THE WHITE HOUSE
WASHINGTON

DOMESTIC POLICY COUNCIL

FOOD SAFETY - "BAD ACTORS" IMPORTS

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COMMENTS: Here's the final import report from FDA & Treasury. It provides timelines for regulatory and internal guidance

DEPARTMENT OF THE TREASURY

DEPARTMENT OF HEALTH & HUMAN SERVICES

The Honorable William J. Clinton
President
The White House
Washington, D.C. 20500

Dear Mr. President:

As you directed in your memorandum of July 3, 1999, we are submitting the enclosed joint report on steps that the Department of Health and Human Services (HHS) and the Department of the Treasury (Treasury) will take to protect consumers from unsafe imported foods. Your memorandum directs that we target the "bad actor" importers who violate the rules and work to subvert the system by moving unsafe food into U.S. markets.

You have asked both departments to take whatever steps are possible, within existing statutory authority and resource limitations, to develop new operational procedures to protect public health. In responding to your directive, we have given particular attention to six specific objectives that you emphasized in your memorandum:

(1) Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by the Food and Drug Administration - The Food and Drug Administration (FDA) of the HHS is preparing guidelines that include criteria for identifying problem importers as well as procedures for imposition of sanctions. The U.S. Customs Service (Customs) of the Treasury is preparing guidelines for its field personnel to ensure that shipments of food products for FDA-designated problem importers can be identified at the time of arrival and held in secure storage until released by FDA.

(2) Destroy imported food that poses a serious public health threat - FDA will establish criteria for determining which health and safety violations are sufficiently serious to require destruction of the imported food. Customs currently has ample seizure and forfeiture authority, and procedures to allow FDA destruction orders to be carried out.

(3) Prohibit the re-importation of food that has been previously refused admission and has not been brought into compliance with United States laws and regulations (so called "port shopping"), and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons - FDA will publish regulations that will provide for marking of refused food products as well as other initiatives discussed in this report. Customs inspectors at ports of entry will enforce the FDA marking requirement.

(4) Set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the United States - FDA has sufficient statutory authority to issue regulations in this area, and will develop a plan to address sample

collection and laboratory issues as well as other initiatives discussed in the enclosed report.

(5) Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the United States - Customs has already published proposed regulations to increase the liquidated damages from three times the entered value to the full domestic value in cases where refused shipments are not redelivered, exported, or destroyed in accordance with law or regulation. The proposed regulations would remove the possibility of monetary gain from the illegal importation and sale of refused food.

(6) Enhance enforcement against violation of United States laws related to the importation of foods, including through the imposition of civil monetary penalties - Customs has instituted aggressive enforcement programs under existing statutory authorities that allow for the imposition of monetary penalties. Customs will ensure that FDA is aware of the assessment of civil monetary penalties against violators involving unsafe food, and FDA will ensure that Customs is aware of any events for which civil monetary penalties are an appropriate regulatory action.

The enclosed report further elaborates on our plan of action in these six areas. The report summarizes progress already made by the Food and Drug Administration and the U.S. Customs Service as well as future activities that will prevent problem importers from jeopardizing the safety of our Nation's food supply.

Sincerely,

Lawrence H. Summers
Secretary of the Treasury

Sincerely,

Donna E. Shalala
Secretary of Health
and Human Services

Enclosure

Presidential Initiative - Safety of Imported Food
Status Report

I. Background

American consumers enjoy one of the safest food supplies in the world. Enhancing the safety of the U.S. food supply is a high priority of the Clinton Administration as evidenced by funding requests for food safety initiatives, the establishment of the Food Safety Council, and directives to improve the safety of the food supply. On July 3, 1999, President Clinton expanded his food safety efforts by directing the Secretary of Health and Human Services and the Secretary of the Treasury to take additional action to further protect consumers from unsafe imported foods. While most imported foods are safe, and most importers comply with U.S. food safety requirements, a few importers try to sidestep U.S. laws to bring unsafe or contaminated food into the country. The President specifically directed the Food and Drug Administration (FDA), the agency responsible for the safety of most imported foods, and the United States Customs Service (Customs) to take all actions available to:

(1) Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA;

(2) Destroy imported food that poses a serious public health threat;

(3) Prohibit the re-importation of food that has been previously refused admission and has not been brought into compliance with U.S. laws and regulations, and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons;

(4) Set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the United States;

(5) Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the United States; and

(6) Enhance enforcement against violations of U.S. laws related to the importation of foods, including through the imposition of civil monetary penalties.

The President further directed the Secretary of Health and Human Services and the Secretary of the Treasury to consult with his Food Safety Council and relevant federal agencies, particularly the United States Department of Agriculture (USDA) and the United States Trade Representative (USTR), to develop steps in the above areas to protect consumers from unsafe imported foods.

II. This Report

The President asked the Secretary of Health and Human Services and the Secretary of the Treasury to report on the steps they will take in each area identified in his directive to protect consumers from unsafe imported foods. This report presents the status of progress made in each area and a plan for accomplishing the President's "problem importers" directive.

To meet the President's goal of curtailing the effect that problem importers may have on the safety of the U.S. food supply, the Departments will exercise the full extent of their statutory authorities to:

(1) Require controlled storage of merchandise entered by firms with a history of failing to hold products, of making false declaration, or of substituting products;

(2) Seize and/or destroy merchandise that poses a serious health threat;

(3) Promulgate regulations to require importers or consignees to mark food products that have been deemed unsafe and refused admission into the United States and prohibit the re-importation of any food product that has been previously refused entry;

(4) Promulgate regulations to establish requirements pertaining to sample collection and private laboratories;

(5) Assess liquidated damages equal to the domestic value of merchandise that has not been redelivered to Customs or that has not been exported or destroyed within the time period prescribed by law after refusal; and

(6) Collaborate more effectively in enforcing the Customs program of assessing civil monetary penalties to importers who attempt to import any food by means of any material false statement, act or omission.

In his directive, the President recognized that there are limitations on the Departments' resources and statutory authorities to take measures to protect consumers against unsafe imported foods. Included in this report are discussions of proposed rulemaking and resource costs to FDA and Customs to enact the new procedures and implement new regulations.

Because public notice and/or comment is desirable and, in some instances, required for the implementation procedures, the Departments plan to invite discussion and comment on these initiatives. This report and its accompanying operational procedural guidance and regulatory enforcement programs will be posted on the Internet sites of FDA and Customs.

The actions outlined in this report are intended to deal with problem importers and unsafe food shipments. The proposed steps are fully in accord with World Trade Organization agreements and should not pose barriers to trade for importers who routinely follow U.S. regulations and procedures.

Food is defined as articles used for food or drink for man or other animals in section 201(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)(1)). Animal food or feed is also imported into this country. Unless stated otherwise, use of the word food in this report includes animal food or feed.

III. Participants

FDA and Customs have the primary responsibility for the plans to accomplish and implement this directive. A joint task force, which developed this report and implementation plan, consisted of members representing various offices within Customs and FDA, as well as the Environmental Protection Agency (EPA), and USDA's Food Safety and Inspection Service (FSIS) and Animal and Plant Health Inspection Service (APHIS). Copies of the working draft were shared with representatives of USDA's Foreign Agriculture Service (FAS) and the USTR. The report was also submitted for comment to the President's Food Safety Council.

IV. Action Areas

1. Prevent distribution of imported unsafe food by means such as requiring food to be held until reviewed by FDA.

Status: FDA and Customs have developed procedures by which importers who have repeatedly distributed imported foods before they were released by FDA, or have provided the U.S. government with false or misleading information on imported foods, will be required to store future shipments in secure facilities operated by an independent third party, under the supervision of Customs, until FDA has reviewed and released the shipments into domestic commerce. If FDA ultimately determines that the food is not admissible into the United States, the importer would be allowed to remove the food from the secure storage facility only for immediate export or destruction. The importer would bear storage costs. Since FDA and Customs expect that, nationwide, no more than two or three dozen importers will be subject to this procedure at any given time, there should be no significant impact on port storage requirements.

Plan: Customs port directors already possess sufficient authority to implement this plan. FDA will draft internal guidance for its field personnel on how to work with Customs under this plan. FDA's internal guidance will include criteria for identifying problem importers as well as

internal procedures for submission of recommendations for review and concurrence by FDA headquarters. Customs will draft internal guidance for its field personnel to ensure that problem importers are identified and that the food products imported by the problem importers are held in secure storage until released by FDA.

Timeframe:

October-December 1999

a. Customs has drafted and will issue field guidance
b. FDA will draft and issue field guidance

January-March 2000

a. FDA will identify importers meeting the criteria for secure storage
b. Customs will load FDA importer data into Customs Screening System (OAS)
c. Implementation of the program

2. Destroy imported food that poses a serious public health threat.

Status: Under section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), the Secretary of the Treasury is directed to destroy any product refused admission into the United States, unless it is exported within 90 days following such refusal. FDA and Customs have discussed procedures whereby, once FDA has determined that a shipment of imported food poses a significant risk to the public health or safety, rather than issue a Refusal of Admission, FDA will refer the shipment to Customs for seizure under 19 U.S.C. 1595a(c)(importation contrary to law). Following forfeiture procedures, the product will be destroyed. These procedures would be consistent with seizure actions normally taken by the FDA against domestic food products that pose a serious risk to public health.

Under Customs' forfeiture provisions, the government is responsible for storage and destruction costs. Preliminary estimates are that approximately 1,500 destructions will occur annually and that the government's cost will range from 1.5 to 3 million dollars. This procedure will impact Customs resources as funds have not been specifically appropriated for destruction of seized foods.

Plan: This plan will use existing Customs seizure and forfeiture authority and procedures. FDA will identify criteria for determining which health and safety violations are sufficiently serious to require destruction of the imported food using FDA's Class I Recall criteria as a basis. Also, FDA will develop guidance for its field personnel on submission of recommendations to FDA headquarters for Customs seizure/forfeiture/destruction actions. Customs will develop guidance for its field personnel to expedite processing of FDA seizure/forfeiture/destruction requests.

Timeframe:

October - December 1999

a. FDA will develop criteria for identifying which health and safety violations are sufficiently significant to require destruction of the imported food

b. FDA will develop guidance for the field on submission of recommendations to FDA headquarters for Customs seizure/forfeiture actions

c. Customs will draft and issue field guidance

January - March 2000

Implementation of the program

3. Prohibit the re-importation of food that has been previously refused admission and has not been brought into compliance with U.S. laws and regulations, and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons.

Status: FDA, in consultation with Customs, is drafting a proposed rule regarding the marking of refused food shipments. FDA is considering requiring an importer or consignee to affix a permanent mark to the outside container of the food product and to an invoice, bill of lading, or other shipping document accompanying the food. (If the mark cannot be affixed to an outside container, as in the case of bulk agricultural products, the proposed rule would consider only requiring the mark to be affixed to an invoice, bill of lading, or other shipping document accompanying the food.) Additionally, the proposed rule would consider requiring that the mark be affixed before the food product leaves the port where refusal occurred and be clear, conspicuous, and permanent. The mark would be similar to a mark used by USDA on imported meat and meat food products that are refused entry into the United States. The mark would facilitate the identification of previously refused food products.

FDA is also considering prohibiting importers and consignees from: 1) refusing to affix a mark on a refused food product; 2) importing or offering to import any food product that has been previously refused admission into the United States and marked as such unless it has been reconditioned to conform with U.S. law; and 3) altering, removing, tampering with, or concealing a refused mark. Failure to comply could result in seizure or other penalties, as appropriate.

Plan: FDA will finalize a proposed rule and publish it in the *Federal Register* for public comment. The agency will develop a plan to invite comment and discussion about marking refused food products as well as other initiatives discussed in this report. FDA has sufficient statutory authority to issue regulations in this area. Customs would verify the FDA export marking requirement. The additional budgetary need for Customs to enforce this new requirement is estimated to be 28 person-years.

Timeframe:

October 1999 - April 2000

a. FDA to complete drafting of the proposed rule and publish in the *Federal Register* for public comment
b. FDA will draft a guidance document for field implementation
c. Customs will draft a guidance document for field implementation

May 2000 - August 2000

a. FDA to evaluate comments submitted to the proposed rule
b. FDA to prepare a final rule

September - October 2000

a. FDA to publish final rule in the *Federal Register*
b. FDA will issue field guidance
c. Customs will issue field guidance

4. Set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the United States.

Status: FDA is considering proposing a rule that would establish requirements for importers and other persons who use sample collection services and/or private laboratories to demonstrate compliance with FDA law, and would establish requirements and standards for the collection and analysis of samples. The proposal would consider requiring persons who use sample collection services and private laboratories to notify FDA of their intent to use a sample collection service or a private laboratory and to explain the reasons for the sample collection or laboratory analysis. The proposal would also consider provisions to ensure that samples are properly identified, collected, maintained, and analyzed. Additionally, the proposal would consider requiring laboratories analyzing samples to be accredited, to use validated or recognized methods to analyze samples, and to submit analytical packages directly to FDA. The proposed rule would be intended to help ensure the integrity and scientific validity of data and results submitted to FDA.

Plan: FDA has sufficient statutory authority to issue regulations in this area. FDA will finalize a proposed rule and publish it in the *Federal Register* for public comment. FDA will develop a plan to invite comment and discussion about sample collection and laboratory issues as well as other initiatives discussed in this report.

Timeframe:

October 1999 - April 2000

a. FDA to complete drafting of the proposed rule and publish in the *Federal Register* for public comment
b. FDA will draft guidance document for field implementation

May 2000 - August 2000

a. FDA to evaluate comments submitted to the proposed rule
b. FDA to prepare a final rule
c. Customs to draft guidance document for field implementation

September - October 2000

a. FDA will publish final rule in the *Federal Register*
b. FDA will issue field guidance
c. Customs will issue field guidance

5. Increase the amount of the bond posted for imported foods when necessary to deter premature and illegal entry into the United States.

Status: Current Customs regulations provide for the assessment of liquidated damages under an import bond equal to three times the entered value of the shipment of food when the importer defaults on the condition of the Customs bond concerning redelivery of the goods. The entered value, however, is generally the price paid by the importer for the merchandise (with certain minor adjustments) prior to shipment to the United States. If a shipment is refused admission by FDA and not redelivered to Customs, exported, or destroyed in accordance with law or regulation, liquidated damages are assessed for breach of the bond. The General Accounting Office (GAO) has reported that even liquidated damages of three times the entered value of the shipment may not deter the illegal sale of imported food because the value of the food on the domestic retail market (i.e., the domestic value) may be far greater than three times the entered value.

Responding to GAO's concern, on August 2, 1999, Customs published a proposed rule to increase the liquidated damages from three times the entered value to the full domestic value in cases where refused shipments are not redelivered, exported, or destroyed in accordance with law or regulation (64 Fed. Reg. 41851). Since the importer normally sells at the domestic value, the proposed rule would remove any possibility of monetary gain from the illegal importation and sale of refused food.

Plan: The comment period for this rule closed October 1, 1999. Customs will conduct an analysis of comments and subsequently draft a final rule for publication in the *Federal Register.*

Timeframe:

October-December 1999

Customs will analyze comments and draft a final rule

January-March 2000

Customs will publish the final rule in the *Federal Register*

6. Enhance enforcement against violations of United States laws related to the importation of foods, including through the imposition of civil monetary penalties.

Status: Customs has instituted aggressive enforcement programs under existing statutory authorities that allow for the imposition of monetary penalties. Under 19 U.S.C. 1592, Customs can penalize any person including any importer that enters or attempts to enter any food (including meats and poultry) by means of any material false statement, act or omission. Penalties can be issued in amounts up to the domestic value of merchandise so imported. Under 19 U.S.C. 1595a(b), Customs can assess penalties against any parties that attempt to import merchandise contrary to law. Penalties assessed under 1595a(b) are also in an amount equal to the domestic value of the merchandise. Customs is successfully using this latter statute against importers that, at the time of exportation of food that has been refused entry by FDA, attempt to substitute other merchandise in place of that which has been refused. In addition to the above, FDA and Customs have pursued, and will continue to pursue, joint criminal investigations and prosecutions, as appropriate.

Plan: While this procedure is currently in operation at Customs, FDA is not always aware of the assessment of civil monetary penalties involving importers of foods. Customs will take steps to ensure that FDA is aware of the assessment of civil monetary penalties against violators involving unsafe food and that Customs is aware of any events for which civil monetary penalties are an appropriate regulatory action. FDA and Customs will take steps to ensure that USDA's Food Safety and Inspection Service is aware of any such regulatory actions that may include meats and poultry.

Timeframe:

October-January 2000

a. FDA will issue field guidance
b. Customs will issue field guidance
c. FDA and Customs will meet with FSIS to discuss appropriate procedures and field guidance

V. Outreach to Public and Trade

Many of the planned activities described in this report represent a significant change in operation of the FDA import program. FDA plans to conduct a series of public meetings to present and discuss these planned activities to both the trade and to the public. Customs will participate in the public meetings and will invite discussion of procedural changes. Where appropriate, the procedural changes will be posted on each agency's Internet website. The proposed and final rules will also be posted on the appropriate agency's Internet website.

VI. Conclusion

The development and implementation of the planned activity in the six areas specified by the President will increase the tools available to the FDA and Customs to protect American consumers from unsafe imported foods. FDA and Customs will use these tools to focus on problem importers. Many of the procedures described in this report will likely serve as a deterrent not only to problem importers but also to any others considering whether to sidestep U.S. laws to bring unsafe or contaminated food into the country.

FDA and Customs anticipate continuing efforts to work together, in cooperation with EPA, FSIS, APHIS, FAS, USTR and the President's Food Safety Council, to protect consumers from unsafe imported food. FDA and Customs also look forward to working with Congress on ways to enhance the agencies' efforts to further ensure the safety of the U.S. food supply.

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