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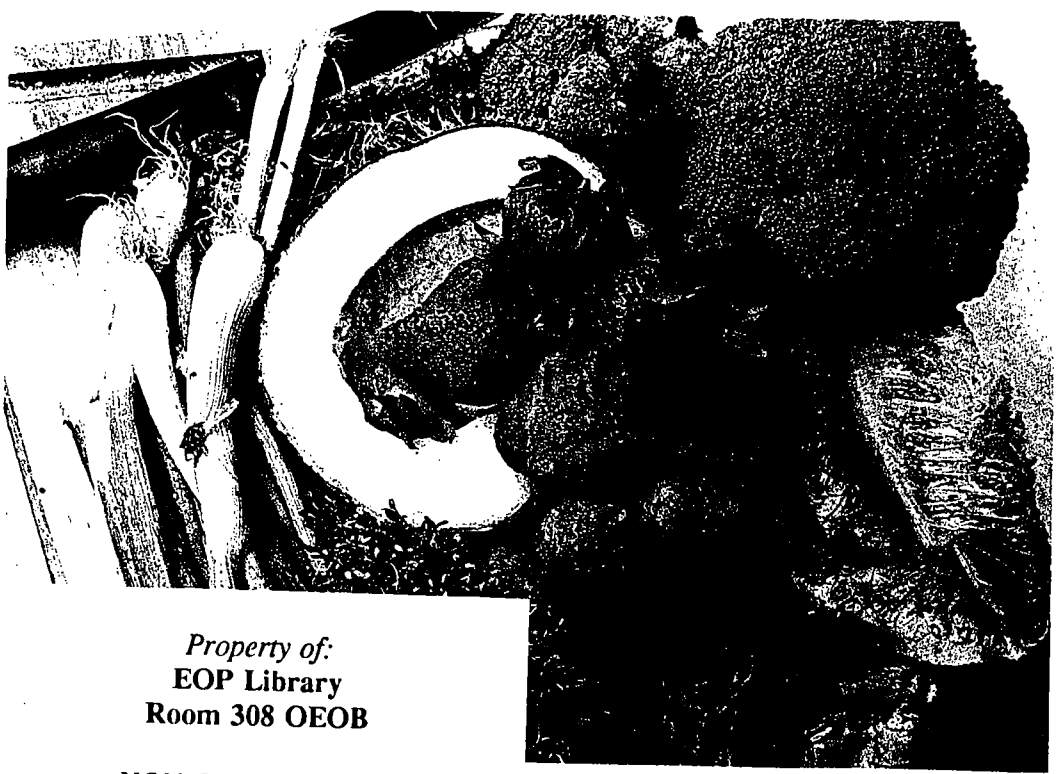
CQ Weekly
CONGRESSIONAL QUARTERLY

Tainted Fruits and Vegetables: Food for Partisan Politics



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Lawmakers have little taste for the political perils of an import crackdown

Unsafe Food Sparks Outbreaks Of Concern, Little Action

By Allan Freedman

Quick Contents

With every new report of food-borne illness, the debate over food safety flares up. In recent months, food safety advocates have focused on the potential threat of imported fruits and vegetables. But Congress has no appetite for legislation being pushed by President Clinton to expand the power of federal regulators.

Susan Collins, an unassuming freshman Republican from Maine, toils mostly in the obscurity reserved for new senators. But early this month, one issue propelled her into the national limelight. She released a General Accounting Office (GAO) report May 11 on the perils of imported fruits and vegetables, netting media attention usually accorded more senior members: a morning interview on CNN and evening network news coverage.

With the spotlight trained on her, Collins boldly declared that the GAO investigation, which she ordered, was "a serious indictment" of the federal food safety system.

But when asked about a legislative fix, Collins sidestepped the issue. Before she would commit to any bill, she said, her Governmental Affairs Permanent Investigations Subcommittee, which held a hearing on the issue May 14, would have to hold more.

"If the first hearing showed us anything, it was that this is an extremely complex issue," she said. "We plan to do a very thorough review."

Collins' response reflects her party's struggle to define itself on an issue the Democrats have seized at every opportunity. President Clinton capitalizes on each new outbreak of food-borne illness by calling on Congress to give federal regulators broad new inspection and enforcement powers.

Republicans have resisted, arguing that the nation's food supply is one of the safest in the world, and incidents of food-related illness — such as one in which nearly 200 Michigan students contracted hepatitis A from eating strawberry shortcake in school lunches in February 1997 — are extremely rare. They say Democrats are shamelessly exploiting isolated cases of food-borne illnesses for political gain.

The bind illustrates the difficulty Republican lawmakers face when proposed solutions to a problem — whether it be managed care or government regulation of nicotine in cigarettes — run counter to their anti-regulatory philosophy of government.

Republicans note that no one is sure exactly how severe the problem is, and contend that the the government already has all the authority it needs to stop contaminated fruits and vegetables at the border.

"Occasionally, we have a problem," said Rep. Henry Bonilla, R-Texas. "But I think it's phenomenal how safe our food supply is."

Some food companies and exporters worry a crackdown on imports could compel other countries to keep out U.S. products. Many U.S. growers fear that a move against imports could hurt their investments abroad and lead to more regulation at home. And U.S. food companies are worried that stricter regulation of imports could disrupt the supply and possibly increase the price of produce on which they have come to rely.

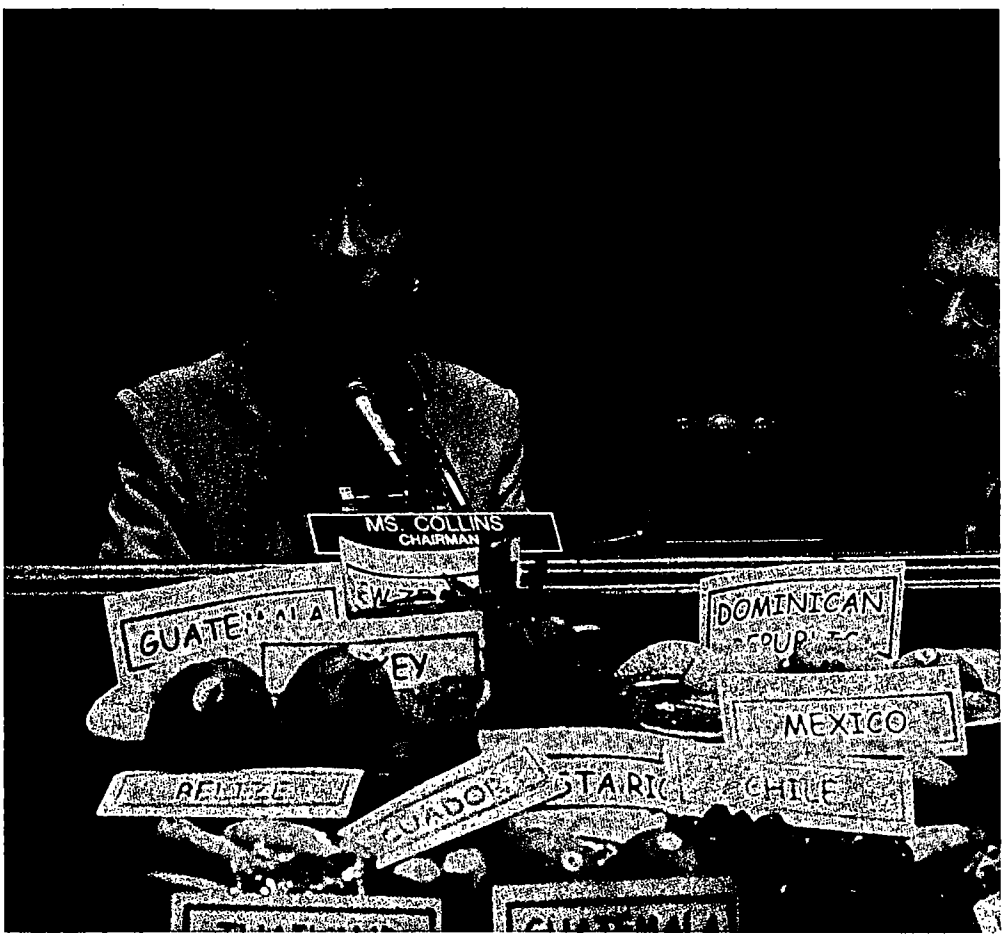
No Republican has signed on as a sponsor of administration-backed legislation (S 1707, HR 3052) that would provide the Food and Drug Administration (FDA) the authority to ban produce from countries that do not have safety systems at least equal to the United States.

Under current law, the FDA has broad authority to bar shipments of produce that appear to be unsafe. But the agency says the present system is inadequate because its border inspection service is understaffed and the most serious threats cannot be detected by visual inspection.

"Children will . . . be safer when Congress passes the president's plan to give the FDA authority to ensure the safety of imported foods," Health and Human Services Secretary Donna E. Shalala said in a May 22 ceremony at which she and Vice President Al Gore unveiled a national computer network to allow authorities to map outbreaks and halt the spread of bacteria in tainted food. "We are not satisfied with the status quo, because far too many Americans still suffer from food-borne illness and from death."

Specifically, administration officials say, the agency needs new authority to regulate imported food where it is grown to stop problems at the source before dangerous viruses and parasites can enter the food supply.

Without such power, Democrats say the FDA will be unable to prevent more cases of people, especially children, suffering from food-related illnesses, including abdominal



CQ PHOTO / DOUGLAS GRAHAM

At a hearing of the Governmental Affairs Permanent Investigations Subcommittee on May 14, Chairman Susan Collins highlighted the perils of imported fruits and vegetables, displaying a collection of foreign produce to demonstrate the abundance of imports in the American diet.

cramps, vomiting and splitting headaches, or even death.

But Republicans are reluctant to take on an issue that holds big political risks. Even a modest imports bill would be a magnet for Democratic proposals to expand regulations anathema to the goals of Republicans and their business allies.

House Agriculture Chairman Bob Smith, R-Ore., said Republicans are keeping a watchful eye on the food imports issue. But he noted that the party has little to gain by trying to compete with the White House.

"We are taking the issue very seriously," he said. "We can't beat him [Clinton] at the bully pulpit. If you can't do that, then maybe you should find a way through this maze of emotionalism that will benefit the industry and produce safe food."

For her part, Collins said she wants to conduct an extensive investigation into the safety of imported food and plans three additional hearings this year.

"I plan to review all of the proposed solutions, including [the Democratic bill] at the final hearing, but until then it would be premature to endorse this or any other specific bill," she said.

Close to Home

Yet the hearing demonstrated that food safety is an issue that hits close to home. Strawberries from the same source that sickened the Michigan children also caused at least 29 cases of hepatitis A in Collins' home state of Maine. And John Glenn of Ohio, ranking Democrat on the full committee, questioned scientists about the best methods for washing lettuce and other produce.

For the Clinton administration, Democrats in Congress and consumer groups, imported produce is emerging as the latest threat to the food supply.

An Agriculture Department study re-

Datafile

In recent years, epidemiologists linked outbreaks of food-borne illness to imported produce. Some recent cases:

- In 1997, 1,012 people in 17 states became ill from cyclospora traced to Guatemalan raspberries. A year earlier, 1,465 people in 20 states were affected by raspberries from the same country.
- In 1997, 270 people contracted hepatitis A; Mexican strawberries were implicated.
- In 1995, 242 people in 17 states and Finland became ill from salmonella stanley traced to alfalfa sprouts from The Netherlands.
- In 1994, 171 people in Illinois became ill from shigella flexneri, type 6. Green onions from Mexico were suspected.

Source: General Accounting Office

leased May 22 estimated that in 1997, 50 cases of food-related illness occurred for every 100,000 Americans. GAO said that as many as 81 million cases of food-borne illnesses and 9,100 food-related deaths occur each year.

But government scientists say that these numbers are unreliable. Frederick J. Angulo, medical epidemiologist at the Foodborne and Diarrheal Disease Branch at the Centers for Disease Control and Prevention (CDC), said the agency lacks key data, and it is not clear if imports are any more of a threat than home-grown produce.

Only a small percentage of illnesses are ever reported to the CDC, and while some illnesses can be traced back to their source, many go unreported.

Even if there were firm numbers, scientists say, the government would have to decide how much risk is acceptable and how far regulators should go to stem the problem.

The Clinton administration agrees that the nation's food supply is still among the safest in the world. But officials say extra steps must be taken to ensure safety, given that Americans have come to expect a high standard from their food, particularly when it comes to fruits and vegetables.

In recent years, the White House has focused its efforts on revamping inspection of meat and poultry, and this year has stepped up its attention to fruits and vegetables, including $25 million in its fiscal 1999 budget request for improved inspection of imports.

Not all produce is of concern. Bananas and oranges are relatively safe because of their protective skins. Lettuce, raspberries and strawberries are more vulnerable because without protective coverings they are more exposed to contaminants from sources such as unwashed hands and manure. *(Animal waste, p. 1443)*

Consumer groups are worried that the situation will only get worse for these vulnerable crops. Americans have come to expect a steady supply of vegetables year round; that demand has been met by imports, which have doubled in the past five years. The FDA projects the number to increase 33 percent by 2002.

Produce is particularly troubling because it can harbor bacteria and other pathogens that consumers are ill-equipped to defend against. Salmonella in chicken and E. coli in hamburgers can be killed with thorough cooking.

But produce such as lettuce is eaten raw, and no technology such as irradiation is readily available to kill E. coli or other contaminants without also wilting or ruining the food.

According to the GAO, imports have brought with them parasites and viruses confined largely to developing countries while at the same time increasing the occurrence of illnesses common in the United States.

The GAO documented tens of thousands of cases of illnesses linked to produce, including parasites on Guatemalan raspberries, viruses believed to have come from Mexican strawberries and bacteria on alfalfa sprouts from The Netherlands.

Mary Ellen Camire, associate professor at the Department of Food Science and Human Nutrition at the University of Maine, said one reason to be concerned about imports is the occurrence of viruses such as hepatitis A.

The virus, which is spread through feces, thrives in nations where sanitation is poor, such as Mexico. Virtually all children in the developing world are exposed and build up immunity with no ill-health effects.

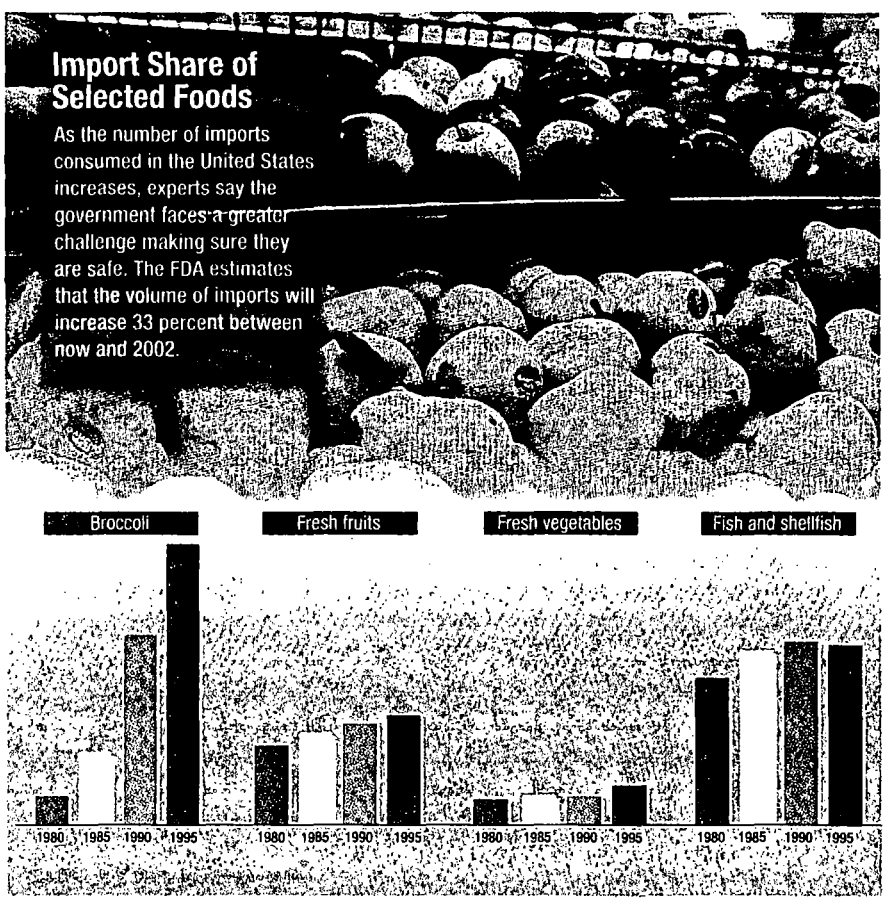
Many American children are never exposed, do not build up immunity and are vulnerable to the virus as adults, when the impact can be more acute. Symptoms linger for months, including fever and jaundice.

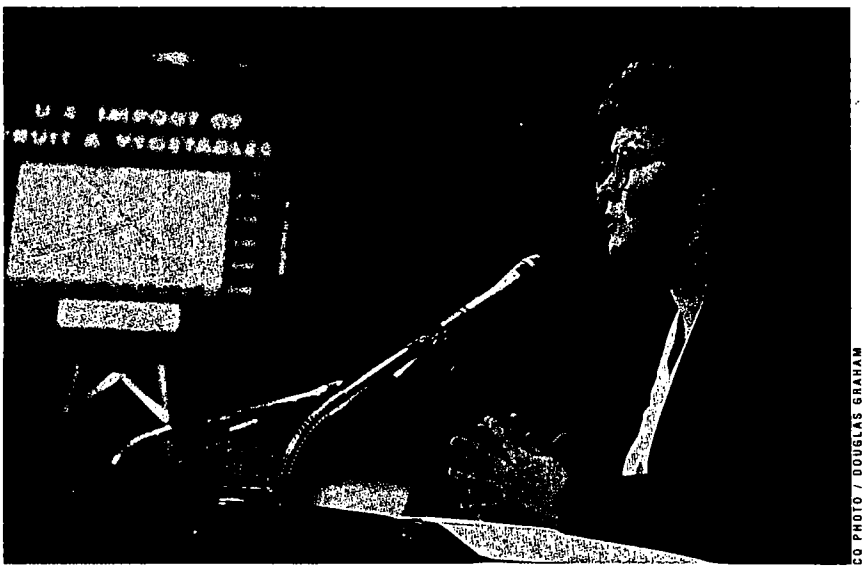
Strawberries cited in the Michigan outbreak were traced to Mexican farms, though government investigators could not determine where exactly the contamination occurred in the process. Camire told the subcommittee that workers at the farms "relieved themselves, then went right back to work using their bare hands to twist the caps off the strawberries."

In addition, health officials have documented cases of food-borne illnesses not previously seen in food in the United States. They cite a 1996 outbreak in which 1,465 people in 20 states became ill after eating Guatemalan raspberries contaminated with cyclospora, a parasite that causes diarrhea, fever, cramping and vomiting.

Consumer advocates worry that these pathogens will eventually find a permanent home in the domestic food supply, rather than being confined largely to imported produce.

"The real question is, are we importing new pathogens that may find a foothold in this country they don't have right now?" asked Caroline Smith De-





CQ PHOTO / DOUGLAS GRAHAM

Mary Ellen Camire, a food expert at the University of Maine, told Collins' panel May 14 that the outlook for food-borne illness from imports and domestic sources is grim.

REUTERS PHOTO / WIN MCNAMEE

Gloria Doyle of Chevy Chase, Md., who became ill from imported raspberries, appeared March 4 with Clinton as he urged Congress to act on food safety legislation.

Waal, director of the food safety program at the Center for Science in the Public Interest, an advocacy group.

Problems related to imports are an outgrowth of an outdated border inspection system, according to consumer groups, the Clinton administration and the GAO.

Under current law, imported produce, which is regulated by the FDA, must meet the same safety standards as domestically grown fruits and vegetables. The agency has sweeping powers to keep out imports that even "appear" to have been "manufactured, processed or packed under insanitary conditions."

Invisible Threats

But the agency contends that enforcing those standards is next to impossible. FDA counts 112 inspectors to examine about 3 million containers, trucks, crates or shipments of food that flow across U.S. borders annually. It inspected less than 2 percent of imports in 1997, down from 8 percent in 1992.

Moreover, the GAO reported that the system was easy to beat. Importers often shop around for a port friendly to their interests and easily skirt paperwork requirements to escape scrutiny.

FDA officials say the current system was created early in the century, when the volume of imports was much lower, and problems could usually be spotted by visual inspection.

Bacteria, parasites and viruses cannot be seen by the naked eye. And there are no reliable or speedy tests that can be performed to detect many of the organisms.

William Hubbard, associate commissioner for policy coordination at the FDA said that while the agency would welcome more inspectors, no amount of personnel would be sufficient to keep tabs on the problem.

"If you gave us the United States Army, we could not cover it," he said. "There is too much of it."

Administration officials are pushing legislation sponsored by Sen. Barbara A. Mikulski, D-Md., and Rep. Anna G. Eshoo, D-Calif., that would provide the agency with what is called "equivalency authority."

That means the agency would have the power to investigate the food safety systems in other countries and bar produce from nations that do not use growing and packing methods that ensure the food will be at least as safe as that which is home-grown.

FDA officials also say it would provide the regulatory leverage they need to get countries to clean up their systems. Importers are likely to be eager to continue their access to the lucrative U.S. market.

The Agriculture Department, which regulates imported meat and poultry, already has the authority, and has determined that 36 countries are eligible to ship into the United States.

Department inspectors go as far as examining conditions in foreign plants, just as they scrutinize facilities on U.S. soil. The department recently barred Paraguay from exporting meat and poultry products to the United States because of repeated contamination.

"I believe food grown in the United States of America is among the safest," said Mikulski. "But you now have food coming in from other countries grown under suspicious circumstances."

Food manufacturers, many growers and Republicans on Capitol Hill say such concerns are overblown, and certainly do not justify giving the agency broad new regulatory powers.

Rather than handing the agency more regulatory authority, Susan Stout, director of federal affairs for the Grocery Manufacturers of America, said the agency should first concentrate its resources on more research to better identify the extent of the problem.

It also should develop better tests for parasites such as cyclospora to more easily detect problems at the border and new technology to kill dangerous organisms without harming food.

"We've got a better chance of dealing with these pathogens by concentrating our scientific resources on how to kill these things," said Stout.

The agency already has sufficient power to keep out unsafe food, said John Aguirre, vice president of government affairs at United Fresh Fruit and Vegetable Association, which represents 1,100 foreign and domestic growers, wholesalers and distributors.

Battles Over Jurisdiction Likely To Block Merger of Agencies

Policing the food supply involves maneuvering a complex web of federal agencies with overlapping jurisdiction. Consider how regulators safeguard the nation's egg supply.

Eggs in shells fall under the purview of the Food and Drug Administration (FDA), but once the eggs are cracked and processed, they come under the jurisdiction of the U.S. Department of Agriculture (USDA).

The USDA is responsible for regulating meat and poultry, while the FDA handles most other food products, including seafood and produce.

These two agencies share responsibility for enforcing the bulk of food safety laws, but other parts of the government also play a prominent role. The Environmental Protection Agency oversees pesticides applied to crops, for example, and the Centers for Disease Control and Prevention tracks food-related illnesses.

Consumer groups and many Democrats say the system is outdated and that the best solution would be to create a single food safety agency that could target inspections, streamline safety programs and use resources more efficiently.

Lawmakers are awaiting the results of a congressionally commissioned study by the National Academy of Sciences. Democrats have introduced legislation (HR 2801, S 1465) that would create such an agency.

But the idea has generated little enthusiasm among lawmakers and industry. Congress itself is perhaps the biggest obstacle, where a battle over turf would doom the idea. House Commerce has oversight of the FDA, while the Agriculture Committee keeps an eye on USDA.

"The whole question of food safety is split, and Agriculture is not about to give up jurisdiction," said House Agriculture Committee Chairman Bob Smith, R-Ore.

The concept is vigorously opposed by growers and manufacturers, who fear a single agency would impose onerous new regulations and could be used by empire-building bureaucrats looking to expand their budget and regulatory authority.

John R. Cady, president of the National Food Processors Association, said the industry fears that a new "food czar" would be armed with the authority to recall products and impose huge fines on their makers.

Caroline Smith DeWaal, shown discussing food safety in November, advocates a single food agency.

"The czar could easily use that unbridled authority to raise money for his agency, especially during tight budget times, destroying a brand product and putting a company and its workers out of business altogether for the slightest reason," said Cady.

But consumer groups and other critics point out that the current system is a patchwork of 12 agencies and 35 statutes.

The system was built up as Congress layered one law atop another, these critics say, with little regard to how it should work as a whole.

The Agriculture Department now employs about 7,500 full-time inspectors located at about 6,200 plants. Inspectors are required to examine every carcass that passes through the slaughterhouse.

The FDA has about 430 inspectors to keep tabs on more than 53,000 establishments that produce, process or store food other than meat and poultry. The agency carries out about 5,000 inspections per year. In contrast to meat and poultry inspection, the average company is subject to FDA inspection every 10 years.

Questions about how to deploy personnel are likely to grow more pressing as the Clinton administration implements new rules (known officially as Hazard Analysis and Critical Control Point, or HACCP) for meat and poultry inspection.

The rules, which went into effect for large companies in January and will be phased in for other companies over the next two years, require slaughterhouses to implement safe-handling procedures at points in the production process where contamination could occur, rather than relying on meat inspectors to eyeball carcasses.

The system is potentially less labor-intensive, but under the current process, USDA inspectors could not easily be reassigned to other agencies such as FDA. Advocates of a single agency say it would solve this problem.

"We cannot let the inside-the-Beltway politics prevent the move to a better system for better food," said Caroline Smith DeWaal, director of the program on food safety at the Center for Science in the Public Interest, a consumer group.

For DeWaal and other advocates, however, creating a new agency remains a distant possibility. They are resigned to a system they say is rife with inefficiencies such as the frequently cited pizza example: Cheese pizzas are FDA's responsibility, but if they have pepperoni on top, Agriculture inspectors step in.

— *Allan Freedman*

"I don't think there has been a clear articulation of the problem with imports or a clear articulation of how to solve it," said Aguirre, contending that the agency has the authority to inspect overseas operations.

Aguirre and others in the industry say that providing the agency new regulatory authority would upset sensitive international markets.

Potential Trade War

Growers are concerned that by requiring other countries to live up to U.S. standards, those nations would then have the justification they needed to place restrictions on U.S. exports.

American producers say competing countries have used trumped-up objections over sanitation issues to keep out U.S. products, and would not hesitate from playing the food safety card.

For example, U.S. tomato growers complain that Japan barred their product for decades on the false argument that the U.S. fruit was contaminated with tobacco blue mold, which can turn leaves yellow, cause plants to wilt and attack stems and roots.

Japan was reportedly concerned that the mold would be transported from the United States and invade its own crop, despite the assertion by U.S. growers that the mold could not be found on U.S. products.

Ed Beckman, president of the California Tomato Commission, said it took almost eight years to lift the ban, and this year California growers are expecting $16 million in sales in Japan.

"Countries are going to be concerned if we are using a method not based on science, and that is seen as a barrier to trade," said Beckman. "Clearly, whatever we do, there is going to be reciprocal action by the foreign country."

Chris Schlect, president of the Northwest Horticultural Council, which represents 6,000 apple, pear and cherry growers and shippers in the Northwest, agreed.

"Whatever the United States does to foreign producers, we can expect that being done to our producers," he said.

Schlect also questioned how such a system would work. The meat and poultry system is concentrated on a much smaller number of countries and factories. Vegetables are scattered throughout small and large farms and in nearly 100 countries.

But FDA officials insist that they would target their efforts, use the power cautiously, and would not do anything to upset international trade. They argue that the system for meat and poultry has worked well for years.

It is also clear that many U.S. growers believe they would benefit from the system. A scare related to foreign produce could hurt sales of products grown domestically.

"If we're truly interested in a safe food supply, then what's the down side to making sure that the countries importing into the U.S. are playing on a level playing field?" asked Greg Flood, senior vice president of sales and marketing at Grimmway Farms Inc., based in Bakersfield, Calif., which produces carrots on more than 40,000 acres in California, Nevada and Arizona. "You want to make sure the people you are competing against have like standards in place. A negative story hurts the entire industry."

The Politics of Food

For Republicans in Congress, wading into the food safety issue promises some clear political risks. Voters, they say, are not calling for action.

"I think the sentiment is we have in place a very successful system that has made it possible for American consumers to enjoy the safest food supply in the world," said Thad Cochran, R-Miss., chairman of the Senate Appropriations Subcommittee on Agriculture, Rural Development and Related Agencies.

Many Republicans still remember the thrashing they took from consumer groups and the Clinton administration in 1995 over a legislative provision included in the Agriculture Appropriations bill to deny funding for White House-backed food safety rules for meat and poultry. *(1995 Almanac, p. 11-8)*

Before dropping the provision under pressure from Democrats, Republicans argued that the standards were misdirected because most illnesses stem from food handling and preparation, rather than on the plant floor.

Likewise, a broader debate on food safety legislation could catch Republicans in the crossfire between rival interest groups, allowing Clinton and the Democrats to use the opening to seize the rhetorical high ground.

Even if Republicans considered a modest food safety bill on imports, they risk losing control of the issue. Democrats are sure to push expanding regulation on food companies and growers, causing fits in the industry and some GOP circles.

While some growers and food companies worry that legislation on imports could hamper free trade, other growers seem eager to use the issue to cast doubts on the safety of rival imports and promote domestic products.

Many Florida growers, for example, favor national legislation requiring that grocers identify the source of vegetables on the shelves, and this so-called country of origin labeling bill (HR 1232, S 1042) could find its way into the imports debate.

"It empowers the consumer to make a judgment of self protection," said Bob Graham, D-Fla., a cosponsor of the Senate measure. "I may want to buy food from a country that I have some special affinity for."

Consumer groups have long contended that Republicans and many Democrats are reluctant to act on food safety because they do not want to offend their industry allies.

And moving forward would provide an additional forum for these groups to level the charge that Republicans are too cozy with industry and invite a round of examination in the press.

Senate Labor and Human Resources Committee Chairman James M. Jeffords, R-Vt., noted that Republicans decided not to address major food safety issues in a 1997 measure to overhaul the FDA. Balancing myriad interests was ultimately too perilous. *(1997 CQ Weekly, p. 2917)*

Republicans say they recognize that even if they passed food safety legislation, Democrats and the White House are unlikely to give the GOP much credit for it.

On the day Susan Collins released the GAO report, White House spokesman Mike McCurry opened his daily briefing for reporters by pointing out the report's conclusions. He used it as an opportunity to release a letter from Clinton to House Speaker Newt Gingrich, R-Ga., and Senate Majority Leader Trent Lott, R-Miss., calling on Congress to give the FDA the authority that it "urgently needs."

McCurry called the document "a good study confirming the wisdom of the administration's food safety legislation."

But Collins was not mentioned. When a reporter asked who requested the report, McCurry replied: "That's a good question. Someone in Congress, obviously." ◆

Edited by Susan Benkelman

Food and Agriculture Organization of the United Nations

Information Note

Training Needs Assessment Workshop on Quality Assurance and Food Safety For Raw Fruits and Vegetables From Mexico and Central America

[Venue]

1 - 3 December 1998

Organized by:

Food and Agriculture Organization of the United Nations

in collaboration with the

Institute of Food Science and Engineering
University of Arkansas

and

[National Host Organization]

1. INTRODUCTION:

The economic importance of the international trade of raw fruits and vegetables is well known. From 1991-1995 the worldwide annual value of imported fresh vegetables ranges from 19.1 to 24.7 billion US dollars and for fresh fruits from 24 to 29.1 billion US dollars. For Latin America the exports of vegetables increased from 8.8% in 1987 to 10.5% in 1995 and fruit exports increased from 14.2% to 14.4% as a percentage of total international exports. These upward trends however could be altered by increasing concern that the quality and safety of imported produce may be less than domestically produced fruits and vegetables. Importing countries are establishing special measures to reduce food safety hazards for fresh fruit and vegetables and to work closely with exporting countries to assure a safe supply of fresh produce.

In response exporting countries are improving their production and distribution systems to be in a better position to maintain or improve their image of producing safe products which meet international standards and guidelines. National authorities in exporting countries are working with producers and research institutions to build the respective technical capabilities related to safe production, handling and transport of fresh produce. The national expertise and capabilities need to be strengthened in view of recent technological developments and food safety guidance measures related to the production, handling and transport of fresh fruits and vegetables.

FAO is organizing the above mentioned Workshop to assess the training and related research needs in participating countries in order to facilitate technical cooperation by FAO with countries requesting technical assistance.

2. OBJECTIVES

- Identify training and related research needs in the area of quality assurance and safety of raw fruits and vegetables for export by Mexico and Central American countries.
- Develop curricula outlines for pilot training courses along with an implementation for training of trainers course.

3. ORGANIZATION

The Workshop is being organized by the Food and Agriculture Organization of the United Nations (FAO) in collaboration with the Institute of Food Science and Engineering at the University of Arkansas and the [National Host Organization].

4. VENUE

FAO will inform the participants of the venue of the Workshop through the FAOR as soon as possible.

5. PARTICIPANTS

The Workshop is oriented to key persons from government, producer/exporter associations and university/research institutions who are responsible for overseeing training to strengthen quality assurance/food safety systems of fresh fruits and vegetables along the food chain in Mexico and Central America . FAO will cover the expenses of one participant for each country. Participants sponsored by FAO will present a paper on training and related research needs in this area. An outline for paper is attached.

6. FOLLOW-UP

It is expected that participants in this Workshop will be able to facilitate the implementation of training of courses to address the needs identified in the Workshop. In addition Workshop participants will be able to better collaborate on the organization of related research in the region. Workshop discussions will assist in the design of the pilot training of trainers program to be implemented in Mexico and Central America as follow-up to this Workshop.

7. TRAVEL ARRANGEMENTS

The participants should make the booking of their flights as well as visa arrangements (final `destination and transit). All participants should arrive to [ ] on 30 November 1998. Registration for the meeting begins at 08:00 1 December and the meeting will begin at 08:30.

It is requested that participants send their travel details to [ ], with a copy to the Chief, Food Quality and Standards Service, ESN, FAO, Via delle Terme di Caracalla 00100, Rome, Italy.

8. HOTEL BOOKINGS

A single room will be booked for each participant sponsored by FAO. It will not be possible for these participants to change the booking made by FAO.

9. LANGUAGE

The meeting will be held in Spanish with simultaneous translation for English.

Country Needs Assessment Paper – Training and Related Research

OUTLINE*

Training and Related Research Needs in Quality Assurance and Safety of Raw Fruits and Vegetables

I.. Assessment of Current Training and Related Research Activities

A. Governmental and private sector training activities for growers, harvestors, handlers, transporters)
B. Intersectoral approaches
C. Evaluation of Training Activities

II. Future Training and Related Research Needs

A. Key training issues and target groups
B. Proposed implementation plan and timeframe
C. Identified research needs

* 20 minutes will be allowed for each country presentation with an additional 10 minutes to address questions.

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PROJECT IDEA

TRAINING OF TRAINERS ON QUALITY ASSURANCE AND FOOD SAFETY OF RAW FRUITS/ VEGETABLES EXPORTED FROM MEXICO AND CENTRAL AMERICA

Prepared by:

University of Arkansas
Institute of Food Science and Engineering
Fayetteville, AR

and the

Food and Nutrition Division (ESN)
Food and Agriculture Organization of the United Nations
Rome, Italy

September 1998

QUALITY ASSURANCE AND FOOD SAFETY OF RAW FRUITS AND VEGETABLES EXPORTED FROM MEXICO AND CENTRAL AMERICA

Background – Key Points:

- From 1991 to1995 the worldwide, annual value of imported fresh vegetables ranged from 19.1 to 24.7 billion US dollars and for fresh fruits from 24 to 29.1 billion US dollars. (FAO, 1995a)

- The export of fruit and vegetables from Latin America has increased. Vegetable exports increased from 8.8% in 1987, to 10.5% in 1995. Fruit exports increased from 14.2% to 14.4% as a percentage of total international exports. (FAO, 1995a)

- Impoundment of low quality fruit and vegetable imports represents only a small percentage of imported fruits and vegetables, however this can result in a significant loss of income for exporting countries. (Friedman, 1998)

- Contaminated produce that clears customs has caused disease outbreaks. These outbreaks damage the reputation of all imported produce and further reduce income for an exporting country (FDA,1998a; Ault, 1998). Concern for the safety of all fruits and vegetables may have also damaged the domestic fruit and vegetable industry.

- Intergovernmental, as well as national governmental agencies, FDA and industry are working to help insure the quality and safety of exported fruits and vegetables. USDA and FDA will work with international agencies including FAO and WHO to provide technical assistance to foreign countries seeking advice (DHHS-FDA, 1998).

- Many of the phytosanitary, sanitary, Good Manufacturing Practices, Good Agricultural Practices, pesticide residue analyses, labeling and import law regulations are already in place in importing countries (FDA 1998a; CFR, 1997; Fillion, 1998)

- Given current port-of-entry inspections FDA cannot realistically ensure that unsafe foods are kept out of US commerce (GAO, 1998).

Justification – Key Points:

- There has been increasing concern that the quality and safety of imported produce may not be as good as domestically produced fruits and vegetables (The White House, 1997) although no evidence has been presented that imported produce is of lesser quality/safety than domestically produced.

- Guidance for industry to minimize microbial food safety hazards for fresh fruits and vegetables are currently being finalized by the United States (FDA, 1998b).

- Appropriate technical information on the safe growing, harvesting, packing, transporting and warehousing of fruits and vegetables must be transferred to the production and packing facilities in exporting countries (IFT, 1998).

- The rules and regulations surrounding the import of produce into the United States need to be well defined, up to date, and well understood by persons importing produce, by those inspecting the produce and by purchasers.

- At present areas of concern regarding the quality and safety of fresh fruits and vegetables include:

  - the hygiene/health status of field workers
  - quality of agricultural production inputs such as water , fertilizer, pesticides
  - incorporating HACCP principles and new technologies to reduce foodborne pathogens
  - ways to sanitize fresh fruits and vegetables without changing the fresh quality
  - the availability of rapid screening methods to detect pathogenic microorganisms, parasites, filth and pesticides in imported fruits and vegetables.
  - practical tests verifying that pathogen reduction measurers are working
  - new and emerging hazards to either consumers or domestically grown produce from exotic pathogens.
  - appropriate risk assessment methods applied to the export /import markets. (Risk assessment would help an exporting country focus its HACCP plan and allow importing countries to work with the best producers.)
  - agricultural and food law issues that need to be resolved to increase harmonization among importing countries.
  - communication strategies to address consumer perceptions in order to assure consumers that the produce they are purchasing is safe for consumption.

- To assist on-going efforts by FAO in the area of food quality and safety, the University of Arkansas is currently working closely with FAO to facilitate needed training and research in these areas.

- Training needs can be identified and curricula developed that will help transfer and adapt, as needed, available technical information to exporting countries on proper handling, storage and transportation of raw fruits and vegetables from Mexico and Central American countries.

- Proposed training activities will take into consideration the work of the FAO/WHO Codex Alimentarius Commission including that by the Committee on Food Hygiene (CCFH) which is preparing a Draft Code of Hygienic Practice for Primary Production, Harvesting and Packaging of Fresh Produce.

Overall Goals/Objectives:

To reduce the amount of imported fruits and vegetables that are impounded due to sanitary or food safety concerns.

To promote the safe handling, storage and transport of raw fruits and vegetables that are exported from Mexico and Central American through a trained and skilled workforce (including producers and government officials) .

Project Activities:

Phase I: Training Needs Assessment Workshop:

It is anticipated that this workshop will take place in early December, 1998 in a country within Central America to be determined. The goal of this first phase is to clearly identify training needs by identifying target training groups and the key issues to be addressed within the training program as well as a strategy to develop the training materials/curricula needed. Representatives from governments in the region will be invited to present information on on-going training activities in these areas and to identify additional training needs. In addition, representatives from the producer industry and academia within the region and from FAO, USDA, FDA and donor agencies will be invited . As an outcome of the workshop target training groups will be identified, training course outlines developed, and available resource materials identified.

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To identify the preliminary needs in the region and to establish preliminary arrangements for the Training Needs Assessment Workshop, a visit to some of the key exporting countries (Mexico, Guatemala, Costa Rica) will be made in September 1998 by a FAO and U of A representative.

Phase II: Curricula Development:

Based on the training of trainer course outlines identified in Phase 1, standardized curricula will be developed for the target audiences identified. A review of existing related curricula developed by industry and regulatory agencies will be made. These curricula will be used in Phase III and adapted for Phase IV training of trainer courses. The FAO Center located at the University of Arkansas will take the lead in organizing the drafting and the review of the standardized curricula and implementation of the training of trainer courses.

Phase III: Pilot Training of the Trainers Workshop

The goal of the third phase is to train identified trainers from the region and to test and evaluate the training of trainer materials. It is anticipated that there will be one Pilot course developed for Mexico and one Pilot regional course for Central American countries. Government officials and representatives from producer/exporter groups from exporting countries will be invited. Advisors for the Pilot training of trainer workshops may include regional experts along with FDA, USDA and FAO staff/consultants.

Phase IV: Training Workshops Held in Mexico and Central American Countries

These training of trainer workshops will take place in individual countries in the region. The goal of this Phase is to transfer information/skills to those individuals directly involved in overseeing the training for the safe handling of raw fruits and vegetables. Training materials developed in Phase II and adapted as needed during Phase III will be used. Participants will include those from the several sectors involved with fruit and vegetable production, packinghouses, labeling issues, transportation, and storage. The needs of brokers and buyers and governmental agency requirements will be addressed. The workshops will be tailored to the needs and specific commodities of individual exporting country and towards the targeted training group while utilizing as much of the standard training materials. It is anticipated that the initial portion of this phase of training will take place during 1999.

Facilitate Related Study Tours: To complement and strengthen the training provided through the Workshops, related study tours will also be arranged as needed for specialized and tailored training to reinforce the principles of food quality and safety. This training could take the form of sabbaticals or commercial internships. Academic institutions, federal regulatory agencies, and multi-national corporations that import fruits and vegetables can assist in providing the venue and expertise for these study tours.

Evaluation and Monitoring:

A formal evaluation and monitoring component will measure the extent to which trainees gained new information. Feedback from the participants and evaluations from the training workshops will be used to update and revise the training materials as needed. This will assist in providing trainers with updated and appropriately revised training materials as needed. Pre and post-training evaluations will be designed for each workshop to measure

the efficiency of the training. Feedback information will be provided back to field trainers and to funding agencies.

Funding:

A budget outlining governmental and industry support will be prepared once there is mutual agreement on the scope of the training activities needed. FAO has agreed to fund Phase I: Training Needs Assessment Workshop to be held in Central America in early December. Funds will be sought by the U of A and FAO for the Curricula Development (Phase II), and the Pilot Training of Trainers (Phase III) and subsequent Training of Trainers programs (Phase IV). It is our understanding that buy-ins from each sector is vital to the continued success of these training efforts.

Additional funding will be sought to support pre-competitive and applied research to address specific concerns which surface as part of the training workshops. It is envisioned that this research will be conducted jointly among scientists among countries participating countries. Governmental and private sector support will be sought for this project.

Expected outcomes and benefits:

Through the development and implementation of appropriate training of trainers program activities in exporting countries , this project should result in:

- Sustainable improvements for maintaining a safe supply of fresh fruits and vegetables in a free market through a skilled and trained workforce. Educated fruit and vegetable producers in exporting countries will be in a better position to negotiate with buyers.

- Improved institutional capacity within exporting countries to address food safety and quality issues.

- Reduced economic hardships (market losses) in exporting countries related to food quality and safety export measures for fresh fruits an vegetables.

- Improved availability of safe and good quality fresh produce in importing countries on a year around basis. In addition, the quality assurance improvements in the export market can lead to improved quality assurance of fresh produce in domestic markets of the exporting country.

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Training Needs Assessment Workshop: Food Quality and Safety of Fresh Fruits and Vegetables from Mexico and Central American Countries

1-3 December 1998
FAO, University of Arkansas, [National Host Organization]
[Venue]

Preliminary Program

1 December 1998

08:00-08:30	Registration of Participants
08:30-09:00	Welcoming Comments FAO Representative University of Arkansas Representative National Host Organization
09:00-09:10	Break
09:10-09:30	Objectives of the Workshop Introduction of the Participants
09:30-10:30	Session I: Country Presentations on Training and Research Needs Costa Rica El Salvador
10:30-10:45	Coffee Break
10:45-12:15	Session I: Country Presentations on Training and Research Needs (cont'd) Guatemala Honduras Mexico
12:30-02:00	Lunch
02:00-03:00	Session I: Country Presentations on Training and Research Needs (cont'd) Nicaragua Panama
03:00-03:15	Coffee Break
03:15-04:15	Session I. Discussion and Summary of Identified Training and Research Needs
04:15-05:00	Sesion I. Draft Curricula Outlines for Pilot Training Programs/Related Research Introduction to Working Group Activities (Dr. Alfredo Gonzalez - International Consultant)

2 December 1998

08:00-10:00 Session II: Overview of International Assistance on Food Safety and Quality
FAO, PAHO, IICA, FDA, USDA, USAID, CDC, OIRSA presentations

10:00-10:30 Session II: Regional Assessment of Needs in Investment on Food Safety (IDB)

10:30-10:45 Coffee Break

10:45-11:30 Session III: Case Study--Mexico

11:30-12:15 Session III: Case Study--Guatemala

12:30-02:00 Lunch

02:00-02:45 Session III: Case Study--Costa Rica

02:45-03:00 Session III: Case Study Discussion

03:00-03:15 Coffee Break

03:15-05:00 Session IV: Working Group Discussions
(a) Training Issues and Target Groups
(b) Research Needs

3 December 1998

08:00-09:00 Session IV: Presentation by Working Groups
(a) Training Issues and Target Groups
(b) Research Needs

09:00-10:30 Session V: Follow-up Actions
Revision of Outlines for Pilot Training Courses and Research Needs

10:30-10:45 Coffee Break

10:45-11:45 Session V: Follow-up Actions
Implementation of Pilot Training Programs - Timeframe
Sustainability of Training Programme and Research Activities
Discussion and Recommendations

11:45-12:00 Concluding Remarks

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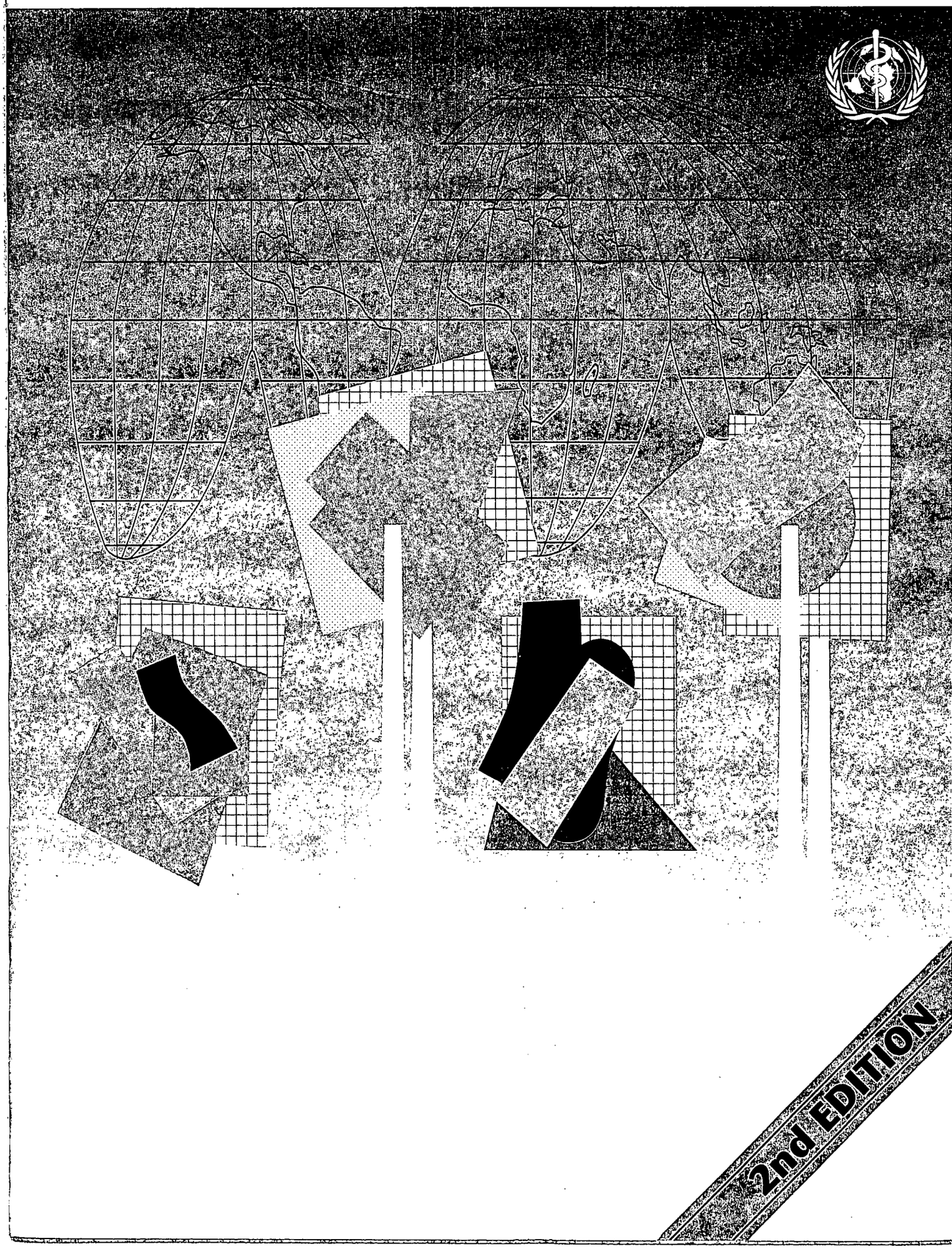

2nd EDITION

May 11, 1998

TEXT OF A LETTER FROM THE PRESIDENT TO THE SPEAKER AND MINORITY LEADER OF THE HOUSE OF REPRESENTATIVES AND THE MAJORITY AND MINORITY LEADERS OF THE SENATE

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release May 11, 1998

TEXT OF A LETTER FROM THE PRESIDENT
TO THE SPEAKER AND MINORITY LEADER OF THE
HOUSE OF REPRESENTATIVES AND THE
MAJORITY AND MINORITY LEADERS OF THE SENATE

May 11, 1998

Dear Mr. Speaker: (Dear Mr. Leader:)

The report to be released today by the General Accounting Office (GAO) calls on Congress to give the Food and Drug Administration (FDA) the authority to ensure that food eligible for import to the United States is produced under food safety systems that will provide the same level of protection as the safety systems in place in the United States. This report is further confirma-tion of the need for Congress to pass the Safety of Imported Food Act, which I called for in October 1997, which Senators Mikulski and Kennedy, and Representatives Eshoo and Pallone have introduced.

This important legislation will do what the GAO says is necessary: it will ensure that the FDA denies the entry of imports of fruits, vegetables, or other food from a foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required in the United States. It will give FDA the authority it urgently needs, comparable to the Department of Agriculture's existing authority to prevent the importation of unsafe meat and poultry, to protect the safety of the food Americans eat.

I have taken several further steps to begin implementing standards to ensure the safety of imported food. My FY '99 budget committed approximately $25 million to enabling the FDA to dramatically expand its international food inspection force in order to implement the pending legislation. In March of this year, I released a report on how the

Secretary of Health and Human Services, in partnership with the Secretary of Agriculture, and in cooperation with the agricultural community, will develop guidance on good agricultural and manufacturing practices that will apply to both domestic and foreign producers.

There is no more important task our government faces than ensuring the safety of the American food supply. That is why last year Vice President Gore and I announced my compre-hensive new initiative, "Food Safety from Farm to Table" -- which detailed a comprehensive program including surveillance, outbreak response, education and research. The Safety of Imported Food Act is another vital step in protecting the safety of all the food Americans eat, and I urge you to pass it promptly.

Sincerely,

WILLIAM J. CLINTON

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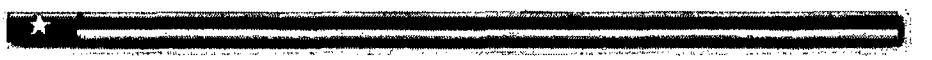

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United States General Accounting Office

GAO

Report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

April 1998

FOOD SAFETY

Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable

GAO/RCED-98-103

GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-279329

April 30, 1998

The Honorable Susan M. Collins
Chairman, Permanent Subcommittee
on Investigations
Committee on Governmental Affairs
United States Senate

Dear Madam Chairman:

This report responds to your request that we evaluate the federal government's efforts to ensure the safety of imported foods. The report contains recommendations to the Congress and to the Secretaries of Agriculture and of Health and Human Services that are designed to enhance the federal government's authority to review the safety of food imports, improve the effectiveness and efficiency of systems and staff to screen imports, and strengthen internal controls.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to interested parties and make copies available to others upon request.

Please call me at (202) 512-5138 if you or your staff have any questions about this report. Major contributors to the report are listed in appendix VI.

Sincerely yours,

Robert A. Robinson
Director, Food and
Agriculture Issues

Executive Summary

Purpose

Each year, millions of Americans become ill after eating tainted foods, and thousands die. Ensuring the safety of domestically produced foods is a daunting task, but the challenge of ensuring the safety of the entire food supply is even more difficult as Americans consume more foods imported from other countries. The primary responsibility for ensuring the safety of imported foods is split between two federal agencies—the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) and the Department of Health and Human Service's Food and Drug Administration (FDA).

Concerned about the safety of imported foods, the Chairman of the Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs, asked GAO to review the efforts of federal programs to ensure the safety of food imports. Specifically, this report discusses (1) the differences in the agencies' authorities and approaches for ensuring the safety of imported foods and (2) the agencies' efforts to target their resources on foods posing risks. In addition, the report discusses weaknesses in the controls over imported foods.

Background

Foodborne illnesses in the United States are widespread and costly. The magnitude of the problem is uncertain, however, because these illnesses are underreported and health officials often cannot determine their source. As GAO reported in May 1996,[1] up to 81 million cases of foodborne illnesses and as many as 9,100 deaths from these illnesses occur each year. According to the U.S. Department of Agriculture's Economic Research Service, the costs for medical treatment and productivity losses associated with these illnesses and deaths range from $6.6 billion to $37.1 billion. Recent outbreaks of foodborne illness demonstrate that imported foods have introduced new risks or increased the incidence of familiar illnesses. The increased consumption of imported foods in the United States further heightens the risk of illness.

FSIS has jurisdiction over meat, poultry, and some egg products, while FDA regulates all other foods. FSIS and FDA work closely with the Customs Service (Customs) and the Centers for Disease Control and Prevention (CDC). Customs refers imported foods to FSIS or FDA for their review before releasing the shipment into U.S. commerce. CDC monitors the incidence of foodborne illness; works with state and local health departments to investigate outbreaks of illness; and collaborates with FSIS, FDA, and others to conduct research on foodborne diseases.

[1] Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

Results in Brief

Federal agencies cannot ensure that the growing volume of imported foods is safe for consumers. Although the Food Safety and Inspection Service and the Food and Drug Administration require imported foods to meet the same standards as domestic foods, their approaches to enforcing these requirements differ. By law, the Food Safety and Inspection Service places the principal burden for safety on the exporting countries by allowing imports only from those countries with food safety systems it deems to be equivalent to the U.S. system. The Food and Drug Administration, lacking such legal authority, allows food imports from almost any country and takes on the burden of ensuring the safety of imported foods as they arrive at U.S. ports of entry. Relying on port-of-entry inspections to detect and prevent unsafe foods is ineffective, given that (1) this approach does not ensure that foods are produced under adequately controlled conditions, (2) the Food and Drug Administration currently inspects less than 2 percent of all foreign shipments, and (3) inspection will not detect some organisms, such as Cyclospora, for which visual inspections and laboratory tests are inadequate.

The Food Safety and Inspection Service and the Food and Drug Administration are not deploying their inspection resources to maximum advantage. The Food Safety and Inspection Service focuses its inspection and testing resources on shipments from exporting firms with a history of violations, such as contamination, processing defects, and incorrect or missing shipping labels. However, many of the violations, such as the incorrect or missing shipping labels, may bear little relationship to food safety. Using available data on health-related risks from shipments that do not meet U.S. standards could help the Food Safety and Inspection Service focus more closely on the imports posing the greater risks. The Food and Drug Administration's annual work plan does not set achievable targets for inspection activities; as a result, inspectors do not have clear guidance for conducting inspections. For example, in fiscal year 1997, the Food and Drug Administration conducted only half of its planned inspections of imported foods. Furthermore, the Food and Drug Administration does not make health risk data readily available to guide inspectors' selections. In addition, when making decisions on which shipments to inspect, the Food and Drug Administration relies on importers' descriptions of shipments' contents, which are often incorrect. As a result, the agency's resources may not be focused on imported foods posing the greater safety risk.

The Food and Drug Administration's procedures for ensuring that unsafe imported foods do not reach U.S. consumers are vulnerable to abuse by

unscrupulous importers. For example, when an exporting firm has a history of violations, the Food and Drug Administration detains shipments from that firm without sampling or analysis. Importers of these detained shipments have the right to present evidence, such as private laboratory tests, showing that the product complies with U.S. standards. However, because the Food and Drug Administration does not have the explicit authority to require importers to use certain laboratories, importers can choose the laboratories that select the samples and perform the tests to prove compliance. For other shipments, importers retain control of the goods while the Food and Drug Administration decides whether to inspect them or while tests are being conducted on them. In some cases, when the Food and Drug Administration decides to inspect shipments, the importers have already marketed the goods. In other cases, when the Food and Drug Administration finds contamination and calls for importers to return shipments to the Customs Service for destruction or reexport, importers ignore this requirement or substitute other goods for the original shipment. Such cases of noncompliance seldom result in a significant penalty.

Principal Findings

Lack of Equivalency Authority Diminishes FDA's Ability to Protect U.S. Consumers

FSIS has the statutory authority to require the exporters of meat and poultry products to have food safety systems equivalent to the system in the United States. In enforcing this requirement, FSIS has determined that 37 countries have food safety systems equivalent to the United States' and are therefore eligible to export meat and poultry products to this country. (App. II lists the eligible countries.) FDA's authority, on the other hand, requires imported foods to meet U.S. standards. FDA does not have the authority to require the exporting country to have an equivalent safety system in place. In 1997, administration initiatives on food safety proposed that FDA be given this "equivalency authority."

FSIS has used its equivalency authority to shift the primary responsibility for food safety to the exporting countries. In so doing, the agency can leverage its resources by reviewing exporting countries' compliance with U.S. requirements, rather than by depending on resource-intensive inspections at ports of entry. FDA, on the other hand, relies on selecting and testing import samples at ports of entry to ensure that foods are safe. Such an approach, when used as the sole means of assessing the safety of

foods, has been widely discredited as an effective protective measure by the Food and Agriculture Organization of the United Nations, an FDA advisory committee, and GAO for a number of reasons. For example, individual products tested at ports of entry may not represent the health risks of the entire shipment. The ineffectiveness of FDA's approach is magnified by its inability to keep pace with a rising level of imports. FDA's coverage of import shipments has fallen from an estimated 8 percent in fiscal year 1992 to an estimated 1.7 percent in fiscal year 1997.

Agencies Could More Effectively Target Resources on Unsafe Foods

Although both FSIS and FDA use computer systems to screen each import shipment and to help identify the import shipments requiring inspectors to take action, the agencies have not designed their systems to take the best advantage of available data so that they can target those imported foods posing the greater health risks. FSIS relies primarily on the violation history of previous shipments from the exporting firm to target entries for inspectors' action; this violation history may not always indicate the shipments more likely to pose health threats. For example, many violations, such as incorrect shipping labels, may not directly affect consumers' safety. As a result, FSIS is using some inspection resources to review shipments that pose lower food safety risks. However, information is available on the relative health risks of specific types of imported foods, such as ground or deboned beef, that would enable FSIS to further improve its computer screening system.

FDA's system for selecting imports for examination relies primarily on inspectors' judgment, and FDA's guidance and information to aid inspectors' decisions are often not useful. FDA's annual work plan, which identifies, among other things, the number of imported food inspections and tests each field office is expected to conduct, guides inspectors' judgment; but the work plan is unrealistic because it does not make allowances for the time needed to investigate emergencies and consumers' complaints. Because the number of activities set out in the work plan is generally not attainable, the work plan is not useful when making inspection and testing decisions, according to managers in field locations who reported the views of inspectors. In addition, FDA's computer system for screening imported food shipments is not programmed to help inspectors effectively use laboratory test results, violation histories, and other information to identify shipments posing the greater food safety risks. Finally, the information identifying the contents of imported food shipments is entered directly into FDA's computer system by importers, some of whom have an incentive to misrepresent their goods in the

interest of avoiding inspectors' attention. After an importer demonstrates competency with the system, FDA retrospectively verifies a sample of the importer-provided information. Although the agency frequently identifies errors, it has recently taken no corrective action other than counseling the filer. Thus, FDA has no assurance that importers are accurately describing their goods and that it is identifying shipments that should be scrutinized.

Weaknesses in Import Controls Allow Entry of Unsafe Products

FDA and Customs have historically had problems stopping importers from distributing unsafe foods under FDA's jurisdiction. Recent investigations by Customs confirm that these problems continue. Nevertheless, the procedures for controlling suspect shipments continue to permit importers to easily circumvent them.

In particular, FDA does not maintain effective control over the products it automatically detains because of past violations. In lieu of requiring that these shipments be destroyed or reexported, FDA requires importers to establish that the contents are safe. As proof, FDA allows them to present evidence, such as private laboratory test results, to show that the shipments meet U.S. safety standards. However, because the agency does not have the explicit authority to require importers to use certain laboratories, importers are free to choose the laboratories that will perform the tests. While FDA expects these laboratories to follow the agency's written sampling guidelines and reviews the test results submitted to the agency, it does not control the selection of the samples tested by the private laboratories or certify acceptable private laboratories to perform these tests. FDA has found numerous discrepancies between its test results and those from private laboratories for the same shipments. Customs officials and FDA inspectors told GAO that importers have been known to substitute shipments that have been tested as safe for samples of other shipments that are suspect.

Unlike FSIS, which controls the storage of imported foods after they are presented for inspection until their release into the U.S. market, Customs usually allows importers to retain possession of their shipments until FDA and Customs clear them for entry into U.S. commerce. According to FDA and Customs officials, imported food shipments under FDA's jurisdiction are often not made available for FDA's inspection as required or are not properly disposed of when refused entry into U.S. commerce. Customs and FDA inspectors have found many instances in which importers substituted safe products for inspection, rather than the imported products FDA wanted to inspect. In other instances, when the tested

products failed laboratory tests, importers substituted other products for destruction, rather than the imported products FDA wanted to destroy. In each situation, FDA inspectors believe the original imported food was sold in the U.S. market and presumably consumed. A joint Customs-FDA operation to test controls over foods at one port found that evasion was common.

The evasion of safety requirements is seldom punished effectively. While FDA and Customs rely on the bonds presented by the importer, which cover the value of the shipment, as the principal deterrent against noncompliance with laws, the collection of damages against violators is uneven and uncertain. For example, at one port, Customs collected about 2 percent of the damages originally assessed in 24 cases in 1997. In a previous report, GAO found that even if the maximum damages had been collected, the importer would still have made a profit on the sale of the shipment.[2] Thus, the bonds do not represent an effective deterrent.

Recommendations

In order to strengthen FDA's ability to ensure the safety of imported foods, GAO recommends that the Congress require all foods eligible for import to the United States, not just meat and poultry, be produced under equivalent food safety systems.

In the body of this report, GAO also makes several recommendations to the Secretary of Health and Human Services and the Secretary of Agriculture to improve the effectiveness and efficiency of their import review systems and procedures by targeting inspection resources on foods posing greater health risks.

Agency Comments

GAO provided copies of a draft of this report to the Department of Health and Human Services' Food and Drug Administration, the U.S. Department of Agriculture's Food Safety and Inspection Service, and the Department of the Treasury's U.S. Customs Service for review and comment. Their comments and GAO's responses are in appendixes III, IV, and V, respectively. The Centers for Disease Control and Prevention provided technical comments in response to the draft report, and these have been incorporated as appropriate.

[2]Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, Sept. 24, 1992).

FDA generally agreed with the report and said it raises a number of issues that need to be addressed. FDA agreed with GAO that FDA needs additional legislative authority to control the safety of imported foods, but the agency disagreed that any authority to require equivalency should be mandatory because such mandatory authority would disrupt trade if implemented at one time. GAO disagrees that FDA should have discretion over applying equivalency requirements and believes the agency could implement the requirements in stages. GAO believes that equivalency should be mandatory for all imported foods and could be implemented in a manner that would not unnecessarily or unfairly disrupt trade. Mandatory authority to require equivalency would address weaknesses in FDA's inspection approach at ports of entry, enable FDA to leverage its staff resources by sharing the responsibility for food safety with the exporting countries, and compel FDA to take a proactive approach in preventing food safety problems instead of requiring equivalency after problems are identified. The Congress could provide reasonable time frames that would allow equivalency to be implemented over a number of years.

FDA also generally agreed with the report's recommendation regarding its import screening system. FDA described planned actions to improve the efficiency of its automated import screening system and to take appropriate corrective actions in its electronic filer program. FDA did not agree with GAO's characterization of its system for communicating inspection priorities to its inspectors or the associated recommendation in GAO's draft report to improve this system. Specifically, FDA said that its annual work plan and compliance programs provide sufficient guidance to inspectors to help them make decisions about which shipments to inspect. GAO continues to believe that the priority-setting guidance provided to inspectors, even as it is described in FDA's comments, is confusing and inconsistent. As a result, inspectors may not be selecting shipments to inspect that pose the greater food safety risk to consumers. GAO has, however, modified its recommendation to better reflect the nature of the problem and to provide FDA with more flexibility to address it.

FSIS concurred with the facts in the report and stated that it will consider GAO's recommendation in its evaluation of port-of-entry inspection procedures and automated systems.

Customs also provided explanations of its actions to enforce requirements for controlling imported foods and raised concerns about the extent of the problem regarding the substitution of safe food products for actual products for inspection.

Contents

Appendixes

Tables

Abbreviations

AIIS	Automated Import Information System
CDC	Centers for Disease Control and Prevention
CLEAN	Closing Loopholes to Ensure Acceptable Nutrition
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
GAO	General Accounting Office
HACCP	Hazard Analysis and Critical Control Point
HHS	U.S. Department of Health and Human Services
OASIS	Operational and Administrative System for Import Support
USDA	U.S. Department of Agriculture

Introduction

Foodborne illnesses constitute a major public health problem in the United States. In May 1996, we reported that up to 81 million cases of foodborne illnesses and as many as 9,100 deaths associated with those illnesses are estimated to occur each year.[1] While foodborne illnesses are often temporary maladies that may not require medical treatment, they can sometimes cause acute and chronic illnesses, such as kidney failure in infants and young children, stillbirths, and various types of arthritis. According to the U.S. Department of Agriculture's Economic Research Service, in 1996, the estimated annual cost of medical treatments and productivity losses associated with these illnesses ranged from $6.5 billion to $37.1 billion. The actual number of foodborne illnesses, however, is unknown because many people who become ill do not seek treatment, and doctors may not associate the illnesses they do see with a food source or, if they do, report it to state or local health agencies.[2] Even when a foodborne illness is reported, health agencies may not be able to trace the illness to a specific food or its origin.

Imported Food's Growing Role in U.S. Food Supply

A growing percentage of the U.S. food supply is imported. The sheer volume of these imports, along with the difficulty in ensuring that they are safe, adds to the risk of foodborne illnesses.

As shown in table 1.1, the import share of some commonly consumed foods is increasing. For example, in 1995, one-third of all fresh fruits consumed in the United States were imported.

[1]Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

[2]Federal and state agencies began in 1995 to collect more comprehensive data on foodborne illness in the United States to overcome the scarcity of data. This effort will help identify the frequency with which specific foods are associated with certain pathogens, but it does not address the difficulties of tracing an adulterated food back to its country of origin.

Table 1.1: Import Share of Selected Foods Consumed in the United States, 1980-95

Import item	Percentage of total U.S. consumption provided by imports				Percent change, 1980-95
	1980	1985	1990	1995	
Fish and shellfish	45.3	53.8	56.3	55.3	22.1
Fresh fruits	24.2	28.0	30.7	33.3	37.6
Fresh vegetables	7.6	8.9	8.4	11.7	53.9
Tomatoes for processing	1.4	7.0	5.7	3.5	150.0
Broccoli for processing	9.1	22.2	57.8	84.9	833.0

Source: U.S. Department of Agriculture, Economic Research Service.

Some imported foods pose a significant risk of foodborne illness. They can introduce pathogens previously uncommon in the United States, such as new strains of Salmonella and the Cyclospora parasite. Imported foods may also contain pathogens, such as hepatitis A, that cannot be easily detected until illness breaks out. (App. I provides information on selected recent outbreaks of foodborne illness related to imported foods.)

As the percentage of imported foods consumed in the United States increases, the importance of ensuring that these foods are safe increases as well. Ensuring food safety therefore cannot be achieved by focusing on domestic products exclusively.

Multiple Agencies Are Responsible for Ensuring the Safety of Imported Foods

Two federal agencies have the primary responsibility for ensuring the safety of imported foods. The Food Safety and Inspection Service (FSIS) in the U.S. Department of Agriculture (USDA) is responsible for meat, poultry, and some egg products. The Food and Drug Administration (FDA) in the Department of Health and Human Services (HHS) is responsible for all other foods.

Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, as amended, FSIS works to ensure that products moving in interstate and foreign commerce are safe and wholesome, and correctly labeled and packaged. In calendar year 1997, FSIS used about 84 staff years, costing an estimated $3.2 million, to review about 118,000 import shipments and to determine that exporting countries met U.S. food safety requirements.

Under the Federal Food, Drug, and Cosmetics Act, as amended, FDA works to ensure that domestic and imported food products are safe, wholesome, and properly labeled.[3] In fiscal year 1997, FDA spent approximately 463 staff years (inspectors, laboratory staff, and support staff), at a cost of approximately $35.1 million, to ensure the safety of about 2.7 million imported food shipments.

To assist these agencies, the U.S. Customs Service (Customs) in the Department of the Treasury and HHS' Centers for Disease Control and Prevention (CDC) provide a number of services, including referring imported shipments for inspection and providing information on outbreaks of foodborne illnesses. Customs is the first federal agency to screen imported products, including food imports, when they enter the United States. Enforcing laws for over 40 federal agencies, Customs has, among other duties, the responsibility for collecting revenues from importers and enforcing various customs and related laws. Customs cooperates with FDA and FSIS in carrying out their regulatory roles in food safety.

CDC is the federal agency primarily responsible for monitoring the incidence of foodborne illness in the United States. CDC assists state and local health departments and other federal agencies in investigating outbreaks of foodborne illness, monitors information on foodborne illnesses, and conducts research related to these illnesses.

Since 1992, we have frequently reported on the fragmented and inconsistent organization of food safety responsibilities in the federal government.[4] These reviews have shown that inconsistencies and differences between the agencies' approaches and enforcement authorities undercut overall efforts to ensure a safe food supply. To address this problem, we recommended the formation of a single food agency. In the fiscal year 1998 appropriation act for USDA, the Congress provided $420,000 for a study by the National Academy of Sciences on the need to reorganize the federal food safety system.

[3]FDA is also responsible for ensuring that certain other products are safe. These products include drugs, cosmetics, medical devices, and electronic products that emit radiation, such as television sets.

[4]Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992); Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety (GAO/T-RCED-94-71, Nov. 4, 1993); Food Safety: A Unified, Risk-Based Food Safety System Needed (GAO/T-RCED-94-223, May 25, 1994); Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192, Sept. 26, 1994); and Food Safety: Fundamental Changes Needed to Improve Food Safety (GAO/RCED-97-249R, Sept. 9, 1997).

How Import Control Processes Work

FDA and FSIS are the two agencies responsible for ensuring that the imported shipments of food entering the United States are safe. Their systems for inspecting, testing, and approving the release of these food import shipments operate independently of each other.

FDA's System for Allowing the Entry of Imported Foods

To ensure that FDA is notified of all imported food products under its jurisdiction, an importer must file both an import notice and certain shipping information and, for shipments valued over $1,250, a bond to cover the goods for release with Customs within 5 days of the shipment's arrival at a U.S. port of entry. The import documents or electronic entry data identify the type of food product, the importer, foreign manufacturer, and country of origin. The bond, which covers potential duties, taxes, and penalties, may allow the importer to retain control of the shipment until FDA decides to inspect samples, test, or release it. If an importer fails to make an import shipment available for FDA's inspection, fails to recondition,[5] or fails to destroy or re-export the shipment, as directed by FDA, Customs may collect penalties against all or part of the bond value.

FDA relies on several sources of information to determine whether an imported food shipment will be inspected or tested or can be released into U.S. commerce. Among these sources are the following:

- FDA's annual work plan. The annual work plan establishes, among other activities, the number of inspections and tests that each FDA district office is to conduct, which are derived from guidance in specific food programs.[6] For example, the work plan for fiscal year 1997 set inspection and testing activities for 10 imported food programs, such as imported low-acid/acidified canned foods and imported seafood,[7] in four major project areas related to food safety—Foodborne Biological Hazards; Pesticide and Chemical Contaminants; Molecular Biology and Natural Toxins; and Food and Color Additives.[8]

[5]Importers can recondition imported products that do not meet U.S. standards so that the products can enter the United States. Examples of reconditioning include changing labels and fumigating raw agricultural products.

[6]FDA refers to these programs as compliance programs.

[7]Low-acid canned foods are products like green beans, mushrooms, and tuna fish. Acidified canned foods are low-acid foods to which acid is added, such as pickles and marinated artichokes. Canned products with low acidity are more prone to bacterial growth and contamination.

[8]Technical Assistance is FDA's fifth major project area related to food safety, but FDA did not identify inspection and testing activities for programs in this area in 1997.

- FDA's Import Alert Retrieval System database. This database contains a list of products that FDA automatically detains because the exporter or the specific food products have shown a history of violations in previous shipments.[9] FDA will not approve the release into U.S. commerce of these automatically detained shipments until the importer shows that the product is not in violation, usually by providing the results of a private laboratory analysis. FDA disseminates information on automatic detentions to district offices through import alerts, which identify problem commodities and/or exporters, foreign firms, the country of origin, the reasons for detention, and the food safety risk.
- FDA's Low-Acid Canned Food database. This database contains information on foreign processors of low-acid and acidified canned foods registered with FDA. Foreign processors wishing to export these foods to the United States must submit descriptions of their canning processes to FDA before it will issue a registration number for the firm and permit the entry of the firm's shipments into U.S. commerce. The descriptions include the manufacturing methods used to prevent spoilage and contamination. FDA issues each foreign establishment a registration number to help track the firm's registration and processing records.

To assist FDA in reviewing all shipments, Customs' computer system uses the information provided by the importer and FDA-developed screening rates to determine which shipments to automatically release into domestic commerce and which shipments to review further. FDA sets the screening rates using several sources of information, such as the annual work plan, compliance programs, type of product, and past violations of products or shippers. Most shipments that are believed to pose minimal safety risks, such as candy and dried pasta products, are frequently released automatically because they have low screening rates. FDA releases these shipments a few minutes after the importer enters the information. Other shipments, such as some seafood and low-acid canned foods, are less frequently or never released automatically, because they pose greater potential risks.

Customs forwards information on products that are not automatically released to FDA for further review, through FDA's automated screening system, known as the Operational and Administrative System for Import Support (OASIS). This system was pilot-tested in 1992 and installed at all

[9]FDA uses the formal term "detention without physical examination" to identify those shipments that are automatically detained.

FDA's district offices by October 1997.[10] (Before OASIS was developed, FDA manually tracked shipments through entry documents submitted by importers to Customs.) Along with the electronic information provided by the importer, FDA officials use the information in OASIS and other sources as needed—such as the databases with information on products to be automatically detained and registration numbers for foreign firms—to determine which samples of imported food shipments should be held for further action, such as inspection and/or laboratory testing, and which can be released without further review. FDA releases most shipments not requiring further review within 3 hours after the importer enters the information. FDA does not visually check or inspect these released shipments.

FDA annually inspects or conducts laboratory analyses on a small percentage—currently less than 2 percent—of all types of imported food shipments. Inspections may occur at ports of entry and at warehouses or other business establishments. If FDA decides to test an imported food shipment, an FDA inspector collects a sample from the shipment and sends it to a FDA laboratory for analysis. (FDA maintains a record of all laboratory test results in its Laboratory Management System database.) For samples found to comply with U.S. standards, FDA notifies Customs and the importer that the shipment can be released. For samples found to violate these standards, FDA notifies Customs and the importer that the shipment has been refused entry into U.S. commerce. Importers generally have three options for handling shipments refused entry. If FDA concurs, importers can recondition the shipment. Otherwise, they must either destroy or re-export the shipment. Whatever option the importer chooses, Customs officials are required to supervise proper disposition of the refused shipment.

FSIS' System for Allowing the Entry of Imported Foods

Before foreign firms can export meat and poultry to the United States, FSIS must have determined that the exporting country has a food safety system for these products that is equivalent to the U.S. system. Unlike FDA, FSIS inspectors visually check every imported shipment of foods under their jurisdiction for correct documentation, transportation damage, and correct labeling at FSIS-approved import inspection stations. FSIS conducts more intensive inspections and tests on a portion of the imported shipments—about 20 percent in 1997—to verify the effectiveness of the foreign food safety system. FSIS calls this process "reinspection" because

[10]FDA began developing an automated system as early as 1987. OASIS succeeds an earlier version called the Import Support and Information System.