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October 2, 1997

PRESS BRIEFING BY MIKE MCCURRY

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 2, 1997

PRESS BRIEFING BY
MIKE MCCURRY

The Briefing Room

1:20 P.M. EDT

MR. MCCURRY: Did you guys get enough stuff from Secretary Shalala and company down below?

Q No -- more questions on that. The GAO and the FDA were urging this step a few years ago. Why has it taken so long?

MR. MCCURRY: Well, both Dr. Kessler -- and I'm not as familiar with GAO. I do know that Dr. Kessler recommended a comprehensive approach to improving food health and safety inspections, I believe in 1993. And the President took that on board and began working a lot of different pieces that you've seen over the last four years. I think they concentrated initially on the seafood regs, but they've implemented various parts of that. It was a comprehensive strategy. This was one element of it. But there were other things that the government chose to address first and foremost with a somewhat greater sense of urgency. But over time I think we've worked towards reviewing and implementing those parts of those recommendations that made sense and passed muster as we went through the regulatory review process.

Q So why now, why is the moment ripened?

Q Ripened? (Laughter.)

MR. MCCURRY: Ripened?

Q On the vine.

MR. MCCURRY: There have been some incidents that have required attention from public health officials. I think there has

required attention from public health officials. I think there has been more attention paid by the press -- I credit The New York Times with having made inquiries that brought some of these matters to light. And I think that it was really a number of these recent incidents that the President referred to today that I think concentrated attention.

Q Mike, is there any concern that our trading partners might find these too intrusive and might issue some reciprocal regulation?

MR. MCCURRY: Well, we would not -- reciprocal measures would only be implemented by countries that have quality health and safety standards that approximate or exceed ours. And I don't think we would be able to fault countries that did hold us to a standard that they were setting and using in their own domestic distribution networks. But at the same time, we have international obligations, and we do respect international law when it comes to trade and commerce, and we would act fully consistent with our international obligations.

Q Do you know how large this international inspection force would be -- how many inspectors there would be going around to different countries?

MR. MCCURRY: That is the sort of thing -- if I understand Joe correctly -- the Secretary has indicated they would review during the 90-day period, that they'll be examining questions like that -- how many inspectors do you need; also issues related to cost, how much additional would it require to fund the kind of inspection program that has been discussed.

Q Does this program envision sending American inspectors to every country that we import fruits and vegetables from?

MR. MCCURRY: I'm not sure if it would be every country because, if I'm not mistaken, with meat and poultry, I think they do spot checks, right now -- if I'm not mistaken. But they would have to design that program in order to meet the stipulations that the President made today in the directive.

Q So you're just not certain, is that it?

MR. MCCURRY: Not certain what would be required to fully implement. That's one of the things, I think, the President instructed the Secretary to look at today.

Q Mike, some consumer groups are concerned about the voluntary nature of the guidelines that HHS and USDA have been instructed to draft?

MR. MCCURRY: Well, the President's view is that by working cooperatively with the industry, with growers, with manufacturers, and looking at the processes, and using -- coming up with the guidance rather than firm regulation on how the best practices can be implemented, that we're likely to get a better result because we've got people working together to implement the kind of standards we're talking about. People can share information. It's not as much a hostile or threatening environment.

At the same time, we'd be making it abundantly clear what FDA would be looking at and looking for when they enforce the directive that the President has put forward and when they enforce regulations. I think it also creates a better environment for compliance in the long run.

for compliance in the long run.

Q Why was there the feeling that you needed this authority to ban imports? Have other countries not been sufficiently cooperative and there hasn't been a stick to use against them?

MR. MCCURRY: Well, we don't have, with respect to fruits and vegetables, the same tools that are available for meat and poultry. That's one fact. The other is that there has been a dramatic increase in imports because of -- frankly, in some cases, just because of the change in dietary habits of Americans. Thankfully, I think we're consuming more fruits and vegetables on recommendations from doctors, and so the overall demand for fruits and vegetables has increases. And of course, also the marketing of those products, because it's not as dependent now on seasonal variations as before. Americans now want access to fruits and vegetables year-round, despite whatever season it is. So there is proportionally more imports coming in.

Q When do you the legislation is going to be ready and what's the sentiment on Capitol Hill? Have you guys gauged that?

MR. MCCURRY: Well, there are a number of members of Congress who have been -- who have introduced measures of their own and who have been advocating faster action on legislation. I did not hear from anyone today when we think we might have a draft legislative proposal, but, presumably, they're preparing it for introduction next year, I would imagine -- not this year.

Q How can you avoid the implication -- or do you want to avoid the implication -- that if it's foreign it's more likely to be tainted?

MR. MCCURRY: Well, I wouldn't say that. I'd put it a little bit different. We have one of the best food safety and health systems in the world, so we have very high standards. And what we have found or what we suspect is that in some cases other countries may not have the same high quality standards that we have. And so we need to act in order to protect the American people and to encourage other countries to think about the quality standards that we're insisting upon for the American consumer and see if there's not a way to work cooperatively with other countries and raise those standards.

Q Is it nailed down scientifically that many of the outbreaks -- most of the outbreaks of various diseases that are food-borne in the last few years are traceable to foreign, as opposed to domestic product?

MR. MCCURRY: I was looking because they had some data, too, that there have been, obviously, some incidents in which there have been increases. There was a number in here, the 2 percent, 5 percent increase.

Q So it's not that there's --

MR. MCCURRY: John, I'll have to bump you back over to HHS, but I had seen somewhere in the stuff we had earlier on this some data about the -- there has been a measurable increase in some reported illnesses that tracks with the increase in imports that we've seen over the last decade. Essentially, that was the value of the data.

Q But my point is, really, it's less that there's a certain sense that, my God, this has been a definitive source that has to be blocked, then what you're saying is, we have domestic standards, let's make them international standards?

MR. MCCURRY: That's correct. It's not that we have suddenly found fault with the quality standards that exist elsewhere. It's just that we have determined that in order to bring -- to meet sufficiently our standard, we need to have these additional protective tools available.

Q Mike, it seems to me these countries would be the first ones to want to have the high standards so that their products will be sold. Remember the grape scare a few years ago -- in Chile that's one of the main exporters -- now the Guatemala raspberry thing. So what can be done instead of hitting them over the head quickly? What can be done to kind of work as a team? Because they're interested in exporting.

MR. MCCURRY: We have -- through all the different kind of bilateral discussions we had with countries that we trade with, when it comes to fruit and vegetables -- in fact, all agricultural products -- we do compare information on consumer demand, on the regulatory environments that exist, and there will be an active effort through our diplomacy to help educate other countries as to the quality standards that American consumers are insisting upon. And I think you're right, I think there would be a strong economic interest on the part of countries that rely on export of those kinds of products to meet those standards. They'll want to do so by force of market.

Q How do you -- with certain countries that are just developing, how do you approach them on this whole issue without insulting them?

MR. MCCURRY: You do so diplomatically. (Laughter.) We have conversations all the time among experts at the Agriculture Department, at the Commerce Department. I even recall the State Department's Bureau of Economic Affairs gets into these discussions from time to time, and we do try to raise it in a sensitive manner. But, remember, they have equally strong economic interest in marketing and selling in the United States, and they will certainly be aware of the fact that the President is insisting upon, and the American consumer is insisting upon, high standards.

Q Do you have a sense of how many countries' products or how many products will be excluded based on current standards, based on this --

MR. MCCURRY: I'm sorry. I didn't see anything on that. You might want to try -- see if Ed has got anything that they've looked at.

? Is the answer none, or that you're not sure?

MR. MCCURRY: I'm not aware of any. But I think that's one of the things they would do in developing and implementing this regulation is to look and see what practices are that are of concern. One of -- of course, we have taken on the obligation of improving practices in our own domestic industry, too. So as they identify the right ways of doing that and work with growers and the manufacturers on how to improve those standards, what they discover and learn about processing here in the United States might be relevant in examining what's going on in other countries, too.

Q How does the President fit this into his -- sort of philosophically, into his overall trade strategy? Do you see this as calming public fears about -- as we become more global, as markets become more global --

MR. MCCURRY: I want to stress, the President does not see this as a trade issue. This is a public health issue. He has an obligation to protect the health and safety of the American people. At the same time, we have to do that in a way that's consistent with the obligations we have as an international trading partner with so many countries that do export, and we will live up to those obligations as well.

Q Mike, on another subject -- some of the Race Advisory Board panel members are saying that they don't find surprise that there's word that President Clinton possibly be taking more of a hands-on approach with the Race Advisory Board, and even possibly taking over. Is that true?

MR. MCCURRY: Well, I don't know that it's -- maybe adjust the question a little bit. The President has always, as he said from the outset when he created this board, seen this as something that would work closely with him and advise him. The whole reason we did not establish any separate, independent commission was that the President wanted this board to be a creature of the White House and a creature of the President personally, because he's going to rely upon the board as he conducts the initiative and then presents the final report of the initiative next year. So he's always intended to have a hands-on role.

I think now that there's been kind of a set-up period here as the board got organized, structured the work they're going to do, and as the President made clear the other day, he now wants to begin using the resources available on the board, particularly the expertise of the board members, to begin shaping and directing the initiative a little more aggressively.

Q But is he upset with the speed that the board has implemented things or not implemented things?

MR. MCCURRY: I wouldn't say upset. I think that he wants -- this is a matter of very high priority to him and he wanted to be very clear in giving directions to the board that would help them shape the work that they're going to do in the coming months.

Q What specifically is different?

MR. MCCURRY: I don't know that anything is specifically different. I mean, they're moving into a new phase of the work of this board now. They've figured out what it is they want to try to tackled to do and now they've got to get down to the work of going out and doing it and shaping the results that will come from the initiative itself.

Q But the way it looks, it looks like this year -- I mean, already three months have been wasted pretty much on just --not wasted, but getting the staff together and then just talking --

MR. MCCURRY: Right, three months -- one of which was August -- it was spent getting organized, getting ready to begin doing the work that lies ahead. And I think that's an appropriate amount of time to pull together, figure out the work that they want to map out to do, and then to begin to do that work. And we clearly are now entering into an accelerated phase of the work of the board and the initiative itself with the things that the President has laid out on the calendar.

Q When he had the conference on corporate responsibility he brought in employers that had successful programs



October 2, 1997

REMARKS BY THE PRESIDENT ON FOOD SAFETY REGULATIONS

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

October 2, 1997

REMARKS BY THE PRESIDENT
ON FOOD SAFETY REGULATIONS

The Rose Garden

10:59 A.M. EDT

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

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

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

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

before they happen, to make sure our supply of food is as safe as it can be.

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

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

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

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

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

I'm asking Secretary Shalala and Glickman to report back to me within 90 days with a complete schedule for developing these standards within a year. I'll also ask them to submit a comprehensive plan to improve the monitoring of food safety programs abroad, to help foreign countries upgrade their safety precautions and toughen food inspections at the border.

Being a parent is perhaps the toughest job in the world. Our parents deserve the peace of mind that comes from knowing the food they set before their children is safe. With today's new actions, we can help make their jobs much easier.

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

(The order is signed.)

THE PRESIDENT: Thanks. (Applause.)

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

--

THE PRESIDENT: Excuse me?

Q Will you be using the line item veto on any of the

appropriations bills that you've just passed -- that you've just signed?

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

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

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

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

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

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

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

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

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

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

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

national campaign, sir?

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

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

THE PRESIDENT: I think that --

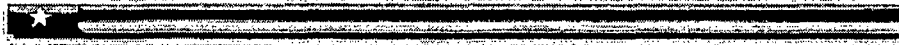
Q -- do you feel that the 90-day investigation would be helpful?

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

Thank you.

END

11:09 A.M. EDT



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October 3, 1997

President Wants to Tighten Rules on Imported Produce

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By JAMES BENNET

WASHINGTON -- Acting after several outbreaks of disease linked to the burgeoning global trade in produce, President Clinton announced Thursday that he would ask Congress to require federal regulators to ban imports of fruit and vegetables from countries that do not meet American food safety standards.

The move, urged by regulators since shortly after Clinton first took office and welcomed Thursday by industry and consumer groups, would empower the Food and Drug Administration to safeguard foreign fruit and vegetables in much the same way that other federal regulators check meat and poultry from overseas.

Clinton said that he would ask for more money from Congress next year for the FDA to hire investigators to inspect not just produce, but also foreign farming methods and government safety systems. In a change that might irk some U.S. trading partners, countries that blocked the new FDA inspections would be forbidden to sell fruit and vegetables in the United States, the administration said.

"At the time when Americans are eating more and more food from around the globe, we must spare no effort to insure the safety of our food supply from whatever source," Clinton said at a Rose Garden ceremony to announce his proposals Thursday. "Our food safety system is the strongest in the world, and that's how it's going to stay."

Imports of produce have increased sharply in recent years, to 38 percent of the fruit consumed by Americans and 12 percent of the vegetables. With those imports, however, have come recent outbreaks of diseases brought across borders by Guatemalan raspberries, Mexican cantaloupes and Thai coconut milk, causing public alarm that might make Congress sympathetic to Clinton's proposals. But American trading partners may eventually choose to protest any ban on their products to the World Trade Organization, much as the United States on Wednesday said it would file a complaint with that organization protesting Japan's stringent test for pesticides on American nectarines, cherries and other fruit. The United States sells twice as much food abroad as it imports.

Donna E. Shalala, the secretary of health and human services, said that Clinton would ask for \$24 million annually to support the FDA's new international inspections. Another official said that if Congress acts on Clinton's proposal, the FDA would phase in its system for such inspections over the next several years.

Thursday, Clinton also directed Shalala and the secretary of agriculture, Dan Glickman, to develop new, voluntary standards within a year for growing, processing, shipping and selling fruit and vegetables. The president said he also expected a report from them within 90 days on how to improve the monitoring of fruit and vegetables grown abroad.

Though they backed the president's proposal, consumer and industry groups said that they were anxious about the details in the legislation, which the administration plans to offer next year.

"What the president proposed today addresses many of the gaps," said Caroline Smith DeWaal, director of food safety for the Center for Science in the Public Interest. But, she added, "I would like to have mandatory standards rather than voluntary guidelines" for food manufacturers and handlers. For their part, White House aides predicted that meeting the voluntary guidelines would become an eye-catching industry selling point.

A senior White House official, who spoke on the condition of anonymity, said that it was hard to predict whether the president's initiative could raise prices of fruit and vegetables. But producers or sellers may have to pass on the costs of any modifications to consumers, he said.

The main initiative announced Thursday -- requiring the FDA to bar foods imported from countries with substandard safety systems -- was recommended more than four years ago by David A. Kessler, then the commissioner of food and drugs. Kessler warned then that the nation's food-safety laws, essentially unchanged since 1938, were in "urgent need" of an overhaul.

Contaminated food, he noted, kills an estimated 9,000 Americans a year and sickens millions, perhaps tens of millions. It still does. The food-safety system was marked by "enormous inefficiencies," he warned. It still is, according to a federal report published in May.

The White House has already moved to institute one of Kessler's central

proposals, a scientific system for controlling the risk of disease borne by seafood, meat and poultry. But no such system yet exists for fruit and vegetables, domestic or imported.

The White House said Thursday that Clinton has been adopting Kessler's proposals piecemeal, addressing the most urgent needs first. Michael D. McCurry, the White House press secretary, said that Clinton was prompted to tighten monitoring of fruit and vegetables partly by several outbreaks of illness and reporting on the potential hazards by news organizations, including The New York Times.

Clinton's move on food safety comes as he is seeking enhanced fast-track authority from Congress to negotiate trade deals. His opponents have charged that such deals lower barriers to food-borne diseases.

Some opponents of granting the president fast-track authority -- a set of rules under which trade deals, once negotiated, would have to be voted on quickly and without amendment by Congress -- hailed Clinton's announcement Thursday. "I'm glad the fast-track debate has energized the president to do this," said Rep. Sherrod Brown, D-Ohio. Brown and 85 other members recently sent Clinton a letter linking food safety and trade pacts.

The White House said Clinton did not connect food safety to promoting his trade goals. The senior administration official said that he expected some members of Congress to use the initiative as political cover for voting to give the president greater trade authority.

Sen. Richard Lugar, R-Ind., who is chairman of the Agriculture Committee, will hold hearings on the initiative next week.

The administration consulted with some foreign governments before Thursday's announcement, one administration official said, but still expects criticism from abroad. "There will be some negative reaction in some places, but it won't be the end of the world," he said.

Some foreign representatives here worried that Clinton's proposals might be used to create trade barriers. The safety of imported food is "a serious issue coming very fast towards all of us in this new global world," said Ambassador John Biehl of Chile. He called the president's initiative "a good thing as long as it is equal for everyone" and not "used as an artificial barrier to free trade."

Administration officials repeatedly said Thursday that there was no evidence that imported fruit and vegetables are less safe than American ones. But there is little data about the relative safety of domestic versus imported food, according to the Centers for Disease Control and Prevention, in Atlanta. One percent or less of the actual number of food-borne illnesses are reported, analyzed, identified and successfully traced.

While the Department of Agriculture monitors meat and poultry, produced here or abroad, the FDA is charged with safeguarding all other food, including fruit,

vegetables, grains and seafood. But, unlike the Agriculture Department, the FDA can now send its investigators abroad only if they are invited, and agency inspections of the imports have dropped to less than half what they were five years ago. If Congress approves the president's proposal, the FDA is expected to hire 100 more investigators, who will examine foreign farming methods and food safety systems.



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DRAFT

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

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Q: What is the President proposing?

A: The President is proposing two legislative and two executive actions that will further ensure the safety of fresh fruits and vegetables especially those imported into the U.S. First, the legislation will authorize the FDA to halt imports of ~~fruits, vegetables, and other~~ food from any foreign country whose food safety systems and standards are not on par with those of the U.S. Second, the President will also provide the necessary funds in his FY99 budget to enable FDA to expand dramatically its international inspection force so that it can ~~inspect~~ ^{inspect} this new authority.

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

Finally, the President has also asked the two Secretaries for a plan on how to improve the use of existing and projected resources to monitor agricultural and manufacturing practices abroad, assist foreign countries to improve those practices, and prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. The plan is due in 90 days.

These efforts all build on the Clinton Administration's long-term commitment to strengthening our food safety system. ~~With the help of the Vice President's National Performance Review~~ We have fundamentally improved the way we ensure the safety of meat, poultry, and seafood. We have also put in place important new protections against the risks of pesticides in our food, especially for our children. ~~And we are hopeful Congress will provide the \$45 million the President requested in his FY98 budget to improve food safety.~~

Is this still in the document - Jim O'Hara was going to check.

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2

Q: Why is he proposing these actions?

A: There have been enormous changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round and that would increase to as many as 50 in the summer. Today, no matter where you live in the United States, the chances are there are 400 or more items in the produce section and they are there all year round. Ten years ago, Guatemala first began planting raspberries vines in their fields, today Guatemalan raspberries account for about 30 percent of the

Replaces questions 3 and 7.

The President submitted a Food Safety Initiative budget to Congress for FY 98. The budget included in the initiative did not highlight "imports". Yet now, when the FY 98 budget is finalized, the President is putting forth an additional initiative for FY 98 as well as a budget request for FY 99. How does this current initiative relate to the FY 98 Food Safety Initiative?

This new initiative complements the Food Safety Initiative requested for FY 98. Included in the May 1997 report "Food Safety From Farm to Table - A National Food Safety Initiative", presented to Vice President Gore, were activities to be accomplished in FY 97. One such activity identified on page 38 of the report calls for FDA and USDA to immediately identify preventive measures to address public health problems, such as those recently associated with fruits and vegetables; for example, hepatitis A virus associated with frozen strawberries.

Moreover, there have been several recent outbreaks of foodborne illness associated with produce.

In 1997, more than 1200 cases of foodborne illness attributed to *Cyclospora cayentanensis* from imported and domestic produce were reported.

In June and July of this year, simultaneous outbreaks of *E. coli* O157:H7 attributed to alfalfa sprouts occurred in Michigan and Virginia. Over 70 people were reportedly sickened with *E. coli* O157:H7 during the outbreak. On July 29, 1997, the Centers for Disease Control and Prevention submitted a suggestion to the FDA's Center for Food Safety and Applied Nutrition that the Center's Food Advisory Committee review the safety of alfalfa sprouts.

These outbreaks coupled with the outbreak of *E. coli* O157:H7 in hamburgers during the past summer, has increased public awareness and concern over the safety of fruits and vegetables consumed by the American Public. Some outbreaks, such as *Cyclospora* have been attributed to imported produce and have created a concern on the part of the American Public regarding the safety of imported produce.

Therefore, this initiative is a logical extension of the Administration's 1998 Food Safety Initiative.

Replaces question number 4.

There have been a number of foodborne illnesses over the past several years traced to fruits and vegetables. Why hasn't FDA taken action to protect Americans from unsafe produce?

FDA has taken a number of actions. These include:

Since 1995, when FDA established the Fresh Produce Subcommittee of the National Advisory Committee on Microbiological Criteria for Foods, the subcommittee has been defining the problem of pathogens in fresh produce and devising appropriate preventive and control measures. A draft White Paper was discussed in August 1997.

In August 1997, FDA instructed the subcommittee to prepare Good Agricultural Practices and Good Manufacturing Practices for the fresh produce farming and processing industry. The committee will make recommendations and will make its report public next year.

USDA's Agricultural Research Service, in cooperation with FDA, is developing a pilot plant to develop and test antimicrobial sanitizers ("washes") for fresh produce.

In August 1997, FDA announced measures to reduce the risk of illness from disease causing microbes in unpasteurized fruit and vegetable juice. These measures included food safety control programs for the industry, new labeling for products, and education programs for consumers and manufacturers. FDA also asked the industry as an interim measure and as a voluntary public health service to their customers, to begin immediate labeling of fresh apple juices and cider products with a statement of risk.

FDA has already begun an education program for fruit and vegetable juices.

Replacements for Questions 5 and 6

Question 5

Q - How will the new guidance that you have asked the Secretaries to develop make our food safer?

A - Under our new plan FDA will coordinate and work with industry to develop basic guidance on how to minimize microbial food safety risks for fruits and vegetables. Following this, FDA will coordinate and work with industry to develop science-based, product specific good agricultural practices and good manufacturing practices. Good Agricultural Practices involve the control of water, manure application, worker/field/facility sanitation, and transportation and handling. Good Manufacturing Practices include the control of water, processing sanitation/quality, employee hygiene, equipment sanitation, and control of storage and distribution temperatures.

Question 6

Q- Are the steps you are taking today sufficient to solve the problem or should we expect additional proposals in the future?

A - We are committed to ensuring that the food we eat is safe. This action regarding fresh fruits and vegetables is a further step in a chain of initiatives to implement this Administration's food safety policies and to improve consumer confidence in the safety of the nation's food supply. Today's directive builds on previous actions the Administration has taken to increase the safety of the nation's food supply.



U.S. DEPARTMENT OF AGRICULTURE

OFFICE OF THE SECRETARY

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MESSAGE: EJTB

DRAFT

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

Q: What is the President proposing?

A: The President is proposing two legislative and two executive actions that will further

Improve ~~ensure~~ the safety of fresh fruits and vegetables especially those imported into the U.S. First, the legislation will authorize the FDA to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the U.S. Second, the President will also provide the necessary funds in his FY99 budget to enable FDA to expand dramatically its international inspection force ~~that it can make good use of this new authority.~~ *and will support accelerate research to improve our knowledge of disease-causing pathogens for*

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

Finally, the President has also asked the two Secretaries for a plan on how to improve the use of existing and projected resources to monitor agricultural and manufacturing practices abroad, assist foreign countries to improve those practices, and prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. The plan is due in 90 days.

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

Q: Why is he proposing these actions?

A: There have been enormous changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round and that would increase to as many as 50 in the summer. Today, no matter where you live in the United States, the chances are there are 400 or more items in the produce section and they are there all year round. ~~Ten years ago, Guatemala first began planting raspberries vines in their fields, today Guatemalan raspberries account for about 30 percent of the~~

~~raspberries sold in U.S. stores.~~

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

~~When you add up all these changes, and ask the question: is raw produce more risky to eat, the experts have told us they don't think so. The increase in the amount of produce and the types of produce we consume is far greater than the illnesses that may have resulted. But the experts have also made suggestions on ways to further improve the safety of raw produce, and the steps we are announcing today follow that advice.~~ respond to these changes.

Q: Why has the Administration waited until now to take these steps?

A: We are taking these steps now because they are the natural next steps in the President's long-term efforts to ensure the safety of the nation's food supply.

One of the first challenges we faced after taking office in 1993 was an outbreak of *E. coli* in hamburger in the northwest. We recommended replacing our old system of responding to problems only after they occur with a new system to prevent problems before they occur. That system, which we are putting in place for meat, poultry, and seafood is greatly increasing our ability to make sure food is safe.

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

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

Q: Given the dramatic increase of food imported into the U.S., and the seemingly related increases in outbreaks in foodborne disease, shouldn't the Administration be taking more immediate steps to protect Americans from unsafe foreign food?

A: First, it is important to remember that the experts in food safety have not concluded that there is an increase in outbreaks of foodborne illness in the U.S. that is the result of imported food.

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 isolated cases 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 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 are catching and quickly responding to outbreaks of foodborne illness that we often missed in the past.

Second, the steps we are taking today are on top of other actions the Administration has already taken. For example, next week we will complete work on an FDA automated import system known as OASIS (Operational and Administrative System for Import Support). OASIS ties together electronically 435 ports of entry around the U.S. and dramatically increases the efficiency of FDA inspection efforts. In the past, some importers engaged in what was known as "port-shopping" taking potentially harmful products through the busiest ports where their products would receive the least scrutiny. OASIS ends that practice.

Q: How will the new guidance that you have asked the Secretaries to develop make our food safer?

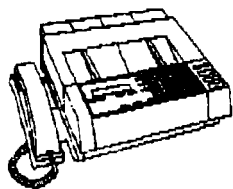
work with industry to provide

A: Today the produce industry is simply required to produce safe food, but is not given direction on how to do so. That is like telling drivers in a big city to drive carefully without providing them road signs, traffic lights, and speed limits. Under our new plan government food safety agencies will provide the industry specific guidance that will alert them to the potential hazards and the hazard-reducing steps they should take ~~to produce safe food~~. For example, FDA will issue guidance on good agricultural practices to minimize the risk of microbial contamination. This guidance will address, among other things, standards for worker and field sanitation, irrigation, and the use of manure.

Q: Are the steps you are taking today sufficient to solve the problem or should we expect additional proposals in the future?

A: We are committed to ensuring that the food that we eat is as safe as possible. It is important to keep in mind that the steps we are taking today are adding additional layers of protection to a food safety system that is already the best in the world. The steps we are announcing today represent the best ideas of our experts in government and the experts outside government in both industry and public health.

- Q:** Why didn't you address this problem in the President's food safety initiative announced in May or in the budget the President introduced last January?
- A:** The food safety initiative did identify imports as an area of concern. The additional measures we are putting in place build on our plan.



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TO: Jerry MondeDATE: 9/30/97FAX: 202-456-6027FROM: Janice Oliver# OF PAGES: 1
(including cover sheet)RE: Q & A's

ACTION TO BE TAKEN

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**ASSURANCE OF MICROBIAL FOOD SAFETY
FOR
FRUITS AND VEGETABLES
QUESTIONS & ANSWERS**

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

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

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

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

3. What is the cause of this apparent increase?

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

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

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

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

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

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

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

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

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

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

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

In addition

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

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

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

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

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

10. Why is further research needed?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 27. How will FDA pay for the overseas inspections?**

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

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

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

No, not at this time. Better scientific data are needed before we can develop HACCP for fresh fruits and vegetables. FDA's plan is to issue guidance documents that help interpret existing requirements, and the agency consider later whether regulations are needed. The agency is contemplating guidance on basic, common-sense sanitation and employee practices in the form of Good Agricultural Practices (GAPs) for farms and Good Manufacturing Practices (GMPs) applicable for those who sort, wash, and otherwise handle fresh fruits and vegetables.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

36. Can FDA make such agreements binding?

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

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

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

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

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

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

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

9/30/97 2:20 PM



DEPART ENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 31, 1993

MEMORANDUM TO THE SECRETARYTHROUGH: DS _____
COS _____
BS _____

Acting ASH/s/ Audrey F. Marley /s/ Tony Itellag APR 26 1993

SUBJECT: Food Safety Initiative--DECISION

PURPOSE

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

INTRODUCTION

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

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

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

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

Prepared by: FDA:WHubbard:3/3/93: (301)443-5004

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Page 2 - The Secretary

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

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

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

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

THE SCOPE OF THE FOOD SAFETY HAZARDS

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

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

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

THE COSTS OF FAILURE TO SOLVE THE PROBLEM

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

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

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

Page 4 - The Secretary

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

Page 3 -- The Secretary

WHAT IS NEEDED TO SOLVE THE PROBLEM

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

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

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THE FOOD SAFETY INITIATIVE

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

Regulations to Ensure Quality Control

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

New Statutory Authority to Control Food Hazards

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

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

Page 7 -- The Secretary

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

Increased Resources to Protect the Food Supply

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

HOW CAN FOOD SAFETY IMPROVEMENTS BE FUNDED?

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

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

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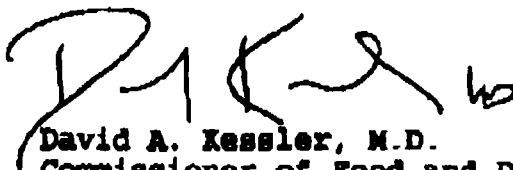
In addition to funding, we may be able to greatly enhance the use of existing resources with more modern inspection and enforcement powers. Also, the states have food safety programs, and it should be possible to design programs in which Federal and state officials ensure against duplication of effort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

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

RECOMMENDATION

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

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



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

DECISION

Announce and implement a new food safety initiative as proposed.

Concur _____ Nonconcur _____ Date _____



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 12, 1993

MEMORANDUM TO THE SECRETARY

THROUGH: DS _____
 COS _____
 ES _____
 Acting ASH _____

SUBJECT: Food Safety Initiative--ACTION

PURPOSE

During the recent budget briefings, I mentioned the urgent need for a comprehensive Federal policy for food safety. This memorandum is intended to explain that concept in more detail, and to request a briefing with you on this subject as soon as possible.

INTRODUCTION

The Food and Drug Administration is the lead food safety agency within the Federal government, through its enforcement of the broad food safety provisions of the Food, Drug, and Cosmetic Act of 1938.¹ Although Theodore Roosevelt spurred passage of the first Federal food law in 1906², that law was "updated" in 1938 to form the current food statute, whose provisions have remained essentially unchanged since enactment.

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

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

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

7-08-93

Page 2 - The Secretary

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

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

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

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

THE SCOPE OF THE FOOD SAFETY HAZARDS

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

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

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

THE COSTS OF FAILURE TO SOLVE THE PROBLEM

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

- o CDC estimates that over 9,000 people die each year from foodborne illness, caused principally by microbiological contamination (although least often from commercially processed foods).
- o A recent study by FDA's Center for Food Safety and Applied Nutrition estimated that there are at least 24 million, and perhaps as many as 81 million, cases of foodborne illness per year.
- o The health care costs associated with foodborne illness are enormous. One estimate of the annual costs associated with one common pathogenic illness, salmonellosis, is about \$2 billion, and total costs of foodborne illnesses are probably well over \$10 billion per year.¹

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

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- o USDA is now reporting to us about 6,000 cases each year of improper drug residues in meat and poultry (USDA regulates the meat; FDA regulates the use of drugs in food-producing animals).
- o The safety of fish and other seafood is increasingly questioned by consumer groups and Congress, and calls have been made to move seafood regulation to USDA. [The safety of meat is also being questioned, and there are calls to transfer meat regulation to FDA or an independent food agency.]
- o Imports of foods from other countries are growing rapidly, now up to over 2 million "entries" per year, posing an ever-increasing challenge to our ability to ensure that those foods are safe and wholesome. In fact, we can only inspect under 10 percent of food imports and, of those inspected, thousands must be "detained" as being in violation of our standards.
- o The cumulative effect of years of exposure to pesticides and other chemical contaminants is uncertain, but public concern about those food contaminants has remained high for a generation.
- o Hardly a month goes by in which there is not a public scare over the latest contaminant in food -- Alar in apples, aldicarb in watermelon, EDB in flour, PCBs in fish, lead in ceramicware, cholera in shellfish, dioxin in food packaging, salmonella in eggs, Listeria in cheese, and more (many of which are not a true health problem, but are perceived as such by the public). The E. Coli incident in Washington is only the latest in a long series.

WHAT IS NEEDED TO SOLVE THE PROBLEM

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

- 1) A Uniform National System of Food Safety Assurance - We need to consider whether to mandate that all segments of the food industry subscribe to a comprehensive food safety assurance program which would govern the handling, processing, transportation, and preparation of food; and that would focus on the areas where we know food is most likely to become contaminated or otherwise threatened (e.g., adequate refrigeration in holding and shipment; adequate protection from chemical contaminants, pests, and pathogens;

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adequate handling and cooking during processing). If implemented, this should comprise a coordinated regulatory framework encompassing the states, HHS, USDA, and other agencies concerned about food safety.

- 2) Authority to Protect the Public - FDA lacks many of the modern enforcement tools available to virtually all other Federal regulatory agencies. For example, the agency is not authorized to detain a contaminated product, cannot require food firms to register, cannot inspect the records of a food processor, and cannot order a recall of a product known to pose a health threat.
- 3) Inspection and Sampling - While the food industry has grown enormously in recent years, and imported foods have increased substantially, FDA's inspectional resources have been reduced. We do not have the resources to inspect many food processing facilities regularly (on average, every eight years), and inspect only a tiny fraction of imported foods.
- 4) Other Needs - There is great need for additional research into the nature and biological action of pathogens, for better analytical methods to test for the presence of chemical and biological contaminants, and for more training for the state, local, and Federal inspectors who are charged with identifying such threats.

THE FOOD SAFETY INITIATIVE

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

Regulations to Ensure Quality Control

We should consider the need for new regulations that would require food producers, processors, transporters and retailers to prepare plans for controlling hazards within their operations. If promulgated, these regulations could be based on the proven concept of "HACCP"--Hazard Analysis Critical Control Points--which focuses on critical points in food processing that might permit food to become contaminated. The regulations could be tailored to each segment of industry, yet be national in scope to ensure consistent, uniform protection of the food supply. We

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believe we could build strong industry support for a widespread HACCP program. In fact, we are working now with the National Fisheries Institute (the industry trade association) on a mandatory HACCP program for seafood processors that will greatly improve seafood safety.

New Statutory Authority to Control Food Hazards

We should examine what new authorities are needed to ensure safe food handling and preparation, for example:

- to require producers to register their facilities, so that we know by whom food is being produced;
- to authorize FDA to require that all food producers, transporters, and retailers establish and maintain a comprehensive program to ensure the safety of the foods they handle;
- to authorize FDA to refuse entry to food imports where the food safety inspection system of the originating country is not equivalent to the U.S. system and the food handler has not registered with FDA, does not have a HACCP program, or has refused FDA access to inspect the manufacturing facility.
- to permit an inspector to review a food producer's processing records;
- to authorize FDA inspectors to detain a suspect food until its safety can be determined;
- to allow FDA to order the recall of a food found to be hazardous to health;
- to give FDA the flexibility to seek punishment for offenders short of criminal action, that is, to impose civil penalties as an intermediate deterrent;
- to authorize the collection of user fees for some of FDA's food safety efforts, as described below.

Increased Resources to Protect the Food Supply

The level of effort to protect the food supply has simply not kept pace with the increasing size and complexity of the food industry and food imports. Indeed, as one comparison, USDA has 9000 employees devoted to the inspection of meat and poultry, while FDA has 770 for the entire rest of the food supply. We need to increase domestic inspections, import coverage, and other related activities such as HACCP development, research, and methods development. We are now

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examining those needs in detail so as to arrive at estimates of their likely costs.

HOW CAN FOOD SAFETY IMPROVEMENTS BE FUNDED?

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

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

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

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

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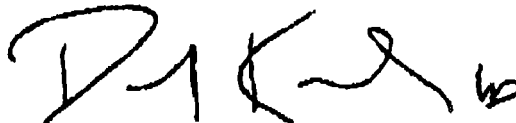
RECOMMENDATION

I believe that food safety reform is essential to carrying out FDA's mission of protecting the food supply and the public health. It will have the ancillary benefits of strengthening the integrity (and thus competitiveness) of American agricultural exports and of lowering health care costs. I recommend that we brief you and your senior staff on these concepts as soon as possible, with the goal of announcing a comprehensive legislative/regulatory food safety plan this spring.

DECISION

Schedule a briefing with FDA officials as soon as possible.

Concur _____ Nonconcur _____ Date _____

A handwritten signature in black ink, appearing to read 'D. A. Kessler', with a stylized flourish at the end.

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

~~being that should to~~
~~at~~

Jerry - let me know if you
 can't figure this out.
 Thanks.

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

as today's
 New York Times
 article indicated

Q: Is increased international trade going to introduce added risk to the U.S. food supply?

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

~~There efforts all build on the~~ ~~During the last four and half years the Clinton Administration~~ ~~has taken significant steps~~
 to strengthen our ~~entire~~ food safety system. With the help of the Vice-President's National Performance Review, we have fundamentally improved the way we ensure the safety of meat, poultry, and seafood. We have also put in place important new protections against the risks of pesticides in our food, especially for our children. And we are hopeful Congress will provide the \$43 million the President requested in his FY98 budget to improve food safety.

~~We are building on these efforts. As we announced last week, the President has asked the Secretaries of Health and Agriculture to take additional steps to improve the safety of fruits and vegetables, particularly those imported from foreign countries. The President will also be sending legislation to Congress that will go a long way to filling the remaining gaps in our food safety system. Specifically, he has asked the Secretaries to issue within one year guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those, foreign and domestic, seeking to sell produce in the U.S., market.~~

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

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

A: No, we are taking these steps now because they are the natural next steps ~~of the President's food safety initiative which he announced in his first radio address of his second term.~~ ~~The Clinton Administration has an especially strong food safety record.~~ ~~of this nation's food supply.~~ ~~The safety~~

One of the first challenges we faced after taking office in 1993 was an outbreak of *E. coli* in hamburger in the northwest. ~~Many children became ill and several died. The Vice-President headed up our response. In 1993, he recommended that we replace our old~~ ~~system of responding to problems only after they occur with a new system to prevent~~

In addition the Pres. has asked the Secs of HHS + Ag to take additional steps to improve the safety of both imported and domestic fruits + vegs. Specifically, etc. [put bracketed sentences here]

problems before they occur. That system, which we are putting in place for meat, poultry, and seafood, ~~and soon will be expanding to other areas of food production~~, is greatly increasing our ability to make sure food is safe.

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

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

Operational
Admin
System
for Import
Support

Elect Entry Processing
Systems

Frank Florch

EPSS

March 1999

N.E. i Buffalo

(3-7466) OASIS

12/96

Last two districts / work.

all districts + all ports.

20 Districts + 370 ports
438

Port-
Shopping

Central Amer
24%

Bee
1140
Guatemala
Resp 0

An automated system for processing
imported shipments for compatibility
3.5 M entries /
7.5 M Shipments

Screening criteria fixed in the computer.
Import broker enters into info^{ns} terminal - product
code each food
has its own code

INTER-AMERICAN DEVELOPMENT BANK

Washington, D.C. 20577



EXECUTIVE DIRECTOR
United States

FACSIMILE

Total pages: 2

Date: 9.29.97

To : Jerry Maute

Fax : 456-6027

From : Allen Rodriguez

Fax : (202) 623-3612

Tel : (202) 623-1031

Subject :

Food Imports and the IDB Background Paper

Issue:

Growing concerns are being expressed in the U.S. about possible outbreaks of disease linked to imported foods from Latin America and other developing countries. What efforts are underway at the Inter-American Development Bank (IDB) to address this pressing problem?

Background.

Since 1968, the Inter-American Development Bank has financed 27 agricultural projects, totaling \$241 million, which included components for animal health in 19 countries in Latin America. A major accomplishment has been the eradication of hoof-and-mouth disease in Argentina, Chile, and Uruguay as well as its prevention in Central America. In Haiti and the Dominican Republic, IDB programs have controlled and eradicated African swine fever.

Beginning in 1990, the IDB has financed programs in Latin America to support plant health. Areas of concentration have included control and eradication of the mediterranean fruitfly as well as the tristeza virus in citrus fruits.

Starting in 1997, the IDB began providing assistance to borrowing countries for the establishment of food safety control systems to comply with the WTO Agreement on Sanitary and Phytosanitary standards. The IDB is also considering requests from Guatemala and Honduras to help them set up Hazard Analysis Critical Control Points (HACCP), the new methodology established by the US FDA to ensure food safety.

Several examples of recently approved IDB projects are:

Peru. Agricultural Health Development Program (\$46 million). Activities include maintenance of a fruitfly-free areas in 25 fruit-growing valleys; training of fruit producers in comprehensive pest management; control and eradication of hoof-and-mouth disease; promotion of biological pest control to reduce costs and environmental damage; and control of scabies (affects wool production and quality in sheep and other cameloids).

Panama. Agricultural Services Modernization Program (\$34 million). Program aims at minimizing losses from pests and diseases and facilitating marketing. Activities include: establishment of laboratory to test for toxic residues in plant and animals; control of rabies and brucellosis; setting up of registry and analysis of pesticides; and establishment of livestock quarantine to prevent entry and spread of diseases.

Tony -

Could you put together one out of 2 + a
for when we announce the directive/legislation.
The 2 + a should address

② One legislation + executive proposals -
what they are
why we're doing them
why we're doing them now
whether they'll be sufficient to
address the problem
what the scope of the problem is
etc.

Thanks - consider this a top priority.

Etana

P.S. The questions I've been this morning
are a very good head start.

2nd DRAFT --- 1:30 p.m.

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

QUESTIONS & ANSWERS

☐ **Why is there a concern about the safety of fruits, vegetables and produce?**

Fruits and vegetables are safe and are a key part of a healthful diet. However, over the past two decades continual improvements in the surveillance of disease outbreaks have documented an increased in the incidence of foodborne illness attributed to the consumption of fresh fruits and vegetables.

☐ **What is the cause of the food safety problems and why have they occurred?**

Foodborne illness outbreaks can occur at any of the various points in the food distribution chain from the farm through transportation, processing, distribution, at retail, and into the home. Although there are a number of possible explanations, identifying the source of contamination of fresh produce-associated outbreaks is very difficult because contamination is generally sporadic and low-level, there is a high turnover of product, and product originate from many sources and are co-mingled. In most cases the cause is not positively determined.

☐ **What is the industry doing to address these concerns?**

The fruit and vegetables industry has taken a leadership role in the effort to minimize food safety risks. They have developed voluntary safety guidelines for various types of product and segments of the industry including model Hazard Analysis and Critical Control Point (HACCP) plans. They have provided growers and processors with information and materials on foodborne outbreaks and needed sanitation practices to control contamination. This educational information will greatly assist the industry in developing and implementing their enhanced sanitation

guidelines and model HACCP programs.

☐ **Is there a concern about imported products?**

There is no data to indicate that there is more of a problem with imported fruits and vegetables compared to domestic products. However, some outbreaks have been traced back to imports, and health officials want to improve the safety of imported fruits and vegetables the same as improving the safety of domestic products. Developing and implementing Good Agricultural Practices (GAP's) and product specific Good Manufacturing Practices (GMP's) will enhance the safety of both domestic and imported products.

☐ **How will this new initiative reduce the incidence of foodborne disease?**

This initiative is a two prong approach. The FDA will develop basic guidance for industry on how to minimize microbial food safety risks for fruits and vegetables. Following this the agency will coordinate and work with industry to develop science based, product specific GAP's and GMP's. This will allow industry to take immediate action to insure that best practices and science is being applied.

☐ **How will new GAP's/GMP's help solve the problem?**

GAP's/GMP's provide the scientific basis for any food safety program. Good Agriculture Practices involve the control of water, manure application, worker/field/facility sanitation, and transportation and handling. Good Manufacturing Practices include the control of water, processing sanitation/quality, employee hygiene, equipment sanitation, and temperature parameters.

☐ **What further research will be applied and what will it accomplish?**

We need additional knowledge and tools to improve food safety. Studies are needed to (1) help identify possible sources of contamination along the chain of harvest, transport, processing, and retailing; (2) develop more rapid tests to detect

and identify pathogens on food products; and (3) develop improved intervention technologies that can be used to eliminate or better control pathogens including detecting new foodborne pathogens.

☐ **What role will education play under the new food safety directive?**

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

☐ **How Does FDA presently inspect produce from other countries?**

Currently there are no statutory provisions which allows FDA to inspect produce prior to exporting to the U.S. Instead all imported foods are subject to FDA inspection at the port of entry. Current FDA resources permit the review of approximately 30% of importation documents and the physical examination of approximately 3% of the products.

☐ **Does FDA have the authority to prevent the entry of foods that are contaminated?**

FDA has authority to refuse the importation of adulterated foods if FDA finds a problem with the food. Because FDA does not have the resources to examine each entry of food, the ability to discovering adulterated foods is limited. If Congress passes new legislation, FDA will be allowed to declare foods from a problem country to be adulterated if the country does not provide the same level of protection that is provided for domestic products. The USDA already has this authority for meat and poultry products and uses it to refuse meat imports from many countries.

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

New import authority and an enhanced budget will allow FDA to develop an international inspection force to prepare country profiles which will assess the conditions under which produce is grown, processed, and shipped. Based upon this information, products from problem countries will be denied entry. FDA will encourage the adoption of appropriate GAP's and GMP's abroad and will work with USDA to provide technical assistance and training. Production and packing facilities will be inspected for compliance with GMP's.

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

An integral part of this initiative will be to develop country profiles assessing the food production, transportation and handling practices in place in importing countries. This assessment will allow FDA to better identify the risks associated with different countries and to focus resources.