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REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

AGC00146

Food And Drug Administration's Program For Regulating Imported Products Needs Improving

Department of Health, Education, and Welfare AGC00022
Department of the Treasury AGC00038

Lack of information on products entering the United States limits the effectiveness of the Food and Drug Administration's efforts to regulate imported products before they are sold to the American public. Without such data the agency cannot determine how effective its import surveillance is; it cannot assess the extent that imports may be violating laws or regulations; and it has no assurance that all imported products are inspected periodically.

Given FDA's limited coverage of imported products at the various U.S. ports of entry, additional surveillance measures are needed, particularly against those imported products which continually violate its regulations.

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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164031(2)

To the President of the Senate and the
Speaker of the House of Representatives

This report shows that a lack of information on products entering the United States limits the Food and Drug Administration's efforts to regulate imported products. The Food and Drug Administration, Department of Health, Education, and Welfare, and the United States Customs Service, Department of the Treasury, are responsible for administering the activities discussed in this report.

We initiated this review because of the large volume of products subject to Food and Drug Administration regulation which enter the United States each year and the concern over the safety of such products.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

We are sending copies of this report to the Director, Office of Management and Budget; the Secretary of Health, Education, and Welfare; and the Secretary of the Treasury.

Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

FOOD AND DRUG ADMINISTRATION'S PROGRAM FOR REGULATING IMPORTED PRODUCTS NEEDS IMPROVING

AGC00156

D I G E S T

With the assistance of the U.S. Customs Service, the Food and Drug Administration is responsible for making sure that about $24 billion worth of foods, drugs, biological products, medical devices, radiation emitting electronic products, and cosmetics imported each year comply with Federal laws and regulations before being sold in the United States.

Products failing to meet Federal requirements are detained at ports of entry for export, destruction, or reconditioning. (See p. 1.)

Most imported products subject to Food and Drug Administration regulations--83 percent in fiscal year 1975--are not inspected. (See p. 8.)

The Food and Drug Administration does not maintain specific enough information on the types and volume of imports to know whether all the various imported products (types of fish or chocolate for example) are inspected.

Without such data the agency cannot determine how effective its import surveillance is nor can it assess the extent that imports comply with regulations.

Food and Drug Administration evaluations of programs to enforce compliance with its import regulations have been slow, thus minimizing their usefulness. Some import programs have not been evaluated.

Although the Food and Drug Administration relies on Customs to notify it of products being imported, Customs has not always done

so. In some cases, Customs has not known what products were subject to Food and Drug Administration regulation; in others, the agency informed Customs it was not interested in inspecting the products.

Customs issues special permits allowing immediate delivery of imported products when (1) this is necessary to avoid loss or inconvenience to the importer or to eliminate port congestion and (2) the importer files a bond with Customs. The bond assures payment in case an importer fails to make the products available for inspection or other regulatory action.

In some cases, the Food and Drug Administration wanted to inspect products moved under special permit but could not do so because the products were marketed before samples could be collected. In other cases, the Food and Drug Administration sampled products and found they did not comply with regulations, but the products had already been marketed and could not be recovered.

The failure to sufficiently penalize importers who marketed their products before the Food and Drug Administration had approved them has contributed to this problem. Although the Food and Drug Administration feels that repeat violators should be dealt with more severely, it had no system for tracking bond violators nationwide.

GAO proposed that the Food and Drug Administration expedite developing a national list of importers who violate Custom's redelivery bonds. The agency has complied with this proposal.

Because of the Food and Drug Administration's limited coverage of imported products, additional surveillance measures are needed--particularly over products which continually violate regulations.

RECOMMENDATIONS

The Secretary of Health, Education, and Welfare should direct the Commissioner of the Food and Drug Administration to:

--Establish a system to provide comprehensive information on specific products showing volume imported, volume inspected, and inspection results. The system should set up a way to (1) guarantee that all imported products are periodically inspected and (2) assess the quality of the various imported products. (See ch. 2.)

--Evaluate, sooner, the effectiveness of the compliance programs. (See ch. 2.)

--Provide Customs with updated lists of products subject to Food and Drug Administration regulation and periodically review Customs entry documents to identify products under the Food and Drug Administration's jurisdiction which were not referred for regulatory action. (See ch. 3)

--Develop uniform criteria for district offices to follow in recommending the penalty that should be imposed when importers violate Customs redelivery bonds. (See ch. 3)

--More aggressively develop cooperative agreements with those countries that continually export violative products to the United States and which can implement such agreements. (See ch. 4.)

--Require importers to certify that imported products meet the requirements of the Federal Food, Drug, and Cosmetic Act. (See ch. 4.)

The Secretary of the Treasury should direct the Commissioner of Customs to notify, or require importers to notify, the Food and Drug Administration before Customs issues a special permit allowing importers to move products from the port of entry under immediate delivery procedures. (See ch. 3.)

AGENCY COMMENTS

The Department of Health, Education, and Welfare questioned whether some of GAO's recommendations provided the most appropriate solutions to the problems. (See pp. 13, 24, and 33 and app. II.)

The Department said the Food and Drug Administration believes that the amount of penalty imposed for violating Customs redelivery bonds should be determined case by case. GAO believes that specific criteria for assessing the facts and circumstances of each violation would provide a uniform basis for setting equitable penalties. (See p. 25.)

HEW replied that the Food and Drug Administration does not believe that importers certifications (that imported products are manufactured, processed, or packed under sanitary conditions and that they are not restricted or forbidden for sale in the country in which they were produced or from which they were exported) would be beneficial or achieve the intended result. GAO, however, believes that such certifications would provide more assurance than the Food and Drug Administration has now.

Such certifications could be particularly useful in those cases where the agency has not established safety and effectiveness standards for certain products it is responsible for regulating. (See p. 34.)

The Department of the Treasury generally agreed with GAO's recommendations pertaining to Customs. (See p. 24 and app. III.)

Contents

ABBREVIATIONS

EDRO	Executive Director of Regional Operations
FDA	Food and Drug Administration
FD&C	Federal Food, Drug, and Cosmetic Act
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare

CHAPTER 1

INTRODUCTION

The Food and Drug Administration (FDA), Department of Health, Education, and Welfare (HEW), estimates that approximately $24 billion worth of imported foods, drugs, biologics, medical devices, radiation emitting electronic products, and cosmetics enter the United States annually. FDA, assisted by the Department of the Treasury's U.S. Customs Service, is responsible for insuring that these products meet the requirements of pertinent Federal laws and regulations before they are marketed in the United States. Products failing to meet these requirements are detained at the port of entry and may be exported, destroyed, reconditioned, or relabeled to bring them into compliance.

FDA is responsible under the Federal Food, Drug, and Cosmetic Act (FD&C act), as amended (21 U.S.C. 381), for insuring that imported products subject to its regulation

--have not been manufactured, processed, or packed under insanitary conditions,

--are not restricted for sale in the country in which they were produced or from which they were exported, or

--are not adulterated or misbranded.

Foods must be safe, pure, and wholesome; human and animal drugs, biological products, and medical devices must be safe and effective; and cosmetics must be safe or they violate the adulteration provisions of the FD&C act. In addition, the misbranding provisions of the act require that these products be honestly labeled.

FDA also administers several other Federal laws which affect imported products: (1) the Fair Packaging and Labeling Act (15 U.S.C. 1451), which prescribes labeling requirements to prevent economic deception and misbranding of food products, (2) the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263b), which concerns the control of unnecessary harmful levels of radiation emitted by electronic products, (3) the Tea Importation Act (21 U.S.C. 41), which requires that imported tea be examined for purity, quality, and fitness for consumption, (4) the Import Milk Act (21 U.S.C. 141), which requires that imported milk and cream be sanitary, and (5) the

Public Health Service Act (42 U.S.C. 262), which requires that biologic products meet safety, purity, and potency standards.

The FD&C act requires Customs to deliver to FDA, upon request, samples of imported products that are subject to FDA regulation. In practice, however, FDA generally collects its own samples. To assist FDA, Customs (1) notifies FDA of products being imported and (2) requires brokers, agents, or shippers (hereafter referred to as importers) to post a bond on imported products distributed to owners or consignees pending FDA approval for release into U.S. commerce.

According to FDA, the United States has 371 ports of entry, including airports, seaports, and border stations, where products subject to its regulation enter the country. Over 75 percent of the imports are shipped, making seaports the most common entry points.

FDA has six operating bureaus organized along product lines for foods, veterinary medicine, radiological health, human drugs, medical devices, and biologics. The bureaus usually develop compliance programs specifying their objectives for surveillance of imported products.

FDA's day-to-day surveillance of imported products consists primarily of wharf examinations 1/ and laboratory analyses or other examinations of samples collected from individual shipments received at the various ports of entry. See pictures on the following pages for examples of FDA's import inspection activities.

FDA district offices administer FDA's import activities at the various U.S. ports of entry. The Executive Director of Regional Operations (EDRO) at FDA headquarters in Rockville, Maryland, provides overall coordination and direction of their activities.

FDA's appropriation for fiscal year 1976 was about $208 million, of which about $64 million was used for surveillance and compliance activities. About $9 million (or 14 percent) was for the surveillance of imported products. Most of FDA's import resources are concentrated

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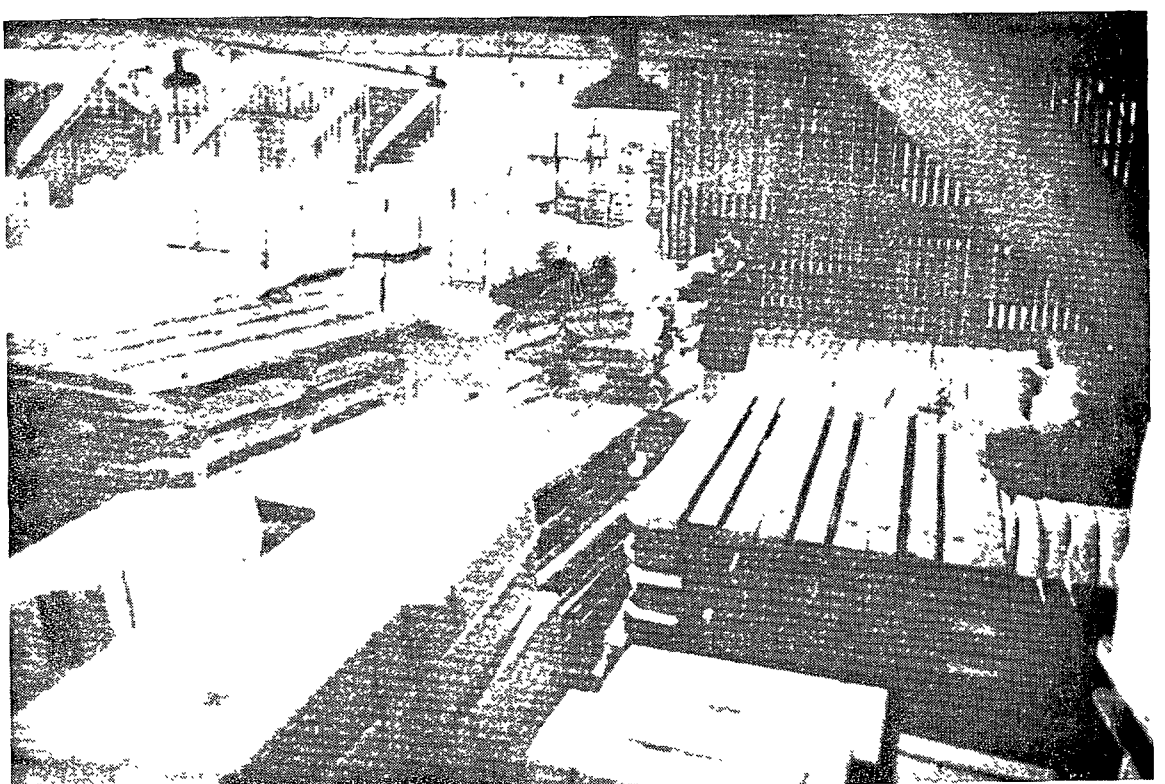
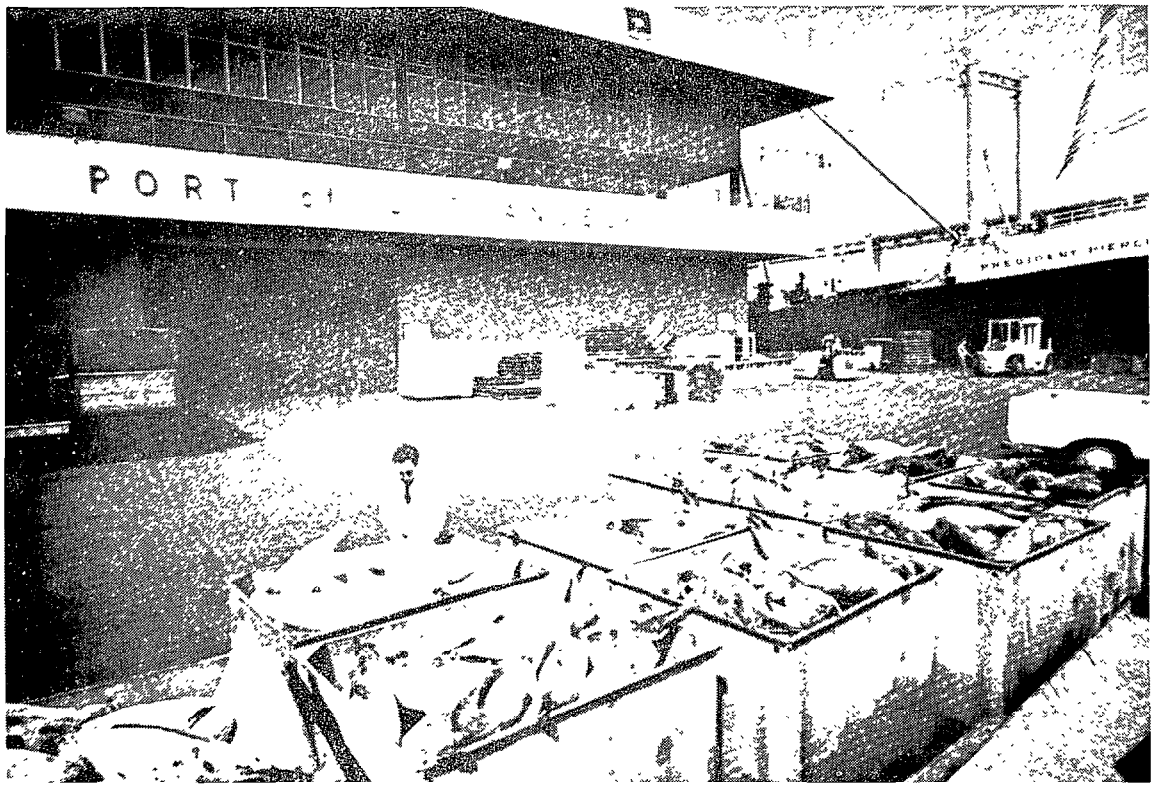
1/Wharf examinations are physical inspections of products on wharves, on piers, and in warehouses.

IN A DOCKSIDE WAREHOUSE, FDA INSPECTORS COLLECT SAMPLES OF IMPORTED SPICES AND MAKE A PRELIMINARY VISUAL INSPECTION BEFORE LABORATORY ANALYSIS.

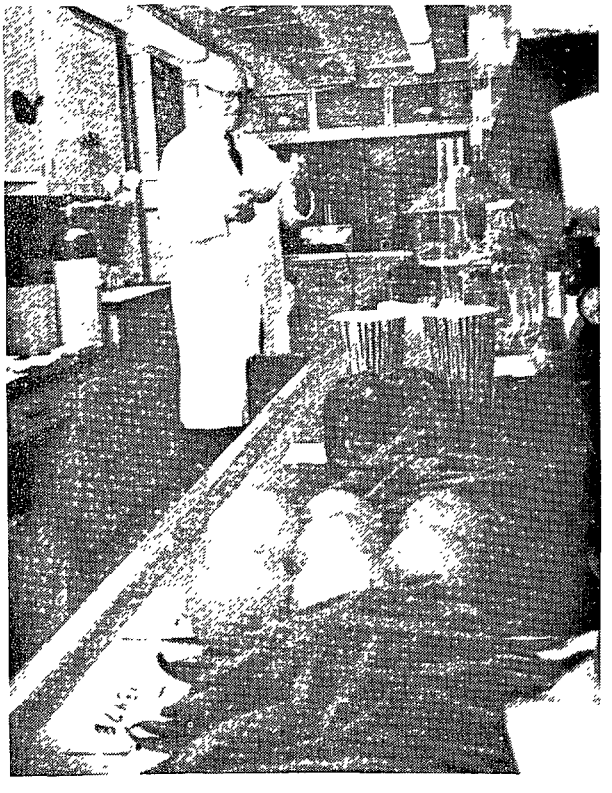


FDA INSPECTOR IN PIER WAREHOUSE MAKES VISUAL CHECK AND TAKES SAMPLES OF PERUVIAN CORN TO ANALYZE FOR INSECT AND RODENT INFESTATION.

Source FDA papers, April 1968 - October 1970



FDA INSPECTOR AT PIER CHECKS UNLOADED FROZEN TUNA FOR DECOMPOSITION.



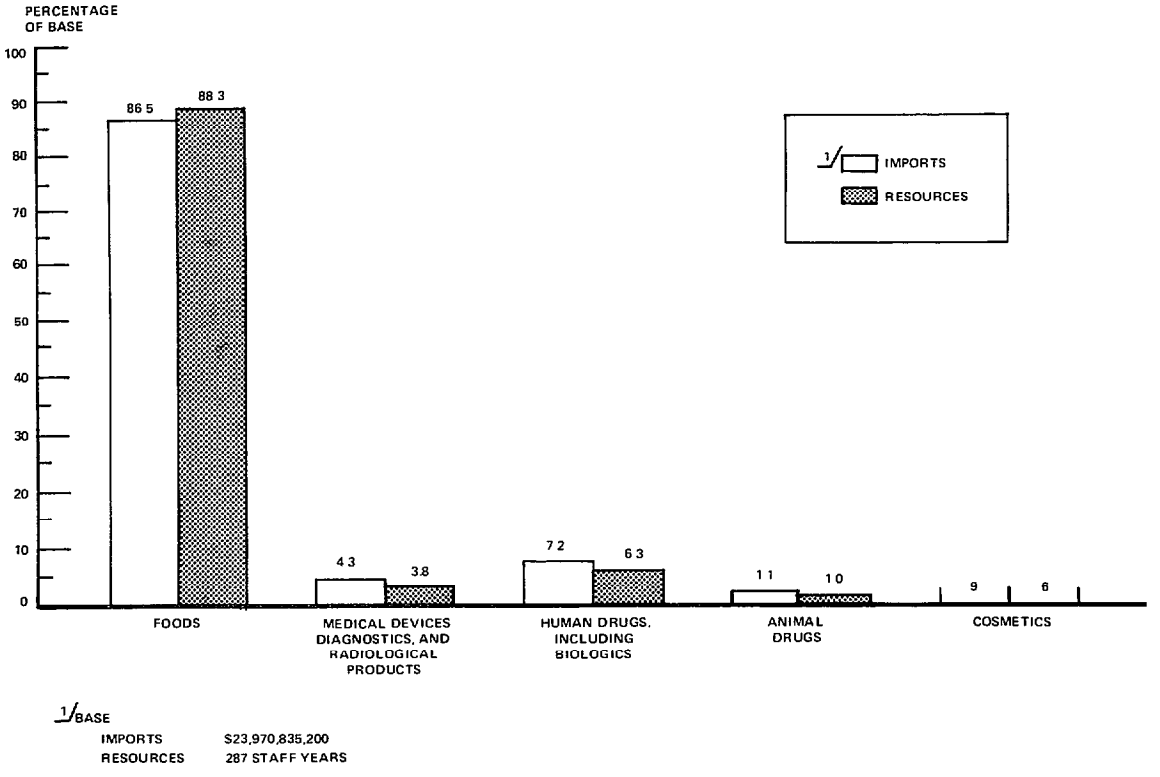
CHEMIST IN FDA LAB TESTS MEXICAN PEPPERS FOR PESTICIDE RESIDUES.

Source: FDA papers, April 1968 - October 1970

FDA INSPECTOR IN COLD STORAGE WAREHOUSE BORING INTO FROZEN CANADIAN SALMON AND HALIBUT.

FDA INSPECTORS TAKE SAMPLES OF CELERY SEED FROM INDIA.

on food products, which account for about 90 percent of the dollar value of all FDA-regulated imports. The following table shows the percentage of FDA's fiscal year 1976 import resources (287 staffyears) allocated to product categories and the percentage of the dollar volume for each category.



1/BASE

IMPORTS	$23,970,835,200
RESOURCES	287 STAFF YEARS

SCOPE OF REVIEW

Our objective was to evaluate the effectiveness of FDA's program for regulating imported products. We reviewed pertinent laws, regulations, policies, and procedures and examined selected transactions to assess FDA and Customs' operating practices and controls for preventing adulterated and/or misbranded FDA-regulated products from entering U.S. commerce. We interviewed FDA and Customs employees and officials that supervise and administer import activities.

Our review was made at FDA headquarters in Rockville, Maryland, and Washington, D.C.; at Customs headquarters in Washington, D.C.; and at FDA and Customs district offices in Los Angeles, New York, and Philadelphia. About 47 percent of all imports subject to FDA regulation enter ports of entry in these districts.

CHAPTER 2

LACK OF DATA LIMITS EFFECTIVINESS OF IMPORT REGULATION

The primary objective of FDA's import program is to prevent adulterated and/or misbranded imported products from being marketed in the United States. To effectively carry out such a program, FDA must know what products are entering the United States, whether the products are being inspected, and the results of the inspections. Also, the program should be evaluated periodically to determine whether its intended objectives are being met.

The data FDA maintains on the types and volume of products imported is not specific enough to enable it to know whether all imported products are inspected. Moreover, FDA has not made timely evaluations of its inspection activities. Comprehensive data for each type of product showing the volume imported, volume inspected, and inspection results should help FDA to improve the effectiveness of its import inspection activities and to better assess the quality of imported products.

COMPREHENSIVE DATA NEEDED ON IMPORTED PRODUCTS

The majority of imported products subject to FDA regulation are not inspected. Although FDA's inspections have been increasing, only about 17 percent of the entries 1/ of the various FDA-regulated products imported during fiscal year 1975 were inspected.

Each of FDA's six operating bureaus is responsible for developing and issuing annual compliance programs to guide district office inspections of imported products. There are two types of compliance programs--general and specific. A general compliance program provides broad inspection surveillance over imported products to determine which products warrant regulatory action. The general programs do not specifically identify products to be inspected but

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1/An import entry represents a transaction valued at over $250 which importers are required to file with Customs.

permit each district to select such products. Specific compliance programs are intended to focus increased surveillance on a problem product to determine the extent of the problem and the need for additional corrective measures.

The compliance programs represent the annual workplan which establishes the overall import program goals in terms of the number of wharf examinations, sample collections, and sample analyses to be made by each district office. While the workplan provides the basis for the district offices' inspection activities, it gives the districts enough flexibility and latitude to meet problems unique to their region or district area. During fiscal year 1975, about 85 percent of the inspections were made under general compliance programs; the remainder were under specific compliance programs.

FDA headquarters officials told us that the district offices are allowed such broad latitude because field inspectors know which products are being imported and which are more likely to be violative. This information is not available at the FDA headquarters level.

According to an EDRO official, the district offices should consider the following factors in selecting imported products for inspection under general compliance programs:

--Volume of product entering the port.

--A weekly listing of all violative products detained by FDA nationwide.

--Alerts issued on potentially violative products having national significance.

--Previous violative history of importers and of products being imported.

--Other leads to potentially violative products from news items, trade journals, complaints by consumers and competitors, and general knowledge of the cultivation and/or processing of the product in foreign countries.

However, FDA district office officials said inspectors' knowledge, judgment, and experience primarily determine which products are inspected. Districts generally did not have information on the volume of each product entering their ports or historical information on problem countries,

shippers, or products; therefore, such factors could not be considered in planning inspection work. Moreover, FDA did not know which products entered the country without being inspected.

EDRO gives the districts information on the volume of products entering the various ports of entry covered by each district. EDRO compiles this information from data accumulated annually by the Bureau of Census on the basis of import documents furnished by Customs.

Information on about 2,300 FDA-regulated import products is accumulated under about 87 broad product categories. (See app. I.) For example, imports of about 200 different types of fresh, frozen, canned, and cured fish products, including products such as anchovies, blue fish, flounder, and tuna, are accumulated under the category "fish and fish products." Such an aggregation makes it virtually impossible to determine the amount of each product imported. Information on many other imported products is similarly maintained. District office officials said the information was of limited use because FDA does not know for each product the total volume imported or the volume imported from each country. While EDRO recognizes that better statistical data on the volume of imported products subject to FDA regulation is needed, little has been done to develop such data.

The districts also received only limited information on inspection results of imported food products. Similar inspection data was not available on other FDA-regulated products such as drugs, medical devices, or cosmetics. A Bureau of Foods official told us that the inspection data was intended to help the districts decide whether to increase or decrease inspection of imported food products under the Bureau's general compliance program. One district office official told us, however, that the data's use was limited because it was compiled on a national rather than district basis and the information was grouped by broad product categories making it practically impossible to identify the inspection results on specific products.

EDRO officials told us they are developing a computer program which will list samples analyzed and analysis results by compliance program for each FDA bureau. This data, however, will not accurately portray a product's overall compliance rate because wharf examinations will not be considered. Further, the data will be based on FDA's present system of grouping products in broad categories. In our view, the data provided under this system is not specific enough to provide detailed information on individual products.

EVALUATIONS OF COMPLIANCE PROGRAMS NEED TO BE MORE TIMELY

Federal programs should be evaluated periodically so that management can determine whether the programs are achieving their intended purposes. According to FDA's "Staff Manual Guide," evaluation reports are needed to insure that

> "* * * field program activities are efficiently contributing to the attainment of FDA objectives. The information in these reports will be used by the Bureaus to measure the compliance state of industry and the existence of product or process problems; to modify existing field programs, where necessary; to concentrate resources on substantial regulatory problems; to provide a better description of program results to the Commissioner; to improve field-headquarters communication; and to provide a desired and understandable communication to consumers."

FDA evaluations of its import compliance programs have generally taken too long, thus minimizing their usefulness. Some import programs have not been evaluated.

For fiscal year 1975, FDA issued 20 general or specific import compliance programs--17 compliance programs for imported foods and 1 each for imported drugs, acupuncture devices, and electronic products.

In January 1974 FDA's Associate Commissioner for Compliance directed FDA bureaus to evaluate all compliance programs completed after July 1, 1974, and to submit the evaluation reports to the FDA Commissioner for approval within 3 to 12 months after the bureaus received program data from the field. As of December 1976, only 1 evaluation of the 20 fiscal year 1975 import compliance programs had been completed. The completed evaluation was on FDA's compliance program for imported dates. The evaluation showed that 13 percent of the samples examined contained insect infestation, insect excreta, and/or dead insects and were consequently denied entry into the United States. The fiscal year 1975 rejection rate was more than double the prior year's rate.

Evaluations of some fiscal year 1975 programs, including programs for imported drugs, acupuncture devices, and food standards, were not made.

Our review of the fiscal year 1975 compliance programs showed that the objectives of some of the programs were not being met.

For example, FDA's general compliance program for food sanitation is intended to reduce the incidence of microbiologically-contaminated and filthy foods. About 46 percent of FDA's total import inspection effort is spent on products covered by this program. FDA devotes a large amount of resources inspecting the sanitation condition of a number of imported products such as spices, coffee beans, and cocoa beans; however, the rate of insanitation found in the samples inspected has remained relatively high. FDA's inspection of imports classified under the category "coffee and tea" (of which 90 percent is coffee) showed a violative rate of 23, 47, and 40 percent for fiscal years 1973, 1974, and 1975, respectively. Similarly, FDA's inspection of imports classified under the category "candy, chewing gum, chocolate, and cocoa products" (of which about 60 percent is cocoa beans) showed a violative rate of 56, 53, and 35 percent for the same 3 fiscal years.

FDA Bureau of Foods officials told us that food products are usually sampled and analyzed when violations of individual product shipments are suspected, rather than on a random basis which considers the total volume of the products expected to be imported. Inspection results can only be related to products sampled from a particular shipment and not to all such imported products. Because of the way products are selected for inspection, according to these officials, it is difficult for FDA to get an accurate picture of a product's overall compliance.

We talked with officials in each FDA bureau and obtained information on the progress being made to evaluate the fiscal year 1975 import compliance programs. According to these officials:

--Evaluation reports have not been completed for imported food products because of a lack of reliable program data, delays in receiving data from the field, and limited staff.

--FDA's inspection of imported drugs has not been evaluated because of a lack of data on what was imported and inspected.

--The evaluation of the Bureau of Radiological Health's imported electronics products compliance program had not been finalized as of the end of January 1977.

--The Bureau of Medical Devices and Diagnostic Products compliance program for imported acupuncture devices was not evaluated because of the low priority the bureau assigned these devices and the lack of sufficient staff to make the evaluation. A Bureau official told us the program was dropped at the end of fiscal year 1976 because of the low medical risk these devices posed to consumers compared to other medical devices the bureau is responsible for regulating. (See p. 17 for information on FDA's regulation of other imported medical devices.)

CONCLUSIONS

The lack of adequate information on products entering the United States limits the effectiveness of FDA's efforts to regulate imported products. Without such data, FDA cannot adequately evaluate its import surveillance activities or assess the extent to which violative imports are entering. In addition, it has no assurance that all imported products are periodically inspected.

Also, FDA has not been timely in evaluating the effectiveness of its import compliance programs. Only 1 evaluation has been completed for the 20 fiscal year 1975 compliance programs.

RECOMMENDATIONS

We recommend that the Secretary, HEW, direct the Commissioner of FDA to:

--Establish a system to provide comprehensive information on specific products, showing the volume imported, the volume inspected, and the inspection results. The system should provide a basis for insuring that all imported products are periodically inspected and for assessing the quality of the various imported products subject to FDA regulation.

--Evaluate, in a more timely manner, the effectiveness of the compliance programs to insure that their objectives are being met.

AGENCY COMMENTS AND OUR EVALUATION

In commenting on an earlier version of this report (see app. II), HEW said that FDA, in its fiscal year 1979 plan,

has proposed to develop an information system on imported products which will include most of the specifications we recommended. HEW said the proposed data system will not be able to determine the compliance status of all imported products unless a substantial share of inspection resources are devoted to a controlled sampling plan; but FDA's experience with similar sampling programs suggests that assessing the quality of every import commodity is not feasible at current resource levels. However, it will provide information on the volume of products imported, those inspected by FDA, and the results of those inspections. Although the system will not provide for controlled sampling of imports, we believe it should give FDA a better basis for assessing its import inspection activities and determining the quality of imported products.

According to HEW, FDA will continue to use data tapes from the Bureau of Census, which lists the volume of imports for each commodity contained in the Tariff Schedules of the United States Annotated, until the new system is operational. HEW said that although these data are not made available at the level of detail we recommended, their use at the district level along with FDA-maintained import inspection data will provide a consistent base of information for determining the extent of imported products entering the United States.

HEW said it is also proposing legislation which would provide an effective means of determining the location and products of foreign food processing establishments who export to the United States. HEW said that by providing for the registration of foreign food manufacturers, the proposed legislation would also enable the Secretary to directly advise foreign food processors who export their products to the United States of current regulatory requirements, rather than continuing his reliance upon importers to be aware of those requirements and to advise such processors.

Regarding our recommendation that FDA evaluate in a more timely manner the effectiveness of the compliance programs to insure that their objectives are being met, HEW agrees that evaluation plays an important role in assessing program effectiveness.

HEW noted, however, that it should not be assumed that a program evaluation has not been accomplished simply because a formal document has not been submitted to the Commissioner. HEW said that frequently the most important evaluation of a compliance program occurs at lower levels of the organization. HEW pointed out that three 1975 Bureau of Foods' import programs--dried milk products, cheese and dairy

products, and polychlorinated biphenyls in food packaging--were evaluated and used at the bureau levels. According to HEW, program managers often must make ongoing judgments based on field reports and data from other sources, and the nature of FDA's compliance programs is such that decisions on program operations cannot await the findings of long-term evaluations. HEW explained that a program manager must balance his formal evaluation efforts with the need to direct ongoing field activities which frequently delays the preparation of formal evaluations.

We recognize that some evaluations of compliance programs occur at lower levels of the organization. However, our review has shown that in several cases no evaluations of FDA import programs were made due to a lack of sufficient data or a low priority assigned to the program. For example, FDA's 1975 programs for imported drugs, acupuncture devices, and food standards were not evaluated. (See p. 11.)

HEW said that FDA is making a concerted effort to increase the quality and timeliness of compliance program evaluations by training employees in evaluation techniques and by encouraging managers to stress evaluation at all stages of the compliance program cycle.

CHAPTER 3

CONTROL OVER IMPORTED PRODUCTS NEEDS TIGHTENING

Before an FDA-regulated product can be imported into the United States, FDA must insure that the product meets the requirements of the various laws and regulations it is responsible for administering. FDA cannot effectively carry out this responsibility because (1) it is not always aware of which products are being imported and (2) it does not maintain adequate control over imported products before approving their release into U.S. commerce.

FDA NOT ALWAYS AWARE OF PRODUCTS BEING IMPORTED

FDA relies on Customs to notify it of products being imported. Customs has not always done this because, in some cases, Customs did not know the products were subject to FDA regulation, and, in other cases, FDA informed Customs that it was not interested in inspecting the products. Better coordination between FDA and Customs is needed.

Importers bringing products into the country must prepare and file entry documents with Customs. For FDA-regulated products, importers submit to Customs an FDA "importers entry notice." Customs submits the completed notice to FDA for use in selecting products for inspection or other action.

To determine whether Customs notified FDA of all imported products subject to FDA regulation, we reviewed 857 randomly selected Customs entries for fiscal year 1975 at the three districts we visited. Of the 857 entries, 116 (about 14 percent) involved FDA-regulated products. Fifty of the 116 (about 43 percent) were not referred to FDA.

Products not referred to FDA included (1) alcoholic beverages such as beer, champagne, and whiskey, (2) medical devices such as surgical and medical instruments, (3) cooking and eating utensils, and (4) cosmetics such as perfume, hair brushes, and combs. We gave a list of these products to FDA headquarters' officials who verified that the products were subject to FDA regulation.

An FDA Bureau of Foods official told us that the districts should be sampling and analyzing alcoholic beverages. The FDA import manager at one of the three district offices

said that, with few exceptions, the district does not inspect alcoholic beverages and accordingly informed Customs it was not interested in reviewing these products. Except for a special FDA program initiated in May 1974 requiring districts to look for a banned food additive in imported wines, the manager said that the incidence of problems in alcoholic beverages was low so they "stopped monitoring entries completely."

For imported medical devices not referred to FDA, FDA officials in two districts said that even had they been referred, they would not have been inspected because FDA headquarters had not issued any specific compliance programs or guidance that the districts would need to inspect such products.

According to 1975 Bureau of Census statistics, the United States imported about $340 million worth of medical devices, including surgical and medical instruments, dental equipment and supplies, hearing aids, hypodermic needles, and catheters. A Bureau of Medical Devices and Diagnostic Products official told us the bureau is currently spending its major effort in implementing recently enacted medical device legislation (P.L. 94-295) and that no specific inspection coverage of imported medical devices was planned in the near future.

Customs officials in one district office said that all imported products may not be referred to FDA because Customs has to serve over 60 Government agencies and it was unreasonable to expect Customs' personnel to be completely familiar with each agency's requirements. Customs' officials in the other two district offices, however, told us FDA had not provided sufficient information or instructions on identifying FDA products and noted that additional information would be helpful.

After our discussion with FDA and Customs officials, FDA briefed Customs personnel at one Customs district on FDA requirements for imported products. Also, FDA began to spot check Customs entries in this district to identify products that were not being referred to them. At the other two district offices, FDA disseminated a list of products subject to its regulation. Also, according to an EDRO official, FDA provided Customs headquarters with information identifying FDA-regulated products.

PRODUCTS MOVED FROM PORTS UNDER SPECIAL AUTHORIZATIONS HAMPER REGULATORY EFFORTS

Under Customs regulations (19 C.F.R. 142), a special permit may be issued for the immediate delivery of imported products to owners or consignees when the release of such products is necessary to avoid unusual loss or inconvenience to the importer or to eliminate port congestion. Importers then have up to 10 days after the products have been released to officially file appropriate entry documents with Customs. A Customs official estimated that at least 50 percent of all FDA-regulated imported products are released under special permits.

According to FDA's "Regulatory Procedures Manual," importers are not required to hold a shipment covered by a special permit at any given location if a bond has been posted. FDA must let the importer know whether it plans to inspect the product. If no inspection is planned, FDA notifies the importer that products are released "without FDA examination." If FDA opts for inspection, it must issue to the importer a "notice of sampling." In such cases, products moved from the port of entry before samples are collected must be returned to the port for sampling. In some cases products that were moved from the port under special permit were marketed before samples were collected and could not be recovered for inspection.

FDA Philadelphia district officials told us that inspectors were limited because there were only two assigned to imported products. Because products are often moved a considerable distance from the port, it becomes less likely that they would be inspected.

To avoid marketing of products before FDA inspection, the Customs New York District Office required that importers advise FDA that they intended to request a special immediate delivery permit before Customs would issue the permit. FDA officials at the Los Angeles District Office said they were working with the Los Angeles Customs District Office to establish a similar requirement. A Customs headquarters official told us he was unaware of this problem and indicated that Customs would review the matter and consider issuing corrective instructions to its district offices.

Uniform criteria needed for establishing bond penalties

Section 801(b) of the FD&C act authorizes Customs to permit the importer to distribute the products to the owner or consignee, pending an FDA decision on the product's admissibility into U.S. Commerce and providing the importer has filed a good and sufficient bond with Customs. The bond is to pay for damages in case the importer fails to redeliver the products to Customs for FDA inspection or other regulatory action.

In spite of the Customs bond, importers still are not complying with FDA regulations. Generally the penalties charged against importers for violating the bond provisions were considerably less than the full bond value. This, in our opinion, has weakened FDA's ability to regulate imported products.

Customs regulations (19 C.F.R. 25.4) provide for a single or term immediate delivery and consumption entry bond and a general term bond for FDA-regulated products. Small importers generally use the single immediate delivery and consumption entry bond for products being entered only once. The term immediate delivery and consumption entry bond covers all product entries of an individual importer at a particular port of entry. The general term bond covers all product entries at all ports of entry for an individual importer. In each case the penalties assessed against the bond are based on the price the importer paid the foreign supplier for the product plus an estimate of duties that must be paid on the product.

The importer can petition Customs to waive or reduce the penalty (19 C.F.R. 172.1); however, joint FDA and Customs regulations (21 C.F.R. 1.321) provide that Customs cannot reduce or cancel penalties to be assessed against bond violators unless FDA is in full agreement with the action.

Penalties assessed against importers varied because FDA did not have uniform criteria to guide the district offices in advising Customs on how much of a penalty should be imposed.

New York District

In fiscal year 1975 penalties of $663,810 originally assessed by Customs against importers in 89 cases were later reduced or canceled except in 3 cases where penalties amounting to $285 were paid in full. For 38 of the 86 remaining cases, Customs canceled penalties totaling $241,503.

Penalties of $422,022 for the 48 remaining cases were reduced to $13,281, or about 3 percent of the initial assessment.

Fifty-six of the 89 cases involved products that were not returned because they were destroyed, exported, or originally shortshipped (quantity received by importers was less than quantity shown on sales invoice). Fourteen case files were incomplete and we could not determine what happened to the products. All or part of the shipment in the remaining 19 cases were marketed.

FDA district office officials told us that none of the violative products, which included apricots, cheese, and shrimp, that were marketed constituted a health hazard. However, we noted that FDA sought regulatory action on most of these products because they contained contaminants such as insects, rodent hairs, pesticides, and other poisonous substances. In one case, the product was decomposed. Thus, it appears that some of these products did constitute health hazards.

The FDA District Director told us he asked FDA headquarters for guidance in recommending penalties to insure some consistency nationwide. Without such guidance, the district in 1974 developed the following criteria:

--First-time violators should generally be assessed 5 to 10 percent of the bond value with a minimum of $50 and a maximum of $500.

--Second-time violators should be assessed 20 to 50 percent of the bond value.

--Third-time violators are to be considered chronic violators and assessed from 50 to 100 percent of the bond value.

The district maintained a card file of repeat violators.

Notwithstanding the district's criteria for bond penalties, the District Compliance Officer told us that he rarely recommended a penalty assessment over 10 percent of the bond value. FDA's Regional Director believed the penalties were too low and should be increased. The District's Compliance Branch Director said that first-time penalties are low and easily affordable by most importers. He maintained, however, that the threat of additional fines for subsequent offenses was expected to deter importers from placing their products into commerce before FDA release. However, the District

Compliance Officer said he has had difficulties persuading Customs to collect higher penalties.

Philadelphia District

We reviewed the penalty files for fiscal years 1974, 1975, and part of 1976 and identified 17 bond cases involving importers' failure to redeliver products FDA found violative. Violations noted included decomposed and/or mercury-contaminated canned tuna, insect-infested cocoa beans, maggots in canned mushrooms, and mislabeled acupuncture needles. It could not be determined from the district office's records whether any of the violative products were marketed.

Penalties of $1,009,377 originally assessed in the 17 cases were subsequently reduced or canceled except in 1 case where the $293 penalty was paid in full. Penalties against importers totaling $714,084 in 10 cases were canceled because the products were destroyed, exported, or shortshipped. Penalties of $295,000 for the remaining six cases were reduced to $2,241 or less than 1 percent of the initial assessment.

The FDA district office did not have procedures or guidelines to follow in computing penalty assessments. A District office official told us penalty assessments were reduced because of the "importers prior good record." According to this official, FDA did not maintain records on repeat violators or on past performance of importers but relied on Customs for that information. However, we noted that Customs did not maintain records on repeat violators either.

Los Angeles District

Penalties of $49,371 originally assessed against importers in 11 cases were either reduced or canceled, except in 1 case where the $257 penalty was paid in full. Penalties totaling $27,445 in eight cases were canceled. Penalties of $21,669 for the remaining two cases were reduced to $2,167, or 10 percent of the initial assessment.

In a December 18, 1975, memorandum to FDA's Director, District Compliance Branch, the import compliance officer for this district indicated that he uses the following guidelines to reduce penalties for failure to redeliver imported products.

--If it is the first time an importer has filed an FDA entry, the amount is reduced to 10 percent of the original assessment.

--If it is not the first time, the penalty is not reduced.

--If the reason the articles are not delivered is due to theft or disaster, no penalty is assessed.

--If FDA contributed to the problem it must be determined whether FDA allowed the problem to exist by failing to take action or by causing the problem through positive action. If FDA erroneously released the products, no penalty is assessed. If FDA did not follow up in a timely manner, such as sending dunning letters, the penalty could be reduced as much as 90 percent.

Because no records were maintained on bond actions against repeat violators, it is questionable whether all these guidelines could be effectively applied. EDRO officials agreed that repeat violators should be dealt with more severely, but FDA had no method of tracking bond violators nationwide. Subsequently, EDRO requested the districts to submit information on all bond actions as they were completed. EDRO plans to use this data to trace importer histories of redelivery violations nationwide.

EDRO also proposed an addition to FDA's "Regulatory Procedures Manual" that would require the districts to maintain a log of bond actions by which past importer violations could be tracked. The proposal states that information currently provided to EDRO by the field will be fed back to the field in the form of a consolidated "national bond action list" as nationwide input for tracking violative importers. According to an EDRO official, the bond action list was to be issued about February 1977.

CONCLUSIONS

FDA is responsible for insuring that imported products are not adulterated and/or misbranded. Our review showed, however, that importers have marketed violative products in the United States.

While Customs has primary responsibility for screening entry documents, it is not familiar with all FDA-regulated products and therefore cannot effectively perform this

function. Better control over products could be maintained if FDA periodically (1) apprised Customs of FDA-regulated products and (2) reviewed Customs entries to identify products Customs may be failing to screen.

Also, products can be prematurely marketed because (1) there is no national requirement for the Customs district offices or importers to notify FDA before Customs authorizes products to be moved under a special permit and (2) FDA lacks sufficient control over the products once it receives entry notification. A requirement that FDA be notified before products are moved under a special permit would enable FDA to more effectively regulate these products. FDA's failure to recommend that Customs assess sufficient penalties against importers that marketed their products before FDA approval, has also contributed to this problem. Maintaining records on bond violators and uniform national guidelines setting forth criteria for the reduction of penalties would provide a more equitable assessment of penalties against importers failing to redeliver products to FDA.

RECOMMENDATIONS

So that FDA can more effectively control imported products, we recommend that the Secretary, HEW, direct the Commissioner, FDA, to:

--Provide Customs with updated lists of products subject to FDA regulation and periodically review Customs entry documents to identify products under FDA's jurisdiction which were not referred for regulatory action.

--Develop uniform criteria for district offices to follow in recommending the penalty that should be imposed when importers violate Customs redelivery bonds.

We also recommend that the Secretary of the Treasury direct the Commissioner of Customs to notify, or require importers to notify, FDA before Customs issues a special permit allowing importers to move products from the port of entry.

In addition, we proposed that FDA move forward as expeditiously as possible to develop a national list of importers that violate Customs' redelivery bonds. HEW advised us that a national bond violators list has been developed and is being distributed to the district offices. The

Department of the Treasury said that it considers this a desirable development which can result in more effective application of the provisions of the law while at the same time simplifying its administration, both for FDA and Customs.

AGENCY COMMENTS AND OUR EVALUATION

HEW and the Department of Treasury generally agreed with most of our recommendations.

Lists of FDA-regulated products

HEW said that FDA most recently provided information on products subject to FDA regulation to the Customs' Training Academy in January 1977. HEW agrees such information should be provided whenever requested or when there is a change in the products that come under FDA jurisdiction.

Department of the Treasury, in commenting on an earlier version of this report (see app. III), said that, on the surface, the assembly of a comprehensive and updated listing of imported products subject to an applicable law or regulation for the guidance of Customs officials in screening imported shipments would appear to be an effective control. Treasury explained, however, that given the volume of imports entering the country daily through ports of entry and the resources available to process these shipments, the maintenance and application of lists is not always administratively feasible. According to Treasury an alternate approach, and the one consistently advocated by Customs with respect to products covered by the FDA requirements, is to place firm responsibility on the importer for identification of products subject to such requirements. Treasury said that submission of the basic document used to notify FDA of imports--the importers entry notice--is not mandatory on the part of the importer. According to Treasury, Customs believes that if FDA would require submission of this form it would greatly strengthen administration of the applicable laws.

In our view, such an alternative approach would seem to require a major effort on the part of FDA to educate importers--especially new importers--as to its reporting requirements. In addition, this approach may not assure that all required shipments are reported to FDA, particularly potentially violative shipments, because FDA would have no basis for determining whether importers complied with the

reporting requirement. Since Customs receives all import documentation for tariff purposes, it is in a better position to insure that importers comply with such mandatory reporting requirements. Therefore, these matters should be considered before this approach is adopted.

Uniform bond penalty criteria

HEW said that FDA believes that the amount of penalty imposed for the violation of Customs redelivery bonds should be determined by the facts and circumstances involved in each violation. According to HEW, FDA's "Regulatory Procedures Manual" provides subjective criteria that should be considered in setting such a penalty. The manual states that the penalty should be sufficient to make the unauthorized distribution of the lot unprofitable. HEW said that if the districts are uncertain about setting the penalty, the manual instructs district offices to submit questionable cases to FDA headquarters. FDA believes that this policy should result in appropriately uniform criteria.

FDA's manual also states that very often penalties are so small that they, in effect, encourage the illegal distribution of future imported lots. Our review has shown that the penalties charged against importers for violating the bond provisions were often for small amounts and at least one district office has requested more specific guidance from FDA in setting such penalties. In view of the many small penalties that are assessed we do not believe that unauthorized distributions are being discouraged and that more definitive criteria for setting penalties, as requested by at least one district, would provide a more practical basis for setting uniform and equitable penalties.

Notification to FDA on special permits

The Department of the Treasury generally concurred with our recommendation and said that the recommended procedure can be applied without serious administrative difficulties at large seaports or other locations staffed locally with FDA inspectors. Thus, Treasury said, it could apply to a great percentage of the total volume of imported products subject to FDA regulation. According to Treasury, application of the procedure at smaller volume locations which are not locally staffed with FDA inspectors could, however, lead to administrative difficulties and possible delays in delivery of products, including perishables, which might create hardships

and additional costs for the importer involved. At small ports where FDA does not have staff readily available, we believe FDA and Customs could work out procedures that are mutually beneficial to each agency and that would minimize any inconvenience to the importers.

CHAPTER 4

WAYS TO STRENGTHEN REGULATION OF IMPORTED PRODUCTS

According to FDA, resource limitations prevent it from giving sufficient inspection coverage to imported products to insure that all violative products are identified and appropriate regulatory action taken. To more effectively regulate imported products, FDA should make a greater effort to (1) enter into agreements with exporting countries to insure that products being exported to the United States comply with requirements of Federal laws and FDA regulations and (2) use its authority under the FD&C act to restrict products which are forbidden or restricted for sale in producing or exporting countries from being marketed in the United States.

COOPERATIVE AGREEMENTS WITH FOREIGN GOVERNMENTS

FDA's policy is to encourage agreements with foreign countries to provide greater assurance that imported products meet FDA requirements. Under the agreements, the foreign countries play an increased role in insuring that products exported to this country are safe and/or effective. Generally the foreign countries that are a party to an agreement certify that certain FDA-regulated products exported to the United States were processed in accordance with proper manufacturing practices to better insure that products comply with the pertinent U.S. laws and regulations. Surveillance over such products then becomes a matter of monitoring the foreign countries' adherence to the agreements' certification provisions. Although FDA has agreements with some countries for a limited number of products, greater effort could be made to enter into agreements with those countries that export problem products requiring extensive FDA inspection.

According to FDA's Director, International Affairs Staff, Office of the Associate Commissioner for Compliance, a determination as to whether an agreement with a foreign country is desirable is based on the following factors:

--The amount of FDA resources used to regulate problem products.

--The capability, expertise, willingness, and authority of the foreign country to implement an effective

export control program for regulating product production to meet FDA standards.

--The availability of FDA staff and resources to interest exporting countries in developing export control programs and to evaluate programs once they have been established.

In October 1974 FDA completed a study, based on an analysis of 1972 food imports, to identify foreign countries for possible future import agreements. According to the study:

--The United States imports food from more than 150 countries.

--Canada is the leading exporter of food to the United States, followed by Brazil and Mexico.

--Almost 38 percent of U.S. food imports are from Latin America. Twenty-two, 17, and 10 percent come from Europe, Asia, and Africa, respectively.

--Since the mid-1960s, U.S. imports of manufactured foods have been greater than imports of crude foods.

The study concluded:

"Although covering all food imports with international agreements would be an immense undertaking, a few agreements with the right countries could cover a significant proportion of FDA regulated foods. For example, agreements with only four countries [Brazil, Colombia, Mexico, and Angola] on coffee and tea alone would cover over 50 percent of coffee and tea imports and over 11 percent of total FDA regulated food imports. Agreements with only two countries [Canada and Japan] could cover over 50 percent of fish and fish products coming into the United States. And finally, an agreement with Mexico alone would cover almost 90 percent of all fresh and frozen vegetables imported by the U.S."

In December 1975 FDA completed another study to identify countries for possible future agreements. This study concentrated on large volumes of imported products requiring an extensive amount of FDA surveillance at the ports of entry.

According to the study, over 50 percent of FDA's field resources spent on food imports involved only the following four commodities:

--Canned vegetables (with or without sauces) and juices.

--Shellfish, crustaceans, and other aquatic animals, except smoked.

--Spices and salt.

--Fish and fish products, except smoked.

The study pointed out that most food imports in a "resource-intensive" commodity are exported to the United States by relatively few countries. For example, the report said that in fiscal year 1974 over 20 percent of FDA's food import resources were spent on regulating canned, cured, and processed vegetable products and juices and that over 50 percent of the dollar value of these imports in 1973 were from Taiwan, Portugal, and Spain. Similarly, about 15 percent of FDA's food import resources were spent on shellfish, crustaceans, and other aquatic animals and 50 percent of these products came from Canada, Mexico, Japan, and India. Also, about 10 percent of FDA's food import resources were spent on spices and salt products, and about 50 percent of the spices came from Canada and Indonesia.

The study concluded that:

"The distribution of Agency resources and the concentration of countries of export in resource intensive commodities indicate that there are identifiable targets of opportunity in terms of the present criterion, i.e., countries exporting large volumes of resource-intensive commodities to the United States."

As of September 1976, FDA had product certification agreements with (1) Canada, Japan, and Korea for certifying the sanitary quality of shellfish exported to the United States, (2) France, the Netherlands, Belgium, and New Zealand for certifying the sanitary quality of dry milk products exported to the United States, and (3) India for certifying that frozen frog legs, exported to the United States, are free of salmonella and arizona contamination--bacteria which can cause food poisoning. Discussions are currently underway with Norway on canned fishery products,

with Spain on canned pimentoes, and with Mexico on fresh produce.

The December 1975 study pointed out, however, that a number of problem products are not covered by agreements. These included vegetable products and juices from Taiwan and Portugal; shellfish, crustaceans, and other aquatic animals from Mexico and India; and spices and salt products from Canada and Indonesia.

FDA's Director, International Affairs Staff, told us that it takes several years to develop effective export control programs with foreign countries. According to the Director, agreements are developed case-by-case and information on the export control capabilities of foreign countries is acquired from general knowledge obtained through visits to foreign countries, conversations with foreign visitors, and FDA's relationships with counterpart personnel in foreign agencies.

The Director said development of export control programs in foreign countries is aided by FDA training programs for counterpart government personnel. He said that workshops have been held to train foreign officials how to detect decomposition in shrimp and for analytical training in the examination of green coffee. Workshops are planned and/or under consideration for examining cocoa and spices. The Director said that FDA anticipates that the trained personnel will, upon return to their respective countries, become instructors and develop export control programs to insure compliance with FDA requirements.

FDA, however, has not prioritized specific problem products which should be covered by bilateral agreements with foreign countries, nor has it evaluated the capability of those countries to develop and implement an effective export control program.

IMPORTED PRODUCTS RESTRICTED OR FORBIDDEN FOR SALE IN FOREIGN COUNTRIES

Under section 801(a)(2) of the FD&C act, if it appears that, from the examination of samples or otherwise, imported products are forbidden or restricted for sale in the country in which they were produced or from which they were exported, such products are to be refused admission into the United States. FDA is not implementing this provision.

Instead, it accepts imported products for marketing as long as they meet U.S. standards. However, FDA's limited inspection resources may not be sufficient to adequately insure that substandard products are not being imported. FDA should require importers to certify that imported products meet this provision of the act.

We could not find in the food and drug laws any explanation as to the congressional intent of this provision of the act, but a treatise on imports and exports 1/ included a discussion on this provision. The study pointed out that:

> "* * * The limitations on imports of this nature, however, do prevent foreign countries from using our shores as a 'dumping ground' for inferior articles. Moreover, in those rare instances in which the requirements of the foreign country may be of a higher degree than those imposed by our law, the standard of our food importations is raised to that extent. It must be admitted, however, that these results are only incidental to the application of the provision. Its principal objective, patently, is to prevent an influx of deleterious and unfit food into this country * * *."

At one time, FDA regulations (21 C.F.R. 2.300; 1939) required shippers of certain imported products to certify, on the declaration form shown on page 32, that the products complied with the requirements of the FD&C act. Among other things, the shipper was required to certify that the products were not prohibited or restricted for sale in the country in which they were produced or from which they were exported. According to the preamble in the regulation, the certification requirement was established for the efficient enforcement of FDA's authority over imported products under the FD&C act. Such certifications have not been required since November 1948. We could not determine from FDA why the requirement was eliminated because so much time had passed since its deletion.

1/Arthur D. Herrick, "Imports and Exports," Food Regulation and Compliance, vol. II (1947), pp. 922-976.

Form No. 197
FOREIGN SERVICE
(Revised June 1940)

DECLARATION OF SHIPPER OF FOOD, DRUG, AND COSMETIC PRODUCTS

I, the undersigned, am the _____ (Seller or owner, or agent of seller or owner) of the merchandise herein mentioned and described. It consists of food, drug, or cosmetic products (or devices as defined by the Federal Food, Drug, and Cosmetic Act) which contain no added substances injurious to health. These products were grown in _____ (Country) and manufactured in _____ (Town and country) by _____ (Name of manufacturer) during the year _____, and are exported from _____ (City) and consigned to _____ (City). They bear no false labels or marks, contain no added coloring matter except _____ (State coloring matter used, if any) no preservative (salt, sugar, vinegar, or wood smoke excepted) except _____ (State preservatives used, if any)

I further declare that such article or articles are not of such a character as to prohibit their entry into the United States in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act in that they have not been manufactured, processed, or packed under insanitary conditions, nor are they of a character to cause prohibition or restriction in sale in the country where made or from which exported, nor are they adulterated or misbranded, nor are they in violation of section 505 of the Federal Food, Drug, and Cosmetic Act.

I further declare that the drug products herein mentioned and described contain no opium, coca leaves, cocaine, or any salt, derivative or preparation of opium, coca leaves, or cocaine, the importation of which into the United States is prohibited by the Narcotic Drugs Import and Export Act, as amended.

I do solemnly and truly declare the foregoing statements to be true, to the best of my knowledge and belief.

Dated at _____ (Place) this _____ day of _____ (Month and year)

(Signature) _____

Marks and Numbers	Description	Price	Amount

NO FEE.
To be numbered in regular invoice series and distributed similarly to an invoice.

16—18341

We discussed with FDA the possibility of requiring importers to certify that imported products are not restricted or forbidden for sale in producing or exporting countries. Such certifications could be particularly useful in those cases where FDA has not established safety and effectiveness standards for certain products it is responsible for regulating. For example, according to an official in FDA's Bureau of Medical Devices and Diagnostic Products, standards have not yet been established for the estimated 7,000 different types of medical devices marketed in the United States, some of which are imported.

Some FDA officials believed certification would be a useless paperwork exercise which could not be adequately monitored. One FDA official, however, told us that he believed the certification would be useful in that it would provide some added leverage in dealing with importers.

He said that it would provide FDA some assurance, which it does not have now, that imported products are manufactured, processed, or packed under sanitary conditions and that they are not restricted or forbidden for sale in the country in which they were produced or from which they were exported.

CONCLUSIONS

Given FDA's limited coverage of imported products at the various U.S. ports of entry, additional surveillance measures are needed--particularly against imported products which are continually violative. Cooperative agreements which place additional responsibility on foreign governments to insure that products exported to the United States meet FDA requirements and requiring importers to certify that imported products meet the requirements of the FD&C act would help improve FDA's import coverage and should also reduce attempted importation of violative products and provide for more effective use of resources at the ports of entry.

RECOMMENDATIONS

We recommend that the Secretary, HEW, direct the Commissioner, FDA, to:

--More aggressively develop cooperative agreements with those countries that (1) continually export violative products to the United States and (2) can support such agreements.

--Require importers to certify that imported products meet the requirements of the FD&C act.

AGENCY COMMENTS AND OUR EVALUATION

FDA believes it has been sufficiently aggressive in developing cooperative agreements with foreign countries in recent years. HEW said that the U.S. Government, through the FDA, has negotiated agreements with 13 countries covering 5 different commodities. Plans are underway to establish more than a dozen additional agreements in the near future. According to HEW, cooperative agreements exist for the benefit of both countries and are designed to (1) assure the safety, effectiveness, and quality of designated products, (2) assure, for the exporting country,

that their goods are accepted and flow easily into U.S. commerce, and (3) improve the quality and/or reduce the resources FDA must allocate to regulate commodities under such agreements.

HEW said that although such agreements are intended to benefit both parties, countries with a history of exporting violative products are frequently the least capable of being able to carry out a source country certification agreement. An example of this, according to HEW, came to light in an agreement which required a foreign government to certify that all shipments of frog legs to the United States were free of salmonella. FDA's monitoring system revealed that numerous shipments certified by the foreign government contained salmonella. Consequently, FDA must again sample frog legs at a relatively high rate thereby greatly reducing the effectiveness of the agreement. HEW said such experiences show the need for caution in developing cooperative agreements.

With respect to FDA's plans to establish more than a dozen additional agreements, we contacted FDA's Director for International Affairs who told us that only three of these agreements were being actively negotiated; the plans for the other agreements were indefinite. An FDA report dated February 1976, analyzing its International Activities, stated that the development of a bilateral agreement normally takes from 3 to 6 years. We believe that FDA should establish more definitive plans for initiating the additional agreements and make a concerted effort to reduce the time frame for developing such agreements so as to realize the benefits as soon as possible.

When a country fails to comply with the terms of the agreement, FDA should take stronger measures, including banning those imports from the violative country, to better insure compliance with the agreement.

With respect to importers' certifications, HEW does not believe that they would be beneficial or achieve the intended result. HEW said that the importer's certificate, itself, would not give FDA any greater assurance that the product was in compliance with the requirements of the FD&C act. Consequently, HEW said FDA would still have to examine such products and there would be no savings of FDA resources. It is possible that some importer might view the requirement as something more than a paperwork requirement and actually test their imports, but this would be of marginal value, according to HEW, unless FDA could continually confirm the validity of such tests.

We disagree with FDA concerning the requirement for importers' certifications. We believe that such certifications could provide FDA some assurance, which it does not have now, that imported products are manufactured, processed, or packed under sanitary conditions and that they are not restricted or forbidden for sale in the country in which they were produced or from which they were exported. Also, as we pointed out earlier in this report, such certifications could be particularly useful in those cases where FDA has not established safety and effectiveness standards for certain products it is responsible for regulating.

Whether this requirement becomes just a paperwork exercise will depend, to a great degree, upon how aggressively it is administered by FDA.

APPENDIX I

EXAMPLE OF IMPORT VOLUME INFORMATION PROVIDED TO FDA'S DISTRICT OFFICES

Customs district	FDA commodity code	Net quantity	Dollar value
New York, New York	01	660,326	$ 1,322,643
New York, New York	03	1,086,876,542	694,299,921
New York, New York	04	53,732,998	247,430,793
New York, New York	05	24,951,630	16,062,889
New York, New York	07	8,353,042	2,777,150
New York, New York	08	7,484,784	2,885,946
New York, New York	09	18,304	14,025
New York, New York	11	52,430,698	4,674,581
New York, New York	13	249,143,068	138,920,767
New York, New York	14	2,696,643,385	539,402,295
New York, New York	15	3,737,668	1,702,739
New York, New York	16	170,774,480	131,509,479
New York, New York	17	1,211,302	641,487
New York, New York	18	120,806,766	51,749,985
New York, New York	20	372,167	261,689
New York, New York	21	54,815,392	42,029,331
New York, New York	85	40	12,571,427
New York, New York	86	6,702	1,723,832
New York, New York	89	11,556,147	93,558,709
New York, New York	94	6,701,855	58,577,456
New York, New York	99	7,926,864	55,762,522
New York, New York		7,935,896,489	$3,426,788,290
		7,935,896,489	$3,426,788,290

Includes such products as

- Breakfast cocoa
- Buttermilk chocolate
- Cocoa beans
- Cocoa bean "press cake"
- Cocoa bean hulls (residue)
- Caramels
- Caramel corn, popped corn, confection
- Caramel apples (candied apples)
- Chewing gum
- Chocolate candy, bars, etc
- Chocolate flavored syrups
- Chocolate liquor, bitter chocolate, chocolate coating, etc.
- Chocolate syrup
- Chocolate syrup substitutes
- Chocolate substitutes
- Cocoa butter
- Cocoa nibs
- Cocoa substitutes
- Confection other than candy,
- Fonfants
- Fudge
- Icings, cake decorations
- Jellied candies, jelly beans, gum drops
- Licorice
- Life savers, mints, etc
- Low fat cocoa
- Marshmallows
- Marshmallow toppings
- Marzipan, cocoanut rolls
- Medium fat cocoa
- Milk chocolate, sweet milk chocolate and coating
- Mixed candies
- Mixed dairy product chocolate
- Nut candies
- Rock candy, hard, etc
- Skim milk chocolate and coating
- Sweet chocolate and coatings
- Sweet chocolate and vegetable fat coating
- Sweetened cocoa
- Taffy "toffee," kisses

Includes such products as

- Alewives (river herring)
- Anchovies
- Barracuda
- Bass (fresh water)
- Blue fish
- Blue pike
- Bonita
- Breaded fish
- Buffalo fish
- Butterfish
- Carp
- Catfish, fresh water and ocean
- Caviar
- Chubs, ciscoes lake herring and tullibees
- Cod
- Croaker
- Cust
- Eels
- Fish cakes
- Fish cocktails and appetizers
- Fish flour, meal (food) NOT whole fish product
- Fish paste
- Fish roe
- Fish sticks
- Flounder
- Gefilte fish
- Groupers
- Haddock
- Hake
- Halibut
- Herring, sea
- Lake trout (char)
- Mackerel
- Mullet
- Pacific ocean perch
- Paddlefish
- Pollock
- Rockfish
- Rosefish (ocean perch)
- Sable fish (black cod)
- Salmon
- Sardines (brisling, sprats, pilchards)
- Sauger
- Sea bass
- Shad
- Shark
- Smelt
- Sole
- Spot
- Squetea (sea trout)
- Swordfish
- Toteava (white sea bass)
- Trout
- Tuna
- Whitefish
- Whiting
- Yellow perch
- Yellow pike
- Yellow tail

APPENDIX II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

APR 28 1977

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Program for Regulating Imported Products Needs Improving." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Thomas D. Morris
Inspector General

Enclosure

APPENDIX II

DEPARTMENT COMMENTS TO GAO DRAFT REPORT ENTITLED, "PROGRAM FOR REGULATING IMPORTED PRODUCTS NEEDS IMPROVING"

GAO RECOMMENDATION:

Establish a system to provide comprehensive information on specific products showing the volume imported, inspected, and the inspection results. The system should provide a basis for insuring that all imported products are periodically inspected and for assessing the quality of the various imported products subject to FDA regulation.

DEPARTMENT COMMENT:

In its FY 1979 plan, the Food and Drug Administration has proposed to develop an information system on imported products which will include most of the specifications recommended by GAO. The system will provide information on the volume of products imported, those inspected by FDA, and the results of those inspections. Until this system is operational, FDA will continue to utilize data tapes from the U.S. Census Department which lists the volume of imports for each commodity contained in the Tariff Schedules of the United States Annotated. Although this data is not made available at the level of detail recommended by GAO, its use at the District level along with FDA maintained import inspection data will provide a consistent base of information for determining the extent of imported products entering the United States.

The Department is also proposing legislation which would provide an effective means of determining the location and products of foreign food processing establishments who import to the United States. By providing for the registration of foreign food manufacturers, it would also enable the Secretary to directly advise foreign food processors who export their products to the United States of current regulatory requirements, rather than continuing his reliance upon importers to be aware of those requirements and to advise such processors.

In some respects, the proposed data system will not provide information suggested by GAO. The data system cannot determine the compliance status of all imported products unless a substantial share of inspection resources are devoted to a controlled sampling plan. This would require a shift in the allocation of resources away from chronic problem areas to commodities where violations are not so likely. If this could be accomplished by redirecting a comparatively small share of the present level of effort, it might be worthwhile, but FDA's experience with similar sampling programs suggests that assessing the quality of every import commodity is not feasible at current resource levels.

FDA's Project IDEA 23, "Nationwide Statistical Sampling of Imported Foods" issued in September 1975, provides some estimate of anticipated costs of a comprehensive sampling effort. In that project, FDA sampled and analyzed four imported products nationwide. The cost of the project was 8000 man-hours. If FDA were to obtain comparable data on 2300 specific commodities, as the recommendation suggests, the effort could be spread over a 10-year cycle requiring statistical surveys of 230 products each year. But this level of effort would require several hundred man-years annually for an analysis of only sanitation characteristics. Conducting a full range of analysis for bacterial problems, heavy metals, pesticides, food and color additives, natural poisons, etc. would require 5-10 times more manpower than a survey of filth problems. Even a scaled-down version of this effort, e.g., grouping of related commodities, no stratification of sampling by country of origin, etc., probably could not reduce the resource requirements to a level that would be feasible within present resource limits.

GAO RECOMMENDATION:

Evaluate on a more timely basis the effectiveness of the compliance programs to insure that the objectives of the program are being met.

DEPARTMENT COMMENT:

We agree that evaluation plays an important role in assessing program effectiveness. However, it should not be assumed that a program evaluation has not been accomplished simply because a formal document has not been submitted to the Commissioner. Frequently the most important evaluation of a compliance program occurs at lower levels of the organization. For example, three 1975 Bureau of Foods' import programs were evaluated and utilized at the bureau levels - imported dried milk products, imported cheese and dairy products, and the PCB in food packaging import program. Furthermore, program managers often must make ongoing judgments based on field reports and data from other sources, and the nature of FDA's compliance programs is such that decisions on program operations cannot await the findings of long-term evaluations. Also a program manager must balance his formal evaluation efforts with the need to direct ongoing field activities. This frequently delays the preparation of formal evaluations. Nevertheless, FDA is making a concerted effort to increase the quality and timeliness of compliance program evaluations by conducting employee training in evaluation techniques, and encouraging managers to stress evaluation at all stages of the compliance program cycle.

APPENDIX II

GAO RECOMMENDATION:

Provide Customs with updated lists of products subject to FDA regulation and periodically review Customs entry documents to identify products under FDA's jurisdiction which were not referred for regulatory action.

DEPARTMENT COMMENT:

As the report notes, FDA headquarters and district offices have provided the U.S. Customs Service with information identifying FDA-regulated products on various occasions. The Agency most recently provided such information to the U.S. Customs Training Academy in January 1977. While we agree such information should be provided whenever requested or when there is a change in the products that come under FDA jurisdiction, we do not believe that mandatory periodic listing is necessary. FDA's last major change in product jurisdiction occurred in 1973. We also feel that FDA cannot assure that all U.S. Customs personnel are aware of FDA regulated products. After this information is made available to U.S. Customs administrators, either at the district or headquarters level, we believe it is their responsibility to disseminate this information to all employees.

With respect to certain products not being referred to FDA for regulatory action, however, certain articles such as stainless steel flatware and cooking utensils have historically maintained a low violative rate. While these products are subject to FDA coverage, FDA has deliberately directed its resources toward more extensive inspection of products that are known or suspected to constitute a greater health hazard.

GAO RECOMMENDATION:

Develop uniform criteria for the district offices to follow in recommending the amount of penalty that should be imposed when importers violate Customs redelivery bonds.

DEPARTMENT COMMENT:

FDA believes that the amount of penalty imposed for the violation of Customs redelivery bonds should be determined by the facts and circumstances involved in each violation. FDA's Regulatory Procedures Manual states criteria that should be considered in setting such a penalty. Included in the subjective list are the following:

(1) the penalty should be sufficient to make the unauthorized distribution of the lot unprofitable

(2) the attitude of the importer

(3) the seriousness of the violation

(4) the degree to which the consumer is harmed

(5) the amount of the shipment distributed and not recovered

(6) previous violations (bond actions) of the importer of record.

If districts are uncertain about setting the penalty, the manual instructs district offices to submit questionable cases to FDA Headquarters. The Agency believes that this policy should result in appropriately uniform criteria.

GAO RECOMMENDATION:

Move forward as expeditiously as possible with the development of the national list of importers that violate Customs redelivery bonds.

DEPARTMENT COMMENT:

The development of a national bond violators list has been completed and the list is now being distributed to the district office.

GAO RECOMMENDATION:

Be more aggressive in developing cooperative agreements with those countries that continually export violative products into the United States and are capable to support such agreements.

DEPARTMENT COMMENT:

The Food and Drug Administration believes it has been sufficiently aggressive in developing cooperative agreements with foreign countries in recent years. The U.S. Government, through the FDA, has negotiated agreements with 13 countries covering five different commodities. Plans are underway to establish more than a dozen additional agreements in the near future. Cooperative agreements exist for the benefit of both countries and are designed to: 1) assure the safety, effectiveness, and quality of designated products; 2) assure, for the exporting country, that their goods are accepted and flow easily into U.S. commerce; and 3) improve the quality and/or reduce the resources FDA must allocate to regulate commodities under such agreements. Although such agreements are intended to benefit both parties, countries with a history of exporting violative products are frequently the least capable of being able to carry out a source country certification agreement. A recent example of this came to light in an agreement which required a foreign government to certify that all shipments of frog legs to the U.S. were free of salmonella. FDA's monitoring system revealed that numerous

shipments certified by the foreign government contain salmonella. Consequently, FDA must again sample frog legs at a relatively high rate thereby greatly reducing the effectiveness of the agreement. Such experiences illustrate the need for caution in the development of cooperative agreements.

GAO RECOMMENDATION:

Require importers to certify that imported products meet the requirements of the Food, Drug, and Cosmetic Act.

DEPARTMENT COMMENT:

We do not believe this recommendation would be beneficial or achieve the intended result. The importer's certificate, itself, would not give FDA any greater assurance that the product was in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. Consequently, FDA would still have to examine such products and there would be no savings of FDA resources. It is possible that some importer might view the requirement as something more than a paperwork requirement and actually test their imports, but this would be of marginal value unless FDA could continually confirm the validity of such tests.

DEPARTMENT OF THE TREASURY
WASHINGTON, D.C. 20220

DEPUTY ASSISTANT SECRETARY

April 14, 1977

Dear Mr. Lowe:

This is in response to your request of March 8, 1977 for our comments on the draft report to the Congress entitled, "Program for Regulating Imported Products Needs Improving." This report is directed at the activities of the Food and Drug Administration (FDA), Department of Health, Education, and Welfare (HEW) in carrying out its responsibilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended (21 U.S.C. 381) and various related Federal laws impacting on imported products subject to its regulation. In this effort FDA is assisted by the United States Customs Service which provides notification of products being imported and certain controls over affected products pending release into U. S. commerce.

The report identifies deficiencies in the administration of the applicable laws and makes recommendations, mainly procedural, for change. Some of these recommendations either impact on, or directly address, Customs role with respect to the imported products. Our comments concerning these points are as follows:

Page 31. "... recommend that the Secretary, HEW, direct the Commissioner, FDA, to: ...Provide Customs with updated lists of products subject to FDA regulation...."

Comment: On the surface the assembly of a comprehensive and updated listing of imported products subject to an applicable law or regulation for the guidance of Customs officials screening imported shipments would appear to be an effective control. In practice, however, this approach would fall short of its intended purpose. A listing of products subject to the provisions of the laws with which this report is concerned would certainly run into thousands of items. These laws are only a few of the more than 400 which are applicable to imported products, and which Customs, in conjunction with more than 40 other Government Agencies, is responsible for applying. Given the volume of imports entering the country daily through our ports of entry and the resources available to process these shipments, the maintenance and application of lists is not always administratively feasible.

APPENDIX III

An alternate approach, and the one consistently advocated by Customs with respect to products covered by the FDA requirements is to place firm responsibility on the importer for identification of products subject to such requirements. Presently, the basic document used to notify FDA of the entry of products subject to the provisions of the FDA statutes is the form FD-701, Importers Entry Notice. Submission of this form is not, however, mandatory on the part of the importer. It is the position of the U. S. Customs Service that requiring its production by FDA regulation would greatly strengthen administration of the applicable laws.

Page 31. "... recommend that the Secretary, HEW, direct the Commissioner, FDA, to: Develop uniform criteria for the district offices to follow in recommending the amount of penalty that should be imposed when importers violate Customs redelivery bonds."

Comment: The report notes that imported products subject to FDA regulations may be released under Customs bond pending a decision by FDA concerning admissibility. Goods subsequently found by FDA to require inspection or other regulatory action may be ordered redelivered for such purposes under the provisions of the bond. Failure to comply with a redelivery order may subject the importer to liquidated damages. The amount of the liquidated damages is usually mitigated depending on the circumstances involved in the violation. The actual amount assessed is determined by Customs after obtaining the recommendation of the local FDA officials.

The report notes further that FDA officials plan to develop more accurate historical information on bond violations on which to base a more consistent application of penalty procedures nationally. We consider this a desirable development which can result in more effective application of the provisions of the law while at the same time simplifying its administration, both for FDA and the U. S. Customs Service.

Page 32. ".... Recommend that the Secretary of the Treasury direct the Commissioner of Customs to notify, or require importers to notify, FDA before Customs issues a special permit allowing importers to move products from the port of entry under immediate delivery procedures."

Comment: The report indicates that a procedure essentially the same as recommended is already in effect in the New York Area Customs Office, and is under consideration elsewhere. Furthermore,

APPENDIX III

Customs Headquarters has the matter under review with a possible aim of extending the procedure further. In our view, the recommended procedure can be applied without serious administrative difficulties at large seaports or other locations staffed locally with FDA inspectors. Thus, it could apply to a great percentage of the total volume of imported products subject to FDA regulation. Application of the procedure at smaller volume locations which are not locally staffed with FDA inspectors could, however, lead to administrative difficulties and possible delays in delivery of products, including perishables, which might create hardships and additional costs for the importers involved. Most shipments arriving, for example, by rail or truck at northern border crossings, are released under immediate delivery procedures as described in the report. Adoption of the recommended notification procedure at some Canadian border ports, where imported cargo is processed 24-hours a day, could result in delays in release of cargo of a full day, or even a weekend. Any recommendation in this area should take this into account.

We welcome the opportunity to comment on the draft report and pledge our support in working toward any needed improvement in the administration of FDA import laws.

Sincerely yours,

John H. Harper
Deputy Assistant Secretary
(Operations)

Mr. Victor L. Lowe
Director, United States
General Accounting Office
Washington, D. C. 20548

PRINCIPAL HEW AND TREASURY OFFICIALS

RESPONSIBLE FOR ADMINISTERING ACTIVITIES

DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:		
Joseph A. Califano, Jr.	Jan. 1977	Present
David Mathews	Aug. 1975	Jan. 1977
Caspar W. Weinberger	Feb. 1973	Aug. 1975
ASSISTANT SECRETARY FOR HEALTH:		
James F. Dickson (acting)	Jan. 1977	Present
Theodore Cooper (note a)	Feb. 1975	Jan. 1977
Charles C. Edwards	Mar. 1973	Jan. 1975
COMMISSIONER, FOOD AND DRUG ADMINISTRATION:		
Donald Kennedy	Apr. 1977	Present
Sherwin Gardner (acting)	Dec. 1976	Apr. 1977
Alexander M. Schmidt	July 1973	Nov. 1976
SECRETARY OF THE TREASURY:		
W. Michael Blumenthal	Jan. 1977	Present
William E. Simon	Apr. 1974	Jan. 1977
COMMISSIONER, U.S. CUSTOMS SERVICE:		
G. R. Dickerson (acting)	May 1977	Present
Vernon D. Agree	May 1972	Apr. 1977

a/Acting Assistant Secretary for Health from February to May 1975.

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