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USDA

U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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

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FROM:

- ☐ DAN GLICKMAN, SECRETARY
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- ☐ PATRICK STEEL, DEPUTY CHIEF OF STAFF, EXTERNAL AFFAIRS
- ☐ 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: Erik. Thanks.

systems

its international inspection force. These funds will allow the hiring of new FDA inspectors to inspect foreign food ~~producers~~ and to inspect food imported into this country and will support research in developing methods to detect and prevent ~~disease-causing pathogens in food~~. contamination.

Improve the use of existing and projected resources for food safety. The President directed the Secretary of Health and Human Services and the Secretary of Agriculture to report within 90 days with a plan to improve the use of existing and projected resources to monitor agricultural and manufacturing practices abroad, assist foreign countries to improve these practices, and prevent the importation of unsafe produce, including detecting unsafe food at the dock and border. The President urged consideration of ways to target inspection and testing resources toward those areas where problems are most likely to occur.

where necessary

to ~~[illegible]~~ improve our knowledge of disease-causing pathogens on food, including but not limited to

Initiative to Improve Food Safety of Both Domestic and Imported Fruits and Vegetables

including / products produced in countries

Today President Clinton announced a major initiative that will improve the safety of fruits and vegetables, ~~especially~~ those imported from foreign countries. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas. Recognizing the need to ensure that these fruits and vegetables are as safe as those produced in the United States, the President proposed legislation that would authorize the FDA to halt imports of fruits, vegetables, and other food that do no meet U.S. food safety standards. The President also directed the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) to work cooperatively to improve the safety of fruits and vegetables by developing guidelines for producers to follow and industry.

This initiative builds on the President's prior actions on food safety -- including a new early warning system to detect outbreaks of foodborne illness as quickly as possible; enhanced safety standards for meat, poultry, and seafood products; ~~and a recent legislative proposal to increase federal recall authority.~~ This initiative has four parts.

FDA prefers to delete - ok w/ USDA

Development of Good Agricultural and Good Manufacturing Practices Guidance. FDA and USDA will work cooperatively with the ~~farmers, producers, and other persons involved in~~ fruit and vegetable ~~production~~ to help develop good agricultural and good manufacturing practices guidance 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 and water quality. 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, the FDA and USDA will develop a series of coordinated outreach and educational activities.

industry and others

Enhanced FDA Oversight for Imported Foods. The President proposed legislation that will authorize 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. This authority, which is equivalent to authority the USDA currently has to halt the importation of meat and poultry, will enable the FDA to prevent the importation of potentially unsafe food products. In coordination with international agencies and organizations, the FDA, USDA, and the CDC will develop information ~~country profiles~~ assessing the food production, transportation, and handling practices in place in foreign countries, re when necessary. These ~~profiles will provide invaluable~~ information that can be used to target import inspection and testing resources. The Administration also supports efforts on the part of the FDA and USDA to ~~help~~ encourage exporting countries to develop their own good practices to address potential food safety issues in those countries. The FDA and USDA will engage in technical assistance, training, and cooperative research efforts with exporting countries to improve the safety of imported fruits and vegetables, where necessary.

FDA edit ok w/ USDA

Expanded Federal Resources for Testing and Inspecting Fruits and Vegetables. The President called for an increase in FDA funding in FY 99 to allow the FDA to expand dramatically

DRAFT

What Will Be The Followup To This Directive?

USDA and FDA will report back to the President. Also, additional actions will be developed to build on this initiative. For example, in addition to farmers and food processors, we may need to develop action plans to address food safety concerns regarding transportation and handling of fruits and vegetables. We will also expand the FoodNet sentinel site program, and educational and outreach efforts to improve awareness of food safety at supermarkets, restaurants, and in homes.

Will Additional Legislation Be Needed?

Currently USDA and FDA are evaluating the need for additional legislation. Imports already must meet U.S. safety standards. What is needed most urgently are the resources to tackle this problem.

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL # of pages ▸ 1

To MARY Smith	From JOHNA
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NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

FDA
Janice Oliver
205-4307

USDA Q&A's

DRAFT

What exactly are Good Agricultural and Manufacturing Practices?

Good Agricultural and Manufacturing Practices are those which minimize the occurrence of foodborne disease by identifying points in the food production, delivery, and preparation process where harmful pathogens may be introduced. Many food producer and manufacturer groups have taken a leadership role in developing processes and procedures aimed at reducing these harmful pathogens in America's food supply. USDA and FDA will continue to support these industry efforts while working cooperatively with farmers and food manufacturers to develop better, quicker, and more accurate methods of preventing and ridding fresh fruits and vegetables of these adulterants.

Are Fruits and Vegetables Safe?

Fruits and vegetables certainly are safe and a key part of a healthful diet. Yet, recent occurrences of foodborne illness traceable to fruits and vegetables demand a redoubled effort to make America's food supply even safer. The difficulty is that food safety experts do not know exactly where or how the contamination occurs. It could be at any number of places between the growing and the consuming of food, including harvesting, transportation, packaging, distribution, retail display, and commercial or at-home preparation.

Are Imports Less Safe Than Domestic Product?

According to available data, we just don't know. However, this initiative is about making both domestic and imported product even safer. In cooperation with exporting countries, USDA and FDA will develop profiles of food production, transportation, and handling practices there. These profiles will give us information that we can use to target our inspection and testing resources to ensure that we are not importing unsafe food from those countries. It also will allow us to help exporting countries develop their own best practices for food safety.

Will This Initiative Require More Federal Resources?

USDA will ask for additional resources to expand the nationwide sampling program for pesticide residue on domestic and imported fruits and vegetables. It will be increased to include microbial pathogens such as E.coli. FDA will seek additional resources to test and inspect fruits and vegetables, including at country of origin.

Where Does Research Fit In?

We need more knowledge and tools to improve food safety. We don't know exactly how certain harmful pathogens show up in meat or on different fruits and vegetables. We need better, more rapid tests to identify these pathogens before they enter the retail food chain. And, we need to develop the methods and equipment to prevent this contamination from occurring.

A fundamental part of the Administration's 1998 initiative involved research. We need to accelerate food safety research in FY 98 and build on that effort in our FY 99 budget.

Imports Swamp U.S. Food-Safety Efforts

By JEFF GERTH and TIM WEINER

WASHINGTON, Sept. 28 — Since the 1980's, food imports to the United States have doubled. But Federal inspections of those imports by the Food and Drug Administration have dropped to less than half what they were five years ago.

Now, public-health scientists say they are seeing more and more outbreaks of disease linked to imported food, particularly fresh fruit and vegetables.

These are known to have sickened thousands of Americans, and those reported cases are a small fraction of the actual number of people made ill, according to scientists at the Centers for Disease Control and Prevention in Atlanta.

The scientists' list of outbreaks in the 1990's implicates imported foods — including raspberries from Guatemala and carrots from

TAINTED IMPORTS

A special report.

Peru; strawberries, scallions and cantaloupes from Mexico; coconut milk from Thailand; canned mushrooms from China; an Israeli snack food, and a multinational batch of alfalfa sprouts — in a variety of infectious diseases.

The increase in imports has strained the nation's food-safety system, said Dr. David A. Kessler, the Food and Drug Administration commissioner from 1990 through February 1997. "We built a system back 100 years ago that served us very well for a world within our borders," he said in an interview. "We didn't build a system for the global marketplace."

Most of the food imported to the United States is wholesome. Consumers, knowing that fresh produce is good for their health, can now buy reasonably priced fruits and vegetables imported from around the world, regardless of the season, and without ill effect.

But the illnesses that have been

Continued on Page A10

Continued From Page A1

imported along with some of the produce are an unintended byproduct of the boom in international trade — a boom long advocated by the Reagan, Bush and Clinton Administrations as crucial to economic growth.

There is "a tension between the two goals of safety and trade," said Mickey Kantor, President Clinton's first trade representative, who helped push global trade to the top of Mr. Clinton's agenda. "You want to open markets but not lower standards. And that's easy to say, but very, very difficult to carry out."

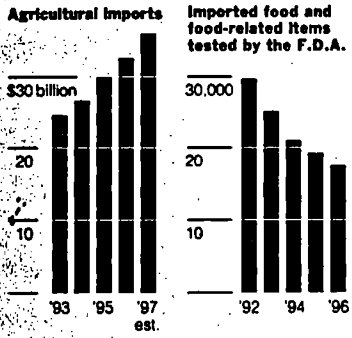
Scientists are recognizing that "free trade may present problems that are associated with food poisoning," said Dr. Marguerite A. Neill, an infectious disease specialist and a member of a Federal advisory panel drafting new food-safety standards. These problems cut both ways: radish sprouts from Oregon seeds sickened people in Japan in March, and South Korea said it detected E. coli bacteria in a shipment of frozen United States beef last week.

The problems imports may pose for American consumers include polluted water used to grow food in third-world nations, faulty safety systems in countries where the foods are produced, and a lack of natural immunity to exotic microbes rarely seen in this country. "Certain viruses, bacteria and parasites may be posing a unique problem

BY THE NUMBERS

More Imports, Fewer Tests

Food imports into the United States have risen while the F.D.A. has reduced the number of imports it examines.



All years are fiscal years ended in September.

Source: Agriculture Department

in the U.S. because we haven't tended to be exposed to them," Dr. Neill said.

Dr. Yasmine Motarjemi, a World Health Organization food-safety scientist, said the organization also believed that global trade "brings new pathogens into countries which are not immune."

Those problems were foreseeable — and foreseen.

In 1994, a Centers for Disease Control report said, "As trade and economic developments like Nafta take place, the globalization of food supplies is likely to have an increasing impact on food-borne illnesses."

In 1993, the Food and Drug Administration, in a memorandum citing "enormous inefficiencies in the current food-protection system" and the "ever-increasing challenges" posed by rapidly growing imports, asked the Clinton Administration for legislation giving it power to bar all food — including fruits, grains, vegetables and fish — imported from any country with an inferior food-safety system.

The Department of Agriculture has such authority over imported meat and poultry. But the F.D.A. never acquired that power though legislation or executive order.

Dr. Kessler said in an interview that he had told the Bush and Clinton Administrations that the safety system for imported food was inadequate and outdated.

"How is it physically possible to insure the safety of imported food?" he said. "You don't have police power throughout the world. Inspecting at the border has a limited value. You're left with real risks."

Now these risks figure in the political debate about free trade.

The Clinton Administration wants the power to sign new free-trade pacts without Congress's changing the language of those agreements. Opponents of this "fast track" authority raise the food-safety flag. Some food growers say that the risks from imports are insignificant, and that the C.D.C. exaggerates them.

The C.D.C. says diseases borne by domestic and foreign foods kill thousands of Americans and sicken millions, perhaps tens of millions, every year — mostly the very young, the very old and the very ill. Its scientists say almost none of those cases are ever traced back to their cause. As a result, they say, they lack the data to show how many people get sick from imported food, and whether that food is safer or less safe than domestic food.

Both sides in the fast track debate use the Centers for Disease Control's data to make their cases — and both sides mischaracterize what the data show, according to the scientists.

Now the Administration is preparing a proposal to address the problems posed by imported food — nine months after announcing a sweeping food-safety initiative that largely ignored them, and days after a bill to revamp the Food and Drug Administration was passed by the Senate.

The Food Chain

Modern-Day Travels Of Tainted Products

The United States has its own food-safety problems at home. Urgent questions about the integrity of America's food supply were raised when three American children died and 144 people were hospitalized after eating fast-food hamburgers in 1993. A reminder of the problem came this summer, when tainted hamburger meat from a Nebraska plant made 16 people sick.

But this spring and last, in an outbreak that attracted less attention, tainted raspberries from Guatemala made thousands of Americans sick. They were victims of a nearly invisible, dimly understood parasite called cyclospora, a species almost never seen in the United States before 1996.

To know the story of raspberries and cyclospora, Dr. Michael T. Osterholm, one of the nation's leading epidemiologists, wrote recently, "is to know food-borne disease in the modern world."

Not a single raspberry grew in Guatemala a decade ago. They grow today because the United States helped introduce them.

In the 1980's, during the height of the Guatemalan Army's campaign against leftist guerrillas, the United States Agency for International Development tried to win over the peasants by introducing them to the riches of global trade. Spurred by the Reagan Administration's Caribbean Basin Initiative, a 1983 free-trade measure that cut or eliminated tariffs on imports, the agency spent tens of millions of dollars promoting "nontraditional" agriculture in Guatemala.

It persuaded rural Guatemalans to switch from planting corn and beans for themselves to growing exotic crops for North Americans. It financed Guatemalan exporters and American importers who bring raspberries and other produce to the United States.

The raspberry trade exploded two years ago. Guatemala shipped less than 4,000 pounds of raspberries to the United States in 1992 — and about 700,000 pounds in 1996. The growers timed their first harvest of 1996 for late April and early May, when they would have the United States market almost completely to themselves.

But every April and May, when the spring rains come to the highlands, thousands of Guatemalans fall ill. They think something in the water flowing from the mountains makes them sick. And when the raspberries came to the United States in spring 1996, thousands of Americans fell ill as well. Many experienced weeks of misery — debilitating diarrhea, severe cramps, chills, fever, nausea, weight loss, depression.

The Centers for Disease Control's scientists never found cyclospora on the raspberries, but they found it in the stools of the Americans who ate them. And they are fairly certain that the parasite lay hiding in the water in Guatemala — the water with which the berries were sprayed and irrigated just before they were picked, shipped and eaten fresh and raw days later in the United States.

The case underscores the C.D.C.'s recent warning that "improving the microbiological safety of drinking water and food production" overseas is crucial "to insure the safety of the increasing amounts of food imported to the United States."

After that experience, American scientists and Guatemalan growers, working together, did everything they could to prevent another outbreak. But when this spring came, it happened again: Hundreds, perhaps thousands, of Americans who ate Guatemalan raspberries fell sick.

The cyclospora case is now the biggest outbreak of food-borne disease in the United States in years. The Centers for Disease Control count at least 2,300 people sickened this year and last. They are "the tip of the iceberg, and we don't know how big the iceberg is," said Dr. Barbara Herwaldt of the

The New York Times
MONDAY, SEPTEMBER 29, 1997

1/2

C.D.C. The Centers for Disease Control still know little about the parasite. But they established this spring that cyclospora is a common cause of diarrhea in Guatemalan children, and is still present in the water that runs through the highlands. The C.D.C. has shown that a polluted stream in a third world field can spawn a mysterious bug that can sicken a diner in midtown Manhattan.

"We eat out of everybody else's garden now," said Dr. Dan Colley, director of the Centers for Disease Control's division of parasitic diseases. And on an increasingly crowded planet, not everyone's garden is well kept.

When cyclospora struck in the United States again this spring, Guatemalan berry growers acted swiftly. First, they voluntarily suspended their shipments. Then they kicked the C.D.C.'s field investigator off their farms. Then they denounced the American scientists as snipers fighting a trade war on behalf of the growers' California competitors.

Roberto Castenāda, vice president of the Guatemalan Berries Commission, said in an interview: "Last year the guerrillas were in the fields asking my workers about their conditions, asking, 'Do you have bathrooms?' And this year, it was the C.D.C. The C.D.C. is killing us. They kill us every time they open their mouths."

Gabriel Biguria, a former president of Gexpront, the Guatemalan agricultural export group, said his country was the victim of an unfair trade practice.

"Cyclospora?" he said. "They can't find it. We find a tremendous possibility that people in California are using this as a very dangerous tool for protectionism. Protectionist forces find bugs or whatever to protect their market. It's a commercial war."

This dispute illustrates how science and politics collide in the arena of trade.

Some of the biggest food-trade fights have centered on the safety of American products. European nations did not want hormone-injected beef or chlorine-rinsed chicken. So far, the United States has won those cases. But now the United States sometimes finds itself on the other side of the fence, fighting with trading partners about the safety standards for their imports.

"Where we see a safety issue, they see a trade issue," said Dr. I. Kaye Wachsmuth, a leading Federal food-safety official.

The Inspectors

Import-Ban Power For the F.D.A.

Things were simpler when most of the food Americans ate was grown near their homes. Traditionally, food illness came from undercooked or mishandled domestic meat and poultry. Today, people depend more on global trade to satisfy their hunger.

"Go to a restaurant and take a look at your supper," said Dr. Robert Tauxe, chief of the food-borne and diarrheal disease branch at the Centers for Disease Control. "How many different continents are on your plate?"

The food chain that fills those plates has become unimaginably intricate.

For example, alfalfa sprouts gave salmonella to hundreds of people in 24 states this year and last. The seeds for those sprouts were bought from Uganda and Pakistan, among other nations, shipped through the Netherlands, flown into New York and trucked around the United States, Dr. Tauxe said.

Previously unknown pathogens are being discovered years after they arrive in the United States. Take the case of the Peruvian carrots, which took years to break.

In a coming issue of the Journal of Infectious Diseases, Dr. Osterholm and his colleagues will report their discovery of a new strain of E. coli bacteria, linked to a shipment of carrots from Peru. It took them six years to connect the new strain to a 1991 outbreak at a Minneapolis convention.

Most of the data on food-borne disease come from a relatively small number of outbreaks at big gatherings — conventions, restaurants and receptions. Most cases are never reported at all, said Dr. Osterholm, Minnesota's chief epidemiologist.

"If you get an outbreak of 500 people in a state, but no more than a few in any one household, you'll never pick it up," he said.

Because one percent or less of the actual number of outbreaks are reported, analyzed, identified and successfully traced back to the source, the C.D.C. says, its scientists cannot identify the causes of a great majority of food-borne diseases.

International food-borne outbreaks, said Dr. Colley of the Centers for Disease Control, are increasing and "can be expected to worsen as the world moves toward a global food economy."

Detecting microbes at the border is about as effective as detecting illegal drugs.

The Food and Drug Administration's inspectors test an ever-dwindling fraction of the 30 billion tons of food now imported into the United States. The responsibilities of individual inspectors have increased, but their resources have dwindled. They sampled 17,000 food items in 1996, less than one percent of 2.2 million food shipments, down from 30,000 samples, or about 3 percent of 1.1 million shipments, in 1992.

A more fundamental defense — insuring the safety of food at its source — does not exist. The F.D.A.'s inspectors can seize suspect imports, but they lack the power to automatically bar imported food just because it comes from a country with an inferior food-safety system.

Congress has never granted them that power. The White House has never publicly asked for it — until now, as it seeks fast track authority for trade pacts that is being seriously challenged in Congress over food-safety issues. The Administration plans to announce a proposal seeking to give the Food and Drug Administration the new powers this week.

The need has been apparent for years, Federal food-safety officials said. They cited the case of the tainted coconut milk from Thailand. In 1991, frozen coconut milk processed at a Bangkok plant, and exported by a Thai trading company to the United States, set off an outbreak of cholera. The life-threatening disease was thought to have been eradicated in this country.

"The Thai authorities were unaware of the existence of the plant," Dr. Tauxe said. "It was unlicensed, uninspected, unregulated."

Nor is it clear that the new powers the White House is planning to seek would have prevented the outbreak.

"I can't imagine an F.D.A. inspector in every country overseas," said Peggy Foegeding, a principal author of a landmark 1994 study on food-borne pathogens.

The United States is second to none at stopping food-borne disease after it breaks out. The Clinton Administration says it will lift up public-health and food-safety standards around the world until they meet those of the United States, in order to insure the safety of imported food.

But the United States' public-health systems today "cannot properly identify, track and control food-related illness, or prevent, to the extent possible, future cases from occurring," said a Federal report published in May as part of a food-safety initiative now nearing passage in Congress.

The Safety Net

Eroding Resources For Surveillance

Some Federal agencies are helping their foreign counterparts improve their public health systems. But "the United States cannot really build public health structures for the world," said Kerri-Ann Jones, a top White House science official.

The Clinton Administration says it wants more surveillance, more research, more F.D.A. inspectors. But "Federal budget constraints will likely prohibit significant funding increases in the future" for the F.D.A., said the food-safety initiative report published in May.

Many state health departments are overburdened and underfinanced, in part because of the AIDS crisis. Twelve states have no system for reporting food-borne disease, largely because of budget restrictions, public health officials say.

And many countries are reducing their own disease-surveillance abilities. "Economic globalization has also increased the need for governmental budget austerity," and countries around the world are cutting spending on public health to streamline their economies, according to a coming study by World Health Organization officials.

Scientists have fought new diseases spread by trade, travel and technology before. One night in 1849, a British doctor, John Snow, had a brainstorm. Having realized that cholera was spread by contaminated water, he ripped the handle off a water pump in a London slum and stopped an epidemic.

Global trade, the gigantic pump bringing the essentials and luxuries of life, and the small but rising threat of disease pose more intricate challenges for scientists.

Dr. Kessler and other prominent scientists, while acknowledging the problems with domestic food, said those challenges could be summarized by two questions:

As the world's nations become more intertwined, interdependent and intensely competitive, will the rest of the world's standards become more like those of the United States, with its relatively safe water, sound hygiene and state-of-the-art science? Or will the United States, despite its high standards, become more vulnerable to the rest of the world's microbes?

"The challenge for the United States," Dr. Kessler said, "is to raise everyone else's standards."

The New York Times

MONDAY, SEPTEMBER 29, 1997

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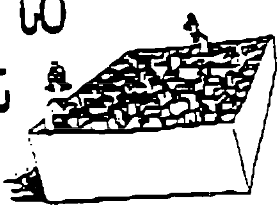

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Mary Smith		6-5571	6-7431

Mary - this is the document that FDA distributed. We submitted our comments on it, and are interested in seeing what document we are now working from (if it has been updated)

Andrea

SECTION# 25

FROM:

PHONE: 202-395-6127

FAX# (202)395- 4579

CONTACT: If you have problems receiving this fax call (202)395- 6127

SUBJECT:

1. GAPs/GMPs for Fresh Fruits and Vegetables:

Directive: The FDA will develop good agricultural practices (GAPs) and good manufacturing practices (GMPs) guidance for fresh fruits and vegetables. The agency will also convene a public meeting on fruits and vegetables, leading to the future development of mandatory HACCP procedures for fresh fruits and vegetables.

FDA will propose mandatory Hazard Analysis and Critical Control Point (HACCP) regulation for the manufacture of juices in January, 1998.

FDA and the USDA's Agricultural Research Service (ARS) will accelerate the research outlined in the FY98 food safety initiative, to develop intervention technologies to eliminate and/or reduce levels of pathogens. This research will provide scientific data for future development of HACCP programs for fresh fruit and vegetable products. ARS will work with FDA to identify needed research, giving high priority to FDA needs associated with fresh fruits and vegetables.

Time: Publish GAPs/GMPs for fresh fruits and vegetables for which data exist and propose mandatory juice HACCP by January, 1998. FDA will urge industry to adhere to the GAP/GMP guidance upon publication. Public comment will be solicited to improve the guidance and to facilitate development of appropriate HACCP programs.

Resources needed:

1. Implementing GAP/GMPs - Additional resources are needed to assimilate data for GAPs/GMPs, as well as conduct surveillance, testing, and other work overseas.

   Implementing HACCP - HACCP requirements for any fruit or vegetable product will require at least 1 year to develop the proposal, 1 year for analysis of comments and preparation of a final regulation, and 2-3 years for phased-in implementation of the regulation.

   Resources Needed: 185 FTEs and $20.0 million

Develop/monitor Mutual Recognition Agreements:	15 FTEs
Foreign visits/evaluations:	100 FTEs
Reg writers, policy, program evaluators:	27 FTEs
Administrative support:	3 FTEs
Filer audits, review of HACCP plans, entry screening:	40 FTEs

2. $ 8.0 million (37 FTEs) - Research to develop intervention/prevention technologies, e.g., antimicrobials, to reduce levels of or eliminate pathogens, and baseline pathogen data for development of HACCP.

FY98 $15 million FY 99. $13 million

2. Legislative proposal:

Directive: a. FDA will develop a legislative proposal, to be put forward by the Administration, requiring that no food may be imported into the U.S. unless it is produced under a food safety system that provides the same level of protection as provided by the U.S. food safety system. This proposal will enhance FDA's ability to prevent the importation of unsafe food in a manner consistent with U.S. trade agreements.

Section 402 of the FFDCA should 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, unless such food has been prepared, packed or held under a system or conditions, or subject to measures, that provide a level of protection that is at least the same as the level of protection provided under this Act for food prepared, packed, or held in the United States at the time such food is offered for import. The importer of the food shall be required to demonstrate objectively that the system, conditions, or measures relevant to such food achieve the same level of protection.
> (2) The Secretary may promulgate regulations to implement this subsection, including regulations identifying those systems, conditions, or measures that are equivalent within the meaning of this section."

The country of export has objectively demonstrated provides

b. FDA will also develop a legislative proposal to facilitate traceback of foodborne illness to the causative food. The Act should be amended by adding a new section 415 requiring maintenance of records as follows:

> "Manufacturers and distributors of food, including importers, shall include among the records they maintain, records of receipt and distribution of such food, which shall include such information as the Secretary finds necessary to permit the distribution of such food to be traced. These records shall be maintained for a reasonable period of time beyond the shelf-life of the food."

The Act should also be amended to permit access to those records by amending section 704 by adding a new paragraph (a)(4) as follows:

> "An officer or employee making an inspection under paragraph 704(a)(1) of a food which may pose a hazard to public health or has been associated with foodborne illness shall be permitted at all reasonable times to have access to and to copy and verify any records required to be kept under section 415."

Finally, the act would be amended to make it a prohibited act (subject to injunction or prosecution) to fail to maintain required records for traceback. A new subsection 301(x) should be added as follows:

> "The failure to maintain the records required under the authority of section 415."

c. The Administration should also pursue mandatory recall authority for FDA; as previously proposed by the agency.

Resources:

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Resources needed:

1. Implementing GAP/GMPs - Additional resources are needed to assimilate data for GAPs/GMPs, as well as conduct surveillance, testing, and other work overseas.

   Implementing HACCP - HACCP requirements for any fruit or vegetable product will require at least 1 year to develop the proposal, 1 year for analysis of comments and preparation of a final regulation, and 2-3 years for phased-in implementation of the regulation.

   Resources Needed: 185 FTEs and $20.0 million

Develop/monitor Mutual Recognition Agreements:	15 FTEs
Foreign visits/evaluations:	100 FTEs
Reg writers, policy, program evaluators:	27 FTEs
Administrative support:	3 FTEs
Filer audits, review of HACCP plans, entry screening:	40 FTEs

2. $ 8.0 million (37 FTEs) - Research to develop intervention/prevention technologies, e.g., antimicrobials, to reduce levels of or eliminate pathogens, and baseline pathogen data for development of HACCP.

2. **Legislative proposal:**

Directive: **a.** FDA will develop a legislative proposal, to be put forward by the Administration, requiring that no food may be imported into the U.S. unless it is produced under a food safety system that provides the same level of protection as provided by the U.S. food safety system. This proposal will enhance FDA's ability to prevent the importation of unsafe food in a manner consistent with U.S. trade agreements.

Section 402 of the FFDCA should 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, unless such food has been prepared, packed or held under a system or conditions, or subject to measures, that provide a level of protection that is the same as the level of protection provided under this Act for food prepared, packed, or held in the United States at the time such food is offered for import. The importer of the food shall be required to demonstrate objectively that the system, conditions, or measures relevant to such food achieve the same level of protection.
> (2) The Secretary may promulgate regulations to implement this subsection, including regulations identifying those systems, conditions, or measures that are equivalent within the meaning of this section."

b. FDA will also develop a legislative proposal to facilitate traceback of foodborne illness to the causative food. The Act should be amended by adding a new section 415 requiring maintenance of records as follows:

> "Manufacturers and distributors of food, including importers, shall include among the records they maintain, records of receipt and distribution of such food, which shall include such information as the Secretary finds necessary to permit the distribution of such food to be traced. These records shall be maintained for a reasonable period of time beyond the shelf-life of the food."

The Act should also be amended to permit access to those records by amending section 704 by adding a new paragraph (a)(4) as follows:

> "An officer or employee making an inspection under paragraph 704(a)(1) of a food which may pose a hazard to public health or has been associated with foodborne illness shall be permitted at all reasonable times to have access to and to copy and verify any records required to be kept under section 415."

Finally, the act would be amended to make it a prohibited act (subject to injunction or prosecution) to fail to maintain required records for traceback. A new subsection 301(x) should be added as follows:

> "The failure to maintain the records required under the authority of section 415."

c. The Administration should also pursue mandatory recall authority for FDA; as previously proposed by the agency.

Resources:

Q&A on the Safety of Imported Food
September 25, 1997

Q: I have young children and I am worried about the safety of the food I buy for them. I am especially concerned about the stories I have read about the outbreaks of foodborne disease linked to imported food. Is food produced in the United States safer than imported food?

A: Both U.S. and foreign produced food are extremely safe. In fact, our nation's food supply today is probably the safest it has ever been, and we are working to make it even safer. During the last four and half years the Clinton Administration has taken a number of steps to further improve the safety of the food we eat. With the help of the Vice-President's National Performance Review, we have fundamentally enhanced the way we ensure the safety of meat, poultry, and seafood. We put in place important new protections against the risks of pesticides in our food, especially for our children. And Congress has recently agreed to provide most of the $43 million the President requested to improve food safety and beginning next month we will be using that money to further reduce the incidence of foodborne illness.

In rare cases, however, food produced either here or abroad has caused an outbreak of foodborne illness. We are committed to taking additional steps to further ensure that all of our food is safe whether domestic or imported.

Q: It seems like we are hearing about more outbreaks of foodborne illness. Are we experiencing an increase in the number of outbreaks of foodborne disease?

A: Even though our food supply is among the safest in the world, each year there are still millions of Americans who get sick from the food they eat. The overwhelming majority of these cases are what is known as sporadic illnesses. These illnesses are individual cases not related to one another and are not caused by a single, specific contaminated food. An "outbreak" of foodborne disease is when many people become sick from being exposed to the same source of contaminated food.

As a result of new steps we have taken over the last four years, we are doing a more thorough job looking for outbreaks than we have ever done before. Experts we have consulted say that our improved surveillance is one of the primary reasons we are hearing about more food-related illnesses. We our catching and quickly responding to outbreaks of foodborne illness that we often missed in the past.

Thomas L. Freedman
09/24/97 08:00:52 PM

Record Type: Record

To: Mary L. Smith/OPD/EOP

cc:
Subject: Food Safety

Here are the Q's i can think of:

How do they new rules work?

When will they go into effect?

How will this improve food safety?

What do farmers think of this, doesn't it regulate farmers?

How does this effect free trade?

How much does this cost?

How many more inspectors will this get?

What countries will this effect?

Why are you doing this now?

How does it fit with the president's food safety intiaitve?

DRAFT

What Will Be The Followup To This Directive?

USDA and FDA will report back to the President. Also, additional actions will be developed to build on this initiative. For example, in addition to farmers and food processors, we may need to develop action plans to address food safety concerns regarding transportation and handling of fruits and vegetables. We will also expand the FoodNet sentinel site program, and educational and outreach efforts to improve awareness of food safety at supermarkets, restaurants, and in homes.

Will Additional Legislation Be Needed?

Currently USDA and FDA are evaluating the need for additional legislation. Imports already must meet U.S. safety standards. What is needed most urgently are the resources to tackle this problem.

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL | # of pages ► 1

To MARY Smith	From JOHNA
Dept./Agency ph- 5577	Phone # 720-4623
Fax # 456-7431	Fax #

NSN 7540-01-317-7368 5099-101 GENERAL SERVICES ADMINISTRATION

DRAFT

What exactly are Good Agricultural and Manufacturing Practices?

Good Agricultural and Manufacturing Practices are those which minimize the occurrence of foodborne disease by identifying points in the food production, delivery, and preparation process where harmful pathogens may be introduced. Many food producer and manufacturer groups have taken a leadership role in developing processes and procedures aimed at reducing these harmful pathogens in America's food supply. USDA and FDA will continue to support these industry efforts while working cooperatively with farmers and food manufacturers to develop better, quicker, and more accurate methods of preventing and ridding fresh fruits and vegetables of these adulterants.

Are Fruits and Vegetables Safe?

Fruits and vegetables certainly are safe and a key part of a healthful diet. Yet, recent occurrences of foodborne illness traceable to fruits and vegetables demand a redoubled effort to make America's food supply even safer. The difficulty is that food safety experts do not know exactly where or how the contamination occurs. It could be at any number of places between the growing and the consuming of food, including harvesting, transportation, packaging, distribution, retail display, and commercial or at-home preparation.

Are Imports Less Safe Than Domestic Product?

According to available data, we just don't know. However, this initiative is about making both domestic and imported product even safer. In cooperation with exporting countries, USDA and FDA will develop profiles of food production, transportation, and handling practices there. These profiles will give us information that we can use to target our inspection and testing resources to ensure that we are not importing unsafe food from those countries. It also will allow us to help exporting countries develop their own best practices for food safety.

Will This Initiative Require More Federal Resources?

USDA will ask for additional resources to expand the nationwide sampling program for pesticide residue on domestic and imported fruits and vegetables. It will be increased to include microbial pathogens such as E.coli. FDA will seek additional resources to test and inspect fruits and vegetables, including at country of origin.

Where Does Research Fit In?

We need more knowledge and tools to improve food safety. We don't know exactly how certain harmful pathogens show up in meat or on different fruits and vegetables. We need better, more rapid tests to identify these pathogens before they enter the retail food chain. And, we need to develop the methods and equipment to prevent this contamination from occurring.

A fundamental part of the Administration's 1998 initiative involved research. We need to accelerate food safety research in FY 98 and build on that effort in our FY 99 budget.

USDA

U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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

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- ☐ ANNE KENNEDY, SPECIAL ASSISTANT FOR POLICY
- ☒ ERIC OLSEN, SPECIAL ASSISTANT FOR POLICY
- ☐ JANET POTTS, COUNSEL TO THE SECRETARY

MESSAGE: This is broad Q+A on food safety generally. More to come specifically on the initiative in 20 minutes.

ENSURING THE SAFETY OF IMPORTED FOODS

Are Imported Foods Safe to Eat?

- At a time when the Congress is considering legislation that would renew presidential authority to negotiate trade agreements that would increase U.S. access to foreign agricultural markets, concerns about the safety of imported foods are being expressed.

- The 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 foods also apply to imported foods.

- The Centers for Disease Control and Prevention (CDC) reports that, while foodborne illnesses associated with imported foods may be different than those associated with domestic products, the overall risks to consumers appear, in general, to be similar for both imported and domestic 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.

What Are The Benefits to the United States of Agricultural Trade?

- The U.S. economy benefits greatly from agricultural trade. Agriculture has consistently shown a trade surplus, every year since 1960. U.S. agricultural exports support almost 1 million jobs.

- Fruits and vegetables are an essential component of a healthy diet, and agricultural trade helps make available to Americans a variety of fresh fruits and vegetables throughout the year.

What Action is the U.S. Government Taking To Improve Food Safety?

- As announced last summer by President Clinton, surveillance and sentinel site activities designed to detect food-borne illness before it spreads are being enhanced as part of the Administration's Food Safety Initiative.

- The initiative includes the development of a new early warning system by Federal, State, and local governments to help detect outbreaks of food-borne illness earlier and allow the regulatory network to respond more quickly. Actions would include stopping shipments at the border and increasing the frequency of testing of imported meat and poultry products.

- The Food Safety Initiative includes risk assessment and research on better detection methods for foodborne pathogens and toxins.

- U.S. food safety agencies continually gather and evaluate information from around the world on potential sources of food-borne illness to prevent entry of suspect foods into the United States.

- When this intelligence indicates a possible problem with an imported food from a given country, the Federal Government increases the monitoring of that food at border checkpoints and takes other action to prevent distribution of the food within the United States. When necessary, the Federal Government will work with the exporting country to address the underlying problems.

- The Federal Government maintains strong research and surveillance activities intended to identify emerging food-borne hazards.

What Are The Federal Government's Food Safety Programs with Regard To Imports?

- With regard to meat and poultry products specifically, the Federal inspection laws require countries that export meat or poultry to the United States to impose inspection requirements equivalent to U.S. requirements.

- Countries exporting meat or poultry to the United States undergo a rigorous review of their infrastructure and programs to gain eligibility to export meat or poultry to the United States.

- The United States evaluates a foreign country's controls on livestock and poultry slaughter and processing establishments in specific areas of risk: animal diseases, residues, contamination, food processing, economic fraud, and labeling.

- In July 1996, a final rule on pathogen reduction and Hazard Analysis and Critical Control Point (HACCP) systems for meat and poultry plants was published.

- In January 1997, the first two components of a new food safety system for meat and poultry became mandatory:

--All domestic meat and poultry plants and foreign meat and poultry plants exporting to the United States are required to adopt and follow written standard operating procedures (SOP) for sanitation to reduce the likelihood of harmful contamination or adulteration of products.

--All domestic and foreign meat and poultry slaughter plants that produce carcasses used in products exported to the United States will be required to conduct microbial testing for generic *E. coli*, to verify that controls on processing are working.

SAFETY OF IMPORTED FOODS

- All domestic meat and poultry plants and those foreign meat and poultry plants exporting to the United States are required to implement HACCP by January 2000.

- In December 1995, the United States government published a final rule requiring HACCP programs at seafood processing plants. That requirement will go into effect on December 18, 1997. HACCP programs will be required at all domestic and foreign seafood processing plants shipping products into the United States.

- The United States regulatory agencies are working with their foreign counterparts to increase the number of international cooperative agreements. Under these agreements, regulatory agencies in each country ensure that food is produced and manufactured under equivalent systems that provide a comparable level of safety.

- U.S. laws require food agencies to go through a public notice and comment process before finding another country's system equivalent.

How Does The North America Free Trade Agreement Assure The Safety Of Our Food Supply?

- U.S. food safety officials hold leadership positions on committees of the North American Free Trade Agreement (NAFTA).

- NAFTA did not change the requirement that imported foods comply with the same food safety standards as domestically produced food. Indeed the ability of countries to preserve safety requirements is explicitly protected.

- In fact, NAFTA provides a framework for increasing the likelihood that food produced in other countries meet U.S. standards.

- For example, under NAFTA, technical working groups have been established to address specific food safety issues, such as microbial contaminants, pesticides and chemical contaminants, for specific food groups such as fruits, vegetables, dairy products, and seafood.

- Through the technical working groups, the three countries share information about their pesticide regulatory systems and are working to coordinate the systems more closely.

- U. S., Canadian, and Mexican officials work together along the borders to monitor food shipments and, if necessary, to stop suspect shipments. This cooperation has resulted in a decrease in the number of detentions of food shipments from Canada and Mexico.

- The United States, Canada, and Mexico have established a technical cooperative initiative to promote staff exchanges and the sharing of information among the three countries.

- In the case of Mexico, the United States is providing information and technical assistance to the Mexican Government and groups of Mexican growers to help that country meet U.S. safety standards for foods intended for export to the United States.

How Will New Trade Agreements Assure The Safety Of Imported Foods?

- U.S. representatives have leadership positions in the international organizations charged with ensuring the safety of food produced around the world.

- U.S. food safety officials frequently meet with their counterparts in foreign governments to evaluate and discuss emerging food safety issues. The bilateral meetings take place routinely--independent of any specific trade agreements or discussions--to develop programs to control microbiological and chemical contaminants in foods.

- The United States participates in the Sanitary and Phytosanitary Committee of the World Trade Organization (WTO) on food safety issues. The U.S. participation ensures that U.S. food safety standards are emphasized and not compromised in the interest of facilitating trade.

- The United States participates in all committees of the Codex Alimentarius Commission, an international food standard-setting forum created in 1962 under the sponsorship of the WHO and the Food and Agriculture Organization of the United Nations.

- U.S. participation in Codex ensures that the views of the United States on critical food safety issues will be addressed in the development of all international food standards.

- In summary, the U.S. government's international activities help to raise the global standards for food safety.

USDA

U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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MESSAGE: More to come

Do you have Q+A for FDA?

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

USDA's role will be threefold:

1. USDA will accelerate the research outlined in the FY98 President's Food Safety Initiative, to develop intervention technologies to eliminate and/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 to improve the safety of their products.

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 Best 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 Extensions, the network of Agricultural Service Centers, county and regional Farm Service Agency offices and local conservation districts.

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.)

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 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.

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 of exporting countries and evaluate the food production, transportation, and handling practices. These profiles will provide information that will target our inspection and testing resources to ensure that food being shipped to the United States is safe.

How will USDA assist exporting countries to develop good agricultural practices?

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

FOOD AND DRUG ADMINISTRATION
OFFICE OF THE COMMISSIONER
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WASHINGTON, D.C. 20204

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DRAFT

Initiative to Safeguard Imported Foods
Summary of Initiative

The Clinton Administration proposes to increase assurances that all foods, from farm to table, and including imported foods, meet high standards of safety. As we recognize the increasing complexity of food systems, from domestic to international, from production to retail and food service, and the gaps in our knowledge about foodborne illness outbreaks, their causes and sources, we need to take the appropriate steps to maintain the safety of our food supply. Therefore, the Administration is proposing the following steps.

Guidance for Fresh Fruits and Vegetables

FDA will develop "Guidance to Minimize Microbial Food Safety Risks for Fruits and Vegetables" in collaboration with USDA and with the food industry. This guidance will include such issues as sanitation in harvesting and production facilities, transportation, water quality, and worker health and safety. FDA and USDA will convene a public meeting to discuss guidance concepts by mid-November 1997. Information from the public meeting will be used to publish this guidance for all fresh fruits and vegetables by January 1, 1998. Working with USDA and the food industry, FDA will publish good agricultural practices (GAPs) and good manufacturing practices (GMPs) guidance by the end of 1998 that will build on the broader guidance and be further tailored to apply specifically to each of four to eight produce categories (representing a significant proportion of the fresh produce consumed annually in the United States)

Enhanced FDA Oversight Authority for Imported Foods

The Administration will propose legislation to enable FDA to ensure that no food may be imported into the United States unless it is produced under a system that provides the same level of public-health protection provided by the U.S. food-safety system. (USDA already has such authority for ensuring the safety of imported meat and poultry.) In addition, legislation will be proposed that will allow FDA to refuse importation of a food that comes from a facility that refused to permit FDA inspection. USDA and FDA will develop country profiles assessing the food production, transportation, and handling practices in place in foreign countries. USDA and FDA will also encourage the adoption of good practices overseas through technical assistance, training, and cooperative research efforts. The agencies will target these activities and assistance to suppliers of products being shipped to the United States.

New Resources to Oversee Imported Foods

The Administration will ask Congress to appropriate new funding, beginning in FY'99, to implement these initiatives. These funds will allow the federal agencies responsible for food safety to carry out such activities as hiring of new FDA inspectors to inspect foreign food producers and to inspect food imported into this country, and to carry out research to develop methods to detect disease-causing pathogens in food.

Report to the President

FDA and USDA will report back to the President by October 1, 1998, with a status report on progress toward the establishment of guidance to minimize microbial food-safety risks for fruits and vegetables, the legislation to enhance FDA's authority to keep unsafe foods out of the United States, and the testing, research, education, outreach and any other actions needed to implement this initiative. For example, this report will detail needs for better understanding of how food becomes contaminated--at every point in its production and distribution--and our needs for better scientific methods to more rapidly identify and eliminate pathogens from our food supply.

DRAFT

MEMORANDUM FOR THE SECRETARY OF AGRICULTURE
SECRETARY OF HEALTH AND HUMAN SERVICES
SECRETARY OF LABOR
ADMINISTRATOR OF THE ENVIRONMENTAL PROTECTION AGENCY

SUBJECT: Initiative to Safeguard Imported Foods

Earlier this year, I directed my Administration to undertake a broad initiative to improve the safety of the nation's food supply. That initiative is designed to address attention to a number of steps at which the safety of food from farm to table can be rapidly improved. The initiative focuses on opportunities in foodborne illness surveillance, enhanced coordination among federal and state agencies with food-safety responsibilities, and enhanced inspection, research, education, and risk assessment programs. I am now directing my Administration to direct specific attention to ensuring the safety of imported foods.

My Administration will take actions to increase assurances that all foods, from farm to table, and including imported foods, meet high standards of safety. Recognizing the increasing complexity of food systems, from domestic to international, from production to retail and food service, and the gaps in our knowledge about foodborne illness outbreaks, their causes and sources, we need to take appropriate steps to maintain the safety of our food supply.

I hereby direct that you work together with the food industry and with our partners in trade to ensure the safety of foods imported into the United States. Your actions should include development of guidance to minimize microbial food safety risks from fresh fruits and vegetables and enhanced oversight authority for imported foods. You should work with the food industry and with consumers and the public to develop outreach and educational efforts to encourage producers to adopt these guidance practices. You should also work to evaluate the potential for food-safety problems in exporting countries, and to help those countries develop their own best practices. You should accelerate food-safety research. You should report back to me in one year with the status of your actions and your further recommendations.

Finally, I am directing the Administrator of the Environmental Protection Agency and the Secretary of Labor to commit staff resources to assist the Secretaries of Health and Human Services and Agriculture in achieving these goals.

THE WHITE HOUSE

WASHINGTON

September 24, 1997

MEMORANDUM FOR ERSKINE BOWLES

FROM: Bruce Reed
Elena Kagan

SUBJECT: Food Safety Initiative

This memorandum sets out a proposal for a new food safety initiative focusing on imported produce. HHS/FDA, USDA, USTR, and OMB have participated in developing this proposal. The memorandum also raises an issue of timing that has arisen in our policy discussions.

The Proposal

The initiative has four elements -- one administrative and three legislative.

1. A Presidential directive to the FDA to issue guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance would deal with such matters as sanitation, worker health, and water use. The guidance would not itself have the force of law (the domestic farmers' groups would object if it did), but would indicate what kinds of practices the FDA believes violate the Food and Drug Act. In so doing, the guidance (we may be able to use the term "enforcement standards") would improve the agricultural and manufacturing practices of all those, foreign and domestic, seeking to sell produce in the U.S. market. As part of this directive, the President would instruct USDA to provide assistance to the FDA through various research activities and educational programs.

2. Proposed legislation giving the FDA authority to bar food imports from any foreign country or establishment that does not provide safety protections that are at least equivalent to those provided by the U.S. food safety system. This legislation would give to the FDA the power now held by USDA (regarding meat and poultry products) to hold foreign countries and establishments to an "equivalency standard." We expect that Jeff Gerth will highlight this difference between USDA and FDA authority, noting that the FDA now relies on essentially unenforceable bilateral agreements to hold other countries to equivalent food safety standards. The legislation would include the authority to bar imports if a foreign country or establishment refused to permit the FDA to carry out inspections.

3. Proposed legislation and budget request to improve and expand the FDA's inspection system, particularly in relation to foreign producers. OMB is still reviewing the numbers, but the FDA has requested $20-25 million for FY 99. This appropriation would allow vastly increased

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inspections abroad and at the dock (though still permitting the inspection of only a minuscule percentage of total imports), as well as some supportive research activities. Some fairly significant funding commitment to hire additional inspectors is critical to the credibility of this initiative.

4. Proposed legislation to require "country of origin" labeling on produce, meat, and certain other food products. This legislation would not itself do much to improve food safety (at least in the short term), but it would provide consumers with more complete information than they currently have about food products. It also may be the part of this package that the public finds most attractive. The agricultural groups are divided on the desirability of such legislation. The Farmers Union and Farmers Bureau like it, as do the cattlemen and most fruit and vegetable growers. Pork producers do not like it (we don't know why), and food processors and retailers think the legislation would place onerous burdens on them.

Timing

Some believe we should not announce this initiative immediately. OMB (OIRA) urges that we take more time to vet the proposal, noting that it is complex and politically sensitive -- and that we have put it together from scratch in 48 hours. OMB also has asked whether we should use these proposals during negotiations over fast track (to buy the support of reluctant legislators), rather than announce them now. Finally, USTR has expressed some uncertainty about whether the "country of origin" proposal in particular could undermine, rather than aid, our position on fast track. (USTR stresses that this is a question only of political strategy; USTR has no objections to any part of this package as a matter of trade policy.)

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inspections abroad and at the dock (though still permitting the inspection of only a minuscule percentage of total imports), as well as some supportive research activities. Some fairly significant funding commitment to hire additional inspectors is critical to the credibility of this initiative.

4. Proposed legislation to require "country of origin" labeling on produce, meat, and certain other food products. This legislation would not itself do much to improve food safety (at least in the short term), but it would provide consumers with more complete information than they currently have about food products. It also may be the part of this package that the public finds most attractive. The agricultural groups are divided on the desirability of such legislation. The Farmers Union and Farmers Bureau like it, as do the cattlemen and most fruit and vegetable growers. Pork producers do not like it (we don't know why), and food processors and retailers think the legislation would place onerous burdens on them.

Timing

Some believe we should not announce this initiative immediately. OMB (OIRA) urges that we take more time to vet the proposal, noting that it is complex and politically sensitive -- and that we have put it together from scratch in 48 hours. OMB also has asked whether we should use these proposals during negotiations over fast track (to buy the support of reluctant legislators), rather than announce them now. Finally, USTR has expressed some uncertainty about whether the "country of origin" proposal in particular could undermine, rather than aid, our position on fast track. (USTR stresses that this is a question only of political strategy; USTR has no objections to any part of this package as a matter of trade policy.)

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 encourace 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.

These profiles will give us information that we can use to target our inspection and testing resources to ensure that we are not importing unsafe food from those countries.

For example, if a profile suggests that a country has a potential problem with a certain pathogen like E.Coli, then we would be able to increase our testing of products from that country.

4. Direct USDA and FDA to Help Exporting Countries Develop Their Own Best Practices

Through technical assistance, training, and cooperative research efforts, USDA and FDA will help exporting countries develop their own best practices to address potential food safety issues in those countries. This will improve the safety of imported fruits and vegetables.

Possibly involve other international development organizations etc.

5. Expanded Federal Resources for Testing and Inspecting Fruits and Vegetables

FDA needs additional resources to enhance their ability to test and inspect fruits and vegetables, including for overseas work. We need the new resources to aggressively act on the new information that we will gain from the country profiles. For example, if a profile shows that country X is likely to have a problem with a particular pathogen, we will be able to increase our testing and monitoring to ensure that no unsafe product enters the U.S.

We also plan to expand USDA's testing program. Currently, USDA has a nationwide, statistically based sampling program for pesticide residues on both domestic and imported fruits and vegetables. USDA will be directed to expand that program to include microbial pathogens like E. Coli. Farmers and handlers prefer to have USDA do this testing.

If USDA finds a problem, USDA will work cooperatively with farmers to find out how to prevent the problem from occurring. (Won't allow unsafe product on market).

6. Accelerate Food Safety Research

We need additional knowledge and tools to improve food safety. For example, we don't know why pathogens like E. Coli appear in animals, or how E.coli has ended up on different fruits and vegetables. We also need better, more rapid tests to identify pathogens on food products, and we need to develop effective tools to prevent contamination from occurring.

A fundamental part of the Administration's 1998 initiative involved research. We need to accelerate that research in FY 98 and build on that effort in our FY 99 budget. Not just fruits and vegetables, but across all food products and throughout the food production, manufacturing and distribution system.

President Clinton Announced Plan to Increase Food Safety Through Development of Good Agricultural and Good Manufacturing Practices Guidance

President Clinton directed the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) to work cooperatively with constituents to improve the safety of fruits and vegetables by developing guidelines for producers to follow. These guidelines will help to improve food safety, both domestically and through imports, by advising growers, producers, importers, and other food suppliers of specific practices that the FDA deems to violate the Food and Drug Act. <u>Today, the President announced six key elements that comprise his new initiative on food safety</u>:

1. **Development of Good Agricultural and Good Manufacturing Practices Guidance.** FDA and USDA will work cooperatively with farmers, producers, and other persons involved in fruit and vegetable production to help develop good agricultural and good manufacturing practices guidance. This guidance, while not the force of law, will help inform those in the produce industry as to practices that are not condoned by the FDA and have been determined by the FDA to violate the Food and Drug Act. Currently, producers of produce are often without any guidance as to practices that might be harmful to the safety of consumers.

2. **Outreach to Constituents to Help Develop Guidance and to Increase Educational Campaign to Adopt These Practices.** FDA and USDA will work with constituents to develop outreach and educational efforts to encourage producers to adopt these practices.

3. **Evaluation of Potential for Food Safety Problems in Exporting Countries.** The President called for the USDA and the FDA to develop profiles of exporting countries. These profiles will assess the agricultural production, transportation, and processing practices in these countries and will provide invaluable information that can be used to target import inspection and testing resources.

4. **Assistance to Exporting Countries to Develop Their Own Best Practices.** The Administration supports efforts on the part of the FDA and USDA to help exporting countries to develop their own best practices to address potential food safety issues in those countries. The FDA and USDA will engage in technical assistance, training, and cooperative research efforts with exporting countries to improve the safety of imported fruits and vegetables.

5. **Expanded Federal Resources for Testing and Inspecting Fruits and Vegetables.** The Administration supports federal legislation to expand FDA's ability to test and inspect fruits and vegetables, both domestically and overseas. The Administration also supports an appropriation to expand USDA's testing program to include microbial pathogens like E. Coli.

6. **Accelerated Food Safety Research**. The President emphasized the need to expand and accelerate research efforts in order to develop faster and better tests to identify pathogens on food products and to develop effective tools to prevent contamination from occurring.

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.

USDA

U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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- ☒ ERIC OLSEN, SPECIAL ASSISTANT FOR POLICY
- ☐ JANET POTTS, COUNSEL TO THE SECRETARY

MESSAGE: Draft Still under Review

Hope this Helps.

It tracks what we said this a.m.

09/24/97 17:58 202 720 0591 USDA OSEC 001/004

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9-23-97

FDA IMPORTED FOOD SAFETY PROPOSAL

1. **Develop and Implement HACCP for Fruits and Vegetables**

   - Propose Good Agricultural Practices Regulations and Good Manufacturing Practices regulations for fruits and vegetables by December 31, 1997.

   - Propose fruit juice HACCP regulations by December 31, 1997.

   - Propose HACCP regulations for all fruits and vegetables by October 1, 1998.

on foreign countries practices
- port of lots
- type of water

2. **Propose legislation requiring that food entering the United States be imported only from countries meeting U.S. food safety standards (i.e., expand the current requirement for imported meat and poultry to all foods)**

guidelines - but not mandatory
- moving toward a regulation
Elena - can't we propose a regulation by Dec 1997

452-7431

DRAFT

Costs of labeling imported meat

S. 617 would amend the Federal Meat Inspection Act (FMIA) to require that imported meat, and meat food products containing imported meat, bear a label identifying the country of origin. Meat from animals imported less than 10 days prior to slaughter would also have to be labeled to identify the country of origin. Meat food products prepared in the United States using any carcass, part thereof, or meat imported into the United States would have to be labeled to identify the country of origin.

The current situation

In 1995, the United States imported 2.4 billion pounds of meat and poultry from 34 countries. FSIS reviews meat and poultry inspection systems in countries that export to the United States. FSIS also reinspects meat and poultry at port-of-entry before they are allowed into U.S. commerce. Because health certificates indicating the wholesomeness of the product and other documents accompany the meat, at the point of reinspection, all meat is identified by its country of origin. However, the country of origin identity is not preserved as the meat moves through the U.S. processing and distribution system.

Meat imports into the United States in 1996 totaled 2.764 billion pounds carcass weight or 1.985 billion pounds retail weight (table 1). Domestic consumption of meat in 1996 was 119.1 pounds per capita or about 31.616 billion pounds, retail basis. Assuming all imported meat is consumed within the United States, imported meats account for about 6.3 percent of domestic meat consumption.

Meat production from imported animals slaughtered with 10 days of arrival is estimated at 1.229 billion pounds, retail weight (table 2). Adding this quantity to amounts imported as meat gives total imported meat of 3.214 billion pounds, retail weight. Thus, using the concept of imported meat from the proposed amendment to the FMIA, imported meat accounted for 10.2 percent of domestic meat consumption in 1996. This assumes that no imported meat or meat from imported animals is exported.

Table 1--Meat imports, 1996

Meat	Carcass weight 1,000 pounds	Retail weight 1,000 pounds	Conversion factor
Beef and veal	2,072,173	1,440,160	.695
Lamb and mutton	72,452	64,483	.890
Pork	618,884	480,254	.776
Total	2,763,509	1,984,897	

Table 2--Live cattle and hog imports, 1996

Animal	Head	Retail weight 1,000 pounds	Conversion factor

Total cattle	1,965,448		
Feeder stock	74,293		
For slaughter	1,891,155	944,790	2.402
Total hogs	2,779,175		
Feeder stock	766,974		
For slaughter	2,012,201	284,075	1.70
Total	4,744,623	1,228,865	

Note: Feed stock number for cattle is only for imports from Canada. Because feeder stock cattle from other origins, primarily Mexico, have not been not accounted for, the number of cattle for slaughter is likely overstated. Imported cattle for slaughter are assumed to average 1,200 pounds live weight. Imported hogs for slaughter are assumed to average 240 pounds live weight. Conversion factors apply to live weight.

Analysis of costs

It is assumed that the intent of the proposed amendment to the FMIA is to require labeling of retail packages of raw and processed meat products, but not to require labeling on imported meat that is served for consumption in hotels, restaurants, and institutions. An unknown amount of imported meat is used in this later way. However, for purpose of analysis, and to present the likely range of costs, it is assumed that all imported meat is sold at retail establishments that would be required to label the packages with the country of origin of the meat.

Costs of the labeling requirement include

- Costs of preserving the country of origin identification of imported meat from the point of entry into the United States to the retail counter. Distributors and retailers would incur costs of marking shipments and segregating imported meat from domestic meat. Retailers or meat packaging firms would incur the costs of affixing the correct label on imported meats.

- Costs of preserving the country of origin of live imported animals and the meat derived from them through to the retail counter. Slaughter plants would incur costs to segregate imported animals in holding pens and to mark carcasses and parts of carcasses shipped to processors and retailers.

- FSIS enforcement costs to ensure compliance. FSIS has little presence in retail establishments. There were 24,557 supermarkets (annual sales of at least $3,469 million) in 1994. There were even more grocery stores and specialized food stores such as meat markets.

Costs of preserving Country of Origin of Imported Meat
Consider first the costs of affixing labels. USDA's analysis of the costs of applying safe food handling labels to meat and poultry provides a basis for estimating this cost (*Federal Register*, November 4, 1993, pp. 58992-58934). It was estimated that the label cost for large retailers who

have efficient equipment that prints and affixes labels would be $0.00375 per package and that other retailers would have costs for labels averaging $0.01 per package. Large retailers were believed to account for 80 percent of the retail packages sold. The safe food handling analysis has an implied average retail package size for meat of about 3 pounds. Thus, the 3.214 billion pounds of imported meat and meat from imported animals equates to about 1.07 billion packages. The cost for labels is about $5,356,000 = ((1.07 bil.*.8*$.00375) + (1.07 bil.*.2*$0.01)). These label costs may be understated because the safe food handling label analysis dealt with the addition of a generic statement while country of origin labeling will require labels for each of the 34 countries exporting to the United States.

Large retailers are assumed to have equipment that simultaneously prints and affixes labels so they have no new recurring costs for applying labels. Other retailers will have recurring labor costs. The safe handling analysis estimated the recurring labor cost associated with the 20 percent of packages labeled by other retailers to be $3.2 million. Adjusting this figure for a smaller number of packages of imported meat (214.3 million) and increases in the employment cost index (1996/1993 of 1.083) gives a recurring labor cost of $371,368. This is just the labor cost involved in affixing labels.

There are other labor, material, and management costs for preserving the identify of imported meat prior to retail packaging. There is little empirical information from which to estimate these costs, but they could be large. Distributors and retailers might have to add separate cold storage rooms or use different trucks to carry domestic and imported product. Costs would depend on the number of shipments of meat and animals, the number businesses dealing in imported meat or animals, the penalties for noncompliance, the level of enforcement, and other factors.

Businesses handling imported meat and animals have little incentive to preserve the identity of imported meat unless it commands a market price premium over domestic meat or the penalties for noncompliance are larger than the potential savings from not labeling. If there is a premium for imported meat, e.g., Danish pork or New Zealand lamb, the industry will voluntarily label retail packages with the country of origin and will have an incentive to misbrand domestic meat as imported.

Costs of Preserving the Country of Origin of Imported Live Animals

Importers of live animals intended for slaughter would likely have costs for maintaining segregating holding pens to ensure that the country of origin is preserved. Batch processing of imported and domestic animals would avoid the need for separate pens but would involve added management costs. Slaughter plants would face costs to mark, tag, or otherwise identify carcasses or carcass parts to preserve the identity. Estimates of the costs of preserving the identity of imported animals cannot be estimated because we do not know what steps importers will take. Ear tags are a low cost system but once slaughter is initiated these tags are separated from the meat. Annual costs can be expected to run into the millions of dollars, because approximately 4 million animals are imported for slaughter every year.

Feeder stock animals--younger, lighter weight animals--are generally fed to higher weights and then slaughtered, but they can be slaughtered at any age. Depending on the enforcement policies

adopted, importers might need to maintain the identity of imported feeder stock, for at least 10 days to establish that imported animals are not being slaughtered and their meat marketed without a country of origin label. Thus, importers of feeder stock would bear the costs of temporarily maintaining the identity of imports and postponing the commingling of anonymous animals.

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Enforcement costs could be very high. Costs will depend on the potential penalty for violations, incentives for noncompliance, and how strictly USDA pursues enforcement. USDA does not now have a routine presence in retail establishments. If USDA visited each retail establishment just 3 times a year, that would involve about 750,000 site visits. If the cost of a visit--labor time, travel costs, records, etc--is conservatively estimated at $100 a visit, the annual costs to taxpayers would be $75 million. This is a low estimate because USDA would also need to visit wholesalers, meat processors, and slaughter plants. Credible monitoring and enforcement could require hiring and training 1,000 additional staff years. Taxpayers at large would bear the costs of enforcement.

Other Costs
The analysis has assumed that meat from domestically produced and slaughtered animals would not be labeled. If it were necessary to label domestic meat, the costs for labels would increase by $87 million and the annual recurring costs for affixing the labels would increase by $6 million. It might be necessary to require labeling domestic meat if labeling foreign meat only were found to violate trade agreements.

Summary

The costs for labeling only imported meat include the following quantifiable costs: label costs, $5.4 million, recurring labor costs to affix labels, $0.4 million, enforcement costs, $75 million. Total quantified costs are $80.8 million per year. Other costs, which could be quite large, include the costs of maintaining the country of origin identity of imported meat and animals from the point of entry through to the retail sales case.

452-7431

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Summary

The costs for labeling only imported meat include the following quantifiable costs: label costs, $5.4 million, recurring labor costs to affix labels, $0.4 million, enforcement costs, $75 million. Total quantified costs are $80.8 million per year. Other costs, which could be quite large, include the costs of maintaining the country of origin identity of imported meat and animals from the point of entry through to the retail sales case.

452-7431

DRAFT

Costs of labeling imported meat

S. 617 would amend the Federal Meat Inspection Act (FMIA) to require that imported meat, and meat food products containing imported meat, bear a label identifying the country of origin. Meat from animals imported less than 10 days prior to slaughter would also have to be labeled to identify the country of origin. Meat food products prepared in the United States using any carcass, part thereof, or meat imported into the United States would have to be labeled to identify the country of origin.

The current situation

In 1995, the United States imported 2.4 billion pounds of meat and poultry from 34 countries. FSIS reviews meat and poultry inspection systems in countries that export to the United States. FSIS also reinspects meat and poultry at port-of-entry before they are allowed into U.S. commerce. Because health certificates indicating the wholesomeness of the product and other documents accompany the meat, at the point of reinspection, all meat is identified by its country of origin. However, the country of origin identity is not preserved as the meat moves through the U.S. processing and distribution system.

Meat imports into the United States in 1996 totaled 2.764 billion pounds carcass weight or 1.985 billion pounds retail weight (table 1). Domestic consumption of meat in 1996 was 119.1 pounds per capita or about 31.616 billion pounds, retail basis. Assuming all imported meat is consumed within the United States, imported meats account for about 6.3 percent of domestic meat consumption.

Meat production from imported animals slaughtered with 10 days of arrival is estimated at 1.229 billion pounds, retail weight (table 2). Adding this quantity to amounts imported as meat gives total imported meat of 3.214 billion pounds, retail weight. Thus, using the concept of imported meat from the proposed amendment to the FMIA, imported meat accounted for 10.2 percent of domestic meat consumption in 1996. This assumes that no imported meat or meat from imported animals is exported.

Table 1--Meat imports, 1996

Meat	Carcass weight 1,000 pounds	Retail weight 1,000 pounds	Conversion factor
Beef and veal	2,072,173	1,440,160	.695
Lamb and mutton	72,452	64,483	.890
Pork	618,884	480,254	.776
Total	2,763,509	1,984,897	

Table 2--Live cattle and hog imports, 1996

Animal	Head	Retail weight 1,000 pounds	Conversion factor

Total cattle	1,965,448		
Feeder stock	74,293		
For slaughter	1,891,155	944,790	2.402
Total hogs	2,779,175		
Feeder stock	766,974		
For slaughter	2,012,201	284,075	1.70
Total	4,744,623	1,228,865	

Note: Feed stock number for cattle is only for imports from Canada. Because feeder stock cattle from other origins, primarily Mexico, have not been not accounted for, the number of cattle for slaughter is likely overstated. Imported cattle for slaughter are assumed to average 1,200 pounds live weight. Imported hogs for slaughter are assumed to average 240 pounds live weight. Conversion factors apply to live weight.

Analysis of costs

It is assumed that the intent of the proposed amendment to the FMIA is to require labeling of retail packages of raw and processed meat products, but not to require labeling on imported meat that is served for consumption in hotels, restaurants, and institutions. An unknown amount of imported meat is used in this later way. However, for purpose of analysis, and to present the likely range of costs, it is assumed that all imported meat is sold at retail establishments that would be required to label the packages with the country of origin of the meat.

Costs of the labeling requirement include

- Costs of preserving the country of origin identification of imported meat from the point of entry into the United States to the retail counter. Distributors and retailers would incur costs of marking shipments and segregating imported meat from domestic meat. Retailers or meat packaging firms would incur the costs of affixing the correct label on imported meats.

- Costs of preserving the country of origin of live imported animals and the meat derived from them through to the retail counter. Slaughter plants would incur costs to segregate imported animals in holding pens and to mark carcasses and parts of carcasses shipped to processors and retailers.

- FSIS enforcement costs to ensure compliance. FSIS has little presence in retail establishments. There were 24,557 supermarkets (annual sales of at least $3.469 million) in 1994. There were even more grocery stores and specialized food stores such as meat markets.

Costs of preserving Country of Origin of Imported Meat

Consider first the costs of affixing labels. USDA's analysis of the costs of applying safe food handling labels to meat and poultry provides a basis for estimating this cost (*Federal Register* November 4, 1993, pp. 58992-58934). It was estimated that the label cost for large retailers who

have efficient equipment that prints and affixes labels would be \$0.00375 per package and that other retailers would have costs for labels averaging \$0.01 per package. Large retailers were believed to account for 80 percent of the retail packages sold. The safe food handling analysis has an implied average retail package size for meat of about 3 pounds. Thus, the 3.214 billion pounds of imported meat and meat from imported animals equates to about 1.07 billion packages. The cost for labels is about \$5,356,000 = ((1.07 bil.*.8*\$.00375) + (1.07 bil.*.2*\$0.01)). These label costs may be understated because the safe food handling label analysis dealt with the addition of a generic statement while country of origin labeling will require labels for each of the 34 countries exporting to the United States.

Large retailers are assumed to have equipment that simultaneously prints and affixes labels so they have no new recurring costs for applying labels. Other retailers will have recurring labor costs. The safe handling analysis estimated the recurring labor cost associated with the 20 percent of packages labeled by other retailers to be \$3.2 million. Adjusting this figure for a smaller number of packages of imported meat (214.3 million) and increases in the employment cost index (1996/1993 of 1.083) gives a recurring labor cost of \$371,368. This is just the labor cost involved in affixing labels.

There are other labor, material, and management costs for preserving the identify of imported meat prior to retail packaging. There is little empirical information from which to estimate these costs, but they could be large. Distributors and retailers might have to add separate cold storage rooms or use different trucks to carry domestic and imported product. Costs would depend on the number of shipments of meat and animals, the number businesses dealing in imported meat or animals, the penalties for noncompliance, the level of enforcement, and other factors.

Businesses handling imported meat and animals have little incentive to preserve the identity of imported meat unless it commands a market price premium over domestic meat or the penalties for noncompliance are larger than the potential savings from not labeling. If there is a premium for imported meat, e.g., Danish pork or New Zealand lamb, the industry will voluntarily label retail packages with the country of origin and will have an incentive to misbrand domestic meat as imported.

Costs of Preserving the Country of Origin of Imported Live Animals

Importers of live animals intended for slaughter would likely have costs for maintaining segregating holding pens to ensure that the country of origin is preserved. Batch processing of imported and domestic animals would avoid the need for separate pens but would involve added management costs. Slaughter plants would face costs to mark, tag, or otherwise identify carcasses or carcass parts to preserve the identity. Estimates of the costs of preserving the identity of imported animals cannot be estimated because we do not know what steps importers will take. Ear tags are a low cost system but once slaughter is initiated these tags are separated from the meat. Annual costs can be expected to run into the millions of dollars, because approximately 4 million animals are imported for slaughter every year.

Feeder stock animals--younger, lighter weight animals--are generally fed to higher weights and then slaughtered, but they can be slaughtered at any age. Depending on the enforcement policies

adopted, importers might need to maintain the identity of imported feeder stock, for at least 10 days to establish that imported animals are not being slaughtered and their meat marketed without a country of origin label. Thus, importers of feeder stock would bear the costs of temporarily maintaining the identity of imports and postponing the commingling of anonymous animals.

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MEMORANDUM

TO: BRUCE REED, ELENA KAGAN

FROM: TOM FREEDMAN, MARY L. SMITH

RE: COUNTRY OF ORIGIN LABELING FOR FOOD

DATE: SEPTEMBER 23, 1997

SUMMARY

A search of Nexis on the keywords "country" and "origin" revealed basically 3 pieces of legislation pending on the Hill that require labeling of country of origin: (1) "Imported Produce Labeling Act of 1997," (2) "Imported Meat Labeling Act of 1997," and (3) H.R. 2332, which amends the Tariff Act of 1930 to require country of origin. All three pieces of legislation have bipartisan support. USDA indicated that it has taken no formal position on any of these pieces of legislation.

LEGISLATION PENDING ON THE HILL

1. **Imported Produce Labeling Act of 1997**
H.R. 1232 (65 Co-sponsors --31 Democrats and 33 Republicans)
S. 1042 (7 Cosponsors --5 Democrats and 2 Republicans)
Sponsored by Rep. Bono (R-CA) and Sen. Larry Craig (R-ID).

This legislation provides that a retailer of a perishable agricultural commodity is required to inform consumers of the country of origin by "means of a label, stamp, mark, placard, or other clear and visible sign." There are fines for failure to inform consumers.

2. **Imported Meat Labeling Act of 1997**
H.R. 1371 (25 Co-sponsors --11 Democrats and 14 Republicans)
S. 617 (9 Cosponsors --3 Democrats and 6 Republicans)
Sponsored by Rep. Chenoweth (R-ID) and Sen. Tim Johnson (D-SD).

This legislation amends the Federal Meat Inspection Act to require that imported meat, and meat food products containing imported meat, bear a label identifying the country of origin.

3. **H.R. 2332 (40 Cosponsors --21 Democrats and 19 Republicans),** Sponsored by Rep. Everett (R-AL): This bill amends section 304 of the Tariff Act of 1930 to require the marking of frozen produce with the country of origin on the front panel of the package for retail sale.

OTHER RELATED LEGISLATION THAT DOES NOT INVOLVE IMPORTS

1. **S.16, "Cattle Industry Improvement Act of 1997,"** Sponsored by Sen. Daschle (D-SD): Part of this legislation amends section 7 of the Federal Meat Inspection Act (21 U.S.C. 607) to require the labeling of meat produced in the United States to indicate the United States origin of the meat.

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USDA

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OFFICE OF THE SECRETARY

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- ☐ JANET POTTS, COUNSEL TO THE SECRETARY

MESSAGE:

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DRAFT

Costs of labeling imported meat

S. 617 would amend the Federal Meat Inspection Act (FMIA) to require that imported meat, and meat food products containing imported meat, bear a label identifying the country of origin. Meat from animals imported less than 10 days prior to slaughter would also have to be labeled to identify the country of origin. Meat food products prepared in the United States using any carcass, part thereof, or meat imported into the United States would have to be labeled to identify the country of origin.

The current situation

In 1995, the United States imported 2.4 billion pounds of meat and poultry from 34 countries. FSIS reviews meat and poultry inspection systems in countries that export to the United States. FSIS also reinspects meat and poultry at port-of-entry before they are allowed into U.S. commerce. Because health certificates indicating the wholesomeness of the product and other documents accompany the meat, at the point of reinspection, all meat is identified by its country of origin. However, the country of origin identity is not preserved as the meat moves through the U.S. processing and distribution system.

Meat imports into the United States in 1996 totaled 2.764 billion pounds carcass weight or 1.985 billion pounds retail weight (table 1). Domestic consumption of meat in 1996 was 119.1 pounds per capita or about 31.616 billion pounds, retail basis. Assuming all imported meat is consumed within the United States, imported meats account for about 6.3 percent of domestic meat consumption.

Meat production from imported animals slaughtered with 10 days of arrival is estimated at 1.229 billion pounds, retail weight (table 2). Adding this quantity to amounts imported as meat gives total imported meat of 3.214 billion pounds, retail weight. Thus, using the concept of imported meat from the proposed amendment to the FMIA, imported meat accounted for 10.2 percent of domestic meat consumption in 1996. This assumes that no imported meat or meat from imported animals is exported.

Table 1--Meat imports, 1996

Meat	Carcass weight 1,000 pounds	Retail weight 1,000 pounds	Conversion factor
Beef and veal	2,072,173	1,440,160	.695
Lamb and mutton	72,452	64,483	.890
Pork	618,884	480,254	.776
Total	2,763,509	1,984,897	

Table 2--Live cattle and hog imports, 1996

Animal	Head	Retail weight 1,000 pounds	Conversion factor

Total cattle	1,965,448		
Feeder stock	74,293		
For slaughter	1,891,155	944,790	2.402
Total hogs	2,779,175		
Feeder stock	766,974		
For slaughter	2,012,201	284,075	1.70
Total	4,744,623	1,228,865	

Note: Feed stock number for cattle is only for imports from Canada. Because feeder stock cattle from other origins, primarily Mexico, have not been not accounted for, the number of cattle for slaughter is likely overstated. Imported cattle for slaughter are assumed to average 1,200 pounds live weight. Imported hogs for slaughter are assumed to average 240 pounds live weight. Conversion factors apply to live weight.

Analysis of costs

It is assumed that the intent of the proposed amendment to the FMIA is to require labeling of retail packages of raw and processed meat products, but not to require labeling on imported meat that is served for consumption in hotels, restaurants, and institutions. An unknown amount of imported meat is used in this later way. However, for purpose of analysis, and to present the likely range of costs, it is assumed that all imported meat is sold at retail establishments that would be required to label the packages with the country of origin of the meat.

Costs of the labeling requirement include

- Costs of preserving the country of origin identification of imported meat from the point of entry into the United States to the retail counter. Distributors and retailers would incur costs of marking shipments and segregating imported meat from domestic meat. Retailers or meat packaging firms would incur the costs of affixing the correct label on imported meats.

- Costs of preserving the country of origin of live imported animals and the meat derived from them through to the retail counter. Slaughter plants would incur costs to segregate imported animals in holding pens and to mark carcasses and parts of carcasses shipped to processors and retailers.

- FSIS enforcement costs to ensure compliance. FSIS has little presence in retail establishments. There were 24,557 supermarkets (annual sales of at least $3.469 million) in 1994. There were even more grocery stores and specialized food stores such as meat markets.

Costs of preserving Country of Origin of Imported Meat

Consider first the costs of affixing labels. USDA's analysis of the costs of applying safe food handling labels to meat and poultry provides a basis for estimating this cost (*Federal Register* November 4, 1993, pp. 58992-58934). It was estimated that the label cost for large retailers who

have efficient equipment that prints and affixes labels would be $0.00375 per package and that other retailers would have costs for labels averaging $0.01 per package. Large retailers were believed to account for 80 percent of the retail packages sold. The safe food handling analysis has an implied average retail package size for meat of about 3 pounds. Thus, the 3.214 billion pounds of imported meat and meat from imported animals equates to about 1.07 billion packages. The cost for labels is about $5,356,000 = ((1.07 bil.*.8*$.00375) + (1.07 bil.*.2*$0.01)). These label costs may be understated because the safe food handling label analysis dealt with the addition of a generic statement while country of origin labeling will require labels for each of the 34 countries exporting to the United States.

Large retailers are assumed to have equipment that simultaneously prints and affixes labels so they have no new recurring costs for applying labels. Other retailers will have recurring labor costs. The safe handling analysis estimated the recurring labor cost associated with the 20 percent of packages labeled by other retailers to be $3.2 million. Adjusting this figure for a smaller number of packages of imported meat (214.3 million) and increases in the employment cost index (1996/1993 of 1.083) gives a recurring labor cost of $371,368. This is just the labor cost involved in affixing labels.

There are other labor, material, and management costs for preserving the identify of imported meat prior to retail packaging. There is little empirical information from which to estimate these costs, but they could be large. Distributors and retailers might have to add separate cold storage rooms or use different trucks to carry domestic and imported product. Costs would depend on the number of shipments of meat and animals, the number businesses dealing in imported meat or animals, the penalties for noncompliance, the level of enforcement, and other factors.

Businesses handling imported meat and animals have little incentive to preserve the identity of imported meat unless it commands a market price premium over domestic meat or the penalties for noncompliance are larger than the potential savings from not labeling. If there is a premium for imported meat, e.g., Danish pork or New Zealand lamb, the industry will voluntarily label retail packages with the country of origin and will have an incentive to misbrand domestic meat as imported.

Costs of Preserving the Country of Origin of Imported Live Animals

Importers of live animals intended for slaughter would likely have costs for maintaining segregating holding pens to ensure that the country of origin is preserved. Batch processing of imported and domestic animals would avoid the need for separate pens but would involve added management costs. Slaughter plants would face costs to mark, tag, or otherwise identify carcasses or carcass parts to preserve the identity. Estimates of the costs of preserving the identity of imported animals cannot be estimated because we do not know what steps importers will take. Ear tags are a low cost system but once slaughter is initiated these tags are separated from the meat. Annual costs can be expected to run into the millions of dollars, because approximately 4 million animals are imported for slaughter every year.

Feeder stock animals--younger, lighter weight animals--are generally fed to higher weights and then slaughtered, but they can be slaughtered at any age. Depending on the enforcement policies

adopted, importers might need to maintain the identity of imported feeder stock, for at least 10 days to establish that imported animals are not being slaughtered and their meat marketed without a country of origin label. Thus, importers of feeder stock would bear the costs of temporarily maintaining the identity of imports and postponing the commingling of anonymous animals.

FSIS Enforcement Costs

Enforcement costs could be very high. Costs will depend on the potential penalty for violations, incentives for noncompliance, and how strictly USDA pursues enforcement. USDA does not now have a routine presence in retail establishments. If USDA visited each retail establishment just 3 times a year, that would involve about 750,000 site visits. If the cost of a visit--labor time, travel costs, records, etc--is conservatively estimated at $100 a visit, the annual costs to taxpayers would be $75 million. This is a low estimate because USDA would also need to visit wholesalers, meat processors, and slaughter plants. Credible monitoring and enforcement could require hiring and training 1,000 additional staff years. Taxpayers at large would bear the costs of enforcement.

Other Costs

The analysis has assumed that meat from domestically produced and slaughtered animals would not be labeled. If it were necessary to label domestic meat, the costs for labels would increase by $87 million and the annual recurring costs for affixing the labels would increase by $6 million. It might be necessary to require labeling domestic meat if labeling foreign meat only were found to violate trade agreements.

Summary

The costs for labeling only imported meat include the following quantifiable costs: label costs, $5.4 million, recurring labor costs to affix labels, $0.4 million, enforcement costs, $75 million. Total quantified costs are $80.8 million per year. Other costs, which could be quite large, include the costs of maintaining the country of origin identity of imported meat and animals from the point of entry through to the retail sales case.

September 21, 1997

MEMORANDUM FOR ERSKINE BOWLES

FROM: **BRUCE REED**
ELENA KAGAN

RE: **FOOD SAFETY AND FAST TRACK**

This morning we convened a meeting of representatives from FDA, USDA, USTR, the White House Fast Track Working Group, and OMB including Sally Katzen, to discuss possible food safety initiatives to mitigate health concerns from imports following passage of fast track legislation.

Below is a list of policy options that we've asked the agencies to explore and respond to by tomorrow morning. We asked that they consider these proposals for their feasibility for a formal Administration announcement within the next two days.

1. **Upgrade Standards**. We are currently implementing new procedures for domestic seafood and meat and poultry production, the Hazard Analysis and Critical Control Points system (HACCP). This is a regulatory scheme, considered more effective than simply increasing the number of inspectors, that involves companies identifying the danger points in their processing system, actions to take to avoid the contamination, and creation of a paper trail for inspectors to periodically review and see whether the program is working. Imported products must be produced under equivalent food safety systems. The proposal would expand HACCP to include fruits and vegetables, essentially creating US standards and then applying them to foreign countries. The FDA is developing this proposal.

2. **Application of Existing US Standards**. There already exist a limited patchwork of existing US standards for fruits and vegetables. This approach would delineate what the existing US standards are, and require them to be applied to imports. This has been tasked to FDA.

3. **Expand USDA Involvement**. USDA has research and education programs in this area that could be expanded. Further, if HACCP is enlarged to include fruits and vegetables, there will be a need for the creation of an education program for US farmers, a program that could be a model for foreign farmers and companies. USDA has a presence in foreign countries and could work cooperatively to encourage the adoption of equivalent practices there.

4. Applications to Trade. Explore the feasibility of the Administration committing that as imports increase there will be a commensurate increase in inspections/safety. Key to critics analysis is the argument that Fast Track will result in increased imports of food. This proposal would involve an Administration funding commitment to increase the level of inspections to keep pace with this increased supply of foreign food.

5. Point of Origin Labeling. This would require all food to be labeled as to origin (US or other nation's) at the grocery store. It would give consumers the choice to purchase domestic or foreign grown food. The proposal requires vetting by USTR. Retailers do not like this proposal.

Dealt w/ that last year w/ have to went to restaurant

MEMORANDUM

TO: BRUCE REED, ELENA KAGAN

FROM: ~~TOM FREEDMAN~~, MARY L. SMITH

RE: COUNTRY OF ORIGIN LABELING FOR FOOD

DATE: SEPTEMBER 23, 1997

SUMMARY

A search of Nexis on the keywords "country" and "origin" revealed basically 3 pieces of legislation pending on the Hill that require labeling of country of origin: (1) "Imported Produce Labeling Act of 1997," (2) "Imported Meat Labeling Act of 1997," and (3) H.R. 2332, which amends the Tariff Act of 1930 to require country of origin. All three pieces of legislation have bipartisan support. USDA has not taken formal position

LEGISLATION PENDING ON THE HILL

1. **Imported Produce Labeling Act of 1997**
H.R. 1232 (65 Co-sponsors --31 Democrats and 33 Republicans)
S. 1042 (7 Cosponsors --5 Democrats and 2 Republicans)
Sponsored by Rep. Bono (R-CA) and Sen. Larry Craig (R-ID).

This legislation provides that a retailer of a perishable agricultural commodity is required to inform consumers of the country of origin by "means of a label, stamp, mark, placard, or other clear and visible sign." There are fines for failure to inform consumers.

2. **Imported Meat Labeling Act of 1997**
H.R. 1371 (25 Co-sponsors --11 Democrats and 14 Republicans)
S. 617 (9 Cosponsors --3 Democrats and 6 Republicans)
Sponsored by Rep. Chenoweth (R-ID) and Sen. Tim Johnson (D-SD).

This legislation amends the Federal Meat Inspection Act to require that imported meat, and meat food products containing imported meat, bear a label identifying the country of origin.

3. **H.R. 2332 (40 Cosponsors --21 Democrats and 19 Republicans),** Sponsored by Rep. Everett (R-AL): This bill amends section 304 of the Tariff Act of 1930 to require the marking of frozen produce with the country of origin on the front panel of the package for retail sale.

OTHER RELATED LEGISLATION THAT DOES NOT INVOLVE IMPORTS

1. **S.16, "Cattle Industry Improvement Act of 1997,"** Sponsored by Sen. Daschle (D-SD): Part of this legislation amends section 7 of the Federal Meat Inspection Act (21 U.S.C. 607) to require the labeling of meat produced in the United States to indicate the United States origin of the meat.

set up certification system