND

COMMITTEES:

APPROPRIATIONS

LABOR AND HUMAN RESOURCES

SUITE 709

HART SENATE OFFICE BUILDING

WASHINGTON, DC 20510-2003

(202) 224-4654

TTY: (202) 224-5223

United States Senate

WASHINGTON, DC 20510-2003

February 10, 1998

Dear Colleague:

I am writing to invite you to join me in cosponsoring the **Safety of Imported Food Act**. This legislation, a major component of the Administration's food safety initiative, amends the Federal Food, Drug and Cosmetic Act to provide for improved safety of imported foods.

Thousands of food-related deaths and millions of food-related illnesses occur each year in the United States alone. These numbers are expected to rise in the coming years. In addition to the health consequences, the financial costs of these illnesses are staggering -- over \$3 billion each year is spent in hospital costs alone.

The percentage of imported food in the country has almost doubled in the past decade. Almost 40% of fruits consumed in the U.S. are imported from foreign countries. It is imperative that those charged with ensuring the safety of our food are given the tools necessary to prevent the importation of unsafe food.

This bill gives the FDA authority to exclude food items from the United States that were produced under a system, or subject to controls or conditions that do not meet the U.S. level of protection. The bill would amend current law 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 otherwise achieve the level of protection required for foods produced domestically. In determining whether such requirements have been achieved, the bill authorizes the Secretary to consider whether the FDA has requested, but been denied, access to inspect a facility where a food was prepared, packed or held. The World Trade Organization agreements allow WTO members, including the U.S., to set individual levels of protection and to exclude imported food that does not meet those standards. This legislation explicitly endows FDA with this authority.

Please join me in sponsoring this important legislation which ensures the safety of the imported foods we all consume. For more information, or to cosponsor this legislation, please contact Bonnie Kirkland in my office at x47962.

Sincerely,



Barbara A. Mikulski
United States Senator

Food Safety

THE WHITE HOUSE
WASHINGTON

October 8, 1997

Dear Henry:

Thank you for your letter dated September 24, 1997, expressing concern about the effects of increased trade on food safety. I share your concern about the safety of food for all Americans, and I will not permit any trade policy to impair the health and safety of the American people.

I have committed this Administration to ensuring that the food that Americans eat is the safest in the world. We have put in place improved safety standards for meat, poultry, and seafood products, and have begun the process of developing enhanced safety standards for fruit and vegetable juices. Together, we have enacted legislation in this area, including the Safe Drinking Water Act of 1996 and the Food Quality Protection Act of 1996.

This month, I announced an initiative to upgrade domestic food safety standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States. I asked Congress to enact legislation that will require the Food and Drug Administration 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. I also directed the Department of Health and Human Services and the Department of Agriculture to work cooperatively with the agricultural community to develop guidance on agricultural and manufacturing practices for fruits and vegetables within one year. Finally, I committed to providing the necessary funds in my

The Honorable Henry A. Waxman
Page Two

Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food inspection force so it can inspect food safety conditions abroad and at points of entry. The added resources will allow the FDA to make effective use of its new legislative authority. I am attaching a fact sheet on my new proposal, as well as the directive I sent to Secretaries Glickman and Shalala.

This new initiative will help guarantee the safety of food in the United States. It provides the improved inspection capacities and increased regulatory powers we need to prevent contaminated imports from reaching American tables. I am committed to continuing to improve the safety of food that Americans eat, and I look forward to working with you on this vital project. Thank you again for your letter.

Sincerely,



The Honorable Henry A. Waxman
House of Representatives
Washington, D.C. 20515

THE WHITE HOUSE**WASHINGTON****PRESIDENT CLINTON ANNOUNCES INITIATIVE TO ENSURE THE SAFETY OF
IMPORTED AND DOMESTIC FRUITS AND VEGETABLES****October 2, 1997**

Today President Clinton will announce an initiative to upgrade domestic food safety standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States. The President 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 will direct 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 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 will also commit to providing the necessary funds in his Fiscal Year 1999 budget to enable the FDA to dramatically expand 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 will direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in cooperation with the agricultural community, to develop guidance on good agricultural and 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 will also direct the FDA and USDA to develop coordinated outreach and educational activities.

Improvement of Monitoring and Inspection Activities Abroad. In addition to committing substantial resources to expand the FDA's international food inspection force, the President will direct the Secretaries of Health and Human Services and Agriculture to report within 90 days 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. The President will urge consideration of ways to target inspection and testing toward those areas where problems are most likely to occur.

Ek - Some info on chickens story.
that we should ask USDA what
else they can do, yes? ~~that we should ask USDA what else they can do, yes?~~

The Administration recognizes the importance of addressing foodborne illness caused by Campylobacter and has taken a number of steps in this regard:

- Under the President's Food Safety Initiative, the Administration added Campylobacter to the FoodNet, which collects data on foodborne illness, in 1997 to gain knowledge on its incidence.
- According to the first year survey results from FoodNet, Campylobacter is the most common foodborne illness, causing approximately 4 million illness per year.
 - It is a relatively mild illness, seldom, almost never fatal. It has been possibly linked to Guillame-Barre syndrome, a temporary neurological disorder.
- Under the Food Safety Initiative, research on the Campylobacter organism is a high priority. USDA is working on a new rapid testing method for Campylobacter to improve our ability to detect the pathogen.

Also under the Administration's food safety initiative, FDA, CDC, and USDA have initiated surveillance to gain greater understanding of strain of campylobacter that has been shown to be resistant to fluorquinolone (a class of antibiotics).

The Administration spent \$1.3 million in FY 97 on Campylobacter research, \$435,000 of which was for a rapid test. In FY 98, the Administration will spend \$2.2 million on research, a little of over 1million of which will be for rapid tests.

There are two flourquinolones approved for food animals in the U.S., both for broilers and turkeys. FDA is reevaluating these products based on the new information about flouroquinolone.

FDA and USDA officials recently participated in a World Health Organization meeting at which this issue was addressed. A follow up meeting is scheduled.

- As HACCP is implemented in January of 1998, USDA expects that Campylobacter will be an identified hazard that will be appropriately addressed in HACCP plans.
- Proper handling is very effective against Campylobacter because it is one of the more easily destroyed bacteria. Safe handling includes

Cooking to 160 degrees,

Avoiding cross-contamination by washing hands and preparation surfaces, and

Keeping raw product separate from cooked product.

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Food Safety

**ASSURANCE OF MICROBIAL FOOD SAFETY
FOR
FRUITS AND VEGETABLES**

QUESTIONS & ANSWERS

1. Why is there a concern about the safety of fruits and vegetables?

Foodborne diseases, including outbreaks, are under-recognized and under-reported, making it difficult to generalize from the available databases and assess overall trends. Efforts are underway to improve the recognition and investigation of disease outbreaks related to food. However, the Center for Disease Control and Prevention's (CDC) system of surveillance for foodborne disease outbreaks shows that there has been a noticeable increase in reported foodborne disease outbreaks associated with fresh produce.

2. Why does there appear to be an increase in the number of foodborne illness outbreaks attributed to fruits and vegetables?

There are a number of possible explanations for why there maybe an increase in the number of reported foodborne diseases associated with fresh produce including (1) an increase in the consumption of fresh produce which increases the number of exposed persons, (2) increased use of salad bars and more meals eaten outside the home which increases the risk of food handling errors, (3) increased consumer preference for 'natural' and 'organically' grown produce which increases the potential for the use of improperly treated manure, (4) increases in global trade which increases the potential exposure of consumers to produce handled under insanitary conditions that may occur in some countries, and (5) increased numbers of consumers at high risk for foodborne disease (e.g., the elderly, persons with compromised immune systems, and persons suffering from chronic diseases).

3. What is the cause of this apparent increase?

The investigation of fresh produce-associated outbreaks is very difficult because contamination generally occurs sporadically and at low levels. In addition, there is a high turnover of product (that is, fresh fruits and vegetables are sold and consumed within a matter of days) and the produce originates from many sources, both domestic and foreign. In majority of the investigations, the cause of reported illnesses is not positively identified. There is no evidence that pathogens naturally occur on fresh produce; rather health officials suspect they are inadvertently added by humans during harvesting, handling, distribution, or preparation. Foodborne diseases associated with fresh produce often involve produce that

has undergone some type of processing step, including chopping, cutting or squeezing, during which pathogens can be introduced into the food. Holding these types of produce items at improper temperatures may permit pathogens to survive and grow.

4. Why has FDA chosen this time to initiate a food safety program for fruits and vegetables?

In 1993 this Administration announced its strong commitment to enhancing food safety in the U.S. Important strides have been made by both FDA and USDA with the adoption of new regulations applying Hazard Analysis and Critical Control Point (HACCP) food safety controls to seafood, meat and poultry. In 1997 the President announced a new Food Safety Initiative that will take additional steps and provide additional money to support of an aggressive food safety policy. In August, 1997 FDA announced an initiative to address safety concerns in the fresh fruit and vegetable juice industry. This action regarding fresh fruits and vegetables is a further step in a chain of initiatives to implement this Administration's food safety policies and to improve consumer confidence in the safety of the nation's food supply.

5. What additional actions will USDA take to build upon this Presidential Directive?

Today's directive builds on previous actions the Administration has taken to increase the safety of the nation's food supply. In addition, USDA will continue to focus on a farm-to-table strategy to assess the risks of food contamination and to aid in the prevention of foodborne outbreaks for both domestically-produced and imported products.

Additional actions will build on the progress made in the 1998 Administration initiative. For example, our FY99 budget will continue our commitment to further expand the FoodNet sentinel site program, expand our educational and outreach efforts to improve awareness of food safety at the farm, retail or restaurant level, and enhance research and risk assessment.

6. How will FDA implement this new initiative to reduce the incidence of foodborne disease associated with fruits and vegetables?

This initiative is a two-pronged approach. Industry and public health officials agree that good agricultural practices (GAP's), product and process specific Good Manufacturing Practices (GMP's) and Hazard Analysis and Critical Control Point (HACCP) systems offer the best strategy to improve safety. The FDA will first work with industry to develop basic guidance on how to minimize microbial food safety risks for fruits and vegetables. Following this, the agency will coordinate and work with industry to develop science based, product specific GAP's and GMP's.

7. What will USDA's role be in developing and supporting the new FDA guidelines (Good Manufacturing Practices and Good Agricultural Practice) for fresh fruit and vegetables?

USDA will work in partnership with FDA and the agricultural community in developing the guidelines. USDA has a wide range of scientific and agricultural expertise in agencies like the natural resource conservation service, the agricultural research service, and the extension service that will help to make the guidance as effective as possible.

In addition

1. USDA and FDA will accelerate the research outline in the FY98 President's Food Safety Initiative, to develop new technologies to more rapidly identify and eliminate or reduce levels of pathogens.
2. USDA and FDA will develop and deliver research-based educational programs to food producers, processors, handlers, and consumers and assist in providing guidance and procedures to reduce or eliminate contaminants.
3. USDA, FDA, and CDC will develop new assessment procedures for imported foods and provide technical assistance to existing countries where necessary to improve the safety of their products.

8. What is the industry's role in addressing this problem?

The fruit and vegetables industry has already developed voluntary safety guidelines for various types of products and segments of the industry. They have provided growers and processors with information and materials on foodborne outbreaks and needed sanitation practices to control contamination. This information will greatly assist the industry in developing and implementing their enhanced sanitation guidelines. These actions show that industry is committed to taking immediate positive steps to enhance the safety of their products.

9. How will new GAP's/GMP's help solve the problem?

GAP's/GMP's are a scientific approach to a fresh fruit and vegetable safety program. Good Agriculture Practices involve the control of water, manure application, worker/field/facility sanitation, and transportation and handling. Good Manufacturing Practices include the control of water, processing sanitation/quality, employee hygiene, equipment sanitation, and control of storage and distribution temperatures.

10. Why is further research needed?

Health officials and industry agree that we need additional knowledge and tools to improve food safety. Studies are needed to (1) help identify possible sources of contamination along the chain including harvest, transportation, processing, and at retail; (2) develop more rapid tests to detect and identify pathogens on fruits and vegetables; and (3) develop improved prevention technologies that can be used to eliminate or reduce levels of pathogens on fruits and vegetables.

11. What role will education play under this new food safety directive?

Food safety programs only work if people handling products along the harvest, transport, process and retail chain understand the hazards that can make the product unsafe, and understand the controls that are needed. USDA and FDA will develop and implement grassroots outreach and education programs that take into account the difference in crops and regional operations, types of processing, and retailing practices. In addition, consumers will be provided with information to better understand safe food handling and preparation practices in the home.

12. What will USDA's role be in outreach and education for farmers?

USDA's network of agencies and programs that operate on a grassroots level, provides an effective, efficient and farmer-friendly interface for the development, delivery, and ultimate evaluation of appropriate agricultural practices for specific commodities on a regional or localized basis. Appropriate USDA-supported agencies with extensive farmer outreach capabilities include, but are not limited to, Cooperative Extension, the network of Agricultural Service Centers, county and regional Farm Agency offices and local conservation districts. FDA and USDA will take advantage of this network of agencies and programs in implementing their outreach and education programs.

13. Is there a concern about imported fruits and vegetables?

There are no data to indicate that there is more of a problem with imported fruits and vegetables compared to domestic products. However, some outbreaks have been traced back to imports, and health officials want to improve the safety of imported fruits and vegetables, as well as domestic products. It should be noted, however, that the sources of contamination of the fruits and vegetables involved in the foodborne outbreaks have not been determined in most instances; i.e., it is not known where in the food distribution chain from farm to table that the contamination took place. Developing and implementing GAP's, and product and process specific GMP's will enhance the safety of both domestic and imported products.

14. How could USDA assist in monitoring and testing domestic and imported fruit?

USDA could expand the scope of its nationwide, statistically valid pesticide residue monitoring program for domestic and imported fresh fruits and vegetables, the Pesticide Data Program (PDP), to develop a scientifically-sound microbiological surveillance program for foodborne pathogens and spoilage microflora on domestic and imported produce. (NOTE: This requires new funding and has not been approved.) These data would provide very useful baseline information.

15. How does FDA presently inspect produce from other countries?

Currently, there is no statutory provision that requires exporters to permit FDA to conduct on-site inspections of fruits and vegetables. Instead, all foods imported into the U.S. are subject to FDA inspection at the port of entry. Current FDA resources permit the review of approximately 30% of importation documents and the physical examination of approximately 3% of the products.

16. Does FDA have the authority to prevent the entry of foods that are contaminated?

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. With new legislation, FDA could declare foods from a country to be adulterated if that country's food system does not provide the same level of protection that is provided for domestic products. USDA already has comparable authority for meat and poultry products.

17. How will FDA assess the ability of foreign countries to provide the same level of public health protection as is provided in the U.S., and what criteria will be used to make the assessment?

New regulatory authority and an enhanced budget will allow FDA to develop an international inspection force to visit foreign countries and assess the conditions under which produce is grown, processed, and shipped. Based upon this information, products from some countries may be denied entry. FDA will encourage the adoption of appropriate GAP's and GMP's abroad and will work with USDA to provide technical assistance and training.

18. What effect will this new strategy have on FDA's ability to assure the safety of imported produce?

This initiative will allow FDA to assess the food production, transportation and handling practices in place in importing countries. This information will enable FDA to better identify

the risks associated with different countries; to develop guidance that reduces those risks; to more efficiently target inspection forces; and to prevent unsafe food from entering this country.

19. **Will this new strategy prevent producers in a foreign country that have a good safety record from being allowed to import?**

No. FDA's Seafood HACCP regulation has provisions which allow individual producers and processors to provide information directly or through competent third parties that they are meeting FDA safety requirements. These regulations will provide a model for any future actions.

20. **How will USDA monitor potential food safety problems in exporting countries? (Assessing agricultural production, transportation, and processing practices in these countries)**

USDA will work with FDA, CDC, and the exporting countries to develop profiles countries and evaluate the food production, transportation, and handling practices profiles will provide information that will target our inspection and testing resources that food being shipped to the United States is safe.

21. **How will USDA assist exporting countries?**

USDA will encourage the adoption of good practices abroad through technical assistance, training, and cooperative research efforts.

22. **You've told us on numerous occasions that the United States food supply is the safest in the world. Has something happened that changed that assertion?**

No. The United States food supply is still as safe as any in the world, but as the Administration's food safety initiative has emphasized, there is need to strengthen the current system and to add resources. New foodborne pathogens, new food products, changing technologies, and increasing antimicrobial resistance among foodborne pathogens present new challenges to the nation's food safety program.

23. Even though this legislative proposal amends the Food, Drug, and Cosmetic Act, doesn't the Senate Agriculture Committee have an interest because of the international trade aspects.

Congressional procedures will determine the bill's committee assignment. Government witnesses from FDA and other agencies can, in any case, brief staff and members of the Senate and House Agriculture committees and, if desired, can present testimony and other information at hearings.

24. What is the level of equivalence that the proposal envisions? Country? Each plant? Farm?

In general, "equivalence" is judged at the country level (for description of exceptions see question 23).

FDA has recently issued a draft guideline for evaluating equivalence of foreign food safety measures, which FDA will publish as a final guideline this Fall. The term "equivalent" has a specific meaning under the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures. The exporting country carries the burden of providing the evidence to demonstrate equivalence. The importing country, in this case the U.S., determines whether the exporting country's measure(s) is equivalent in meeting the United States' appropriate level of protection.

25. What is the possibility of other countries using a similar type requirement on U.S. products, i.e., as a barrier to trade to U.S. products?

Importing countries have always required that their food safety requirements be met. We believe that most trading partners will not be as concerned about the U.S. establishing the authority to restrict trade based on lack of equivalence as they will about how we intend to apply this authority.

26. How will this initiative change how we handle pesticide residues on imports?

This initiative will not change how we handle these situations. Pesticide residues on imported produce must meet the same strict standards as for domestic produce.

27. How will FDA pay for the overseas inspections?

The current thinking is that FDA will pay for overseas inspections through additional appropriated funding in the FY99 budget and future appropriations that include an increase

in Full-Time Equivalents (FTEs). We would not rule out alternatives, provided they are consistent with the World Trade Organization agreements. The Administration is proposing to increase FDA resources through additional appropriations for additional food safety activities, including overseas inspections.

28. Will you require HACCP for fresh fruits and vegetables?

No, not at this time. Better scientific data are needed before we can develop HACCP for fresh fruits and vegetables. FDA's plan is to issue guidance documents that help interpret existing requirements, and the agency consider later whether regulations are needed. 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.

29. How will a U.S.-owned farm in a third-world country be treated under the equivalence system?

Fruits and vegetables grown on a foreign-based U.S.-owned farm are imports under the FD&C Act. Thus, such foods would not be handled any differently by U.S. regulatory agencies than products of other farms in that country. It is possible that only a limited number of firms may be designated as equivalent, and the U.S.-owned farm, if it meets the safety criteria, could be on the list of companies allowed to export to the U.S.

30. Wouldn't country of origin labeling be just as effective in protecting people?

No. Country of origin labeling is not an effective food safety control measure. Imports are not all unsafe, any more than all domestic products are safe, so the consumer cannot infer safety or lack of safety from product origin. People may have other policy reasons for wanting country of origin labeling, but it is no substitute for the new initiatives being presented.

31. Has FDA ever taken action against a farmer? Do you have authority to take action against a farmer?

FDA has authority under the FD&C Act to take actions "against farmers" at present but these actions are very infrequent. For example, intentional use of a banned animal drug such as DES might result in an enforcement action. Ordinarily, when FDA deals with a food safety problem that is found to originate on a farm, the agency's focus is on identifying the source of the problem and removing unsafe food from commerce.

32. **How can all this be consistent with the WTO? It sounds like we are applying Good Agricultural Practices as a guidance document domestically and as a requirement for imports?**

We are applying our requirements and our guidance equitably. In each case, the FD&C Act applies general requirements that forbid food adulteration, and in some instances--such as our GMPs for food processors--we have regulations that elaborate on the statutory requirements. Guidance documents further elaborate on how to avoid food adulteration. They will help both domestic and foreign growers and processors to meet legal requirements.

33. **Why do you need a bill? Doesn't FDA have this authority now? What about the Public Health Service Act and its authority over quarantine for communicable disease?**

We want the strongest approach to the food safety concerns that have been raised, and specific legislative authority is a stronger and potentially faster and more certain response.

The President's proposed legislation will strengthen FDA's existing authorities under the Federal Food, Drug, and Cosmetic Act. Although FDA might be able to craft a regulation that moves in this direction, our strong preference is for a bill to give FDA statutory authority that resembles the USDA meat and poultry laws' provisions. Legislation is a much stronger response by the Administration and the Congress to the food safety concerns that have been raised.

34. **How does the U.S. government now work with foreign countries to improve the safety and quality of foods exported to the U.S.?**

FDA, USDA, and EPA work directly with many foreign countries to enhance the food production system and regulatory oversight infrastructure of these countries to better ensure that exports meet U.S. standards. The U.S. provides technical assistance to help correct deficiencies in Production practices or foreign monitoring and enforcement programs. In addition, the U.S. serves in leadership positions in international food safety standard-setting organizations.

35. **Does FDA have sufficient authority to enter into bilateral agreements concerning food imports with foreign countries?**

Yes, FDA does have authority to enter into such agreements.

36. **Can FDA make such agreements binding?**

In some cases these agreements are binding, and in other cases, they are not binding.

37. **How will the Administration ensure effective coordination among federal agencies involved with foreign food importation?**

In most cases, FDA works directly with foreign counterparts and clears its agreements with the State Department. FDA, USDA, and EPA have various mechanisms for coordinating their positions regarding international food safety issues (e.g., the Codex Alimentarius, an international standard-setting organization for food).

38. **How do you resolve the tension between food safety and food trade?**

The major international trade agreements have not changed the requirement that imported foods comply with the same food safety standards as domestically produced food.

39. **What assurance can you offer that food imports under a "fast track" system would be no more likely to present health risks than domestically produced food?**

Fast track authority does not affect food safety standards. These standards would remain the same for imported foods and for domestic foods.

9/30/97 2:20 PM

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.

OCT-17-1997 16:05

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P.01

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TO: Kevin Brosch
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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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DRAFT:clcoppp/OCC/FDA:October 17, 1997:2:00pm
(C:\files\fdsafe\billnew.017)

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 "(b) 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 and implementing regulations or that otherwise achieve the level of protection
11 required, as determined by the Secretary, for such food prepared, packed, or held in the United
12 States. In determining whether a system, conditions, or measures meet the requirements of this
13 Act or otherwise achieve the level of protection required, the Secretary may consider whether an
14 officer or employee duly designated by the Secretary has requested, and has been refused, access
15 to the establishment or location where such food was prepared, packed, or held for the purpose of
16 inspection (including sample collection), testing, or other relevant procedures, at a reasonable
17 time and in a reasonable manner."

18 (b) **IMPLEMENTATION OF AUTHORITY.—**

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

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IACP:OGC:USDA

202 690 2061 P.04

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(C:\files\fdsafe\billred.017)

A BILL

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

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

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

~~"(h)(1) If it is a food offered for import into the United States, 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 for the purpose of inspection (including sample collection), testing, or other relevant procedures, at a reasonable time and in a reasonable manner:~~

~~-----"(2) If it is a food offered for import into the United States, unless such food has been prepared, packed, and held under a system or conditions, or subject to measures, that meet the requirements of this Act and implementing regulations or otherwise achieve the level of protection required, at the time such food is offered for import, for such 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 meet the requirements of this Act or otherwise achieve the appropriate level of protection.~~

~~-----"~~

~~-----"~~

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
3 inspection (including sample collection), testing, or other relevant procedures, at a reasonable
4 time and in a reasonable manner."

5 (b) IMPLEMENTATION OF AUTHORITY.--

6 (1) PLAN.—The Secretary shall develop a plan for the initial implementation of
7 the authority under section 402(h)(2) of the Federal Food, Drug, and Cosmetic Act, as
8 added by subsection (a), and shall carry out the authority of such subsection consistent
9 with such plan.