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Of Pages Not Including Cover: 13

Comments:

COMMENTS OF THE FOOD AND DRUG ADMINISTRATION ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED, FOOD SAFETY: Federal Efforts to Ensure Safety of Imported Foods Are Inconsistent And Unreliable GAO/RCED-98-103

Thank you for the opportunity to review the subject draft report. In general, we agree with the report, as the report raises a number of issues that need to be addressed, both by the Food and Drug Administration (FDA or Agency) and by the Congress. It is our hope that the report will provide an added impetus for resolving the issues it identifies. We strongly disagree, however, with the "Results in Brief" characterization of FDA's Workplan.

Specifically, the draft report has misinterpreted the purpose and function of FDA's Workplan. The Workplan is developed annually by Center Directors, the Office of Regional Operations, and the Office of financial Management. The plan reflects the allocation of field resources-based on a given year's established priorities. This tool is a guide for management in utilizing the field resources consistent with the established annual priorities. The Workplan is an implementing instrument for FDA's Program Management System (PMS) which incorporates all the Agency's activities into discrete, mutually exclusive programs, establishes their respective priorities, assigns the numbers of operations (e.g., wharf examinations, sample collections, and analyses) to be done, and allocates resources accordingly. The Workplan does not attempt to plan every operation that is performed by the field, nor does it provide guidance to enable inspectors to make decisions about which entries to examine or the admissibility of entries.

The Compliance Programs, rather than the Workplan, provide guidance to inspectors making decisions about which entries to examine, whether an entry should be sampled and analyzed, and other relevant factors for determining an entry's compliance status. The Compliance Programs are the building blocks for the Workplan. Resources are distributed to the Compliance Programs through the Workplan, with higher-risk food programs given more resources. The risk factors have been incorporated into Operational and Administrative System for Import Support (OASIS), which automatically makes the initial decisions regarding entry admissibility. When there is a question as to which of two or more entries of equal priority to examine, inspectors refer to other guidance documents such as appropriate Compliance Programs, Import Alerts, the frequency at which a product has been examined, the country of origin, any available information about to the product, the importer, the shipper or the country of origin, and other relevant information.

The draft report characterizes the numbers of planned activities reflected in the Workplan as unrealistic, and links this alleged weakness with the difficulty inspectors have in deciding what to inspect and test. While FDA agrees that the planned number of operations most often is not achieved because inspectors may not be available to do routine import work if emergencies arise, the apparent discrepancy between planned and actual operations is not linked with individual decisions by inspectors at the import entry level. The Workplan is only a projection. The overall priorities established by the Workplan, however, remain the same for routine work, and inspectors are expected to make their decisions based on those priorities.

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Moreover, there are a number of activities, such as recall and investigations of consumer complaints, for which time is allocated outside of the Workplan. In other words, the hours in these activities are considered separately from those contemplated in the Workplan. While FDA believes that the best approach is to plan for full utilization of its workforce, such planning, of course, includes consideration of the resources that might need to be directed to emergencies and consumer complaints. Emergencies are dealt with immediately, regardless of where or when they occur. Decisions are made after the fact about which category or Compliance Program will be tapped for the resources that were utilized.

AREAS OF AGREEMENT

NEED FOR STATUTORY AUTHORITY

We agree that FDA needs additional authority for controlling the safety of imported foods. Legislation has been introduced in both the House of Representatives and the Senate to expand FDA authority to ensure the safety of imported food. The legislation applies to food safety systems of control. Before an action can be taken against an imported food product, the Secretary must determine that the product does not meet the U.S. food safety requirements or otherwise achieve the level of protection required. The legislation permits the Secretary to consider a refusal to allow necessary inspection, testing, or other relevant factors in determining whether imported food products meet U.S. food safety requirements or otherwise achieve the level of protection required. GAO's support of this legislation is welcomed.

UPDATES TO THE OPERATIONAL AND ADMINISTRATIVE SYSTEM FOR IMPORT SUPPORT (OASIS)

FDA currently is updating OASIS to incorporate automatic review of the Import Alert and Low Acid Canned Food (LACF) databases. The Agency also is incorporating access to the Laboratory Management System database into OASIS. Both will be completed by the end of FY1998. We agree with the General Accounting Office (GAO) that these enhancements will make the system more user friendly and reduce the amount of inspector time required to determine which entries to examine and/or sample.

THIRD PARTY SAMPLING

In general, we agree with GAO that FDA needs to exercise control over the practice of permitting importers of articles subject to Detention Without Physical Examination (DWPE), which are identified on the Import Alert List, to select a laboratory to analyze their products and to certify such products do not violate the Federal Food, Drug, and Cosmetic Act (FFDCA or the Act.) To that end, FDA is issuing new instructions to the Districts regarding the use of independent laboratories. While it has been FDA's policy to accept only analyses done by well-qualified laboratories, and even then to verify the results, this policy is stated more explicitly in the new guidance. Nevertheless, the report should make it clear that FDA does not have explicit authority

to require importers to use certain laboratories, nor to provide a list of accredited laboratories to importers who may inquire. We do provide, however, the laboratory performance guidance used by the Agency upon request. This guidance should help importers select laboratories based on the qualifications of the analysts and how well the laboratories are equipped to do the particular analyses.

TAKE CORRECTIVE ACTION WHEN FILERS HAVE UNACCEPTABLY HIGH ERROR RATES

FDA is in agreement with GAO that corrective action should be taken against filers (importers and brokers) who continue to submit erroneous entry data to FDA. Since implementation of the automated electronic entry processing system, FDA has been working with the filers to help them learn the system in order to submit correct data consistently. We believe this has been an appropriate approach in light of the recent implementation and complexity of the system. To reduce filer problems in determining the correct product code to use for an entry, filers have been furnished a copy of FDA software that enables them to determine the correct product codes. As GAO is aware, FDA conducted two surveys in 1997 to determine how well filers were complying with the new electronic filing requirements. The surveys showed that the error rates were still unacceptably high overall, with some filers consistently exceeding the acceptable error rate of 10%. Consequently, on March 6, 1998 the Director of the Office of Regional Operations directed all District Directors to work with FDA's Division of Import Operations to identify filers who fail to meet the requirements and to determine what action should be taken by the Agency to improve compliance. Such action could include removing the error-prone filers from the paperless entry system by requiring that they submit both paper documentation and electronic data until they demonstrate their ability to meet the requirements for electronic filing. This dual filing approach should provide a strong incentive for improvement, because submitting paper documentation delays entries by several days.

GAO RECOMMENDATION TO CONGRESS

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

FDA COMMENT

FDA has the authority, based on the implementing legislation for the World Trade Organization's Agreement on the Application of Sanitary/Phytosanitary Measures, to enter into equivalency agreements with other countries. We do not require such agreements, however, before trade can occur. The wording in the recommendation as written seems to require a finding of equivalence as a precondition of entry. If this is GAO's intent, we do not concur. Such a requirement could have the undesirable effect of forcing FDA to bar entry to imports from most of the world until such time as the Agency could make a determination of equivalency, a process which must be

done on a country-by-country basis, and potentially, a product-by product basis. In contrast, the Administration's proposed import legislation introduced in both House of Congress (S1707/HR3052) would give FDA the authority to deny entry to a food product that has been prepared, packed, or held under conditions, or subject to systems or measures that do not meet U.S. food safety requirements or otherwise achieve the U.S. level of protection. The legislation would not require that FDA have evaluated such systems, conditions, or measures and made an equivalency determination as a condition precedent to entry of imports.

GAO RECOMMENDATION

To provide more accurate and accessible information to FDA and thus minimize inconsistencies in inspectors' subjective decisions, we recommend that the Secretary of Health and Human Services direct the Commissioner, FDA, to

> make annual Workplans more realistic by setting aside time for unplanned activities, such as investigating emergencies and consumer complaints.

FDA COMMENT

We do not concur. For the reasons stated above, FDA continues to believe that the current Workplan approach most clearly reflects priorities while permitting flexibility to handle emergencies as they arise.

GAO RECOMMENDATION

> Modify the Operational and Administrative System for Import Support system so that (1) it automatically reviews the Import Alert and low acid canned food databases and recommends appropriate actions to inspectors and (2) inspectors can consider previous laboratory test results, which are stored in the Laboratory Management System database, in choosing shipments for inspections and tests.

FDA COMMENT

We concur. The automatic review of the Import Alert data already is in place, and the automatic review of the low acid canned food database is under development. FDA also is developing the necessary software to provide inspectors with the capability to review previous laboratory test results through OASIS. Both of these enhancements to the system will be completed and operational by the end of FY1998.

GAO RECOMMENDATION

> Ensure that district offices are taking appropriate corrective action, when warranted, against importers that repeatedly enter incorrect shipping information into [the] Operational and Administrative System for Import Support.

FDA COMMENT

We concur. As stated above, FDA District Directors were reminded recently of the Agency's policy that non-compliant filers should be identified and appropriate corrective action taken, including removal of filers from paperless filing status. We also continue to believe that it is incumbent on the Agency to work with the filers through education and training, which is a form of corrective action, to improve compliance.

TECHNICAL COMMENTS

1. Page 3, first partial paragraph, lines 4-5: Change to read, "The increased consumption of imported foods in the United States may increase the risk of illness." This is conjecture. FDA has no concrete evidence that imported foods are more or less safe than domestically produced foods. Recently, FDA's concerns have increased, however, based on the limited knowledge available about growing/processing conditions in some foreign countries.

2. Page 3, first partial paragraph, line 5: Change to read, "...or FDA for their review before releasing..." When FDA releases a product, it does not "approve" it.

3. Page 3, last paragraph, first line: Change to read, "Federal agencies cannot ensure that all entries of the increasing amount of imported..."

4. Page 3, last paragraph, line 5: Change to read, "...by allowing imports of meat only from..."

5. Page 3, last paragraph, line 8: Change to read, "...takes on the burden of ensuring the safety of all other imported foods as they arrive..."

6. Page 3, last partial sentence: This is incorrect. It ignores the memoranda of understanding and mutual recognition agreements that FDA has with many foreign governments, which are designed to provide enhanced consumer protection. While these agreements do not extend to all countries or products, their existence should be mentioned at this point in the report, as should the new HACCP regulations that require both domestic producers and seafood importers to take responsibility for the safety of their products.

7. Page 4, second line: Change to read, "...produced under adequately controlled conditions and..."

8. Page 4, first full paragraph, lines 8-12: First, the statement that the workplan doesn't set priorities is incorrect. The overall workplan is based on general priorities set by the Agency as reflected in Compliance Programs, and on the resources available to the Agency to carry out all its inspection, sampling, analyses, and investigative responsibilities. The Agency's priorities are risk-based, with the higher-risk products (such as LACF) given higher priority than low-risk products. The resources are assigned to implementing Compliance Programs on a priority basis, with the higher-priority programs being assigned greater proportionate shares of FDA's limited resources than lower-priority programs.

   Second, in a limited sense, it is true that emergencies and consumer complaints may prevent completion of the Workplan, although there is a separate, additional set-aside for recalls and other specified activities. In a broader context, however, the situations we would define as emergencies are those that fall under FDA's jurisdiction, and are of a

high-priority nature in that human health is at risk if the situation is not remedied promptly. Merely mislabeling a product, for example, would not create an emergency situation unless the mislabeling could lead to injury to human health.

9. Page 4, second paragraph, lines 12-13: The statement that, "FDA does not make health risk data readily available to guide inspectors selections." is incorrect. The Agency's automated import entry review system is based to a great extent on health risk criteria, which are encoded into OASIS. OASIS also contains admissibility information, such as products that are to be DWPE because of prior problems, special compliance programs that require some FDA action, the rate at which a product is to be sampled prior to release, and other information relevant to admissibility. OASIS is designed to determine whether a product may proceed into commerce without examination and to give guidance to inspectors for entry decisions that must be made by inspectors because the issues are not so clear-cut as to be amenable to computer-assisted selection.

FDA has determined that many food products do not pose a health risk and can be admitted into commerce without being subject to examination. At the other end of the spectrum, FDA places firms on DWPE based on as few as one previous violation that involved a potential health risk (i.e., microbial pathogen, pesticide residue, toxic metal, etc.). Inspectors are expected to make decisions affecting product admissibility for the remaining imports, about which there may or may not be any compliance history data that could enlighten the decision. The process does make "heath risk" information readily available to the inspectors for the majority of entries. If more information is needed, the inspectors refer to Import Alerts, compliance programs, LACF registrations, and other relevant databases. Finally, the inspectors are expected to contact the Center For Food Safety and Applied Nutrition staff or the Division of Import Operations and Policy staff if they have questions about the admissibility of a particular entry. As noted in the General Comments above, databases that are not currently directly accessible through OASIS are being integrated into the system to make it more convenient for inspectors to reference them.

10. Page 4, second paragraph, lines 13-15: Change to read, "... FDA, FSIS, and USCS rely on importers descriptions of shipment contents..."

11. Page 4, last paragraph: The report consistently misstates which agency has the responsibility for allowing importers to retain possession of products pending FDA examination, which agency is responsible for setting the amounts of bonds, and which agency determines the amount to be forfeited or penalties to be assessed for failing to redeliver products to Customs when a released product is found to be violative. Change the paragraph to read as follows, and make appropriate corrections throughout the report.

> "FDA 's procedures for ensuring that unsafe imported foods do not reach U.S. consumers are vulnerable to abuse by unscrupulous importers. For example, FDA

detains shipments without sampling or analysis when the exporting firm has a history of violations. The FFDCA provides for the offering of testimony by the owner or consignee once a sample has been delivered to FDA. Although not explicitly stated in the Act, the understood purpose of the testimony is to show why FDA should not find the food shipment subject to refusal of admission. The sampling and examination of a food shipment by the importer is a necessary extension of the right to introduce testimony, which in this case is the analytical results. Importers select the laboratories to perform sampling and analysis that they submit to FDA as proof of compliance. FDA does not have the explicit authority to recommend, certify or otherwise direct an importer to a particular laboratory. FDA is not bound, however, to accept the results from the private laboratories. Private laboratories submitting data in support of an entry must demonstrate to FDA's satisfaction that they have the necessary equipment and expertise to perform the analysis.

After execution of a bond with the U. S. Customs Service, importers retain control of the goods while FDA decides whether to inspect the shipment or while tests are being conducted on it. In some cases, when FDA takes and analyses samples of a shipment, the importers send the food to market before FDA has made a determination about its admissibility, usually because the food is a perishable commodity. When this occurs, and the food product is not in compliance with U.S. food safety requirements, the U.S. Customs Service may assess liquidated damages against the bond. In other cases, when FDA finds contamination..."

It also should be noted that FDA no longer uses the term "automatic detention." As a statutory matter, the U.S. Customs Service has the authority over whether importers must retain control of their goods while FDA determines admissibility. The U.S. Customs Service also sets the amount of any bond and decides whether liquidated damages are assessed for failure to retain control of the imported product, as well as any penalties. Section 801 (b) of the Federal Food, Drug, and Cosmetic Act states that, "Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond..."

12. Page 5, last paragraph, last sentence on page --should read, "Such an approach, when used as the sole means of assessing the safety of foods, has been widely discredited..."

13. Page 6, last paragraph, second sentence: Delete "are supposed to guide inspectors' judgement." The Workplan provides general numerical goals and resources to be expended. With the exception of seafood, it is not designed to tell the inspectors which specific products to inspect and/or sample. Such decisions are made by inspectors using the relevant Compliance Programs for guidance, not the Workplan.

14. Page 7, first partial paragraph, lines 4-11: These statements are incorrect. FDA verifies the accuracy of each filer's electronically submitted data until the filer is submitting reliable data routinely. During this initial phase of a filer submitting entry data electronically, the filer is required to submit paper copies of entry documentation as well as the electronic submission. When FDA is confident that the filer is capable of submitting accurate data electronically, the filer is allowed to discontinue submitting paper documentation. Also, during the initial phase, FDA works with filers to help them develop the capability of filing correctly. In addition, FDA regularly follows up by conducting supplemental training for specific filers whose data does not meet FDA's requirements for accuracy, and working with the management of filer firms to correct problems with entry data. This approach often is taken when the districts believe the filers' data errors are not deliberate.

To determine whether filers were deliberately recording the wrong product codes to circumvent FDA coverage, FDA reviewed 100% of imported canned mushrooms and water chestnuts for a three-month period between January 6 and April 4, 1997. Canned mushrooms from China currently are on the DWPE list, which could tempt importers to miscode them as water chestnuts to avoid the DWPE. A total of 1081 entries of canned mushrooms and canned water chestnuts were reviewed. Although there were a few coding errors, there was no pattern to suggest deliberate miscoding. There were no instances of miscoding Chinese mushrooms, nor were there any repeat miscodings by the same importer/broker, indicating that the few miscodings that occurred were not deliberate. When the miscodings were brought to the attention of the filer, they were corrected.

FDA has, in the past, brought criminal charges against firms and individuals who engaged in practices such as submitting erroneous data (i.e., Sigma case), and will do so in the future, if necessary. Where there is no suspicion of deliberate fraud, FDA's Filer Evaluation Procedure states that the corrective action to be taken is to remove the filer who continues to have error rates greater than 10% from the "paperless" entry system. The filer then would be required to submit both paper documentation and electronic entry data until he/she demonstrates an ability to submit accurate data consistently. On March 6, 1998 the Director, Office of Regional Operations, instructed all District Directors to review their import operations to determine which filers exhibit unacceptable error rates, promptly remove such filers from the "paperless" status, or provide additional training and assistance where appropriate.

15. Page 7, last paragraph, line 6: The statement that, "...the agency does not have guidelines to control the selections of samples tested..." is incorrect. Private laboratories are expected to conduct sampling in accordance with FDA written sampling guidance found in the Compliance Programs and Laboratory Procedures Manual (LPM).

It should be noted that the agency does not have the legislative authority to certify private laboratories. The LPM, Chapter 21, provides guidance on the review of analytical data

generated by private laboratories. The guidance is provided to assure the scientific credibility, accuracy, validity and reliability of analytical data submitted by private laboratories. Private laboratory analytical packages are reviewed by FDA for each sample tested by private testing laboratories to assure validity of the tests performed.

16. Page 8, top partial paragraph, full sentence: Change to read, "...importers have been known to substitute shipments that have...." Importers usually do not share shipments or samples between importers but substitute one of their own shipments/samples for another of their own shipments/samples. Also a sentence should be added to state that when FDA finds such activity, the Agency takes regulatory action and, if appropriate, pursues criminal charges.

17. Page 8, first full paragraph, lines 2-3: Change to read, "...until their release into U.S. domestic markets, the U.S. Customs usually allows importers to..." The report also should note that FDA often deals with perishable products such as fresh produce and seafood that deteriorate rapidly. Such products warrant consideration of how best to balance FDA's need for inspectional oversight against the possibility of loss of the shipment because of spoilage.

18. Page 15, last paragraph: This paragraph should state clearly whether the "staff years " and import numbers represent all FDA regulated products or only foods.

19. Page 16, first line: Change to read, "...safety of about 2.7 million food import shipments." It is confusing to include the total number of FDA-regulated import shipments per year when the report is about food imports only.

20. Page 16, first full paragraph, second-to-last sentence: The sentence as written is confusing. Please clarify.

21. Page 18, first bullet, line 3: Change to read, "...and testing activities for 10 food programs, such as...." There are only 10 Compliance Programs dealing with imported food.

22. Page 18, second bullet, lines 4-5: Change to read, "...shipments until the importer provides a showing that the product is not violative." Importers can supply evidence other than a private laboratory result to remove the appearance of a violation, although in the vast majority of cases this is done through private laboratory reports.

23. Page 18, Footnote 5, line 1: Change to read, "...mushrooms, and tuna fish which have a pH value greater that 4.6, water activity values of greater than 0.85 are thermally processed and are stored and distributed non-refrigerated."

24. Page 19, first paragraph, sentence 2: Change to read, "Foreign processors must register with FDA and submit descriptions of their canning processes. These processes must be found acceptable by the Agency before FDA will permit entry of these products."

25. Page 19, second paragraph, last sentence: Change to read, "Shipments, such as some seafood, are less frequently...because they may pose...." Low acid canned foods are never automatically released—there is 100% review of all entries because of the potential risks to consumers.

26. Page 20, second paragraph, line 11: Change to read, "Importers may recondition the shipment if FDA concurs, or they must destroy or re-export the shipment to any country of their choosing." Importers do not need FDA concurrence to destroy or re-export a shipment.

27. Page 21, first full paragraph, 3rd sentence: The sentence should state the total number of FSIS-regulated entries per year. As written, it allows for misleading comparisons between FSIS's and FDA's workloads.

28. Page 21, second full paragraph: Add a sentence stating, "FDA lacks authority to require that shipments be held in a specific warehouse."

29. Page 24, paragraph 2, sentence 2: Change to read, "...by importers, agencies' practices, and USCS's procedures for (1) controlling...." USCS, not FDA, is responsible controlling imports before FDA release, ensuring that refused entries are properly disposed of, and levying penalties.

30. Page 27, second paragraph, sentence 5: Delete. The statement is not true. FDA does not have extra territorial inspectional authority.

31. Page 28, last paragraph, first sentence: Change to read, "...seeking new FDA discretionary authority to require...."

32. Page 29, top partial paragraph: The legislation also has been introduced in the Senate.

33. Page 33, second paragraph: The report does not mention imported seafood HACCP regulations, voluntary equivalence agreements, or MOU's as additional mechanisms that FDA uses to assure the safety of imported products. These should be included. They each contribute significantly to FDA's ability to regulate the safety of imported food.

34. Page 35, second paragraph: Again the workplan, in general, is not designed to identify priorities. The priorities are listed in the import Compliance Programs, with additional guidance from the Centers. Delete "workplans that do not set clear priorities for inspectors in making selection decisions."

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35. Page 37, 1st paragraph: The inspectors do not "use the workplan to guide their decisions." The workplan is used to provide general numerical guidance, not to make decisions about which products will be inspected/sampled. Delete "FDA inspectors attempt to use these numbers to guide their decisions on which products to inspect and test."

36. Pages 40-42: The report acknowledges that some improvements already are underway. The draft fails to recognize in a balanced fashion, however, that much relevant health risk information already has been considered in developing the Workplans, e.g., Compliance Programs, the screening criteria and rates used in OASIS, and the Import Alert and Bulletin system. Furthermore, inspectors currently have access to risk information and databases to inform their decisions, although not necessarily in a user friendly format. We agree that making the relevant information more accessible would be beneficial, and are taking steps to do so through enhancements to the OASIS.

37. Page 41, top partial paragraph, last three sentences: The inspectors are trained, knowledgeable professionals who can be relied upon to know what entries to select for sampling. It would be highly unusual and disturbing if FDA inspectors could not remember the many, if not most, of the factors that apply to selecting entries for examination and sample collection. Just as professionals in other fields know their professions, so do FDA inspectors. We suggest that the paragraph be modified to reflect the demonstrated competence of FDA inspectors and that their selecting samples on the basis of their memory of the field is not inappropriate.

38. Page 42, last paragraph, first sentence: - Delete, "...no corrective actions have been taken...." Meetings with filer firms, additional training courses, and letters to firm management are among the corrective actions taken. In addition, FDA has conducted criminal investigations when fraudulent behavior by filers is suspected.

39. Page 46, first paragraph, sentence 3: While this sentence may be true, a more careful observation would note that FDA does not blindly accept the work of private laboratories submitted to demonstrate compliance of a product offered for import. FDA reviews the laboratory worksheets, the qualifications of the analysts, and whether the particular laboratory is equipped to do the required work accurately and with the degree of specificity required. FDA also audits the samples and, when necessary, visits the laboratories. The Agency's LPM, Chapter 21, provides guidance for use when an FDA District office determines that a private laboratory does not produce consistently valid data. The specific analyses submitted in support of a product are not accepted by the Agency for the release of products tested. The Agency will accept only results from private laboratories that demonstrate acceptable performance.

40. Page 47, last paragraph, sentence 2: Change to read, "... importers have the right under 801(a) of the Act to introduce testimony concerning the compliance of products they are

importing. Frequently, this takes the form of private laboratory analysis that shows a food free of the contaminant for which it was detained without physical examination. FDA evaluates the submitted analytical results to determine if they are sufficient to remove the appearance of the violation, and if so, may release the product."

41. Page 48, top partial paragraph, lines 2-3: As we have stated before, FDA does not "generally recognize the results from any private, independent laboratory ...." In fact. the Agency has written criteria, published in the LPM, which outline the Agency's position on acceptance of private laboratory results.

42. Page 50, first full paragraph, line 8: The 90 days referenced have nothing to do with reconditioning. The draft apparently is confusing detention with refusal and what is done under each circumstance. We will be pleased to clarify this point further with the evaluators.

43. Page 50, first full paragraph, item(2): Delete FDA. The agency does not control bond actions on importers.

44. Page 52, first paragraph, line 4: Delete "(of an FDA-selected laboratory tested)." FDA does not select private laboratories for any producers of FDA-regulated products, either foreign or domestic.

Right To Sue Health Pl s Debated At Senate Hearing

HEALTH

SUPPORTERS OF legislation to make it easier for patients to sue their health plans struck back Thursday at business community charges that such changes would be so expensive that employers would drop health insurance coverage.

"We have actual experience" showing that patients in plans who already have the ability to sue do not raise costs dramatically, Assistant Labor Secretary Olena Berg told a hearing of the Senate Labor-HHS Appropriations Subcommittee.

"We don't see a big difference in premiums" between plans covered under the federal Employee Retirement Income Security Act, where patients can generally sue only for the actual cost of a denied benefit, and those where patients denied care can collect for medical expenses and other damages arising from the denied service, Berg said.

Combining the ERISA changes with a requirement for an external appeals process, testified Ronald Pollack of Families USA, could even result in fewer lawsuits because more complaints would be resolved before going to court.

"Consumers are interested in front end protections, not just back end," said Pollack, meaning not having services denied in the first place rather than being able to sue after a denial results in injury or death.

But business community witnesses continued to complain that changing ERISA would result in companies dropping coverage or passing costs to employees to such an extent that they would drop coverage.

"You can indemnify all you want," testified Mark Smith, on behalf of the National Association of Manufacturers, "but the costs will come back to the employers."

The business representatives also argued that amending ERISA would do little more than enrich trial lawyers.

"What it would do is turn a rational system for allocating resources into basically a lottery in which a few people, including trial attorneys, would get a lot of money," testified Robert Gallagher for the Association of Private Pension and Welfare Plans.

Legislators, both at the hearing and elsewhere, remain divided over what many say could be the central issue in patient protection legislation that is moving towards action in both chambers.

"I feel deeply for people who are denied basic rights," said **Sen. Lauch Faircloth**, R-N.C., adding that he supports many of the patient protection provisions in various bills that have been introduced.

"But I cannot in any way in good conscience support any approach that would result in more litigation. We already have too much of that," he said.

Others, disagreed. "Every other industry in America can be held responsible for its actions," said **Labor and Human Resources ranking member Edward Kennedy**, D-Mass., who attended the hearing as a guest. "Health plan decisions can truly mean life or death, and they do not deserve immunity."

Meanwhile, **Senate Banking Chairman D'Amato** said he is still keeping his options open in terms of holding up the Senate in order to get a vote on his bill to ban "drive-through" mastectomies — despite his success Thursday in appending the measure to the tobacco bill during the Finance Committee's markup *(see related story, page 1)*.

At the same time, Kennedy said that in light of D'Amato's action, he may try to also append his broader "Patient Bill of Rights" bill to the tobacco measure as well.

— *BY JULIE ROVNER*

Panel Shows Little Appetite For Food Inspection Funds

AGRICULTURE

CONGRESS APPEARS unsure how to respond to a report indicating the government cannot guard adequately against imported food that could make people ill, the *Associated Press* reported.

At a hearing of the Senate Governmental Affairs Permanent Investigations Subcommittee Thursday, legislators showed little appetite for spending millions of dollars to increase port-of-entry inspections of fruit, vegetables, seafood and processed items by the FDA.

The hearing focused on a report this week by the GAO showing that the FDA physically inspected only 1.7 percent of 2.7 million food shipments in 1997. It also noted other flaws in the system — even as imports skyrocket.

"We don't need to have more money pumped into a system where things are being done in a slipshod way," said **Sen. Thad Cochran**, R-Miss. "We need to make some important reforms."

There is no agreement on exactly what reforms are necessary.

President Clinton and many Democrats say the top priority is GAO's main recommendation — that the FDA be given authority to require foreign countries to have safety standards equal to U.S. standards. The Agriculture Department already has similar powers for imported meat and poultry.

Republicans, however, have not embraced legislation to enact the change for the FDA. The U.S. food industry is generally opposed, contending the move would simply mean more costly regulations.

"Sending inspectors into facilities in other countries would be expensive while accomplishing nothing more than is already achieved at our borders," said Claire Regan of the Grocery Manufacturers of America.

Permanent Investigations Subcommittee Chairman Susan Collins, R-Maine, said the immediate aim should be to ensure "our current programs are being effectively managed, and that existing resources are focused on those imports posing the greatest risk."

However, Collins appeared willing to consider giving FDA inspection power in other countries.

Hill Briefs

House OKs Religious Persecution Measure

■ COUNTRIES THAT THE United States says are guilty of a pattern of religious persecution would face automatic sanctions under a bill that cleared the House Thursday.

Supporters said the bill, which passed 375-41, would force the United States to pay greater attention to religious persecution around the globe. Opponents said it would create a "damaging hierarchy of persecution" that puts faith-based oppression above other forms of victimization, the *Associated Press* reported. A similar measure is pending in the Senate.

The White House, while expressing support of religious tolerance, says the legislation would hinder the president's ability to conduct foreign policy and is threatening a veto.

The automatic sanctions the bill would authorize against guilty countries include denial of nonhumanitarian aid, a ban on certain exports, denial of visas to known persecutors and the rejection of loans by international financial institutions, such as the International Monetary Fund.

The president could waive sanctions for national security reasons or by certifying that lifting them would help end religious persecution.

But the White House contends sanctions would be counterproductive and could cause added harm to minority religious groups viewed as causing a rift in relations with the United States.

The bill, meanwhile, is a top priority of conservative groups such as the Christian Coalition.

House Subpanel Passes OSHA Reform Bills

■ THE HOUSE EDUCATION and the Workforce Workforce Protections Subcommittee Thursday approved three bills to reform OSHA, *LEGISLATE News Service* reported.

A bill to exempt voluntary employer self-audits from disclosure requirements passed on a voice vote.

The bill's sponsor, **Workforce Protections Subcommittee Chairman Cass Ballenger**, R-N.C., said current disclosure requirements have caused employers' audit findings to be used as a "threat" against them in OSHA enforcement proceedings.

"That is a serious disincentive," he said, arguing that current policy "reduces both the quality and quantity of audits."

But **subcommittee ranking member Major Owens**, D-N.Y., argued the legislation "protects employers who wish to hide the fact that they were aware of health and safety hazards but failed to correct them."

The panel also passed, by a party line vote of 6-4, a measure requiring OSHA to provide an industry-specific analysis of risks, benefits and costs of new regulations. Finally, the panel cleared a bill requiring OSHA to appoint an independent panel of experts to examine the data on which proposed OSHA standards are based.

Senate Approves WIPO Internet Copyright Bill

■ THE SENATE THURSDAY approved comprehensive copyright legislation covering information, music and other creative works on the Internet by a vote of 99-0.

The bill would implement two copyright treaties — one for written material and one for sound recordings — adopted in 1996 by the United Nations' World Intellectual Property Organization.

Senate Judiciary Committee Hatch said the bill is vital for the growth of Internet commerce and the U.S. lead in online commerce.

DeLay Launches Anti-Campaign Reform Move

■ **HOUSE MAJORITY WHIP DeLay** and a half dozen other Republicans Thursday launched their effort to defeat campaign finance reform, while proponents of reform vowed to push their bills forward.

Billed as the "Free Speech Coalition," DeLay said it was important to protect the First Amendment and said portions of reform bills such as those sponsored by **Reps. Christopher Shays**, R-Conn., and **Martin Meehan**, D-Mass., were unconstitutional.

"Money is not the root of all evil in politics," DeLay said. "In fact, money is the lifeblood of politics."

DeLay included protection of the First Amendment one of five principles he considered true reform, and also called for full disclosure of campaign spending, an end to strict spending limits, no public funding of campaigns and enforcement of current laws.

When floor debate over campaign reform proposals begins next week, the coalition is expected to offer a series of partisan amendments in an attempt to divide support. A floor vote is not expected until after the Memorial Day recess.

Meehan later spoke in defense of the Shays-Meehan bill, and said the pending discharge petition — which drew as many as 204 signatures, but now stands at 191 — on their reform bill drive shows that campaign finance reform has "enough support to prove a threat."

Shays defended as constitutional provisions of his bill would impose financing and disclosure rules on independent expenditure ads similar to those of campaign committee ads.

"They'll have the same voice," Shays said. "They'll just have to play by the same rules."

Imports
— EU
— 400 [illegible]

202 556-7735

ABZ

GAO — FDA [illegible] have resources

key to make sure they are grown in sanitary

FDA power

[illegible] import ban

Cut [illegible] F. [illegible]

CB3 — cannot ensure — simply [illegible] . Less inspected
— need legislation [illegible]

worst ABZ — GAO

Thurs.
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8-2[illegible]
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8 Sept.
13 [illegible]

11:30 a.m.
5/11/98

Statement from Dr. Michael Friedman, Lead Deputy Commissioner of the FDA, on GAO Food Safety Report

The General Accounting Office's study is a wake up call to Congress to pass legislation to help ensure the safety of imported foods. While FDA believes that imported foods are generally safe, recent outbreaks of food-borne illnesses demonstrate that imported foods can introduce new risks and the increased consumption of imported foods heightens those risks. The President has called for increased resources, better coordination, more scientific research and greater authority for the FDA.

GAO recommends legislation that gives FDA new authority that requires food-exporting countries to have in place essentially the same food safety system as the United States. The Department of Agriculture already has such legal authority over imported meats and poultry. In October 1997, President Clinton proposed legislation to give FDA similar authority and the Administration has expressed its support for the "Safety of Imported Food Act" currently languishing in Congress.

While most of GAO's recommendations mirror solutions FDA already is implementing, the Agency rejects GAO's criticism that the agency fails to use its resources appropriately. The agency has faced a steadily rising workload with the number of food imports more than doubling in the last five years and FDA has warned that it was in danger of being overwhelmed by the volume of products reaching U.S. ports. The Agency is doing what it can with available resources and continues to recommend that additional resources are needed to ensure that the food Americans set on their table – both domestic and imported – is safe, wholesome and nutritious.

FDA Backgrounder on GAO Food Safety Report

The food supply in the United States is among the safest in the world. In recent years, however, there have been a number of serious outbreaks of food-borne illnesses, some of which have been associated with imported foods. Last year, President Clinton launched two separate food safety initiatives designed to lower the risk of food-borne disease from both domestic and imported foods. In his budget submission to Congress for FY '99, the President asked for an additional $100 million for the national food safety program, including $25 million for to enable FDA to expand its international food inspections.

Now, the General Accounting Office has released its evaluation of the safety of imported foods. In its report, "Food Safety: Federal Efforts to Ensure Safety of Imported Foods Are Inconsistent and Unreliable," GAO concludes that some of FDA's import control activities are inadequate. The agency agrees that more needs to be done to safeguard the quality of imported foods and already has undertaken many of the steps outlined in the GAO report. To make adequate progress, however, FDA will require additional legal authority and resources. The GAO itself has recommended legislation to give FDA additional authority.

The major concerns raised by GAO, and FDA's responses, include:

Equivalency Authority. GAO proposes that FDA be given authority to require that food-exporting countries have in place a food safety system that is essentially equivalent to those in the United States. GAO notes that the Department of Agriculture's Food Safety and Inspection Service (FSIS) already has that authority and blocks the importation of meat and poultry from any country whose food safety system does not measure up to the U.S. standard. Under current law, FDA cannot prevent food from being shipped to this country. The agency must attempt to identify all unsafe food at the port of entry, an extremely difficult task given the enormous volume of imports. Thus, FDA and the Administration agree with GAO that it is imperative that Congress enact legislation giving FDA authority to require that, as a condition to exporting to the United States, foreign governments adopt adequate measures in their own countries to ensure that food exported to the U.S. is safe.

Civil Money Penalties. When food importers or brokers bring in shipments, they are required to post a $1,250 bond. If the brokers do not hold the product on the docks while FDA conducts its tests, they may forfeit their bonds. GAO observed that many brokers and importers distribute their products even when ordered to wait and

simply include the bond as the cost of doing business. Once the product enters U.S. distribution, U.S. Customs Service has a difficult time getting it back. There are cases where contaminated foods have been distributed. FDA lacks the legal authority to then penalize brokers who violate the law. GAO recommends -- and FDA agrees -- that it should have legal authority to seek sufficiently large civil money penalties (fines) to make it too costly for brokers to flout U.S. law. Legislation will be required to give FDA this authority.

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workplan sets targets and anticipates that unforseen activities or emergencies will supersede planned/routine tasks. Typically, about 80 percent of the tasks on the annual work plan are completed. FDA disagrees, however, with GAO's conclusion that the work plans have failed. Inspectors do not complete all the items on their annual list because they get reassigned as new problems and emergencies arise. It does not mean they are not working 100 percent of the time. FDA is re-evaluating how it constructs the annual work plans to avoid the appearance of inefficiency.

Overall, there is much in the GAO report with which FDA agrees. The agency shares GAO's concerns about the magnitude of the task it faces in regulating the rapidly rising volume of imported foods. FDA agrees with GAO that it needs additional legislative authority to safeguard the nation's food supply. The American public deserves – and expects – nothing less.

Imported Foods

PRESIDENT CLINTON ANNOUNCES INTRODUCTION OF SENATE FOOD SAFETY LEGISLATION AND REPORT TO ENSURE THE SAFETY OF IMPORTED AND DOMESTIC FRUITS AND VEGETABLES

March 4, 1998

Today President Clinton will announce the introduction of legislation by Senators Milkulski and Kennedy to ensure the safety of all imported foods, including fruits and vegetables. This legislation will enhance the Food and Drug Administration's authority to prevent the import of fruits, vegetables, and other food products that do not meet U.S. food safety requirements. The President also will announce the release of a report that provides a blueprint on how the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA) will work cooperatively with the agricultural community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

Enhanced FDA Oversight for Imported Foods. The President will call on Congress to pass the food safety legislation to be introduced today in the Senate to give the FDA greater authority over imported foods. This legislation will ensure that the FDA halts imports of fruits, vegetables, and other food products from any foreign country with food safety systems that do not provide the same level of protection required for U.S. products. The legislation also permits the FDA to consider refusal of inspection as a factor in halting imports from a country or facility. This legislation gives FDA authority that is comparable to USDA's existing authority to prevent the importation of unsafe meat and poultry. The President already has committed to providing approximately $25 million in his Fiscal Year 1999 budget to enable the FDA to dramatically expand its international food inspection force in order to implement this legislation. Reps. Eshoo and Pallone previously have introduced this legislation in the House of Representatives.

Development of Guidance on Good Agricultural and Manufacturing Practices. The President will announce the release of a report on how the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in cooperation with the agricultural community, will develop guidance on good agricultural and manufacturing practices. This report outlines the progress already made -- and the measures that must still be taken -- to develop guidance for the growing, processing, shipping, and marketing of fruits and vegetables by October 1998. The guidance -- the first-ever specific safety standards for fruits and vegetables -- will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. The report also provides both short- and long-term plans for technical assistance, education, and outreach activities to support the appropriate application of the guidance.

Clinton Administration Accomplishments In Improving Food Safety

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

*February, 1998. Administration announces its proposed food safety budget, which requests an approximate $101 million increase for food safety initiatives.

*May, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply --"Food Safety from Farm to Table" -- detailing a $43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

*January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop foodborne disease outbreaks quickly and to improve prevention systems further.

*August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

*August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

*July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

*December, 1995. Administration issues new rules to ensure seafood safety, utilizing HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

*1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.

*1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

Imported Food - GW

THE WHITE HOUSE

WASHINGTON

May 11, 1998

Dear Mr. Speaker:

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

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

I have taken several further steps to begin implementing standards to ensure the safety of imported food. My FY '99 budget committed approximately $25 million to enabling the FDA to dramatically expand its international food inspection force in order to implement the pending legislation. In March of this year, I released a report on how the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture, and in cooperation with the agricultural community, will develop guidance on good agricultural and manufacturing practices that will apply to both domestic and foreign producers.

There is no more important task our government faces than ensuring the safety of the American food supply. That is why last year Vice President Gore and I announced my comprehensive new initiative, "Food Safety from Farm to Table" -- which detailed a comprehensive program including surveillance, outbreak response,

education and research. The Safety of Imported Food Act is another vital step in protecting the safety of all the food Americans eat, and I urge you to pass it promptly.

Sincerely,

Bill Clinton

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

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Sincerely,

Bill

The Honorable Thomas A. Daschle
Democratic Leader
United States Senate
Washington, D.C. 20510

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Bill Clinton

The Honorable Trent Lott
Majority Leader
United States Senate
Washington, D.C. 20510

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Ron

The Honorable Richard A. Gephardt
Democratic Leader
House of Representatives
Washington, D.C. 20515

Imported food - GW 11:30 a.m. 5/11/98

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1ST DOCUMENT of Level 1 printed in FULL format.

Bill Tracking Report

105th Congress
1st Session

U. S. House of Representatives

HR 3052

1997 Bill Tracking H.R. 3052; 105 Bill Tracking H.R. 3052

SAFETY OF IMPORTED FOOD ACT OF 1997

<=1> Retrieve full text version

DATE-INTRO: November 13, 1997

LAST-ACTION-DATE: November 13, 1997

STATUS: Referred to committee

SPONSOR: Representative Anna G. Eshoo D-CA

TOTAL-COSPONSORS: 16 Cosponsors: 16 Democrats / 0 Republicans

SYNOPSIS: A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for improved safety of imported foods.

ACTIONS: Committee Referrals:
11/13/97 House Committee on Commerce

Legislative Chronology:

1st Session Activity:

11/13/97 143 Cong Rec H 10954 Referred to the House Commerce Committee

BILL-DIGEST: (from the CONGRESSIONAL RESEARCH SERVICE)

Digest :

of Imported Food Act of 1997 Safety of Imported Food Act of 1997 - Amends the Federal Food, Drug, and Cosmetic Act (FDCA) to deem imported food adulterated if it has not been prepared, packed, and held under conditions meeting FDCA requirements (or conditions otherwise achieving the protection required) for domestic food. Allows consideration of whether inspection, testing, or other procedures have been refused. Allows importation denial on the basis of such refusal and other relevant factors.

CRS Index Terms:

Food
Agriculture
Agriculture in foreign trade
Business
Food adulteration and inspection
Food industry
Food safety--Planning
Import restrictions
Imports
Packaging
Trade

CO-SPONSORS: Original Cosponsors:

Pallone D-NJ

Added 02/26/98:

Clement D-TN	Frost D-TX	Furse D-OR
Kennedy II D-MA	Lampson D-TX	Maloney D-NY
Manton D-NY	Millender-McDona D-CA	Rivers D-MI
Wynn D-MD		

Added 04/21/98:

Martinez D-CA	McGovern D-MA	Rush D-IL
Stark D-CA		

Added 04/30/98:

Pascrell D-NJ

2ND DOCUMENT of Level 1 printed in FULL format.

Bill Tracking Report

105th Congress
2nd Session

U. S. Senate

S 1707

1998 Bill Tracking S. 1707; 105 Bill Tracking S. 1707

SAFETY OF IMPORTED FOOD ACT OF 1998

SAFETY OF IMPORTED FOOD ACT OF 1998

DATE-INTRO: March 4, 1998

LAST-ACTION-DATE: March 4, 1998

STATUS: Pending

SPONSOR: Senator Barbara Mikulski D-MD

TOTAL-COSPONSORS: 4 Cosponsors: 4 Democrats / 0 Republicans

SYNOPSIS: A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for improved safety of imported foods.

ACTIONS: Committee Referrals:
03/04/98 Senate Labor and Human Resources Committee

Legislative Chronology:

1st Session Activity:

2nd Session Activity:

03/04/98 144 Cong Rec S 1336 Referred to the Senate Labor and Human Resources Committee
03/04/98 144 Cong Rec S 1343 Remarks by Sen. Mikulski MD

BILL-DIGEST: (from the CONGRESSIONAL RESEARCH SERVICE)
Congressional Research Service Bill Digest for S1707 not yet available

CO-SPONSORS: Original Cosponsors:

Bumpers D-AR Byrd D-WV Durbin D-IL
Kennedy D-MA

DATE: MAY 11, 1998

CLIENT:
LIBRARY: LEGIS
FILE: BILLS

YOUR SEARCH REQUEST IS:
"IMPORTED FOOD"

NUMBER OF REFERENCES FOUND WITH YOUR REQUEST THROUGH:
LEVEL 1... 11

1ST REFERENCE of Level 1 printed in FULL format.

Bill Tracking Report

105th Congress
1st Session

U. S. House of Representatives

HR 3052

1997 Bill Tracking H.R. 3052; 105 Bill Tracking H.R. 3052

SAFETY OF IMPORTED FOOD ACT OF 1997

<=1> Retrieve full text version

DATE-INTRO: November 13, 1997

LAST-ACTION-DATE: November 13, 1997

STATUS: Referred to committee

SPONSOR: Representative Anna G. Eshoo D-CA

TOTAL-COSPONSORS: 16 Cosponsors: 16 Democrats / 0 Republicans

SYNOPSIS: A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for improved safety of imported foods.

ACTIONS: Committee Referrals:
11/13/97 House Committee on Commerce

Legislative Chronology:

1st Session Activity:

11/13/97 143 Cong Rec H 10954 Referred to the House Commerce Committee

BILL-DIGEST: (from the CONGRESSIONAL RESEARCH SERVICE)

Digest :

of Imported Food Act of 1997 Safety of Imported Food Act of 1997 - Amends the Federal Food, Drug, and Cosmetic Act (FDCA) to deem imported food adulterated if it has not been prepared, packed, and held under conditions meeting FDCA requirements (or conditions otherwise achieving the protection required) for domestic food. Allows consideration of whether inspection, testing, or other procedures have been refused. Allows importation denial on the basis of such refusal and other relevant factors.

CRS Index Terms:

Food
Agriculture
Agriculture in foreign trade
Business
Food adulteration and inspection
Food industry
Food safety--Planning
Import restrictions
Imports
Packaging
Trade

CO-SPONSORS: Original Cosponsors:

Pallone D-NJ

Added 02/26/98:

Clement D-TN	Frost D-TX	Furse D-OR
Kennedy II D-MA	Lampson D-TX	Maloney D-NY
Manton D-NY	Millender-McDona D-CA	Rivers D-MI
Wynn D-MD		

Added 04/21/98:

Martinez D-CA	McGovern D-MA	Rush D-IL
Stark D-CA		

Added 04/30/98:

Pascrell D-NJ

2ND REFERENCE of Level 1 printed in FULL format.

Bill Tracking Report

105th Congress
2nd Session

U. S. Senate

S 1707

1998 Bill Tracking S. 1707; 105 Bill Tracking S. 1707

SAFETY OF IMPORTED FOOD ACT OF 1998

SAFETY OF IMPORTED FOOD ACT OF 1998

DATE-INTRO: March 4, 1998

LAST-ACTION-DATE: March 4, 1998

STATUS: Pending

SPONSOR: Senator Barbara Mikulski D-MD

TOTAL-COSPONSORS: 4 Cosponsors: 4 Democrats / 0 Republicans

SYNOPSIS: A bill to amend the Federal Food, Drug, and Cosmetic Act to provide for improved safety of imported foods.

ACTIONS: Committee Referrals:
03/04/98 Senate Labor and Human Resources Committee

Legislative Chronology:

1st Session Activity:

2nd Session Activity:

03/04/98	144 Cong Rec S 1336	Referred to the Senate Labor and Human Resources Committee
03/04/98	144 Cong Rec S 1343	Remarks by Sen. Mikulski MD

BILL-DIGEST: (from the CONGRESSIONAL RESEARCH SERVICE)
Congressional Research Service Bill Digest for S1707 not yet available

CO-SPONSORS: Original Cosponsors:

Bumpers D-AR Byrd D-WV Durbin D-IL
Kennedy D-MA

7TH REFERENCE of Level 1 printed in FULL format.

FULL TEXT OF BILLS

105TH CONGRESS; 1ST SESSION
IN THE HOUSE OF REPRESENTATIVES
AS INTRODUCED IN THE HOUSE

H. R. 3052

1997 H.R. 3052; 105 H.R. 3052

<=1> Retrieve Bill Tracking Report

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

DATE OF INTRODUCTION: NOVEMBER 13, 1997

DATE OF VERSION: NOVEMBER 20, 1997 -- VERSION: 1

SPONSOR(S):
Ms. ESHOO (for herself and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Commerce

TEXT:
* Be it enacted by the Senate and House of Representatives of the United*
*States of America in Congress assembled, *
SECTION 1. SHORT TITLE.
This Act may be cited as the "Safety of Imported Food Act of 1997".
SEC. 2. CRITERIA FOR DEEMING IMPORTED FOOD ADULTERATED.
(a) AMENDMENT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.-SECTION 402 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (21 U.S.C. 342) IS AMENDED BY ADDING AT THE END THE FOLLOWING:
"(H) IF IT IS A FOOD OFFERED FOR IMPORT INTO THE UNITED STATES THAT HAS NOT BEEN PREPARED, PACKED, AND HELD UNDER A SYSTEM OR CONDITIONS, OR SUBJECT TO MEASURES, THAT MEET THE REQUIREMENTS OF THIS ACT OR THAT OTHERWISE ACHIEVE THE LEVEL OF PROTECTION REQUIRED, AS DETERMINED BY THE SECRETARY, FOR SUCH FOOD PREPARED, PACKED, OR HELD IN THE UNITED STATES. IN DETERMINING WHETHER A SYSTEM, CONDITIONS, OR MEASURES MEET THE REQUIREMENTS OF THIS ACT OR OTHERWISE ACHIEVE THE LEVEL OF PROTECTION REQUIRED, THE SECRETARY MAY CONSIDER WHETHER AN OFFICER OR EMPLOYEE DULY DESIGNATED BY THE SECRETARY HAS REQUESTED, AND HAS BEEN REFUSED, ACCESS TO THE ESTABLISHMENT OR LOCATION WHERE SUCH FOOD WAS PREPARED, PACKED, OR HELD FOR THE PURPOSE OF INSPECTION (INCLUDING SAMPLE COLLECTION), TESTING, OR OTHER RELEVANT PROCEDURES, AT A REASONABLE TIME AND IN A REASONABLE MANNER, AND MAY DENY THE IMPORTATION OF SUCH FOOD FROM SUCH ESTABLISHMENT OR LOCATION ON THE BASIS OF SUCH REFUSAL AND OTHER RELEVANT FACTORS.".
(B) IMPLEMENTATION OF AUTHORITY; PLAN.-THE SECRETARY OF HEALTH AND HUMAN SERVICES SHALL DEVELOP A PLAN FOR THE INITIAL IMPLEMENTATION OF THE AUTHORITY UNDER SECTION 402(H) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS ADDED BY SUBSECTION (A), AND SHALL CARRY OUT THE AUTHORITY OF SUCH SECTION CONSISTENT WITH SUCH PLAN.

LOAD-DATE: December 10, 1997

10TH REFERENCE of Level 1 printed in FULL format.

FULL TEXT OF BILLS

105TH CONGRESS; 2ND SESSION
IN THE SENATE OF THE UNITED STATES
AS INTRODUCED IN THE SENATE

S. 1707

1998 S. 1707; 105 S. 1707

<=1> Retrieve Bill Tracking Report

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

DATE OF INTRODUCTION: MARCH 4, 1998

DATE OF VERSION: MARCH 5, 1998 -- VERSION: 1

SPONSOR(S):
Ms. MIKULSKI (for herself, Mr. KENNEDY, Mr. DURBIN, Mr. BUMPERS, and Mr. BYRD) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

TEXT:
* Be it enacted by the Senate and House of Representatives of the United*
States of America in Congress assembled,
SECTION 1. SHORT TITLE.
This Act may be cited as the "Safety of Imported Food Act of 1998".
SEC. 2. CRITERIA FOR DEEMING IMPORTED FOOD ADULTERATED.
(a) AMENDMENT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.-SECTION 402 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (21 U.S.C. 342) IS AMENDED BY ADDING AT THE END THE FOLLOWING:
"(H) IF IT IS A FOOD OFFERED FOR IMPORT INTO THE UNITED STATES THAT HAS NOT BEEN PREPARED, PACKED, AND HELD UNDER A SYSTEM OR CONDITIONS, OR SUBJECT TO MEASURES, THAT MEET THE REQUIREMENTS OF THIS ACT OR THAT OTHERWISE ACHIEVE THE LEVEL OF PROTECTION REQUIRED, AS DETERMINED BY THE SECRETARY, FOR SUCH FOOD PREPARED, PACKED, OR HELD IN THE UNITED STATES. IN DETERMINING WHETHER A SYSTEM, CONDITIONS, OR MEASURES MEET THE REQUIREMENTS OF THIS ACT OR OTHERWISE ACHIEVE THE LEVEL OF PROTECTION REQUIRED, THE SECRETARY MAY CONSIDER WHETHER AN OFFICER OR EMPLOYEE DULY DESIGNATED BY THE SECRETARY HAS REQUESTED, AND HAS BEEN REFUSED, ACCESS TO THE ESTABLISHMENT OR LOCATION WHERE SUCH FOOD WAS PREPARED, PACKED, OR HELD FOR THE PURPOSE OF INSPECTION (INCLUDING SAMPLE COLLECTION), TESTING, OR OTHER RELEVANT PROCEDURES, AT A REASONABLE TIME AND IN A REASONABLE MANNER, AND MAY DENY THE IMPORTATION OF SUCH FOOD FROM SUCH ESTABLISHMENT OR LOCATION ON THE BASIS OF SUCH REFUSAL AND OTHER RELEVANT FACTORS.".
(B) IMPLEMENTATION OF AUTHORITY; PLAN.-THE SECRETARY OF HEALTH AND HUMAN SERVICES SHALL DEVELOP A PLAN FOR THE INITIAL IMPLEMENTATION OF THE AUTHORITY UNDER SECTION 402(H) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS ADDED BY SUBSECTION (A), AND SHALL CARRY OUT THE AUTHORITY OF SUCH SECTION CONSISTENT WITH SUCH PLAN.

LOAD-DATE: March 10, 1998

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

Unpacked food

FAX TRANSMITTAL FORM

DATE: 3-3-98

PAGE(S) (INCLUDING THIS FORM

IS/ARE FOR: Mary Smith

FROM: Laura Chapin 224-0574

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

****

(ADDITIONAL INFORMATION):

THE FOLLOWING 19 pp + cover

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

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

BARBARA A. MIKULSKI
MARYLAND

COMMITTEES:
APPROPRIATIONS
LABOR AND HUMAN RESOURCES

United States Senate

WASHINGTON, DC 20510-2003

SUITE 709
HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510-2003
(202) 224-4654
TTY: (202) 224-5223

February 10, 1998

Dear Colleague:

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

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

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

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

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

Sincerely,

Barbara A. Mikulski
United States Senator

WORLD TRADE CENTER, SUITE 2
401 E. PRATT STREET
BALTIMORE, MD 21202-3079
(410) 962-4510

40 WEST STREET, SUITE 202
ANNAPOLIS, MD 21401-2448
(410) 263-1805

9658 BALTIMORE AVENUE, SUITE 208
COLLEGE PARK, MD 20740-1346
(301) 345-5517

94 WEST WASHINGTON STREET
HAGERSTOWN, MD 21740
(301) 797-2826

SUITE 1E, BUILDING B
1201 PEMBERTON DRIVE
SALISBURY, MD 21801-2403
(410) 546-7711

O:\ALD\ALD98.045

S.L.C.

105TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

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

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

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

SEC. 2. CRITERIA FOR DEEMING IMPORTED FOOD ADULTERATED.

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

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

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

KEY STATISTICS ON FOODBORNE ILLNESS IN THE UNITED STATES

- **DISEASE/DEATH STATISTICS:** Up to **9,000** food-related deaths and up to **33 million** illnesses are estimated to occur each year (these numbers may actually be much higher--50-100 times higher)

- **ECONOMIC IMPACT OF FOODBORNE ILLNESS:** Hospitalization costs are estimated at over **$3 billion** per year--with costs for lost productivity estimated at **several billion dollars**

- **FOOD POISONING MAY CAUSE MORE THAN VOMITING AND DIARRHEA, INCLUDING:**
  - -spontaneous abortion
  - -birth defects, including mental retardation
  - -chronic reactive arthritis
  - -Guillian-Barre' syndrome (including life-threatening paralysis)
  - -HUS (a highly fatal disease in children causing kidney failure)

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

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

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

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

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

FDA inspects the average plant about **once every 10 years.**

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

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

THE WHITE HOUSE

WASHINGTON

October 2, 1997

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

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

American consumers today enjoy the safest food supply in the world, and I am proud of my Administration's record in this area. We have taken significant steps to ensure that we maintain the safest food possible. We have put in place improved safety standards for meat, poultry, and seafood products, and we have begun the process of developing enhanced safety standards for fruit and vegetable juices. We have also expanded research, education, and surveillance activities through coordinated efforts of all agencies involved in food safety issues. Together, these measures will greatly improve the safety of the Nation's food supply.

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

To help accomplish this task, I plan to send to the Congress proposed legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the United States. This legislation, which will be similar to existing law requiring the USDA to halt the importation of meat and poultry from such countries, will enable the FDA to prevent the importation of potentially unsafe foreign produce. My Fiscal Year 1999 budget will provide the necessary funds to enable the FDA to expand dramatically its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

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

First, I direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue within 1 year from the date of this memorandum, guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should address ways to prevent potential sources of contamination, should take into account differences in both crops and regions, and should address food safety issues throughout the food production and distribution system. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities.

Second, I direct the Secretary of Health and Human Services and the Secretary of Agriculture, to report back to me within 90 days from the date of this memorandum with a status report and complete schedule for the good agricultural and manufacturing practices, and a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve those practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. I especially urge you to consider the best ways to target inspection and testing toward those areas where problems are most likely to occur.

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

William J. Clinton

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

FOR IMMEDIATE RELEASE
November 14, 1997

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

Eshoo and Pallone Move To Boost Imported Food Safety

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

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

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

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

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

(more)

Under the legislation, if an FDA inspector has requested and been denied access to the establishment or location where a food product is prepared, packed, or stored for the purpose of inspection (including sample collection), testing, or other relevant procedures, at a reasonable time and in a reasonable manner, the agency can stop the importation of that food into the United States. Further, the legislation authorizes the FDA to develop a plan for implementing this overseas food inspection program.

On October 2nd, President Clinton announced a new initiative to ensure the safety of imported and domestic fruits and vegetables. At that time, he said he would ask Congress to enact legislation that will require the FDA to halt imports of foreign fruits, vegetables, and other food products that do not meet U.S. food safety requirements. This legislation is comparable to existing law that requires the U.S. Department of Agriculture to halt the importation of potentially unsafe meat and poultry.

The President also directed the Department of Health and Human Services and the Department of Agriculture to work cooperatively with the agriculture community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables within one year. This guidance will take into account differences in both crops and regions and will address potential food safety problems throughout the food production and distribution system, such as sanitation, worker health, and water quality. The guidance—the first safety standards ever developed specifically for fruits and vegetables—will improve farming and manufacturing practices for anyone who wants to sell produce in the U.S.

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

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19TH STORY of Level 1 printed in FULL format.

The Washington Post

July 08, 1997, Tuesday, Final Edition

SECTION: HEALTH; Pg. Z10

LENGTH: 2989 words

HEADLINE: Forbidding Fruit; How Safe is Our Produce?

BYLINE: Sandra G. Boodman

BODY:

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

Not anymore.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Traveler's Diarrhea -- at Home

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

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

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

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

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

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

Parasite Packs a Big Punch

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

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

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

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

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

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

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

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

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

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

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

Searching for the Elusive Source

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Simple Steps to Reduce the Risk of Contamination From Produce

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

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

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

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

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

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

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

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

soap and hot water.

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

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

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

GRAPHIC: Photo, max hirshfeld; Photo, max hirshfeld

LANGUAGE: ENGLISH

LOAD-DATE: July 08, 1997

SAFETY OF IMPORTED FOOD ACT OF 1998
"FREE TRADE FOR SAFE FOOD"
--SEN. MIKULSKI

Importation of food PRODUCED in unsanitary conditions

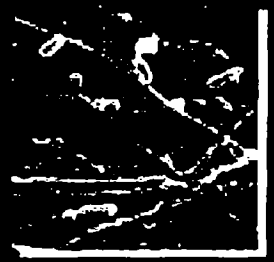
Importation of food from countries that deny FDA INSPECTION

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

Every Year

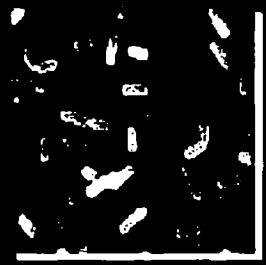
- 38% of fruits consumed in the U.S. are imported
- 12% of the vegetables consumed are imported
- As many as 33 million illnesses are caused by contaminated meat, poultry, & produce
- Over $3 billion is spent in hospitalization due to food borne illness

Least Wanted Foodborne Pathogens



E. Coli O157:H7

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

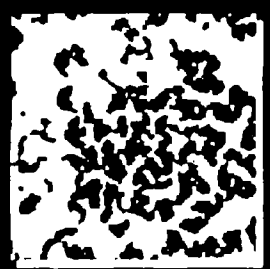


Listeria monocytogenes

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

Salmonella

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



Staphylococcus aureus

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

Shigella

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

Yersinia enterocolitica

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

FAX TRANSMISSION

To: Tom Freedman **Date:** 5/11/98

Fax #: 202/456-5581 **Pages:** 8 , including this cover sheet

From: Office of Public Affairs
Food and Drug Administration
Lorrie McHugh-Wytkind
Associate Commissioner for
Public Affairs

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COMMENTS:

FROM: 5/11/98
11:30 a.m.

Qs and As on GAO Report on Imported Foods

Q: What are the GAO's findings re: imported foods?

A: The GAO has affirmed the Clinton Administration's conclusions that greater attention should be paid to the safety of imported foods. In particular, the report recommends that Congress give FDA the authority to require foreign countries to have a safety system in place equivalent to the U.S. system before those countries can export food to the U.S. The Administration submitted such legislation to Congress earlier this year.

Q: Is Congress moving to enact the legislation that the Administration has submitted to give FDA greater authority over food imports?

A:: No hearings have been scheduled and this issue does not appear to be on the Congressional agenda for this year.

Q: Does FDA agree with the conclusions reached by GAO on the imported food issue?

A: FDA agrees with the major conclusion that FDA needs additional authority. This conclusion is consistent with FDA's (and the Administration's) past pronouncements about how to strengthen protection against unsafe foods imported into the United States. The report also strongly implies that FDA does not have sufficient resources to inspect imported food; the President's FY 1999 budget request now before Congress seeks an additional $25 million to strengthen the regulation of imported food.

Q: Are there some findings and recommendations that FDA disagrees with?

A: Only relatively minor points. For example, the report notes that each year FDA plans to conduct a certain number of import inspections yet falls short of those plans. The "workplan" is merely a way of targeting resources, not a mandatory exercise whose failure to carry out to the letter will result in a threat to the public health. FDA does not expect to carry out 100% of the plan, as emergencies arise that pull staff off of routine duties.

Q: The report also notes that some importers illegally distribute imported foods into U.S. commerce and that FDA does not have adequate deterrent power to prevent that. Do you agree with their recommendation that Congress give FDA civil money penalty authority for these violations?

A: Yes. FDA agrees with the recommendation that Civil Money Penalties would be an effective tool.

Q: Are imported foods safe?

A: In general, yes. However, recent outbreaks of illness associated with imported and domestic foods demonstrate that there is a problem and that the government needs to improve food safety. Current statistics on foodborne illness do not show conclusively that imported foods are riskier than domestic foods.

Q: What safety problems have been associated with imported foods?

A: Problems similar to those we see with domestic foods--occasional contamination with microbiological, physical or chemical contaminants. Some problems, such as last year's outbreak from raspberries containing the pathogen *cyclospora*, have caused outbreaks of foodborne disease and have been difficult to trace and contain.

Q: **How does FDA inspect imported foods?**

A: Under current law, which was originally enacted at the turn of the century, FDA is empowered to inspect foods at the border or port of entry and refuse entry to foods that appear to be contaminated. That system worked well earlier in the century, when food imports were relatively few. However, today the agency's ability to examine such imports is severely stressed by the volume of imports.

Q: How many imports come into the U.S. each year?

A: Since 1990, the volume of imports of FDA-regulated products has increased from about 1.2 million entries to almost 4 million in 1997. That volume is expected to double again (to over 8 million) by the year 2000. The majority of those imports are foods.

Q: What does FDA inspect imported food for?

A: A variety of things related to safety--pesticides and other chemical contaminants; microbiological contamination; natural toxins (such as molds); unapproved food and color additives. Inspectors also look for inaccurate labeling or other things less directly related to safety.

Q: How many inspectors does FDA have at the borders to examine these imports?

A: There are over 300 ports of entry at which imported foods arrive from other countries, including seaports, border entry points, and airports. In 1997, FDA assigned 222 inspectors to review imports entering the U.S.; about ½ of that effort was focused on food imports. Another 240 staff in FDA laboratories analyzed imports for their safety (202 focused on foods).

Q: **If the legislation the President has proposed is enacted, will it make mandatory the requirement that foreign countries have equivalent food safety systems before their exports are allowed into the U.S. (as USDA does now for meat and poultry)? If not, what not make the authority mandatory?**

A: The authority requested by the President would allow FDA to bar entry into the U.S. of imported foods that come from countries that do not meet the same level of protection required of U.S. food manufacturers. If the legislation is enacted, FDA would immediately begin to assess the systems in other countries and would act first against food coming from countries where the risk is highest. An immediate requirement that foreign systems be equivalent to the U.S. would result in a ban on all food imports into the U.S., not because they were unsafe but because FDA would not have the time to make a judgement about other countries' systems.

May 8, 1998

Wendy A. Taylor 05/11/98 11:52:06 AM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: FOR RELEASE AT 11 A.M. EDT

---------- Forwarded by Wendy A. Taylor/OMB/EOP on 05/11/98 11:51 AM ----------

ERBACH_A@A1
05/11/98 11:42:00 AM

Record Type: Record

To: Wendy A. Taylor@EOP, K. Lisa Grove@eop, ESQUEA_J@A1@CD@LNGTWY

cc:
Subject: FOR RELEASE AT 11 A.M. EDT

Date: 05/11/98 Time: 08:40
FFor release at 11 a.m. EDT

WASHINGTON (AP) More than one-third of all fresh fruit and 12 percent of vegetables consumed in America now come from overseas. But a study released today by Congress' investigative agency said the federal government is unable to ensure that imported foods are safe.

The findings by the General Accounting Office could boost President Clinton's efforts to strengthen the Food and Drug Administration's authority to require that other countries adopt safe practices for fruit, vegetables, fish and processed foods.

If Congress passed pending legislation giving FDA that authority which the Agriculture Department already has for imported meat and poultry it would ``provide greater assurance that the imported foods it is responsible for are safe,'' the report said.

The study did not conclude that imported foods are more dangerous than those produced domestically, but imports grew more than 50 percent since 1990 to reach some $33 billion in 1996.

There have been some high-profile incidents of illness from imported foods, including Guatemalan raspberries, Mexican cantaloupes and alfalfa sprouts from the Netherlands.

``An increase of this magnitude demands more certainty that our food supply is safe,'' said Sen. Susan Collins, R-Maine, who requested the GAO report as chairwoman of the Senate Permanent Subcommittee on Investigations.

The study found that the FDA's reliance on port-of-entry inspections meant that only 46,395, or 1.7 percent, of more than

May 10, 1998

Dear Majority Leader Lott and Speaker Gingrich,

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

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

I have taken several further steps to begin implementing standards to ensure the safety of imported food. My FY '99 budget committed approximately $25 million to enabling the FDA to dramatically expand its international food inspection force in order to implement the pending legislation. In March of this year I released a report on how the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture, and in cooperation with the agricultural community, will develop guidance on good agricultural and manufacturing practices ~~that will apply~~ for use by U.S. to both domestic and foreign producers.

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

Sincerely,

FAX TRANSMISSION

To: Tom Freedman **Date:** 5/11/98

Fax #: 202/456-5581 **Pages:** 8 , including this cover sheet

From: Office of Public Affairs
Food and Drug Administration
Lorrie McHugh-Wytkind
Associate Commissioner for
Public Affairs

15-05 Parklawn, HFI-1
301-827-~~0857~~ 6244 (phone)
301-594-6004 (fax)
301-443-3819 (fax)

COMMENTS:

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11:30 a.m.

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Q: **If the legislation the President has proposed is enacted, will it make mandatory the requirement that foreign countries have equivalent food safety systems before their exports are allowed into the U.S. (as USDA does now for meat and poultry)? If not, what not make the authority mandatory?**

A: The authority requested by the President would allow FDA to bar entry into the U.S. of imported foods that come from countries that do not meet the same level of protection required of U.S. food manufacturers. If the legislation is enacted, FDA would immediately begin to assess the systems in other countries and would act first against food coming from countries where the risk is highest. An immediate requirement that foreign systems be equivalent to the U.S. would result in a ban on all food imports into the U.S., not because they were unsafe but because FDA would not have the time to make a judgement about other countries' systems.

May 8, 1998

FINAL

Q&A for Presidential Announcement on Food Safety Legislation and Report to Ensure Safety of Imported Fruits and Vegetables
March 4, 1998

Q: What did the President announce today?

A: The President announced the introduction of food safety legislation in the Senate that will ensure that the FDA denies the entry of imports of fruits, vegetables, or other food from any foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also permits FDA to consider refusal of inspection as a factor in halting imports from a facility or country. This legislation was introduced in the House in November of last year. The President also announced the release of a report on how the Secretary of Health and Human Services, in cooperation with the Secretary of Agriculture and the agricultural community, will develop guidance on good agricultural and good manufacturing practices for any fruits and vegetables that are sold in the U.S. market.

Q: Why is your Administration proposing these actions?

A: There have been dramatic changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round, increasing to as many as 50 in the summer. Today, the chances are that there are 400 or more items in the produce section and they are there all year round. Last year, 38 percent of the fruit and 12 percent of the vegetables Americans ate were imported.

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

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

Q: Are you saying that imported produce is unsafe?

A: There is no data indicating that imported fruits and vegetables are more unsafe than domestic products. But some recent outbreaks of foodborne illness have been traced back to imports, and it is important to ensure that foreign fruits and vegetables meet U.S. food safety requirements or otherwise achieve the level of protection required. The steps we are taking today are adding additional layers of protection. We am making sure that there

are no gaps in our food safety system -- that high safety standards apply to imported as well as domestic food, and to fruits and vegetables as well as to meat, poultry, and seafood.

Q: What steps is the Administration taking to improve food safety?

A: Last year we launched a new Presidential food safety initiative, and added more than $40 million to the FY '98 budget. With that money we started putting in place new science-based preventive systems to improve the safety of seafood, meat and poultry and began work on a new early warning system to help detect and respond to outbreaks of foodborne illness. This year, our budget seeks an even more substantial increase in resources, $101 million, to improve food safety. The resources will go to a variety of initiatives, including: giving FDA authority to prevent the import of produce from countries without safety precautions equivalent to our own; hiring FDA inspectors to improve the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on proper food handling; and further expanding our early warning system and strengthening state surveillance activities for foodborne illnesses.

Questions on Food Safety Legislation

Q: What does the legislation do?

A: This legislation helps ensure that the FDA will refuse imports of any food regulated by the FDA, including fruits and vegetables, from any country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also permits FDA to consider refusal of inspection as a factor in halting imports from a facility or country.

Q: How is this different from current authority?

A: This legislation increases the FDA's authority to refuse imports for foods from countries or facilities that do not meet U.S. food safety requirements or otherwise achieve the level of protection required. Currently, the FDA can only refuse imports after inspection or testing at the border when the FDA determines that the food appears to be unsafe or otherwise violates U.S. law. This new legislation will enable the FDA to ensure that food products entering this country were grown and processed in conditions that meet U.S. food safety requirements or otherwise achieve the level of protection required. This authority is necessary because experience has shown that inspection and testing of products at the border may not be sufficient in all cases to ensure the safety of food products. It may be necessary to identify and address the source of potential

contamination to ensure that products offered for sale in the United States meet domestic food safety requirements or otherwise achieve the level of protection required. FDA currently has such authority with respect to domestic production.

Q: Does this legislation give FDA additional authority to inspect in other countries?

A: No. Foreign inspections will continue to be done by consent. In making the determination that a food offered for import into the U.S. is adulterated, the legislation does permit the Secretary to consider whether FDA has been refused access to conduct inspection of the places where such food has been prepared, packed or held. The Secretary may deny importation to foods from such location or establishment on the basis of such refusal and other relevant factors. Because denying reasonable access is one factor in making that determination, the exporting country and the food establishment both have a strong incentive to allow such access.

Q: There is concern that this legislation is the first step in providing FDA with the authority to inspect farms in the U.S. Is that next?

A: Under current law, FDA already has authority to inspect establishments where food is prepared, packed, or held, which would include places where food is grown, such as domestic farms. While such inspections are infrequent, FDA has taken action against a U.S. farmer when a violation occurs. When FDA is involved in a food safety problem that is found to originate on a farm, the agency's focus generally is on identifying the source of the problem and removing the unsafe food from commerce.

Q. Doesn't this legislation impose trade barriers to food imports at a time when you are saying you want to lower them? Is this legislation consistent with free trade?

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

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

A: The new legislation would give the FDA the same kind of responsibility that the USDA already has for meat and poultry. The USDA system has worked well to ensure that unsafe meat and poultry, produced in foreign facilities which do not provide the same level of protection that is required in domestic facilities, will not be imported. The FDA should be able to run a similarly effective system that ensures food safety and prevents

imports from any foreign country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required.

Questions Related to Report on Guidance

Q: Why has this report been prepared?

A: On October 2, 1997, President Clinton announced an initiative to ensure the safety of imported and domestic fruits and vegetables which included the development of good agricultural practices and good manufacturing practices for fresh fruits and vegetables that would include ways to prevent potential contamination. This voluntary guidance will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. The guidance effort will include outreach and education, reflecting the Administration's commitment to direct resources toward improving food safety and the availability of food safety technologies.

The President requested this status report about progress made toward providing industry with good agricultural and good manufacturing practices guidance for fresh fruits and vegetables. It also presents a plan for outreach to the domestic and foreign industry.

Q: When you say good agricultural practices (GAPs) and good manufacturing practices (GMPs), are you talking about mandatory GAPs and GMPs?

A: No, the GAP/GMP guidance is voluntary. We are developing this science-based guidance with input from USDA, states, the agricultural community, industry, academia, consumers, and organizations representing the foreign produce industry. The guidance is intended for appropriate use by growers, packers, manufacturers of minimally processed products and produce distributors. Because the guidance is broad-based, it may be used, where applicable, by both the domestic and foreign produce industry to reduce the risk of microbial contamination.

Q: Does the report give a timeline for publishing the guidance?

A: Yes, we anticipate publishing the draft guidance in late March with a 75-day comment period. We anticipate that the guidance will be available in final form in October 1998.

This may come up because the deadline for the importation of Guatemalan raspberries is March 15.

Q: What is the status of the Guatemalan raspberries?

A: On November 20, 1997, FDA notified the Guatemalans that fresh raspberries will not be allowed entry into the U.S. during the period of March 15 through August 15, 1998. However, if the source of *Cyclospora* contamination is found and corrected or if intervention technologies are developed that will prevent cyclosporiasis in humans, we will revisit this decision. FDA has assisted Guatemala in seeking a resolution to this problem since 1996. In fact, we currently have people in Guatemala reviewing the interventions they have reportedly put in place.

Mike From Friedman

Includes Janice's edits

202-456-7431 Tom Friedman

FDA Statement on GAO Food Safety Report

The General Accounting Office's study is a wake up call to Congress to pass legislation to help ensure the safety of imported foods. While FDA believes that imported foods are generally safe, recent outbreaks of food-borne illnesses demonstrate that imported foods can introduce new risks and the increased consumption of imported foods heightens those risks. The President has called for increased resources, better coordination, more scientific research and greater authority for the FDA.

GAO recommends legislation that gives FDA new authority that requires food-exporting countries to have in place essentially the same food safety system as the United States. The Department of Agriculture already has such legal authority over imported meats and poultry. In October 1997, President Clinton proposed legislation to give FDA similar authority and the Administration has expressed its support for the "Safety of Imported Food Act" currently languishing in Congress.

While most of GAO's recommendations mirror solutions FDA already is implementing, the Agency rejects GAO's criticism that the agency fails to use its resources appropriately. The agency has faced a steadily rising workload with the number of food imports more than doubling in the last five years and FDA has warned that it was in danger of being overwhelmed by the volume of products reaching U.S. ports. The Agency is doing all it can with available resources and continues to recommend that additional resources are needed to ensure that the food Americans set on their table – both domestic and imported – is safe, wholesome and nutritious.

GAO's conclusion that the work plans have failed. Inspectors do not complete all the items on their annual list because they get reassigned as new problems and emergencies arise. It does not mean they are not working 100 percent of the time. FDA is re-evaluating how it constructs the annual work plans.

Overall, there is much in the GAO report with which FDA agrees. The agency shares GAO's concerns about the magnitude of the task it faces in regulating the rapidly rising volume of imported foods. The workload threatens to overwhelm FDA because it has historically received too few resources to adequately manage the quantity of products entering this country. FDA agrees with GAO that it needs additional legislative authority to safeguard the nation's food supply. The American public deserves – and expects – nothing less.

FDA Backgrounder on GAO Food Safety Report

The food supply in the United States is among the safest in the world. In recent years, however, there have been a number of serious outbreaks of food-borne illnesses, some of which have been associated with imported foods. Last year, President Clinton launched two separate food safety initiatives designed to lower the risk of food-borne disease from both domestic and imported foods. In his budget submission to Congress for FY '99, the President asked for an additional $100 million for the national food safety program.

Now, the General Accounting Office has released its evaluation of the safety of imported foods. In its report, "Food Safety: Federal Efforts to Ensure Safety of Imported Foods Are Inconsistent and Unreliable," GAO concludes that some of FDA's import control activities are inadequate. The agency agrees that more needs to be done to safeguard the quality of imported foods and already has undertaken many of the steps outlined in the GAO report. To achieve some of the improvements, however, FDA will require additional legal authority and resources. The GAO itself has recommended legislation to give FDA additional authority.

The major concerns raised by GAO, and FDA's responses, include:

Equivalency Authority. GAO proposes that FDA be given authority to require that food-exporting countries have in place a food safety system that is essentially equivalent to those in the United States. GAO notes that the Department of Agriculture's Food Safety and Inspection Service (FSIS) already has that authority and blocks the importation of meat and poultry from any country whose food safety system does not measure up to the U.S. standard. ~~Because FDA lacks that authority, it allows food imports from almost any country to reach the nation's ports of entry and then assumes the burden of ensuring the safety and wholesomeness of the food products. Nearly everyone – from the President to FDA to GAO – agrees that this is not the best approach. The President proposed legislation giving FDA the authority to prevent food imports from countries without equivalent safety systems. FDA supports that proposal.~~ Insert a: to ensure that all imported food product meet the U.S. level of protec

Civil Money Penalties. When food importers or brokers bring in shipments, they are required to post a $1,250 bond. If the brokers do not hold the product ~~on the docks~~ while FDA conducts its tests, they may forfeit their bonds. GAO observed that many brokers and importers distribute their products even when ordered to wait and simply include the bond as the cost of doing business. Once the product enters U.S. distribution, FDA has a difficult time getting it back.

There are cases where contaminated foods have been distributed. FDA lacks the legal authority to then penalize brokers who violate the law. GAO recommends -- and FDA agrees -- that it should have legal authority to seek sufficiently large civil money penalties (fines) to make it too costly for brokers to flout U.S. law. Legislation will be required to give FDA this authority.

Private Laboratories. FDA automatically detains imported foods that, on the basis of prior violations, have a high probability of being contaminated. Importers have the option of hiring private laboratories to test their products and certify that they meet U.S. standards. If the lab report clears the product, it can enter distribution. FDA, however, does not control the choice of samples or laboratories, raising questions about the validity of these reports. FDA lacks the authority to restrict brokers to certain laboratories, but the agency is issuing a new guidance to the district offices, emphasizing that results must come from reliable labs and, in some cases, the results should be verified.

OASIS Computer Update. Last year, OASIS, the Operational and Administrative System for Import Support, became fully operational in every U.S. port of entry where FDA-regulated products come into the country. This computerized system electronically links all FDA inspection offices with the brokers who import foreign products. Based on the information supplied by the broker, OASIS can give automated and immediate clearance for the imports or trigger an inspection by a FDA official. GAO noted that the current computer system requires inspectors to switch between OASIS and other related data bases, such as the FDA Import Alert Retrieval System and the low acid canned food database. Because it takes time to shut down one program and open another, many inspectors do not check all of the necessary databases. FDA has recognized the problem and is already moving to link OASIS to all of the other relevant databases.

Error Rates. FDA agrees with GAO that action should be taken against importers who continue to submit erroneous entry data to FDA. Most of the errors result from the complexity and the recent introduction of the OASIS system. FDA expects to require error-prone brokers to file both electronic and paper copies of their import documents until they learn to use the electronic system correctly.

ask ORA

Work Plans. FDA agrees with GAO that the work plans developed each year for the inspectors in regional offices do not always reflect how they actually spend their time, ~~but they are not designed to specifically accomplish this task~~. Typically, only about 80 percent of the tasks on the annual work plan are completed. FDA disagrees, however, with

but as with any annual plan, the workplan sets targets & anticipates that [illegible] activities or emergencies will supersede

Under current law, FDA cannot prevent food from being shipped to this country. The agency must attempt to identify unsafe food at the port of entry, an impossible task given the enormous volume of imports. Thus, FDA and the Administration agree with GAO that the better approach is to give FDA authority to require that foreign countries ensure that the food is safely produced in its originating country.

3:09 AM (ET) 5/11

GAO: Imported Foods May Not Be Safe

WASHINGTON (AP) -- More than one-third of all fresh fruit and 12 percent of vegetables consumed in America now come from overseas. But a study released today by Congress' investigative agency said the federal government is unable to ensure that imported foods are safe.

The findings by the General Accounting Office could boost President Clinton's efforts to strengthen the Food and Drug Administration's authority to require that other countries adopt safe practices for fruit, vegetables, fish and processed foods.

If Congress passed pending legislation giving FDA that authority -- which the Agriculture Department already has for imported meat and poultry -- it would "provide greater assurance that the imported foods it is responsible for are safe," the report said.

The study did not conclude that imported foods are more dangerous than those produced domestically, but imports grew more than 50 percent since 1990 to reach some $33 billion in 1996.

There have been some high-profile incidents of illness from imported foods, including Guatemalan raspberries, Mexican cantaloupes and alfalfa sprouts from the Netherlands.

"An increase of this magnitude demands more certainty that our food supply is safe," said Sen. Susan Collins, R-Maine, who requested the GAO report as chairwoman of the Senate Permanent Subcommittee on Investigations.

The study found that the FDA's reliance on port-of-entry inspections meant that only 46,395, or 1.7 percent, of more than 2.7 million imported food shipments in 1997 were actually checked by an inspector. Of those, only 16,000 underwent a laboratory analysis for disease-causing organisms or other problems.

The Agriculture Department, on the other hand, visually checked every shipment and did inspections on about 20 percent of 118,000 meat and poultry imports. In addition, USDA officials visited 30 countries and checked 336 foreign plants to ensure their safety practices were equal to those in this country.

In a written response to the audit, FDA Associate Commissioner Diane Thompson said the agency is seeking congressional approval for authority to check foreign practices. But to prevent disruptions in foreign trade, Thompson said they should not be a requirement for all imported foods.

"Such a requirement could have the undesirable effect of forcing FDA to bar entry to imports from most of the world" until each countries' practices were certified, she wrote.

The FDA also has proposed safety rules regarding seafood and juice processing that would apply to imports. The agency is pushing voluntary agriculture practices for both foreign and domestic fruit and vegetable growers and processors.

The GAO report found other gaps in the imported food safety system, including:

--USDA's food inspection service focuses too much on violations such as missing shipping labels that "bear little relationship to food safety" and should instead use health data to zero in on foods likely to pose the greatest hazards.

--Importers, not the FDA, choose which laboratories do sampling when a shipment is held up over food safety questions. In addition, importers often retain control of shipments even if the FDA decides to inspect them and, in some cases, goes ahead and markets them anyway.

--The FDA was able to conduct only about half its planned inspections and about 65 percent of its planned laboratory analyses on imported foods in 1996 and 1997. The agency said these plans are only projections and that inspectors often are called upon to do emergency work that leaves routine tasks undone.

White House Press Release

PRESIDENT CLINTON ANNOUNCES INITIATIVE TO ENSURE THE SAFETY OF IMPORTED AND DOMESTIC FRUITS AND VEGETABLES

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release October 2, 1997

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

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

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

abroad and at points of entry, the FDA will be able to make effective use of its new authority.

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

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

Clinton Administration Accomplishments In Improving **Food Safety**

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

* October, 1997. President announces new initiative to enhance FDA oversight over imported **foods** and develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

* May, 1997. Administration announces comprehensive new initiative to improve the **safety** of nation's **food** supply -- **Food Safety** from Farm to Table -- detailing a $43 million **food safety** program, including measures to improve surveillance, outbreak response, education, and research.

* January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop **food** borne disease outbreaks quickly and to improve prevention systems further.

* August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

* August, 1996. President signs **Food** Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

* July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

* December, 1995. Administration issues new rules to ensure seafood **safety**. Utilizes HACCP regulatory programs to require **food** industries to design and implement preventive measures and increase the industries' responsibility for and control of their **safety** assurance actions.

* 1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are **food** borne, making significant progress toward this goal in each successive year.

* 1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

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GAO

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

Draft Report

April 1998

FOOD SAFETY

Federal Efforts To Ensure Safety of Imported Foods Are Inconsistent And Unreliable

Notice
This draft is restricted to official use.

This draft report is being provided to obtain advance review and comment from those with responsibility for the subjects it discusses. It has not been fully reviewed within GAO and is, therefore, subject to revision.

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EXECUTIVE SUMMARY

PURPOSE

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

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

BACKGROUND

Foodborne illnesses in the United States are widespread and costly. The magnitude of the problem is uncertain, however, because these illnesses are underreported and health officials often cannot determine their source. As GAO reported in May 1996,[1]

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

up to 81 million cases of foodborne illnesses and as many as 9,100 deaths each year result in costs for medical treatment and productivity losses ranging from $6.6 billion to $37.1 billion. Recent outbreaks of foodborne illnesses demonstrate that imported foods have introduced new risks or intensified with familiar illnesses. The increased consumption of imported foods in the United States heightens the risks of illness.

The Food Safety and Inspection Service and the FDA have the primary responsibility for ensuring the safety of imported foods. The Food Safety and Inspection Service has jurisdiction over meat, poultry, and some egg products, while FDA regulates all other foods. The Inspection Service and FDA work closely with the Customs Service and the Centers for Disease Control and Prevention. The Customs Service refers imported foods to the Inspection Service or FDA for their approval before releasing the shipment into U.S. commerce. The Centers for Disease Control and Prevention monitors the incidence of foodborne illness and works with the Food Safety and Inspection Service and FDA to investigate outbreaks of illnesses and conduct research on foodborne diseases.

RESULTS IN BRIEF

Federal agencies cannot ensure that the growing amount of imported foods are safe for consumers. Although the Food Safety and Inspection Service and FDA require imported foods to meet the same standards as domestic foods, their approaches to enforcing these requirements differ. By law, the Inspection Service places the principal burden of safety on the exporting countries by allowing imports only from those countries with food safety systems it deems to be equivalent to the U.S. system. FDA, lacking such legal authority, allows food imports from almost any country and takes on the burden of ensuring the safety of imported foods as they arrive at U.S. ports of entry. Relying solely on port-of-entry inspections to detect and prevent

unsafe foods is ineffective, given that (1) this approach does not ensure that foods are produced under proper conditions and (2) FDA currently inspects less than 2 percent of all foreign shipments.

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

FDA's procedures for ensuring that unsafe imported foods do not reach U.S. consumers are vulnerable to abuse by unscrupulous importers. For example, FDA automatically detains shipments when the exporting firm has a history of violations. However, FDA allows importers to select the laboratories that perform sampling and analysis that it accepts as proof of safety. For other shipments, importers retain control of the goods while FDA decides whether to inspect the shipment or while tests are being conducted on it. In some cases, when FDA decides to inspect a shipment,

the importers have already marketed the goods. In other cases, when FDA finds contamination and calls for importers to return shipments to the Customs Service for destruction or reexport, importers ignore this requirement or are found to have substituted other goods for the original shipment. Such cases of noncompliance seldom result in a significant penalty.

PRINCIPAL FINDINGS

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

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

The Inspection Service has used equivalency authority to shift the primary responsibility for food safety to the exporting country. In so doing, the agency can leverage its resources by reviewing exporting countries' compliance with U.S. requirements rather than by depending on resource-intensive port inspections. FDA, on the other hand, relies on selecting and testing import samples at ports-of-entry to ensure that foods are safe. Such an approach has been widely discredited by the United Nations Food and Agriculture Organization, an FDA Advisory Committee, and

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GAO as an effective protective measure because, among other things, individual products tested at the ports-of-entry may not represent the health risks of the entire shipment. The ineffectiveness of FDA's approach is magnified by its inability to keep pace with a rising level of imports. FDA's coverage of import shipments has fallen from an estimated 8 percent in fiscal year 1992 to an estimated 1.7 percent in fiscal year 1997.

Agencies Could More Effectively Target Resources on Unsafe Foods

Although both agencies use computer systems to screen each import shipment and to help identify the import shipments requiring inspector action, neither agency has designed its system to take the best advantage of available data so that they can target those imported foods posing the greater health risks. The Inspection Service relies primarily on the violation history of previous shipments from the exporting firm to target entries for inspector action, which may not always indicate the shipments more likely to pose health threats. For example, many violations, such as incorrect shipping labels, do not directly affect consumer safety. However, information is available on the relative health risks of specific types of imported foods, such as ground or deboned beef.

FDA's system for selecting imports for examination relies primarily on inspectors' judgment and FDA guidance and information to aid their decisions are often not useful. FDA's annual workplans which identify, among other things, the number of imported food inspections and tests each district is expected to conduct are supposed to guide inspectors' judgment, but the workplans are unrealistic because they do not set aside time for investigating emergencies and consumer complaints. Because the workplan activities are generally not attainable, inspectors said they are not useful

when making inspection and testing decisions. In addition, FDA's computer system for screening imported food shipments is not programmed to help inspectors effectively use laboratory test results, violation histories, and other information to identify shipments posing the greatest food safety risks. Finally, the information identifying the contents of imported food shipments is entered directly into FDA's computer system by importers, some of whom have an incentive to misrepresent their goods in the interest of avoiding inspectors' attention. FDA retrospectively verifies a sample of the importer-provided information, but although it frequently identifies errors it takes no corrective action when it discovers errors. Thus FDA has no assurance that importers are accurately describing their goods and that FDA is identifying shipments that should be scrutinized.

Weaknesses in Import Controls Allow Entry of Unsafe Products

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

In particular, FDA does not maintain effective control over products it has automatically detained because of past violations. In lieu of requiring that these shipments be destroyed or reexported, FDA requires importers to establish that the contents are safe. As proof, FDA allows them to present private laboratory test results to show that the shipment meets U.S. safety standards. However, the agency does not have guidelines to control the selection of the samples tested by the private laboratories or to certify acceptable private laboratories to perform these tests. FDA has found numerous discrepancies between its test results and those from private

laboratories for the same shipments. Customs officials and FDA inspectors told GAO that importers have been known to share shipments that have been tested as safe, substituting them for samples of other shipments.

Unlike the Inspection Service, which controls the storage of imported foods after they are presented for inspection until their release into U.S. domestic markets, FDA usually allows importers to retain possession of their shipments until FDA and the Customs Service clear them for entry into U.S. commerce. According to FDA and Customs officials, imported food shipments under FDA's jurisdiction are often not made available for FDA inspection as required or are not properly disposed of when refused entry into U.S. commerce. Customs and FDA inspectors have found many instances in which importers substituted safe products for inspection, rather than the actual imported products. In other instances, importers substituted other products for destruction, rather than the actual imported products, when the tested products failed laboratory tests. In each situation, FDA inspectors believe the original imported food was sold in U.S. markets and presumably consumed. A joint Customs-FDA operation to test controls over foods at one port found that evasion was common.

Evasion probably occurs because it is seldom effectively punished. While FDA and the Customs Service rely on the bonds presented by the importer as the principal deterrent against noncompliance with laws, Customs' collection of damages against violators by Customs is uneven and uncertain. For example, at one port, the Customs Service collected about 2 percent of the damages originally assessed in 24 cases in 1997. In previous reports, GAO found that even if the maximum damages had been collected the importer would still have made a profit on the sale of the shipment. Thus the bonds do not represent an effective deterrent.

RECOMMENDATIONS

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h) 301-320-3043
pager 301-914-0457

5/8
7 p.m.

Qs and As on GAO Report on Imported Foods

Q: What are the GAO's findings re: imported foods?

A: The GAO has affirmed the Clinton Administration's conclusions that greater attention should be paid to the safety of imported foods. In particular, the report recommends that Congress give FDA the authority to require foreign countries to have a safety system in place equivalent to the U.S. system before those countries can export food to the U.S. The Administration submitted such legislation to Congress earlier this year.

Q: Is Congress moving to enact the legislation that the Administration has submitted to give FDA greater authority over food imports?

A: No hearings have been scheduled and this issue does not appear to be on the Congressional agenda for this year.

Q: Does FDA agree with the conclusions reached by GAO on the imported food issue?

A: Yes. The major conclusion that FDA needs additional authority is consistent with FDA's (and the Administration's) past pronouncements about how to strengthen protection against unsafe foods imported into the United States.

Q: Are there some findings and recommendations that FDA disagrees with?

A: Only relatively minor points. For example, the report notes that each year FDA plans to conduct a certain number of import inspections yet falls short of those plans. The "workplan" is merely a way of targeting resources, not a mandatory exercise whose failure to carry out to the letter will result in a threat to the public health. FDA does not expect to carry out 100% of the plan, as emergencies arise that pull staff off of routine duties.

Q: The report also notes that some importers illegally distribute imported foods into U.S. commerce and that FDA does not have adequate deterrent power to prevent that. Do you agree with their recommendation that Congress give FDA civil money penalty authority for these violations?

A: Yes. FDA agrees with that recommendation, that CMPs would be an effective tool..

Q: Are imported foods safe?

A: In general, yes. However, recent outbreaks of illness associated with imported and domestic foods demonstrate that there is a problem and that the government needs to improve food safety. Current statistics on foodborne illness do not show conclusively that imported foods are riskier than domestic foods.

Q: What safety problems have been associated with imported foods?

A: The same kinds of problems we see with domestic foods--occasional contamination with microbiological, physical or chemical contaminants. Some problems, such as last year's outbreak from raspberries containing the pathogen *cyclospora*, have caused major outbreaks of foodborne disease and have been difficult to trace and contain.

Q:: **How does FDA inspect imported foods?**

A: Under current law, which was originally enacted at the turn of the century, FDA is empowered to inspect foods at the border or port of entry and refuse entry to foods the agency believes may be risky. That system worked well earlier in the century, when food imports were relatively few. However, today the agency's ability to examine such imports is overwhelmed by the volume of imports.

Q: How many imports come into the U.S. each year?

A: Since 1990, the volume of imports of FDA-regulated products has increased from about 1.2 million entries to almost 4 million in 1997. That volume is expected to double again (to over 8 million) by the year 2000. The majority of those imports are foods.

Q: What does FDA inspect imported food for?

A: A variety of things related to safety--pesticides and other chemical contaminants; microbiological contamination; natural toxins (such as molds); unapproved food and color additives. Inspectors also look for inaccurate labeling or other things less directly related to safety.

Q: How many inspectors does FDA have at the borders to examine these imports?

A: There are over 300 ports of entry at which imported foods arrive from other countries, including seaports, border entry points, and airports. In 1997, FDA assigned 222 inspectors to review imports entering the U.S.; about ½ of that effort was focused on food imports. Another 240 staff in FDA laboratories analyzed imports for their safety (202 focused on foods).

May 8, 1998

Talking Points on GAO Food Safety Report
Friday, May 8, 1998

* While our food supply remains among the world's safest, Americans are increasingly eating more food from around the world and we need to do all we can to ensure the safety of our food supply from whatever source.

* Since taking office, the President recognized the importance of protecting the wholesomeness and safety of our food supply and launched a major cross-Department initiative. The President has also called for an additional $50 million in his FY'99 budget for food safety. ($25 M would be for imports.)

* The GAO report echoes the Administration's call to Congress to promptly pass legislation giving FDA greater authority to ensure the safety of imported foods.

* With the volume of imports having doubled in the past five years and anticipated to double again by the end of the decade, the Agency has long recognized that it needs greater authority and more resources and hopes this report is a catalyst for Congressional action. Moreover, many of GAO's recommendations mirror solutions FDA has championed for more than a year.

(Quote given to the AP on 5/8: "Although the Agency has not seen the final report, it appears to echo the Administration's call to Congress to promptly pass legislation giving FDA greater authority to ensure the safety of imported foods. With the volume of food imports having doubled in the past five years, the Agency has long recognized that it needs greater authority and more resources and hopes this report is a catalyst for Congressional action. Moreover, many of GAO's recommendations mirror solutions FDA has championed for more than a year")

---- We are also sending you draft Qs and As. On Monday morning, you will receive a one page statement from FDA and most likely a backgrounder that gets into more of the specifics.

Q: What safety problems have been associated with imported foods?

A: The same kinds of problems we see with domestic foods--occasional contamination with microbiological, physical or chemical contaminants. Some problems, such as last year's outbreak from raspberries containing the pathogen *cyclospora*, have caused major outbreaks of foodborne disease and have been difficult to trace and contain.

Q:: **How does FDA inspect imported foods?**

A: Under current law, which was originally enacted at the turn of the century, FDA is empowered to inspect foods at the border or port of entry and refuse entry to foods the agency believes may be risky. That system worked well earlier in the century, when food imports were relatively few. However, today the agency's ability to examine such imports is overwhelmed by the volume of imports.

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May 8, 1998

5/8
7 p.m.

Qs and As on GAO Report on Imported Foods

Q: What are the GAO's findings re: imported foods?

A: The GAO has affirmed the Clinton Administration's conclusions that greater attention should be paid to the safety of imported foods. In particular, the report recommends that Congress give FDA the authority to require foreign countries to have a safety system in place equivalent to the U.S. system before those countries can export food to the U.S. The Administration submitted such legislation to Congress earlier this year.

Q: Is Congress moving to enact the legislation that the Administration has submitted to give FDA greater authority over food imports?

A:: No hearings have been scheduled and this issue does not appear to be on the Congressional agenda for this year.

Q: Does FDA agree with the conclusions reached by GAO on the imported food issue?

A: Yes. The major conclusion that FDA needs additional authority is consistent with FDA's (and the Administration's) past pronouncements about how to strengthen protection against unsafe foods imported into the United States.

Q: Are there some findings and recommendations that FDA disagrees with?

A: Only relatively minor points. For example, the report notes that each year FDA plans to conduct a certain number of import inspections yet falls short of those plans. The "workplan" is merely a way of targeting resources, not a mandatory exercise whose failure to carry out to the letter will result in a threat to the public health. FDA does not expect to carry out 100% of the plan, as emergencies arise that pull staff off of routine duties.

Q: The report also notes that some importers illegally distribute imported foods into U.S. commerce and that FDA does not have adequate deterrent power to prevent that. Do you agree with their recommendation that Congress give FDA civil money penalty authority for these violations?

A. Yes. FDA agrees with that recommendation, that CMPs would be an effective tool..

Q: Are imported foods safe?

A: In general, yes. However, recent outbreaks of illness associated with imported and domestic foods demonstrate that there is a problem and that the government needs to improve food safety. Current statistics on foodborne illness do not show conclusively that imported foods are riskier than domestic foods.

May 10, 1998

Dear Majority Leader Lott and Speaker Gingrich,

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

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

I have taken several further steps to begin implementing standards to ensure the safety of imported food. My FY '99 budget committed approximately $25 million to enabling the FDA to dramatically expand its international food inspection force in order to implement the pending legislation. In March of this year I released a report on how the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture, and in cooperation with the agricultural community, will develop guidance on good agricultural and manufacturing practices that will apply to both domestic and foreign producers.

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

Sincerely,

Q&A for GAO Report on Imported Foods
May 11, 1998

Q: What are the GAO's major findings regarding imported foods?

A: The GAO affirmed the Clinton Administration's conclusions that greater attention should be paid to the safety of imported foods. In particular, the report states that "[i]n order to strengthen FDA's ability to ensure the safety of imported foods, GAO recommends that the Congress require food eligible for import to the United States, not just meat and poultry, be produced under equivalent food safety systems." The Administration submitted legislation to Congress earlier this year which addresses this concern. The major conclusion that FDA needs additional authority is fully consistent with the Administration's position about how to strengthen protection against unsafe foods imported into the United States.

Q: The report also notes that some importers illegally distribute imported foods into U.S. commerce and that FDA does not have adequate deterrent power to prevent those imports. Does the Administration agree with GAO's recommendation that Congress give FDA civil money penalty authority for these violations?

A: Yes, FDA agrees with the recommendation that civil monetary penalties would be an effective tool.

Q: What does the Administration's legislation do?

A: This legislation ensures that FDA will refuse imports of any food regulated by the FDA, including fruits and vegetables, from any country or facility that does not meet U.S. food safety requirements or otherwise achieve the level of protection required. The legislation also permits FDA to consider refusal of inspection as a factor in halting imports from a facility or country. In essence, it would do exactly what the GAO says is necessary to ensure the safety of imported food.

Q: Is Congress moving to enact the legislation that the Administration has submitted to give FDA greater authority over food imports?

A: No hearings have been scheduled, and this issue does not appear to be on the Congressional agenda for this year. The President today called on Congress to take action on this legislation.

Background Questions and Answers:

Imported - new foods

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that will provide the same level of protection as the safety systems in place

Dear XX, Kathleen

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Sincerely,

will do what the GAO says is necessary. it

Q: Why did your Administration propose new legislation?

A: There have been dramatic changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round, increasing to as many as 50 in the summer. Today, the chances are that there are 400 or more items in the produce section and they are there all year round. Last year, 38 percent of the fruit and 12 percent of the vegetables Americans ate were imported.

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

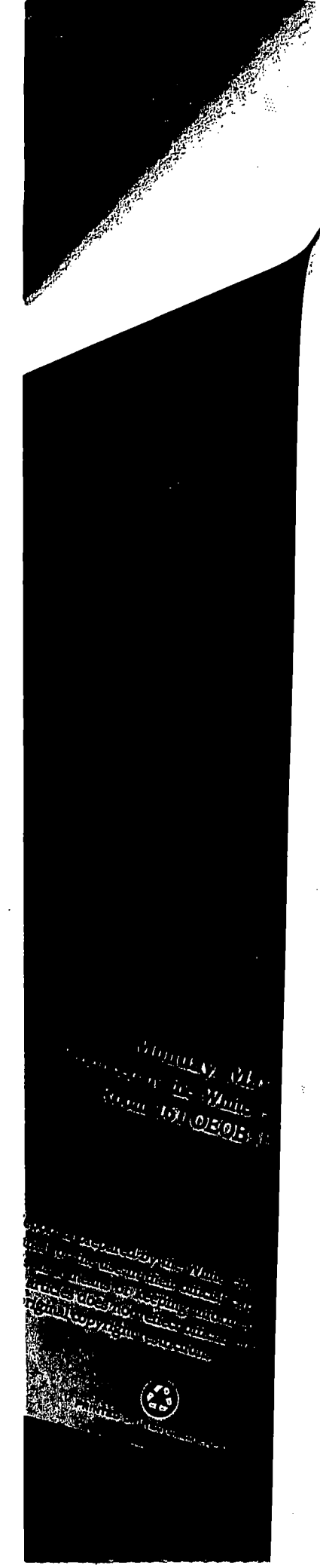
We must ensure that these changes do not increase the risk to American consumers of foodborne illnesses. Although raw produce -- including that imported from foreign countries -- is now safe, experts have suggested ways to make further improvements, and my actions accord with their recommendations.

Q: Are you saying that imported produce is unsafe?

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

Q: What steps is the Administration taking to improve food safety?

A: Last year we launched a new Presidential food safety initiative, and added more than $40 million to the FY '98 budget. With that money we started putting in place new science-based preventive systems to improve the safety of seafood, meat and poultry and began work on a new early warning system to help detect and respond to outbreaks of foodborne illness. This year, our budget seeks an even more substantial increase in resources, $101 million, to improve food safety. The resources will go to a variety of initiatives, including: giving FDA authority to prevent the import of produce from countries without safety precautions equivalent to our own; hiring FDA inspectors to improve the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on proper food handling; and further expanding our early warning system and strengthening state surveillance activities for foodborne illnesses.



Proposal Would Bar Food Exported by Some Nations

Accounting Office Seeks to Prevent Illnesses

By TIM WEINER

WASHINGTON, May 10 — Federal investigators are calling on the United States to stop importing food from nations that do not meet American health and safety standards. They say the Clinton Administration and Congress have failed to create a system to prevent imported food-borne diseases from sickening and killing people.

The fact that booming global imports have overwhelmed Federal efforts to protect the public against food-borne disease is well-recognized, say investigators from the General Accounting Office. So is the fact that the present system of stopping tainted food at the nation's borders is outdated and ineffective, a new report by the agency said. And scientists are seeing outbreaks caused by little known pathogens, like a dimly understood parasite called cyclospora, which sickened about 2,500 Americans who ate imported Guatemalan raspberries in the last two years.

One solution is to demand that foreign nations create food-safety systems that meet American standards, said the accounting office, the investigatory arm of Congress. But Federal officials fear this would disrupt trade, and have not made that demand.

Federal scientists are recognizing that "free trade may present problems that are associated with food poisoning," said Dr. Marguerite A. Neill, a member of a Federal food-safety advisory board. But what American officials see as a safety issue, foreign nations see as a free-trade issue. And free trade, with the billions of dollars of commerce it brings to exporting and importing nations, may have the power to trump food safety when it comes to laws and regulations, some Federal scientists said.

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

In 1993, the Food and Drug Administration, citing "enormous inefficiencies in the current food-protection system" and the problems posed by ever-increasing food imports, asked the Clinton Administration for the power to bar fruits, vegetables, grains, fish and other food from a country with an inferior food-safety system.

The Department of Agriculture has that power over imported meat and poultry. The power is called equivalency — requiring a country that exports food to have a food-safety system equal to that of the United States. Last year, the Clinton Administration, in the heat of the battle to win "fast-track" free-trade authority, proposed giving the F.D.A. the power to demand equivalence.

But nothing has happened on that front — not by executive order, not by legislation.

The General Accounting Office, in its new report on the flawed Federal food-safety system,to be published this week, recommended that "Congress require all foods eligible for import to the United States, not just meat and poultry, to be produced under equivalent food safety systems.

But senior Federal food safety officials disagreed with that recommendation, arguing that "such mandatory authority would disrupt trade if implemented at one time," the report said. F.D.A. officials now believe that the authority should be discretionary, not mandatory, the report said.

The Centers for Disease Control and Prevention has confirmed thousands of cases of people sickened by pathogens in fruits and vegetables imported from abroad in recent years. These diseases may be caused by polluted water used to irrigate fields, poor sanitary practices at warehouses, a lack of regulation by ineffective governments or other factors.

Some food growers say that the risks from imports are insignificant, and that the Centers for Disease Control has exaggerated them.

But roughly 99 percent of food-borne diseases are never traced to their source, the C.D.C. said, so the actual number of illnesses or deaths attributable to imported food-borne

Free trade tests the country's system of protecting its food from disease.

disease is unknown. The number is probably far greater than, for example, the number of Americans injured or killed by terrorism abroad. Overall, the centers said, domestic and imported food-borne disease kills thousands of Americans and sickens millions, perhaps tens of millions, every year.

The F.D.A.'s inspectors test an ever-dwindling fraction of the 30 billion tons of food now imported into the United States. The responsibilities of individual inspectors have increased, but their resources have dwindled.

The agency inspects less than 2 percent of foreign food shipments, down from 8 percent in 1992. In 1997, it conducted only half the inspections it planned to conduct. The system of inspecting foods where they enter the United States is an anachronism, an F.D.A. advisory panel reported seven years ago.

In any case, the inspections cannot detect some food-borne pathogens introduced abroad by unhealthy links in the chain of imported food. And unscrupulous importers can easily circumvent the inspection system, according to the report by the accounting office.

Senator Susan Collins, Republican of Maine, requested the report and will hold the first of four Senate hearings on the food-safety system this week. She called the report "a serious indictment that raises very alarming concerns."

Ms. Collins said Americans ate more than $33 billion of imported foods in 1996, an increase of almost 50 percent over 1990 imports. While food imports were booming, she said, F.D.A. inspections of those foods were declining, a situation she called "an invitation to trouble." The nation now spends $1 billion trying to protect the safety of the food supply, but may not be spending the money wisely, she said.

"Congress can strengthen the law, and it should," Ms. Collins said. "I'm not certain yet what direction we're going, but we need more inspectors, and we need a better system too, a system that will allow consumers to be confident in the safety of the food they eat."

The New York Times
MONDAY, MAY 11, 1998

Imported Food - GW

White House Press Release

PRESIDENT CLINTON ANNOUNCES INITIATIVE TO ENSURE THE SAFETY OF IMPORTED AND DOMESTIC FRUITS AND VEGETABLES

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release October 2, 1997

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

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

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

abroad and at points of entry, the FDA will be able to make effective use of its new authority.

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

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

Clinton Administration Accomplishments In Improving **Food Safety**

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

* October, 1997. President announces new initiative to enhance FDA oversight over imported **foods** and develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

* May, 1997. Administration announces comprehensive new initiative to improve the **safety** of nation's **food** supply -- **Food Safety** from Farm to Table -- detailing a $43 million **food safety** program, including measures to improve surveillance, outbreak response, education, and research.

* January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop **food** borne disease outbreaks quickly and to improve prevention systems further.

* August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

* August, 1996. President signs **Food** Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

* July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

* December, 1995. Administration issues new rules to ensure seafood **safety**. Utilizes HACCP regulatory programs to require **food** industries to design and implement preventive measures and increase the industries' responsibility for and control of their **safety** assurance actions.

* 1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are **food** borne, making significant progress toward this goal in each successive year.

* 1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.



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White House Press Release

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

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release October 2, 1997

October 2, 1997

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

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

American consumers today enjoy the safest **food** supply in the world, and I am proud of my Administration's record in this area. We have taken significant steps to ensure that we maintain the safest **food** possible. We have put in place improved **safety** standards for meat, poultry, and seafood products, and we have begun the process of developing enhanced **safety** standards for fruit and vegetable juices. We have also expanded research, education, and surveillance activities through coordinated efforts of all agencies involved in **food safety** issues. Together, these measures will greatly improve the **safety** of the Nation's **food** supply.

We need to build on these efforts, and today I ask you to do so by focusing on the **safety** of fruits and vegetables. Although the produce Americans eat is very safe, we can and must do even better, especially at a time when Americans are eating more fruits and vegetables from all over the world. Last year, 38 percent of the fruit and 12 percent of the vegetables consumed by Americans came from overseas. We must

ensure that fruits and vegetables coming from abroad are as safe as those produced in the United States, especially as we upgrade our own domestic standards.

To help accomplish this task, I plan to send to the Congress proposed legislation that will require the **Food** and Drug Administration (FDA) to halt imports of fruits, vegetables, or other **food** from any foreign country whose **food safety** systems and standards are not on par with those of the United States. This legislation, which will be similar to existing law requiring the USDA to halt the importation of meat and poultry from such countries, will enable the FDA to prevent the importation of potentially unsafe foreign produce. My Fiscal Year 1999 budget will provide the necessary funds to enable the FDA to expand dramatically its international **food** inspection force. With this greatly increased ability to inspect **food safety** conditions abroad and at points of entry, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

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

First, I direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue within 1 year from the date of this memorandum, guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should address ways to prevent potential sources of contamination, should take into account differences in both crops and regions, and should address **food safety** issues throughout the **food** production and distribution system. By providing the first-ever specific **safety** standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities.

Second, I direct the Secretary of Health and Human Services and the Secretary of Agriculture, to report back to me within 90 days from the date of this memorandum with a status report and complete schedule for the good agricultural and manufacturing practices, and a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve those practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe **food** at the dock or border. I especially urge you to consider the best ways to target inspection and testing toward those areas where problems are most likely to occur.

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

WILLIAM J. CLINTON

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To comment on this service: *feedback@www.whitehouse.gov*

White House Press Release

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

THE PRESIDENT: I think that -

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

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

Thank you.

END 11:09 A.M. EDT

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release October 2, 1997

October 2, 1997

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

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

American consumers today enjoy the safest food supply in the world, and I am proud of my Administration's record in this area. We have taken significant steps to ensure that we maintain the safest food possible. We have put in place improved safety standards for meat, poultry, and seafood products, and we have begun the process of developing enhanced safety standards for fruit and vegetable juices. We have also expanded research, education, and surveillance activities through coordinated efforts of all agencies involved in food safety issues. Together, these measures will greatly improve the safety of the Nation's food supply.

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

To help accomplish this task, I plan to send to the Congress proposed legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the United States. This legislation, which will be similar to existing law requiring the USDA to halt the importation of meat and poultry from such countries, will enable the FDA to prevent the importation of potentially unsafe foreign produce. My Fiscal Year 1999 budget will provide the necessary funds to enable the FDA to expand dramatically its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

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

more

First, I direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue within 1 year from the date of this memorandum, guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should address ways to prevent potential sources of contamination, should take into account differences in both crops and regions, and should address food safety issues throughout the food production and distribution system. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities.

Second, I direct the Secretary of Health and Human Services and the Secretary of Agriculture, to report back to me within 90 days from the date of this memorandum with a status report and complete schedule for the good agricultural and manufacturing practices, and a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve those practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. I especially urge you to consider the best ways to target inspection and testing toward those areas where problems are most likely to occur.

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

WILLIAM J. CLINTON

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THE WHITE HOUSE

Office of the Press Secretary

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 meet 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.

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THE PRESIDENT: Thanks. (Applause.)

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Thank you.

END 11:09 A.M. EDT

Questions and Answers on Food Safety
January 19, 1998

Q: What steps is the Administration taking to improve food safety?

A: Last year we launched a new Presidential food safety initiative, and added more than $40 million to the FY '98 budget. With that money we started putting in place new science-based preventive systems to improve the safety of seafood, meat and poultry and began work on a new early warning system to help detect and respond to outbreaks of foodborne illness. This year, our budget will seek an even more substantial increase in resources to improve food safety. The resources will go to a variety of initiatives, including: giving FDA authority to prevent the import of produce from countries without safety precautions equivalent to our own; hiring FDA inspectors to improve the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on proper food handling; and further expanding our early warning system and strengthening state surveillance activities for foodborne illnesses.

Q. A recent story revealed that USDA did not close down a plant despite 1,700 violations. What are you doing to make sure our meat and poultry are safe to eat?

A. We have to keep improving our food safety systems. And I am committing more resources than ever to the problem, and modernizing food safety for meat and fruits and vegetables and the water we drink. There are several important facts to remember in regard to this specific story. First, although the inspectors did not close the plant -- and in my view that was a wrong decision -- they did take actions to correct the plant's bad practices and to prevent all unsafe food they found from reaching the public. Second, those events occurred in 1996 -- before my Administration began implementing the Hazard Analysis and Critical Control Point (HACCP) system for meat. Under this system, inspectors will document food safety violations; they will shut down the plant where there are repeat failures; and they will insist that the plant take a wide range of measures to prevent any future contamination before the plant can reopen. Finally, the Administration has asked Congress for additional enforcement authority to fine companies for violations of food safety standards. Currently, USDA can't fine companies that violate food safety standards.

Questions and Answers on Food Safety
January 12, 1998

Q: What steps will the Clinton Administration take to improve food safety?

A: Last year we were able to increase spending on food safety by approximately $40 million. This year, our budget will seek an even more substantial increase in resources to improve food safety. The resources will go to a variety of initiatives, including: giving FDA authority to prevent the import of produce from countries without safety precautions equivalent to our own; hiring FDA inspectors to improve the safety of our nation's fruits and vegetables, both domestic and imported; developing new ways for federal inspectors to detect food-borne illnesses in meat and poultry and determine the source of contamination; improving educational outreach on proper food handling; and expanding CDC's surveillance activities for food-borne illnesses.

Q. Is this a new issue for the Administration?

A. No, our actions are part of a continuing effort that has seen real accomplishment every year:

* October, 1997. President announces new initiative to enhance FDA oversight over imported foods and to develop guidance on good agricultural and manufacturing practices for fruits and vegetables; to seek legislation to give FDA the same authority that USDA has to inspect imports; and to seek funds to greatly expand FDA's inspection force.

* January, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply detailing a $43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

* August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

* August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

* July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

* December, 1995. Administration issues new rules to ensure seafood safety. Utilizes HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

* 1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.

* 1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

Q&A for Presidential Initiative to Improve the Safety of Imported Fruits and Vegetables
October 10, 1997

Q: What did the Administration propose with regard to food safety?

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

In addition, I directed 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, I 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.

Q: Why is your Administration proposing these actions?

A: There have been dramatic changes in the produce department of the grocery store. Thirty years ago, most produce sections only had around a dozen items year round, increasing to as many as 50 in the summer. Today, the chances are that there are 400 or more items in the produce section and they are there all year round. Last year, 38 percent of the fruit and 12 percent of the vegetables Americans ate were imported.

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

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

Q: Are you saying that imported produce is unsafe?

A: There is no data indicating that imported fruits and vegetables are more unsafe than domestic products. But some recent outbreaks of foodborne illness have been traced back

to imports and it is important that foreign fruits and vegetables be held to the same safety standards as American products. The steps we are taking today are adding additional layers of protection. I am making sure that there are no gaps in our food safety system -- that high safety standards apply to imported as well as domestic food, and to fruits and vegetables as well as to meat, poultry, and seafood.

Q: Will foreign countries have to comply with Good Agricultural and Manufacturing Practices if they want to export fruits and vegetables to the U.S.?

A: We expect that exporting countries will develop similar practices that address potential food safety problems in their countries for one simple reason: they want to be able to sell food in our market, and they want that food to be safe.

We do not know whether a country that does not comply with the new guidance will be able to import fruits and vegetables into the United States. The answer to this question depends on the exact content of the guidance, as well as on intricate legal determinations regarding equivalency between different countries' food safety systems. What is clear is that the FDA will have to cut off imports from countries that do not comply with existing legal standards applicable to domestic produce.

Q. Doesn't this legislation impose trade barriers to food imports at a time when you are saying you want to lower them? Is this legislation consistent with free trade?

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

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

A: No. This is a part of my broad food safety agenda -- my longstanding commitment to ensuring that Americans' food supply is the safest in the world. It does not relate to Fast Track.

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

A: My proposed legislation would give the FDA the same kind of responsibility that the USDA already has for meat and poultry. The USDA system has worked well to ensure that countries with inferior safety standards can't import their meat and poultry. The FDA

should be able to run a similarly effective system that inspects food safety systems and standards abroad and prevents imports from countries that do not provide the protections that the U.S. does.

Clinton Administration Accomplishments In Improving Food Safety

* October, 1997. President announces new initiative to enhance FDA oversight over imported foods and develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

* May, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply -- "Food Safety from Farm to Table" -- detailing a $43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

* January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop food borne disease outbreaks quickly and to improve prevention systems further.

* August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

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* 1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

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

Q: What is the President proposing?

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

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

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

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

Q: Why is the President proposing these actions?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Q: Are you saying that imported produce is unsafe?

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

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

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

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

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

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

Q: Will foreign countries have to comply with Good Agricultural and Manufacturing Practices if they want to export fruits and vegetables to the U.S.?

A: We expect that exporting countries will develop similar practices that address potential food safety problems in their countries for one simple reason: they want to be able to sell food in our market, and they want that food to be safe.

We cannot yet know whether a country that does not comply with the guidance will be able to import fruits and vegetables into the United States. The answer to this question depends on the exact content of the guidance, as well as an intricate legal determinations regarding equivalency between different countries' food safety systems. What is clear is that the FDA will have to cut off imports from countries that do not comply with existing legal standards. And at the very least, the FDA will target countries that do not comply with the Good Agricultural and Manufacturing Practices for increased inspection and testing.

Clinton Administration Accomplishments In Improving Food Safety

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

*October, 1997. President announces new initiative to enhance FDA oversight over imported foods and develop guidance on good agricultural and manufacturing practices for fruits and vegetables.

*May, 1997. Administration announces comprehensive new initiative to improve the safety of nation's food supply --"Food Safety from Farm to Table" -- detailing a $43 million food safety program, including measures to improve surveillance, outbreak response, education, and research.

*January, 1997. President announces new Early-Warning System to gather critical scientific data to help stop food borne disease outbreaks quickly and to improve prevention systems further.

*August, 1996. President signs Safe Drinking Water Act of 1996. The law requires drinking water systems to protect against dangerous contaminants like cryptosporidium, and gives people the right to know about contaminants in their tap water.

*August, 1996. President signs Food Quality Protection Act of 1996, which streamlines regulation of pesticides by FDA and EPA and puts important new public-health protections in place, especially for children.

*July, 1996. President Clinton announces new regulations that modernize the nation's meat and poultry inspection system for the first time in 90 years. New standards help prevent E.coli bacteria contamination in meat.

*December, 1995. Administration issues new rules to ensure seafood safety. Utilizes HACCP regulatory programs to require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety assurance actions.

*1994. CDC embarks on strategic program to detect, prevent, and control emerging infectious disease threats, some of which are food borne, making significant progress toward this goal in each successive year.

*1993. Vice-President's National Performance Review issues report recommending government and industry move toward a system of preventive controls.

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

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

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

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

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
and
U.S. DEPARTMENT OF AGRICULTURE
Washington, D.C.

FEB 24 1998

The Honorable William Jefferson Clinton
The White House
Washington, DC 20500

Dear Mr. President:

Attached is our report, as requested in your October 2, 1997 Directive, on progress made on the Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables. The report is a synopsis of the progress we have made in providing Good Agricultural Practices and Good Manufacturing Practices guidance to domestic and international growers, harvesters, handlers, and transporters of fresh fruits and vegetables.

The report also discusses our plans for extending existing programs in order to improve the monitoring of agricultural and manufacturing practices domestically and abroad, to assist domestic and foreign producers to improve those practices, where necessary, to prevent the distribution and importation of unsafe produce, and to accelerate research to support these activities.

Sincerely,

Donna E. Shalala
Secretary of Health and Human Services

Dan Glickman
Secretary of Agriculture

Enclosure

Initiative to Ensure the Safety of Imported and Domestic Fresh Fruits and Vegetables: Status Report

Background

American consumers enjoy one of the safest food supplies in the world. However, over the last several years there has been an increase in reported outbreaks of foodborne illness associated with both domestic and imported fresh fruits and vegetables. In May 1997, as part of the President's Food Safety Initiative, the Department of Health and Human Services (DHHS), the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) sent to the President a report that identified produce as an area of concern. On October 2, 1997, President Clinton announced a new initiative to ensure that our fruits and vegetables, including those imported from other countries, meet the highest health and safety standards.

The President called on Congress to give the Food and Drug Administration (FDA) the authority to better assure that food imports meet existing United States food safety laws and regulations. Legislation has been introduced in the House of Representatives that would enhance FDA's ability to ensure the safety of all foods imported into the U.S. The legislation would enhance FDA's ability to protect U.S. consumers while being consistent with U.S. trade rights and obligations.

In addition, the President directed 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 safety guidance for the growing, processing, shipping, and selling of fruits and vegetables. This voluntary guidance will address potential food safety problems throughout the production and distribution system and help ensure the sanitation and safety practices of all those seeking to sell produce in the U.S. market. This second component of the President's Directive — voluntary guidance — is an important outreach and education effort, reflecting the Administration's commitment to direct resources toward improving food safety and the availability of food safety technologies.

The President's FY 1999 budget includes funds necessary to expand FDA's international capabilities; full implementation in FY 1999 will be contingent on receiving adequate appropriations.

This Report

The President asked the two Secretaries to report back to him with a plan and schedule for developing this guidance. This report presents the progress made to develop voluntary guidance for the growing, processing, shipping, and selling of fruits and vegetables and the schedule and plans to accomplish these and the other elements of the President's produce initiative. To meet the President's goal that our produce meet the highest health and safety standards, the Departments will develop voluntary Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs) guidance for produce (henceforth referred to as guidance). GAPs cover production practices including growing, harvesting, handling, and transportation. GMPs primarily address harvesting and transportation, but also include aspects of manufacturing such as processing and packaging. GAPs and GMPs by necessity, overlap and are interrelated.

This report also describes interdependent activities that will help industry successfully apply the voluntary guidance. For example, the domestic and foreign industry may require technical assistance from U.S. agencies to effectively apply the voluntary guidance. Education and outreach efforts will be provided to the domestic and foreign industry and these activities will be based on a strong underlying, accelerated research program. In the long-term, research and risk assessment on fresh produce will be incorporated in the multi-year Food Safety Initiative research planning process. Development of this interagency research planning process is being facilitated by the White House Office of Science and Technology Policy.

The U.S. produce industry, states, and many countries exporting fresh fruits and vegetables to the U.S. have already taken significant steps to develop and implement improved agricultural practices and guidelines. Activities in this initiative, particularly in developing the voluntary GAP/GMP guidance, recognize this effort and build on it.

I. Good Agricultural Practices/Good Manufacturing Practices Guidance

Status: FDA, working with the USDA, is preparing a general GAP/GMP guidance document. FDA plans to publish the document as proposed voluntary guidance with opportunity for public comments. This guidance, titled "Guide to Minimizing Microbial Food Safety Hazards for Fresh Fruits and Vegetables", describes science-based good agricultural practices that farmers and producers may use for water quality, manure management, sanitation (both field and facility sanitation, as well as worker hygiene), and handling and transportation. The guidance also describes use of producer identification and information on the flow of the product through distribution channels. This information can facilitate source identification, should a commodity be associated with a foodborne illness outbreak. This guidance can be used by both domestic and foreign fresh fruit and vegetable producers to help ensure the safety of their produce. The guidance, which is a science-based evaluation of risks, will be consistent with World Trade Organization obligations and will not impose unnecessary or unequal restrictions or barriers on either domestic or foreign producers. The agencies recognize that appropriate use of pesticides and related antimicrobial agents play an important role in controlling microbial contamination, but caution that excessive or inappropriate use of these substances does not take the place of GAPs/GMPs.

FDA and USDA sponsored, with states, a series of public meetings from mid-November to mid-December, 1997, in which the agricultural community, the international trade community, consumers, and the scientific community participated. The purpose of these meetings was to give participants the opportunity to offer their perspective on the working draft guidance and provide comments, technical information, and suggested modifications to the draft guidance. The National Advisory Committee on Microbiological Criteria for Foods' Fresh Produce Subcommittee (a USDA/FDA advisory committee) was present at the first public meeting. Based on information exchanged at that first public meeting and Subcommittee members' expertise, the Subcommittee provided recommendations that were incorporated into the working draft guidance document. This revised working draft document was subsequently used as the basis of discussion at a series of meetings for the agricultural community. These "grassroots" meetings were held at six regional locations around the country during December. The agencies also presented the draft guidance to representatives of embassies and individuals associated with importing produce into the U.S. at an international meeting in December. Feedback from the agricultural community through the "grassroots" meetings and other fora is essential to be sure that the guidance being developed is practical and applicable. Development of the final guidance will draw on scientific data and

otherinformation that describes the fresh fruit and vegetable industry domestically and in countries exporting products to the U.S.

FDA, with USDA, will oversee a task force (with representation from other federal agencies and states) to assist in developing additional guidance if sound science, risk, or experience with general guidance indicate a need. The additional guidance may be tailored to reduce the potential for microbial contamination with specific pathogens (e.g., *E. coli* O157:H7, *Cyclospora*) and to reduce contamination associated with particular hazards (e.g., microbially-derived toxins) and commodities. This type of guidance can also be designed to minimize microbial contamination through particular pathways, such as control of water quality, worker sanitation and health, field and facility sanitation, and transportation and handling of produce. Options are being explored to determine the most efficient ways to provide industry with effective guidance that yields the most benefit for the resources expended. Any additional guidance will be developed through an open process involving industry, consumers, academia, states, and public health professionals, including the FDA public review and comment process.

The general guidance may be augmented as information about scientific advances and risks associated with fresh produce received from a variety of sources, (e.g., foodborne illness outbreaks and research) indicates the need for targeted guidance or refinement of the general guidance.

Timeline:

Short-term — October - December 1997

a. FDA drafted proposed voluntary GAP/GMP guidance
b. FDA and USDA held a public meeting and a meeting of the National Advisory Committee on Microbiological Criteria for Foods to solicit comments and recommendations on the guidance
c. FDA and USDA conducted grassroots and international meetings to receive comments and information from the public

Mid-term — January - May 1998

a. FDA, working with representatives from USDA, EPA, Occupational Safety and Health Administration (OSHA), and the State Departments of Agriculture and of Health from California, Florida, and Michigan, will analyze comments and information from the public, grassroots, and international meetings and revise guidance incorporating that information
b. Publish revised guidance as a proposal in the Federal Register
c. Comment period of 75 days for public to submit comments and information pertaining to the guidance

Long-term — June 1998 and beyond

a. Evaluate comments and revise guidance into final guidance
b. Publish final guidance in the Federal Register by October 2, 1998
c. Create an interagency committee to evaluate the need for additional guidance and, if additional guidance is needed, oversee and direct the development of that guidance
d. Develop a strategy to refine existing guidance, incorporating advances in science and knowledge about produce safety and information about new risks
e. Develop risk assessment techniques to use in evaluating the effectiveness of and refining (based on that evaluation) implemented food safety control strategies

Supporting Information: To complement data and information being developed domestically, comparable data and country information, such as epidemiologic data on human health and food safety legislation and regulations affecting production, handling, and storage of produce for selected countries that export produce to the U.S. will be compiled by mid-July, 1998.

Timeline:

Short-term — November 1997 - June, 1998

a. Identify and compile current data concerning primary sources of fresh fruits and vegetables
b. Identify and compile available data about domestic agricultural practices and foreign food safety legislation and regulation for selected countries that export produce to the U.S. This information will support the scientific (including evaluation of risks) approach.
c. Identify gaps in current data

Mid-term — June - August 1998

Federal and state government agencies will develop a proposal to fill data gaps in consultation with industry

Long-term — September 1998 and beyond

Using available funding, implement a plan to fill gaps.

II. Technical Assistance and Education and Outreach

Technical Assistance:

Technical expertise and resources must complement the voluntary guidance to achieve improvement in the safety of fresh fruits and vegetables. The guidance will be most effective when safety is bolstered at every step in the process, from in-field operations through distribution to the consumer. U.S. government agencies, FDA and USDA in particular, will work with appropriate U.S. and foreign government public health and agricultural agencies, as well as with industry groups, to provide technical assistance needed to support appropriate application of the guidance by the produce industry. If a foreign government is interested in learning more about the U.S. guidelines and systems for assuring the safety of domestically produced and imported fresh fruits and vegetables, overseas personnel from USDA and State Department will collaborate as necessary to facilitate these visits. Likewise, in order to provide technical assistance or followup to foodborne illness outbreaks, these overseas personnel will facilitate visits of FDA and/or Centers for Disease Control and Prevention (CDC) investigators or scientists to foreign operations to ascertain the source of problems that may pose a safety hazard in produce exported to the U.S.

USDA and FDA plan to work with a broad spectrum of representatives from the public and private sector in foreign countries and in the U.S. to promote appropriate application of the guidance and improve production and processing practices. These include officials from the health and agriculture agencies in foreign countries, the Food and Agriculture Organization, the World Health Organization, and subsidiary organizations (e.g., Pan American Health Organization), as well as exporter associations and multinational banks. In the U.S., the agencies will work with appropriate land grant colleges and universities, state agencies, and industry associations. In working with domestic and foreign groups, it is critical that in addition to technical assistance, we provide clear guidance on the legal requirements for offering fresh food for sale in the U.S. With this understanding, the foreign and domestic government, industry, and academic groups can

guide producers' decisions about what, if any, modifications of current practices are appropriate for industry to satisfy U.S. legal requirements for foods. As part of this effort, USDA and FDA will share new technologies as they are developed to enhance the safety of fresh fruits and vegetables, such as improved manure treatment methods, more sensitive analytical methods, and post-harvest treatments to reduce levels of or eliminate pathogens on produce.

Timeline:

Short-term — November 1997 - September 1998

a. Form an interagency cadre to establish procedures to develop technical assistance and education outreach programs, to identify gaps in data to understand agricultural practices, and to assess effectiveness of the programs
b. Identify ongoing programs providing technical assistance to domestic producers and selected foreign countries that export to the U.S. related to produce safety
c. Integrate the goals of the President's Directive into ongoing programs where appropriate
d. Identify gaps where technical assistance may not be available

Long-term —September 1998 and beyond

a. Develop and implement a strategy to provide technical assistance necessary to achieve the goals of the President's Directive
b. Evaluate effectiveness of GAP/GMP guidance and update the guidance accordingly

Education and Outreach: Education and outreach programs are essential to foster appropriate application of the guidance by the domestic and international fresh fruit and vegetable industry. These programs are pivotal to industry's understanding of the essential principles of the guidance, as well as the scientific and practical reasons for application of the guidance as everyday production and processing practice. Others in the distribution chain from the fruit and vegetable producers to the final user— the consumer — must be reached by these programs in order to assure that the care taken to prevent microbial contamination in growing, harvesting, processing, and transporting is not thwarted by later mishandling.

USDA, through its partnership with State Cooperative Extension Services in the United States, will provide leadership for the Directive's producer outreach and educational strategy. USDA, FDA and CDC will plan a national food safety scientific and education conference in 1998 to share current scientific and educational information on food safety risks that can further enhance the microbiological safety of fresh fruits and vegetables, to apprise scientific experts and extension professionals of the voluntary general guidance document, and to discuss methods for promoting appropriate application of the guidance. The guidance will be incorporated into extension programs focused on the best management practices in fruit and vegetable production. It will also serve as a basis for directing program resources to help assure appropriate application of production practices which minimize contamination of fruits and vegetables. State and local extension agents can play a vital role in the successful application of the guidance, since they are knowledgeable about on-farm production practices and can provide expert advice on how producers can incorporate interventions recommended in the guidance to reduce the risk of microbial contamination at the farm level.

To reach the domestic produce industry workforce, the guidance and associated educational materials must be available in native languages and must use terms understood by this diverse community. Multi-lingual materials are also needed for use in foreign countries. To meet these needs, FDA and USDA will work with industry and foreign governments to provide translations of the guidance documents, as well as associated training and information materials, as the documents are finalized.

We anticipate that education and outreach activities will reach beyond the immediate needs of the growers, harvesters, processors, and distributors of fresh produce to the wholesale and retail segments of the industry and to the consumer. Expanded education efforts will be directed to increasing awareness of how to enhance the safety of fresh fruits and vegetables, as well as about use of safe practices for handling and storing fresh produce.

The information provided at the grassroots and international meetings will help the agencies prioritize outreach activities and preparation of materials. FDA and USDA anticipate drawing on the resources and expertise of other agencies and industry groups to provide outreach and education, particularly targeted to specific regional needs in the U.S. The agencies have met with representatives of state agriculture departments and the industry to begin discussions of how best to make available needed training and information. We anticipate that industry itself will be a primary vehicle for outreach and education activities.

In the international arena, USDA will be instrumental in facilitating the development of education and training programs. The USDA's International Cooperation and Development staff can facilitate development of cooperative training programs on the guidance, in collaboration with other agencies capable of providing funding for these activities. The State Department will facilitate FDA and USDA contacts with foreign governments and industry groups to inform them of the guidance and provide technical assistance. USDA will also explore mechanisms to obtain the resources and expertise from other international organizations, such as the Food and Agriculture Organization and the Inter-American Institute for Cooperation on Agriculture, in order to facilitate discussions on produce safety issues. FDA and USDA will evaluate the scope of GAP/GMP education programs and materials needed to educate foreign governments and organizations, factoring in information provided at the international meeting.

Timeline:

Short-term — March - May 1998

a. Working with industry, develop a program to provide growers, harvesters, distributors, and other aspects of the industry with background and information about the hazards, particularly microbial, associated with fresh produce
b. FDA and USDA will convene a National food safety and education conference on fruits and vegetables to discuss the draft guidance
c. Pending finalization of the guidance, take preliminary steps to determine mechanisms for providing information and assistance to the domestic industry in applying guidance. Likewise, preliminary steps will be taken to develop a program targeted to foreign producers.

Mid-term — July - September 1998

a. FDA and USDA will develop a strategy to educate producers and promote the appropriate application of the final voluntary general guidance which involves federal agencies, states, and the industry.

b. Work with other groups (foreign governments, foreign industry groups) to develop a strategy for promoting the appropriate application of voluntary guidance

Long-term — October 1998 and beyond

a. Develop a strategy for refining outreach efforts to meet needs identified by specific producer and industry sectors.

III. Focused Inspections and Verifying Application of Guidance

Inspection and Testing: Inspections of fresh fruit and vegetable operations in combination with sampling and testing provides FDA and USDA with scientific information about the microbial quality of both domestic and imported products. Identification of microbiological problems allows implementation of prevention or intervention measures before illness occurs. It also aids in targeting educational outreach and technical assistance.

FDA will expand its fresh fruit and vegetable inspection and testing program for domestic and imported produce. Additional resources will be focused particularly on sampling products from areas, in the U.S. and abroad, where there is evidence that a potential hazard exists and preventive measures are lacking.

Verification: Verifying the application of the guidance, particularly in segments of the industry where microbial foodborne illnesses have occurred, is integral to determining its effectiveness in reducing the risk associated with fresh fruits and vegetables. The USDA and FDA will use evaluation of risks and survey techniques, such as USDA's Fruit Survey and Vegetable Survey and FDA field surveys of processors, to determine the extent of application of the guidance by both the domestic and foreign industry and the effectiveness of the GAP/GMP program in reducing the occurrence of pathogenic microorganisms and the incidence of produce-associated illnesses. The first survey will be conducted to determine current practices, specifically those practices that have the most impact on public health and those that are covered in the general guidance. This baseline information will be augmented with information from other sources, such as foreign governments and state agencies, on current practices. A second, more extensive, survey on practices will be conducted at a later date. This information — from the surveys and other sources — will be used to evaluate application of the guidance and to make necessary adjustments in the GAP/GMP program, including refinements of the guidance.

Timeline: FDA's inspection and sample collection and analysis activities will be expanded. Increased inspection and testing efforts are budget dependent and would be desirable to help evaluate the effectiveness of the general and additional guidance. The verifying activity will begin in FY 1999.

IV. Accelerated Food Safety Research

Successful implementation of this initiative relies on scientific research and characterization of the risks to public health posed by microbial contamination. The overall research goal identified in this initiative is development of cost-effective intervention and prevention strategies to reduce the incidence of foodborne illness. Research will also support development of improved detection methods useful in a variety of environments and targeted to sources of contamination. These methods will be used to support long-term surveillance and monitoring of both domestic and

imported produce at the point of production and harvest (e.g., methods for detection of *Cyclospora* and Hepatitis A on produce) and to support development of control and prevention strategies that augment use of general and additional GAP/GMP guidance.

FDA and USDA both have vigorous research programs in areas related to development of pathogen detection and quantification methodology, as well as development of control and prevention interventions. EPA and USDA research would be conducted to assess the significance of pathogen concentrations in natural (free-flowing) and agricultural water supplies and potential subsequent contamination of fruits and vegetables through irrigation practices.

FDA and USDA are individually and collectively reviewing their respective FY 1998 research projects related to fresh fruits and vegetables to identify specific research that can be accelerated. USDA and FDA have held research planning meetings with other agencies conducting food safety related research, including the CDC, EPA, Department of Defense, Department of Energy, National Science Foundation, and National Institutes of Health (NIH). In addition, the agencies have met with industry and consumer representatives to determine what food safety research is currently ongoing or in the developmental stages outside the government and to identify research needs from this outside perspective.

The agencies are developing a coordinated research plan for reducing microbial risk in produce. The research plan is scheduled to be available in early 1998. Four specific areas for research focus have been identified as: improved detection methods, resistance to traditional preservation techniques, antibiotic resistance, and development of intervention strategies. Research is currently underway in all these areas. Among the areas to be further investigated are: packaging, storage, and preservation technologies; production practices; and use of post-harvest treatments to reduce levels of unavoidable microbial contamination. NIH research on pathogenicity and clinical human disease will support both development of detection methods and the risk assessments necessary to evaluate control strategies for the target pathogens.

Research and characterization of risks is a high priority. Research on preventive technologies and intervention strategies to reduce or eliminate microbial contamination is a specific priority. Work will be conducted on manure treatment or composting techniques to assure that the manure is acceptable for application to a specific commodity. Post-harvest chemical (such as use of antimicrobial agents in wash water) and physical treatments will be investigated for fruits and vegetables, as will methods of preventing the persistence and growth of pathogens on both whole and minimally processed produce during storage and transportation. Another area of research that will be accelerated is methods development, specifically methods to detect *Cyclospora* and Hepatitis A on produce. Studies of chemical pattern recognition (trace-element fingerprints) to identify where specific foods were grown or processed will also aid in tracebacks to determine both the source of foods and the pathogens implicated in foodborne illness outbreaks.

Timeline:

Short-term — September 1997 - March 1998

a. Initiated interagency review of research related to safety of fresh fruits and vegetables
b. Research plan will be available in early 1998 that will identify fresh fruit and vegetable-related research

Long-term — April 1998 and beyond

a. Develop an ongoing process for interagency review of research progress and identification of new research needed
b. Develop schedule for making the updated research plan available periodically

V. Participants in this Initiative

The following agencies are contributing to this initiative: the Food and Drug Administration, the National Institutes of Health, and the Centers for Disease Control and Prevention in the Department of Health and Human Services; the Agricultural Marketing Service, the Agricultural Research Service, the Animal and Plant Health Inspection Service, the Cooperative State Research, Education, and Extension Service, the Economic Research Service, the Foreign Agricultural Service, the Food Safety and Inspection Service, the National Agricultural Statistics Service, the Natural Resources Conservation Service, and the Office of Risk Assessment and Cost Benefit Analysis in the U.S. Department of Agriculture; the Environmental Protection Agency; the Department of Labor's Occupational Safety and Health Administration; and the Department of Defense's U.S. Army-Natick Research Development and Engineering Center are also working on segments of the initiative.

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

FAX TRANSMITTAL FORM

DATE: 3-3-98

PAGE(S) (INCLUDING THIS FORM

IS/ARE FOR: Mary Smith

FROM: Laura Chapin 224-0574

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

****

(ADDITIONAL INFORMATION):

THE FOLLOWING 19 pp + cover

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

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

BARBARA A. MIKULSKI
MARYLAND

COMMITTEES:
APPROPRIATIONS
LABOR AND HUMAN RESOURCES

United States Senate

WASHINGTON, DC 20510-2003

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February 10, 1998

Dear Colleague:

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

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

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

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

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

Sincerely,

Barbara A. Mikulski
United States Senator

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O:\ALD\ALD98.045

S.L.C.

105TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

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

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

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

SEC. 2. CRITERIA FOR DEEMING IMPORTED FOOD ADULTERATED.

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

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

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

KEY STATISTICS ON FOODBORNE ILLNESS IN THE UNITED STATES

- **DISEASE/DEATH STATISTICS:** Up to **9,000** food-related deaths and up to **33 million** illnesses are estimated to occur each year (these numbers may actually be much higher--50-100 times higher)

- **ECONOMIC IMPACT OF FOODBORNE ILLNESS:** Hospitalization costs are estimated at over **$3 billion** per year--with costs for lost productivity estimated at **several billion dollars**

- **FOOD POISONING MAY CAUSE MORE THAN VOMITING AND DIARRHEA, INCLUDING:**
  - -spontaneous abortion
  - -birth defects, including mental retardation
  - -chronic reactive arthritis
  - -Guillian-Barre' syndrome (including life-threatening paralysis)
  - -HUS (a highly fatal disease in children causing kidney failure)

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

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

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

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

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

FDA inspects the average plant about **once every 10 years.**

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

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

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THE WHITE HOUSE

WASHINGTON

October 2, 1997

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

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

American consumers today enjoy the safest food supply in the world, and I am proud of my Administration's record in this area. We have taken significant steps to ensure that we maintain the safest food possible. We have put in place improved safety standards for meat, poultry, and seafood products, and we have begun the process of developing enhanced safety standards for fruit and vegetable juices. We have also expanded research, education, and surveillance activities through coordinated efforts of all agencies involved in food safety issues. Together, these measures will greatly improve the safety of the Nation's food supply.

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

To help accomplish this task, I plan to send to the Congress proposed legislation that will require the Food and Drug Administration (FDA) to halt imports of fruits, vegetables, or other food from any foreign country whose food safety systems and standards are not on par with those of the United States. This legislation, which will be similar to existing law requiring the USDA to halt the importation of meat and poultry from such countries, will enable the FDA to prevent the importation of potentially unsafe foreign produce. My Fiscal Year 1999 budget will provide the necessary funds to enable the FDA to expand dramatically its international food inspection force. With this greatly increased ability to inspect food safety conditions abroad and at points of entry, the FDA will be able to determine when to halt the importation of fruits and vegetables from foreign countries.

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

First, I direct the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue within 1 year from the date of this memorandum, guidance on good agricultural practices and good manufacturing practices for fruits and vegetables. This guidance should address ways to prevent potential sources of contamination, should take into account differences in both crops and regions, and should address food safety issues throughout the food production and distribution system. By providing the first-ever specific safety standards for fruits and vegetables, the guidance will improve the agricultural and manufacturing practices of all those seeking to sell produce in the U.S. market. To ensure that this guidance has the widest possible effect, I also direct the development of coordinated outreach and educational activities.

Second, I direct the Secretary of Health and Human Services and the Secretary of Agriculture, to report back to me within 90 days from the date of this memorandum with a status report and complete schedule for the good agricultural and manufacturing practices, and a plan on how to improve the monitoring of agricultural and manufacturing practices abroad, to assist foreign countries to improve those practices where necessary, and to prevent the importation of unsafe produce, including by detecting unsafe food at the dock or border. I especially urge you to consider the best ways to target inspection and testing toward those areas where problems are most likely to occur.

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

William J. Clinton

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

FOR IMMEDIATE RELEASE
November 14, 1997

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Eshoo and Pallone Move To Boost Imported Food Safety

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

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

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

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

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

(more)

Under the legislation, if an FDA inspector has requested and been denied access to the establishment or location where a food product is prepared, packed, or stored for the purpose of inspection (including sample collection), testing, or other relevant procedures, at a reasonable time and in a reasonable manner, the agency can stop the importation of that food into the United States. Further, the legislation authorizes the FDA to develop a plan for implementing this overseas food inspection program.

On October 2nd, President Clinton announced a new initiative to ensure the safety of imported and domestic fruits and vegetables. At that time, he said he would ask Congress to enact legislation that will require the FDA to halt imports of foreign fruits, vegetables, and other food products that do not meet U.S. food safety requirements. This legislation is comparable to existing law that requires the U.S. Department of Agriculture to halt the importation of potentially unsafe meat and poultry.

The President also directed the Department of Health and Human Services and the Department of Agriculture to work cooperatively with the agriculture community to develop guidance on good agricultural and manufacturing practices for fruits and vegetables within one year. This guidance will take into account differences in both crops and regions and will address potential food safety problems throughout the food production and distribution system, such as sanitation, worker health, and water quality. The guidance--the first safety standards ever developed specifically for fruits and vegetables--will improve farming and manufacturing practices for anyone who wants to sell produce in the U.S.

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

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The Washington Post

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SECTION: HEALTH; Pg. Z10

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HEADLINE: Forbidding Fruit; How Safe is Our Produce?

BYLINE: Sandra G. Boodman

BODY:

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

Not anymore.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Traveler's Diarrhea -- at Home

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

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

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

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

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

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

Parasite Packs a Big Punch

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

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

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

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

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

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

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

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

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

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

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

Searching for the Elusive Source

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Simple Steps to Reduce the Risk of Contamination From Produce

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

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

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

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

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

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

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

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

soap and hot water.

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

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

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

GRAPHIC: Photo, max hirshfeld; Photo, max hirshfeld

LANGUAGE: ENGLISH

LOAD-DATE: July 08, 1997

SAFETY OF IMPORTED FOOD ACT OF 1998
"FREE TRADE FOR SAFE FOOD"
--SEN. MIKULSKI

Importation of food PRODUCED in unsanitary conditions

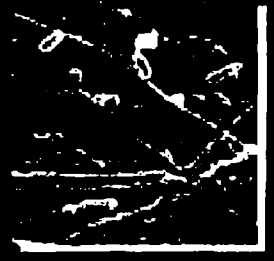
Importation of food from countries that deny FDA INSPECTION

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

Every Year

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

Least Wanted Foodborne Pathogens



E. Coli O157:H7

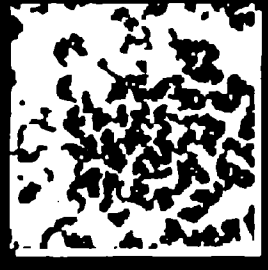
A bacterium that can produce a deadly toxin; Sources: meat, especially undercooked or raw hamburger, raw milk and produce

Listeria monocytogenes

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

Salmonella

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



Staphylococcus aureus

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

Shigella

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

Yersinia enterocolitica

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