29415

BY THE COMPTROLLER GENERAL Released

Report To The Chairman, Subcommittee On Oversight And Investigations, House Committee On Energy And Commerce

OF THE UNITED STATES

Legislative Changes And Administrative Improvements Should Be Considered For FDA To Better Protect The Public From Adulterated Food Products

Some adulterated food products identified by the Food and Drug Administration (FDA) occasionally enter the market. The amount of such adulterated products entering the market could be reduced if FDA had authority to require food producers or distributors to refrain from marketing those products, while FDA processes a formal seizure order through the courts. In addition, FDA's attempts to determine the cause of product adulteration and recover such products after they have been distributed or sold are hampered because it lacks authority to review a firm's production and shipping records. The Congress should consider amending the Federal Food, Drug, and Cosmetic Act to give FDA these additional authorities.

Criminal prosecutions have resulted in small fines. The maximum fine per violation was established by law in 1938 and has been eroded by inflation. The Congress should consider increasing the maximum fine to permit greater flexibility in assessing penalties.

This report also recommends actions FDA should take to improve the timeliness of the process for seizing adulterated food products and verify the destruction or reconditioning of recalled foods.

530133

GAO/HRD-84-61
SEPTEMBER 26, 1984

Request for copies of GAO reports should be sent to:

U.S. General Accounting Office
Document Handling and Information
Services Facility
P.O. Box 6015
Gaithersburg, Md. 20760

Telephone (202) 275-6241

The first five copies of individual reports are free of charge. Additional copies of bound audit reports are $3.25 each. Additional copies of unbound report (i.e., letter reports) and most other publications are $1.00 each. There will be a 25% discount on all orders for 100 or more copies mailed to a single address. Sales orders must be prepaid on a cash, check, or money order basis. Check should be made out to the "Superintendent of Documents".

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

B-210249

The Honorable John D. Dingell
Chairman, Subcommittee on Oversight
and Investigations
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman:

At your request, we have reviewed the Food and Drug Administration's (FDA's) efforts to remove adulterated food products from the market. We also determined what additional legislative authorities would assist FDA in assuring that food offered to the public is pure, safe, and wholesome. The report asks the Congress to consider amending the Federal Food, Drug, and Cosmetic Act to grant FDA authority to (1) detain adulterated products while processing seizure actions and (2) review manufacturers' production and shipping records for adulterated products. Also, the Congress should consider increasing the maximum fine associated with criminal prosecutions.

As agreed with your office, we have obtained written comments from the Secretary of Health and Human Services and from the Attorney General. Their comments are included as appendixes to this report.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 10 days from its issue date. At that time we will send copies to the Secretary of Health and Human Services, the Department of Justice, other congressional committees and interested parties, and make copies available to others upon request.

Sincerely yours,

Charles A. Bowsher

Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT TO THE CHAIRMAN, SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS, HOUSE COMMITTEE ON ENERGY AND COMMERCE

LEGISLATIVE CHANGES AND ADMINISTRATIVE IMPROVEMENTS SHOULD BE CONSIDERED FOR FDA TO BETTER PROTECT THE PUBLIC FROM ADULTERATED FOOD PRODUCTS

D I G E S T

The Food and Drug Administration (FDA) is responsible for assuring that food offered to the public is pure, safe, wholesome, and properly labeled. Food found to be adulterated, mislabeled, or potentially harmful (adulterated food products) may be voluntarily recalled by food firms under FDA's direction or seized through legal action. Adulterated products might consist of such items as parasite infested scallops or flour contaminated with rodent excreta or urine. Firms producing adulterated products and officials of such firms may be prosecuted.

The Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, asked GAO to evaluate FDA's efforts in removing adulterated products from the market and to determine if FDA needs additional authority to carry out its responsibilities. GAO reviewed (1) 163 of the 585 food recalls which occurred in fiscal years 1980-82, (2) all 131 fiscal year 1982 seizures and 71 of the 310 seizure actions against adulterated food products in fiscal years 1980-81, and (3) all 22 prosecution actions carried out by FDA during fiscal years 1980-82. (See pp. 3 and 4.)

FDA MUST RELY ON OTHERS TO DETAIN ADULTERATED FOODS

Although the Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to seize adulterated food products, it does not give FDA authority to detain--prohibit movement or marketing--such products while processing seizure actions through a U.S. attorney's office and the courts. Once the court approves the seizure, a U.S. marshal is ordered to seize the product. On the average, this process takes about 65 days.

Since FDA lacks detention authority, it often requests states to use their authority to detain or firms to voluntarily hold food products while seizure actions are processed. (See p. 5.)

In 154 of the 190 seizure actions reviewed by GAO, either states detained or firms agreed to voluntarily hold adulterated products while FDA obtained a court-approved seizure. Similar information was not available for 12 additional seizure actions GAO had selected for review. In the 154 cases, more than 90 percent of the adulterated products were seized by U.S. marshals. In the other 36 seizures, FDA records did not indicate and there was no reasonable way to determine if states or local agencies were requested to detain or firms were asked to voluntarily hold food products. In these cases FDA acted on its own and was able to seize 55 percent of the adulterated foods. In eight of these cases, none of the adulterated products was available for seizure because the products were distributed by the firms. (See p. 6.)

For example, an FDA inspection identified 1,800 pounds of pinto beans and 1,450 pounds of rice being stored under insanitary conditions. In addition, a later FDA laboratory analysis showed the rice to be contaminated with rodent excreta and urine. FDA learned that none of the product was available for seizure from the firm's officials who told FDA that the products were distributed within 1 week of the FDA inspection. (See p. 7.)

FDA cannot always rely on states to detain or food firms to voluntarily hold products. In some cases, states disagree with FDA as to whether the product is adulterated and should be seized. In 19 of 76 cases where FDA requested and the firms agreed to voluntarily hold the product, the firms distributed or sold all or part of the food before the seizure action was completed. FDA records did not indicate why the firms distributed or sold the products. (See p. 8.)

FDA could prevent greater amounts of adulterated products from getting on the market if it had legislative authority to detain adulterated food products while it obtains a seizure notice. FDA does have detention authority for other products that it regulates, including imported products falling under its jurisdiction and medical devices (see app. II).

FDA COULD ACCELERATE ITS SEIZURE APPROVAL PROCESS

The seizure process begins when a suspected food product is sampled and subsequent laboratory analysis shows that the product is adulterated. An FDA district office recommendation to seize the product is reviewed by the Center for Food Safety and Applied Nutrition, the Associate Commissioner for Regulatory Affairs, and FDA's General Counsel. These units review the recommended seizure to confirm that a violation occurred and to insure consistency with FDA policies and compliance with legal requirements. During fiscal years 1980-82, FDA headquarters approved 98 percent of district-recommended seizures. GAO's review of 202 seizures showed that FDA's review process took 41 days on the average, ranging from 5 to 206 days. On the average, an additional 24 days, ranging from 1 to 150 days, was needed to process the seizure through the U.S. attorney's office and the courts. (See pp. 10 and 11.)

FDA has recognized the need to speed up the seizure review process and has developed a direct reference process that eliminates headquarters review levels (primarily the Center for Food Safety and Applied Nutrition) for certain seizures. Of the 202 seizures GAO reviewed, 39 were processed under the direct reference procedure. FDA approval of these 39 seizures took, on the average, 26 days, or 15 days less than seizures not using direct reference. However, for 11 of the 39 seizures, FDA approval took between 30 and 54 days. (See pp. 13 and 14.)

GAO believes that FDA could process more routine seizures under the direct reference procedure. FDA officials consider routine seizures to be

those involving filth (rodent and insect contamination) and economic adulteration (shortweighting). Because such seizures seldom involve new policy issues, review and approval by headquarters officials in the Center for Food Safety and Applied Nutrition and the Office of the Associate Commissioner for Regulatory Affairs could be eliminated. Of the 202 seizures GAO reviewed, 146 involved shortweighting, defective containers, and filth (see p. 12). FDA should take steps to speed up the seizure approval process since more timely actions could help keep more adulterated products from reaching the market. (See p. 15.)

FDA NEEDS AUTHORITY TO REVIEW MANUFACTURERS' RECORDS ONCE ADULTERATED PRODUCTS ARE IDENTIFIED

FDA's ability to remove adulterated products from the market is hampered because it has no legislative authority to review a manufacturer's production and distribution records. Before FDA can take action to have a suspect product removed from the market, it must prove the product is adulterated and has been shipped in interstate commerce. Once product adulteration is proven, the amount of the product produced and the extent of distribution must be determined.

In 30 of the 163 recalls GAO reviewed, FDA was denied access to a firm's records. These records denied FDA were needed to determine what caused the product to be adulterated, to whom the product was distributed, and how the firm disposed of the recalled food. (See p. 16.)

In addition, GAO noted that in some instances FDA seizure efforts were either delayed or prevented because firms refused FDA access to shipping records. Obtaining a copy of the firms' shipping records is the most convenient way to document interstate shipment. Because FDA investigators were denied shipping records in one FDA district, 11 of the district's seizure actions were delayed from 1 to 12 days. In another district, an investigator had to follow a delivery vehicle across a state line in order to document interstate shipment. (See p. 18.)

FDA NEEDS TO IMPROVE ITS MONITORING OF RECALLED FOOD

FDA has not developed guidelines for its districts to use in verifying the reconditioning or destruction of recalled food. FDA verification decisions are made on a case-by-case basis. In 77 of the 163 recalls GAO reviewed, FDA did not verify (witness or obtain third party confirmation), or verified to a limited extent, the destruction or reconditioning of the recalled food. FDA, in many cases, accepted the recalling firm's verbal or written statement that the food was destroyed or reconditioned. FDA does not always have sufficient resources to verify product destruction or reconditioning of large nationwide recalls, and firms do not always notify FDA when such actions are to take place. (See p. 18.)

Problems can arise because of inadequate FDA verification. During recent recalls, involving significant health hazards, products were later sold without being properly reconditioned. For example, in one case, because the product was sold to retail outlets without being properly reconditioned, it had to be recalled a second time. GAO believes FDA should develop guidelines regarding the verification of the destruction or reconditioning of recalled foods. The guidelines should address such factors as the firm's reputation, FDA's resources, the type of product being recalled, and the reason for the recall.

MAXIMUM FINE FOR VIOLATING THE ACT SHOULD BE INCREASED

Food firms and individuals do not always take the necessary actions to correct insanitary conditions even after such conditions result in criminal prosecutions under the FD&C Act. FDA inspection reports showed that 5 of the 19 firms prosecuted for the first time and convicted during fiscal years 1980-82 did not correct insanitary conditions; 3 additional firms were prosecuted a second time. (See p. 25.)

FDA is selective in seeking court action and generally recommends that U.S. attorneys prosecute only firms that have continued to produce adulterated food products and operate under insanitary conditions.

In 1938, the Congress believed that fines higher than those in existence were needed to bring about compliance with the FD&C Act and raised the fines to the current maximum level. However, the amounts established have never been adjusted and have been eroded by inflation. For example, persons or firms violating provisions of the FD&C Act can receive fines up to $1,000 per violation and/or up to 1 year's imprisonment on the first conviction and up to $10,000 per violation and/or up to 3 years' imprisonment can be assessed on a second conviction or where such violation was committed with the intent to defraud or mislead. Considering inflation, a comparable fine today for the first conviction would be about $7,500.

Fines assessed against firms and individuals during fiscal years 1980-82 averaged about $500 per violation or about $3,000 per prosecution for first-time offenders. Firms and individuals prosecuted a second time were fined about $4,200 per violation or $12,700 per prosecution. Fines assessed are small, considering that each of the firms had estimated annual sales that exceeded several hundred thousands of dollars. (See pp. 25 to 29.)

RECOMMENDATIONS TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

GAO recommends that the Secretary direct the Commissioner of FDA to:

--Initiate steps to improve the timeliness of seizure actions by identifying more routine seizure cases involving filth and economic adulteration that could be referred by district directors directly to U.S. attorneys after concurrence by FDA's General Counsel.

--Develop guidelines specifying required verification procedures to ensure that the destruction or reconditioning of recalled foods is adequately verified directly by FDA or through some alternative means, such as appropriate state or local officials. (See pp. 15 and 24.)

MATTERS FOR CONSIDERATION BY THE CONGRESS

The Congress should consider amending the FD&C Act to provide FDA authority to detain food products suspected of being adulterated and to review manufacturers' production and distribution records of adulterated products. Also, the Congress should consider increasing the maximum fine associated with criminal prosecutions for persons or firms convicted of violating provisions of the act. GAO discusses several issues, such as how detention authority should be applied, that the Congress should consider in deliberating these matters. (See pp. 14, 24, and 31.)

AGENCY COMMENTS

The Department of Health and Human Services stated that the report has identified and appropriately delineated issues of significant concern to FDA. The Department agreed with the recommendations to the Secretary and pointed out actions that would be taken. For example, guidelines specifying required verification procedures to ensure the destruction and reconditioning of recalled foods will be developed.

Written comments were also obtained from the Department of Justice concerning matters in this report. The Department emphasized that it stands ready to take expedited action in those cases where adulterated food products pose a serious threat to health and safety. The Department acknowledged that the seizure process cannot always be completed as rapidly as the Department would like.

Contents

ILLUSTRATIONS

ABBREVIATIONS

ACRA	Associate Commissioner for Regulatory Affairs
EDRO	Executive Director of Regional Operations
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
GAO	General Accounting Office
HHS	Department of Health and Human Services

CHAPTER 1

INTRODUCTION

An estimated 280 billion pounds of food are marketed in the United States each year for human consumption. If the food (except for meat and poultry products, which are regulated by the U.S. Department of Agriculture) is involved in interstate commerce, it is under the jurisdiction of the Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS). Although the food industry has primary responsibility for ensuring that its products are pure and wholesome, the Congress gave FDA the responsibility for protecting the consumer through enforcement of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended (21 U.S.C. 301). The act prohibits the introduction or delivery of adulterated or misbranded products[1] into interstate commerce. (In this report, adulterated or misbranded products are identified as adulterated products.)

FDA consists of a headquarters staff, 10 regional offices, and 22 district offices located throughout the United States and in Puerto Rico. The Center for Food Safety and Applied Nutrition, in conjunction with the Associate Commissioner for Regulatory Affairs (ACRA), establishes the basic policies used by FDA in implementing its food compliance activities. In addition, ACRA responsibilities include evaluating and coordinating FDA activities to ascertain compliance with regulatory policy and enforcement objectives. The Executive Director of Regional Operations (EDRO), based on policies established by ACRA and the Center for Food Safety and Applied Nutrition, is responsible for coordinating the inspection and enforcement activities of FDA's field operations.[2] FDA's efforts to protect the consumer depend largely on its ability to identify and quickly remove from the market products suspected or known to be adulterated. FDA identifies such products by inspecting the firms' facilities and by testing finished products. Section 704 of the FD&C Act authorizes FDA investigators to visually inspect the manufacturing practices, facilities, and conditions under which food products

---

[1]The statute defines an adulterated product as one that is defective, unsafe, filthy, or not produced under sanitary conditions. A misbranded product is one with labeling that is false or misleading or with labeling that fails to provide important and/or required information.

[2]On April 11, 1983, the Commissioner of FDA forwarded to the Secretary of HHS and to the Assistant Secretary for Health a recommendation to combine ACRA and EDRO. As of July 1984, the recommendation was awaiting approval.

are manufactured, processed, or packed and take samples of food products suspected of being adulterated. Upon completion of the facility inspection, a written report identifying objectionable conditions is provided to the firms' management.

FDA uses four methods--seizures, injunctions, recalls, and the voluntary destruction of products by firms--for removing or keeping adulterated products from the market. Seizures are authorized under section 304 of the FD&C Act. A complaint for seizure is filed by the U.S. attorney's office within the appropriate district court. The court then orders a U.S. marshal to seize the adulterated product. Seizures are limited to the specific quantity and location of products identified in the seizure complaint. However, the act does not give FDA authority to detain products suspected or known to be adulterated.

Recalls and voluntary destruction of products are made by the voluntary action of the manufacturer or distributor. When a firm widely distributes an adulterated product, it is often impractical for FDA to seize the product at many locations nationwide. FDA relies on the firms to recall the product and evaluates their efforts through monitoring. In some cases, when the recall is nationwide and the violation presents a serious health hazard, state and local agencies give FDA assistance in its monitoring of the firms' effectiveness in recalling the product.

Recalls began ad hoc and were first widely used in the 1960's when FDA asked certain drug firms to recall products as an alternative to its multiple seizure actions. The firms complied to avoid seizure action, and FDA's new tool for removing products from the market had its beginning. However, seizures and recalls require time to be initiated. (For a description of the recall process, see app. III.)

The FD&C Act gives FDA authority to seek court-ordered injunctions to prevent individuals or firms from distributing adulterated products nationwide. In addition, persons and firms can be prosecuted for violating provisions of the act. Fines up to $1,000 per violation and/or up to 1 year's imprisonment can be assessed on the first conviction involving a violation of the act and up to $10,000 per violation and/or up to 3 years' imprisonment can be assessed on a second conviction involving a violation of the act or where such violation was committed with the intent to defraud or mislead.

OBJECTIVES, SCOPE, AND METHODOLOGY

Since the early 1970's, there have been several debates within the Congress concerning FDA's effectiveness in removing

adulterated products from the market and its authority to accomplish this. Because of the Congress' continuing interest in this subject, the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce, in a June 18, 1982, letter, asked us to review FDA's efforts to remove adulterated products from the market. Specifically, the Subcommittee asked us to (1) identify the roles and responsibilities of FDA and food firms in a recall; (2) determine what is FDA's basis for a recall, what are its criteria for determining the actions to be taken to remove the product from the market, and what assurance it has that the product has been either reprocessed or destroyed; and (3) explore other alternatives available to FDA to assure that adulterated products are removed from the marketplace. The Subcommittee's other interests centered on the 1982 canned salmon recall, which is being reported upon separately. In addition, we also examined what changes in FDA's operating procedures might more effectively protect the public from adulterated food products.

The review was performed at FDA headquarters in Rockville, Maryland, and at the Detroit, Dallas, Los Angeles, and Seattle district offices. We selected these districts because they were involved in the largest number of recalls during fiscal years 1980-82. We reviewed 163 of 585 food recalls (28 percent) monitored by FDA during this period.

We also reviewed 202 of 441 seizures (46 percent) implemented by FDA during the same 3-year period. Information was obtained on 31 fiscal year 1980 seizures, 40 fiscal year 1981 seizures, and all 131 fiscal year 1982 seizures. We reviewed seizure files at seven FDA districts for 141 of the 202 seizures. In addition to reviewing seizures for fiscal years 1980-82 at the four districts indicated above, we visited the Atlanta, Buffalo, and Brooklyn districts to obtain information on fiscal year 1982 seizures. These three were visited because they were involved in the largest number of seizures (39) carried out during fiscal year 1982. FDA obtained for us information on the other 61 fiscal year 1982 seizures.

For each seizure we attempted to determine the amount of adulterated product identified, the amount seized, and the time required by FDA and the Department of Justice to implement the seizure action. Information was available on all 202 seizure actions concerning FDA and Department of Justice processing time. However, information on the amount of product seized was not available in FDA files for 12 of the 202 seizures reviewed. We also attempted to determine what caused food to become adulterated. We discussed with district officials whether some repetitive seizure actions could be considered as routine and whether headquarters review of these seizure actions could be eliminated.

In addition, we reviewed all 22 food prosecution cases which were completed during fiscal years 1980-82. The cases, which involved violations of section 402(a)(3) and section 402(a)(4) of the FD&C Act,[3] were reviewed to obtain information on how firms are prosecuted and the fines and sentences imposed. At the time we began our review, the 3 fiscal years reviewed represented the most current data available.

We also developed data to show instances when FDA incurred an access to records problem in the 163 recalls we reviewed. We did not develop similar data for seizure actions because the seizure files we reviewed contained limited data concerning FDA's access to records problem.

For comparison purposes, we gathered information on the legislative authority that other agencies had for seizing and recalling products and prosecuting firms, including the Department of Justice, which is responsible for prosecuting FDA cases and seizing adulterated food products, the Department of Agriculture, the Environmental Protection Agency, the Department of Transportation, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission.

To obtain input from the food industry, we contacted officials at the Food Marketing Institute, the Grocery Manufacturers Association, and the National Food Processors Association regarding their individual views on the issues discussed in this report.

We also reviewed agency policies and procedures concerning regulatory actions, appropriate laws, regulations, and manuals to become more knowledgeable about FDA actions and to determine FDA's authority and procedures for implementing these actions. We interviewed FDA district directors and headquarters officials to obtain their views on the matters discussed in this report.

Our review was conducted during July 1982 through December 1983. It was performed in accordance with generally accepted government auditing standards.

---

[3]Sections 402(a)(3) and (a)(4) define adulterated food as (1) any food that consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food, or (2) if the food has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.

CHAPTER 2

FDA NEEDS DETENTION AUTHORITY AND SHOULD ACCELERATE ITS SEIZURE APPROVAL PROCESS TO PREVENT ADULTERATED FOOD FROM ENTERING THE MARKET

Some adulterated food products identified by FDA occasionally enter the market because FDA does not have authority to detain most food products while it obtains a seizure order, even in obvious cases of product adulteration, such as insect or rodent infestation. FDA does have detention authority for other products it regulates, such as imported products (including food) and medical devices. Since FDA lacks detention authority, it often asks states to detain suspected foods or firms to voluntarily hold the food. When states and firms cooperated, more than 90 percent of the adulterated food was seized. When states did not assist or FDA seized products without the voluntary cooperation from firms, an average of 55 percent of the adulterated food originally identified was recovered. In 25 of 190 seizure actions we reviewed, all or a large portion of the food had been sold before it could be seized. For example, in 12 seizure actions none of the product was seized. In 13 seizure actions 50 percent or less of the product was seized.

Current FDA and Justice procedures require several levels of review to process most seizure recommendations. FDA records showed that it took an average of 65 days to implement a seizure order. FDA's headquarters review accounted for an average of 17 days of this process, while district offices and Justice each used an average of 24 days. More seizure actions, which are relatively simple and repetitive, such as insect and rodent contamination, and do not involve new policy determinations (referred to hereafter as routine seizures), could be referred directly to U.S. attorneys without review and approval by some headquarters officials.

EFFECTIVENESS OF FDA'S ACTIONS DEPENDS ON COOPERATION OF OTHERS

Although FDA is the federal agency responsible for ensuring that the nation's food supply (except red meat and poultry) is pure and wholesome, it must seek the cooperation of state and local agencies and the food industry if it is to be successful in seizing adulterated foods, since it has no authority to detain adulterated foods on its own. As illustrated below, when FDA is able to obtain the cooperation of states and food firms, the percentage of adulterated food seized is substantially greater than when FDA must act on its own.

Type of Actions and Number of Seizures

Percent of product seized	State or local agency detained product for FDA	Firm agreed to voluntarily hold product for FDA	FDA acted without assistance	Total seizures
76 -100	75	68	15	158
51 - 75	2	2	3	7
26 - 50	0	2	5	7
1 - 25	0	1	5	6
0	1	3	8	12
Total	78	76	36[a]	190[b]

aIn these 36 cases, FDA records did not indicate if states or local agencies were requested to detain or firms were asked to voluntarily hold food products while FDA processed the seizure action.

bAlthough we selected 202 seizures for review, information on the amount of product seized and whether state agencies detained and firms voluntarily held the product or FDA acted without assistance was available for 190 seizures.

When FDA had either a state or local agency detain the adulterated product for them--in 78 of the 190 seizure actions reviewed--an average of 97 percent of the adulterated food identified was seized.

--For example, FDA investigators identified on December 18, 1981, 96,400 pounds of sesame seeds which they suspected to be contaminated with filth. State officials were immediately notified, and a detention was placed on the product. Laboratory analysis confirmed the filth contamination. The product remained under detention until the seizure order could be implemented. On February 25, 1982, all of the adulterated product was seized.

Adulterated products get on the market when FDA has to act on its own

Although FDA, in implementing 154 of the 190 seizure actions we reviewed, asked states or local agencies to detain or firms to voluntarily hold adulterated products while processing seizure actions, there were 36 instances when FDA attempted to seize a product without such assistance. In these cases, an average of 55 percent of the adulterated food was recovered. In 8 of the

36 cases, FDA did not recover any of the adulterated food, and in another 10 cases, 50 percent or less of the adulterated product was recovered.

--For example, FDA sampled 24,000 pounds of scallops from a North Carolina scallops processor on January 6, 1982. Laboratory analysis on January 25 showed that the scallops were infested with parasites. When the U.S. marshal attempted to seize the scallops on March 16, the firm advised him that all 24,000 pounds of the scallops had been sold. The scallops were sold within 3 weeks from the time FDA took the sample.

--In another example, on January 25, 1982, FDA sampled about 12,000 pounds of products being stored by a Chicago firm. Laboratory analysis on February 18 showed that the products were contaminated with rodent excreta and urine. The district office forwarded a recommendation to seize the products to FDA headquarters on March 11, 1982. However, the seizure recommendation was withdrawn on March 26 because all 12,000 pounds had been sold.

Some state and local agencies do not always agree with FDA that products should be detained for FDA. Each state has its own food and drug laws, and the product must also be shown to violate the state's standard for implementing its food law.

--For example, FDA completed a joint inspection of a firm with state inspectors on December 15, 1981, and identified 1,800 pounds of pinto beans and 1,450 pounds of rice being stored under insanitary conditions. FDA requested the state to detain the products. State officials denied the request because the state inspector did not agree with FDA that the condition was sufficiently bad to warrant detaining the product. FDA's analysis of the rice showed that in addition to it being stored under insanitary conditions, the rice was contaminated with rodent excreta and urine. FDA did not ask the Justice Department to seize the beans and rice because on January 15, 1982, it learned that none of the adulterated food was available. Officials from the firm told FDA that the products had been distributed within 1 week of FDA's inspection.

Also, FDA is reluctant to ask for state assistance in "grey areas" where district officials are not sure the seizure request will be approved by headquarters officials.

--For example, FDA attempted to seize 18 cases of herbal tea which contained a common wormwood poison found naturally in the tea. The state was not asked to detain nor was the

firm asked to voluntarily hold the product because of disagreement among food experts as to whether the substance is harmful. The case was dismissed by the U.S. attorney on November 13, 1980, because none of the tea was available for seizure.

Because of the uncertainty of such cases as described in the example above, an FDA district official advised us that FDA usually will ask for state assistance only when the product contains visible filth or when laboratory analysis confirms that the product is adulterated.

FDA has succeeded in getting most firms to voluntarily hold adulterated foods until they can be seized. FDA officials in two districts prefer to have firms voluntarily hold the product whenever possible. However, if a firm has not cooperated with FDA in the past, or FDA has reason to believe the firm will move the product, it will process the seizure action without the firm's knowledge.

In 76 of the 190 seizures which we reviewed (40 percent), FDA asked the firm to voluntarily hold the product. In each case the firm agreed, and an average of 91 percent of the adulterated food was seized. The amount of adulterated food seized would have been higher, but 19 of the 76 firms distributed or sold all or part of the food while awaiting FDA's seizure action.[1]

--For example, FDA investigators on December 14, 1981, identified 6,228 jars of insect-contaminated peanut butter. The firm agreed to hold the peanut butter until the seizure order could be implemented. When FDA returned on February 25, 1982, to seize the peanut butter, all 6,228 jars had been sold. The product was later recalled, but only 237 jars were obtained.

PRECEDENT EXISTS FOR DETENTION AUTHORITY

FDA has detention authority for such items as imported products (including food) and medical devices. (See app. II for a description of FDA's detention authority.)

We discussed FDA's need for detention authority with officials from three food associations. Officials from two of the associations agreed that FDA needs detention authority provided the authority is subject to appropriate procedural safeguards,

---

[1]FDA records did not indicate the reasons for the firms' actions.

such as time limitations (detention should not exceed 30 days), a finding that the food in question is adulterated as defined by specific sections of the act, and a provision for an expedited appeal of the detention to the Secretary of HHS.

The president of the third food association stated that he was not comfortable with the idea of FDA having detention authority. He also stated that he would like to see how it would be implemented before taking a position either for or against such authority.

FDA has sought authority to detain food products periodically since 1972. All attempts have been unsuccessful. FDA advised us that administrative detention proposals were part of omnibus bills proposed to amend the FD&C Act during the 93rd and 94th Congresses. According to FDA, the administration did not introduce an omnibus bill to amend the act in the 95th Congress, but an administrative detention proposal was contained in a draft bill, approved by FDA, which was never cleared through the Office of the Secretary. The proposal was again included in an omnibus bill in the 96th Congress. The Congress did not pass any of the omnibus bills.

FDA headquarters officials and district directors interviewed believe that detention should be for a period of 30 days. The district directors stated that authority for detaining adulterated products should be delegated to district directors, thereby eliminating certain headquarters review levels (see table, p. 11), and that detention appeals brought by firms should be as simple as an informal meeting with the district director. The officials stated, however, that detention authority with an appeals process similar to what they have for medical devices would be a handicap. They said this appeals process requires that FDA's general counsel and the firm's attorneys argue the case before an agency official. The officials believed that this process is too formal, too complicated, and time consuming.

FDA headquarters officials stated that as a result, limited use has been made of the medical device detention authority--21 times since the enactment of the Medical Device Amendments on May 28, 1976. They added that many FDA officials would welcome this additional enforcement authority for foods if it could be enacted with less cumbersome requirements.

FDA HEADQUARTERS REVIEW IS NOT NEEDED FOR EVERY SEIZURE ACTION

FDA records show that it takes an average of 65 days to seize an adulterated food product. While current procedures require multilevel headquarters review of most seizures recommended

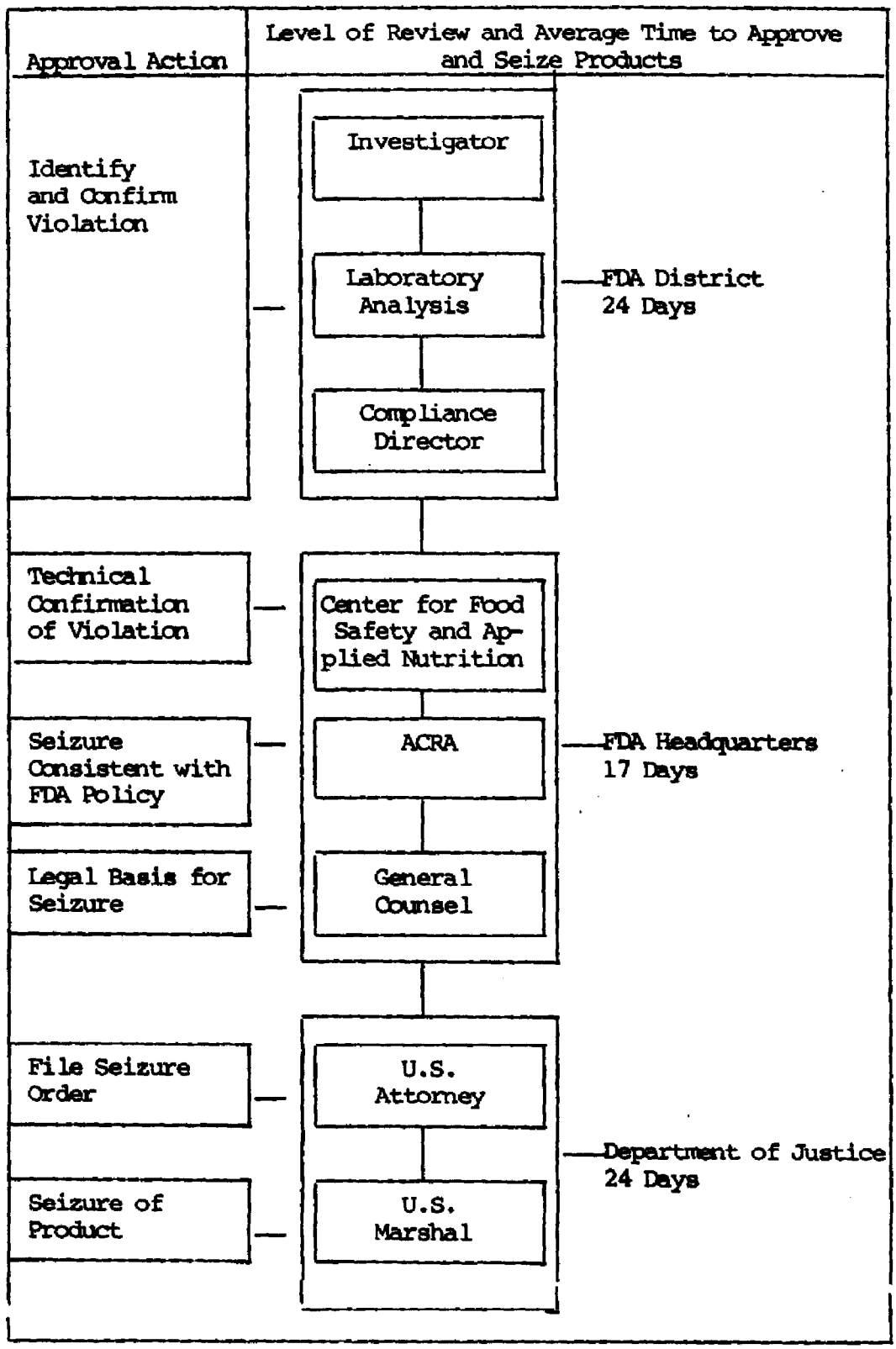
by the districts, FDA has a fast-track review process (direct reference) for routine seizures which eliminates certain headquarters review levels. Opportunities exist for FDA to process more routine seizures under direct reference and to simplify its review process to permit more rapid processing of routine seizures to U.S. attorneys. The 146 seizure actions we reviewed were of a routine nature involving filth, shortweighting, or defective containers. FDA processed 39 of these seizures under direct reference.

The approval process for seizures should be faster, especially if the Congress were to grant FDA authority to detain food products for any period less than the current 65-day average time required to process seizure orders. Even if detention authority is not granted, FDA should take steps to speed up its seizure approval process since timely actions on FDA's part should help keep more adulterated products from reaching the market. FDA district officials said that some seizures could be implemented without headquarters review by the Center for Food Safety and Applied Nutrition and ACRA.

FDA's multilevel approval process is time consuming

The seizure process begins when an FDA investigator collects a sample of food suspected of being adulterated and continues until the item is seized by the U.S. marshal. When laboratory tests confirm adulteration, the recommendation to seize must clear several levels of review at FDA headquarters. A nonroutine seizure recommendation is reviewed by the Center for Food Safety and Applied Nutrition for technical merit and compliance with policy, ACRA for compliance with overall agency policy, and FDA's General Counsel for legal merit. The request is then forwarded to the U.S. attorney who files the seizure request in the appropriate federal district court. If the court approves the seizure, the U.S. marshal is ordered to seize the food. The following chart shows the average length of time needed to process the 202 seizure actions we reviewed. FDA's review process averaged 41 days, ranging from 5 to 206 days. An additional 24 days on the average, ranging from 1 to 150 days, was needed to process the seizures through the U.S. attorney's office and the courts.

FDA Seizure Process[a]



[a]For processing of direct reference seizures, see page 13.

Routine seizures could be approved at the district

The same multilevel review process was used for 163 of the 202 seizures we reviewed, many of which involved routine matters, such as filth from insect and rodent contamination.

We noted that FDA headquarters approved 441 of 448 seizure recommendations (98 percent) made by district officials during fiscal years 1980-82. Our review of 202 of the 441 seizure actions showed that 146 of the seizures (over 72 percent) were considered as routine by district officials. The officials said that seizures involving filth (insect and rodent contamination), economic adulteration, such as shortweighting, and defective containers can be considered as routine.

Reason Product Was Adulterated

Reason for seizure	Number of seizures	Percent of seizures
Economic adulteration	31	15
Defective containers	7	4
Filth	108	53
Subtotal	146	72
Other types of contamination[a]	56	28
Total	202	100

[a]Nonroutine seizures involve other types of contamination, such as improper homogenization, spoilage, chemical/pesticide contamination, yeast/bacterial contamination, and excessive mold.

As shown in the above table, the reason for 53 percent of the 202 seizures was filth. Economic adulteration (mislabeling, misbranding, or shortweight) accounted for another 15 percent, and defective containers (leaking and/or swollen cans) accounted for 3.5 percent. Examples of some lengthy times required to seize products contaminated by filth follow.

--It took 55 days to seize noodles contaminated with rodent excreta. Although the district confirmed that the product was adulterated and provided this information to FDA headquarters on November 26, 1980, the seizure recommendation was not received by the U.S. attorney until December 21, 1980, 26 days later. When the U.S. marshal visited the firm on January 8, 1981, to seize the noodles, he found only 15 of 72 cases (20 percent) available for seizure. The remaining noodles had been distributed.

--Cheese contaminated with insect filth took 70 days to be seized. Headquarters review accounted for 27 of the 70 days.

--Vinegar contaminated with insects (fruit flies) took 76 days to be seized. Headquarters review accounted for 30 of the 76 days.

--Dried lemon peels adulterated because of rodent contamination took 36 days to be seized. Headquarters review accounted for 22 days.

District officials we interviewed believe that seizure recommendations of the above type could go directly from the district to the appropriate U.S. attorney's office for filing in the respective U.S. district court.

An FDA headquarters policy official stated that the multilevel headquarters review process is necessary to assure consistent and equal enforcement of the act. The official said that the current system assures that similar violations in different parts of the country are treated the same and that only quality cases are taken to the courts. The official also said that headquarters has to decide what type of violations to pursue in order to support overall agency policy. The official added that the current system is extensive, but it helps the agency retain its credibility with industry.

- - - -

The reasons given for maintaining the multilevel review process have merit. However, we believe headquarters review of every seizure action is not necessary. Establishing specific policies and criteria to guide district officials in determining when a seizure action is appropriate would be, in our opinion, a more efficient method of accomplishing the same results. A postreview of selected seizure actions would provide headquarters officials with information concerning consistency, accuracy, and completeness of the districts' seizure recommendations. Through a postreview, the officials would have data they need to make timely revisions to the program.

FDA has recognized the need to speed up the seizure approval process for routine seizures. FDA officials stated that these seizures, referred to as direct reference, are initiated by the districts, by-pass headquarters review, and go directly to the Office of the General Counsel. FDA officials stated that guidance for direct reference seizures has been developed in 82 instances involving adulterated foods and that FDA is involved in studying its direct reference seizure criteria to see if additional food products can be added.

FDA used the direct reference procedure for processing 39 of the 202 seizures we reviewed. This procedure eliminated one or more levels of headquarters review (primarily the Center for Food Safety and Applied Nutrition) in 34 of the 39 seizure cases. Seizures using the direct reference procedure were processed on the average in 26 days, or 15 days faster than seizures not using this process. However, 11 of these seizures took between 30 and 54 days to approve. In addition to FDA time, the Department of Justice required, on the average, 21 days to carry out the seizures.

CONCLUSIONS

Adulterated foods identified by FDA are occasionally sold before they can be seized because FDA lacks the authority to restrict sales or distribution without an approved seizure order. Since FDA records showed that it took an average of 65 days to implement a seizure order, and that FDA cannot always rely on states to detain or food firms to voluntarily hold products during this time, it could keep more adulterated food from the marketplace if it had detention authority.

Moreover, FDA's direct reference procedure is a good first step in attempting to reduce its time for processing seizure orders, but it does not go far enough. There appear to be more opportunities for FDA to expand its direct reference seizure process to more routine seizures involving rodent and insect contamination and economic shortweighting which would permit more rapid processing of these seizures to U.S. attorneys. Of the 146 routine seizures identified, 39 were processed through direct reference. To make the processing of seizure recommendations faster and simpler, some FDA headquarters reviews could be eliminated for routine and repetitive cases and those involving no new policy questions.

MATTER FOR CONSIDERATION BY THE CONGRESS

The Congress should consider whether FDA needs specific authority to detain adulterated foods while the agency processes seizure requests internally and through the Department of Justice. In deliberating on this matter, and in balancing concerns about due process and the expeditious resolution of seizure actions with the need to protect the public health, the Congress could consult with FDA, industry, and Department of Justice officials in terms of how such authority should be applied and the time restrictions which it may wish to impose on the application of such authority, particularly in view of FDA's limited application of medical device detention authority.

RECOMMENDATION TO THE SECRETARY OF HHS

We recommend that the Secretary direct the Commissioner of FDA to initiate steps to improve the timeliness of seizure actions by identifying more routine seizure cases involving filth and economic adulteration that could be referred by district directors to U.S. attorneys after concurrence by FDA's General Counsel.

AGENCY COMMENTS

HHS agreed that to the extent possible, district directors, with the General Counsel's concurrence, would refer routine seizure recommendations directly to the U.S. attorneys and determine whether additional products qualify for direct reference seizure actions and include those that do qualify in guidelines issued to district directors.

Justice commented that it considers adulterated food product cases that pose a serious threat to health and safety to be very important and stands ready to take expedited action to obtain judicial authority to proceed in such cases. Justice added that the U.S. marshal must seize and make arrangements to secure and/or destroy the items in question, a process which cannot always be completed as rapidly as Justice would like.

CHAPTER 3

FDA NEEDS ADDITIONAL ACCESS TO RECORDS AUTHORITY AND SHOULD IMPROVE EFFORTS TO VERIFY DISPOSITION OF RECALLED FOOD PRODUCTS

Although FDA works with a food firm when the firm recalls an adulterated product, it does not have authority to review records relating to the production, distribution, or interstate shipment of the product. These records are needed by FDA to determine how much of the product has been produced and to what extent and where the product has been distributed. Many food firms voluntarily provide FDA such records. In 30 of 163 recalls we reviewed (18 percent), however, FDA was denied access to these records.

In addition, we noted that FDA seizure efforts were either delayed or prevented because firms refused access to shipping records. Without shipping records, FDA has difficulty establishing that the firm does business in interstate commerce. As a result, FDA was forced to take more time-consuming approaches to document interstate shipment of adulterated foods before it could act to seize an adulterated food product.

When products are recalled or seized, they must be destroyed or reconditioned for subsequent resale. FDA does not always verify that this is done. Of the 163 recalls we reviewed, FDA did not verify, or verified on a limited basis, product destruction or reconditioning in 77 cases. We found some recalled food was remarketed without being examined or reconditioned. FDA advised us that it did not have sufficient resources to verify product destruction or reconditioning in all cases and that not all firms notify FDA when they destroy or recondition adulterated products. Guidelines defining appropriate methods for verification of this process could reduce the possibility of recalled food being remarketed unless it has been properly reconditioned.

RECORD REFUSALS HAMPER FDA'S EFFORTS TO REMOVE ADULTERATED PRODUCTS FROM THE MARKET

Section 704 of the FD&C Act generally limits FDA's investigators to visual examination of food manufacturing practices, facilities, and conditions under which products are manufactured, processed, packed, or stored. Before action can be taken against a suspected adulterated food product, FDA must obtain sufficient evidence to prove that the product is, in fact, adulterated and within FDA's jurisdiction.

During fiscal years 1980-82, FDA investigators in three district offices which we visited reported that they experienced access to records problems in 30 of 163 recalls that these districts monitored. A total of 59 record refusals were recorded concerning the 30 recalls. Records denied FDA were those needed to determine (1) what caused the product to be adulterated, (2) how widely and where it was distributed, and (3) how the firm disposed of the recalled food. Lack of records also hampered FDA's ability to make informed decisions about the best action to take to protect the public.

--For example, FDA received a consumer complaint on September 4, 1981, that an orange drink in a 12-ounce can had caused one person to suffer stomach cramps, nausea, and dizziness. FDA analyzed the remaining orange drink in the consumer's can and found mold in the drink.

FDA inspected the firm in response to the complaint and sampled the lot of orange drink involved in the complaint. During the inspection, officials at the firm refused to provide FDA any information concerning production, quality control, formulation, shipping, or other consumer complaints.

Laboratory analysis of a second sample of orange drink as well as samples of three other lots of the product disclosed leaking cans, mold in one can, and a high lead content in the drink.

The firm refused FDA distribution information on other lots of the product and agreed to recall only those specific quantities identified by FDA. As a result, FDA had no assurance that other lots of the product were not adulterated and had to use its investigators to locate quantities distributed to retail outlets.

We also found instances where FDA seizure efforts were delayed or prevented because firms refused to grant FDA access to shipping records. District officials stated that shipping records are needed to identify the location of adulterated products.

--For example, FDA inspected a firm and found processing equipment contaminated with filth. The firm had 300 cases of cookies on hand which were produced using the filthy equipment. FDA requested the state to detain the cookies. By the time the state could act, only 72 cases of the cookies remained at the manufacturer's plant. FDA was unable to determine the location of the other 228 cases of adulterated cookies because officials of the firm refused to give FDA distribution information.

In one action involving adulterated food where officials of the firm refused to provide FDA with shipping information, two FDA investigators had to follow a truck loaded with the adulterated product from Alabama to a truck terminal in Chattanooga, Tennessee, to establish interstate shipment of the product. In another instance, officials of a firm refused to provide shipping information which FDA needed to document that the firm was involved in interstate commerce and, therefore, under FDA's authority. As a result, an FDA investigator from the Baltimore district was sent to document interstate commerce at the New Jersey producer of one ingredient used in the firm's product.

FDA officials in one district told us that its investigators spend considerable time documenting interstate commerce for products involved in seizure actions because firms refuse FDA access to shipping records. Our review of the district's 65 seizure actions completed during fiscal years 1980-82 showed that the district was delayed 1 to 12 days in 11 of its seizure actions because access to shipping records was refused by the firms' officials.

We discussed FDA's access to records authority with officials from three food associations. All of the officials recognized FDA's need to have greater access authority. While they believed greater authority was needed, they all expressed concern over how it might be used. A major concern of the officials was the Freedom of Information Act and FDA's ability to safeguard certain data. The officials were concerned that a firm's competitors could get access to proprietary data (trade secret) which the FD&C Act defines as any method or process entitled to protection. In this regard FDA has a process for screening Freedom of Information requests which, if carried out, should safeguard proprietary data. Consequently, we do not believe that the associations' concerns should be a deterrent to expanding FDA's access to records authority.

Another concern expressed by two officials was that the records authority would allow FDA to require firms to provide information without justification or cause. One official believed, and we agree, that FDA should have access to records only when the request was tied into a specific adulterated product.

FDA DOES NOT ALWAYS VERIFY THAT RECALLED PRODUCTS ARE DESTROYED OR RECONDITIONED

FDA has not developed guidelines for its districts to use in verifying the destruction or reconditioning of recalled food products. FDA district officials said that they do not have the resources necessary to witness the destruction or reconditioning

of all recalled food products, considering the other responsibilities of the district. When this is not done, FDA cannot be assured that the adulterated products have been properly disposed of or reconditioned and have not improperly reentered the marketplace.

Our review disclosed that FDA did not verify or verified to only a limited extent the destruction or reconditioning of recalled food in 77 of 163 recalls (47 percent) that we reviewed. In most cases, FDA accepted the recalling firm's verbal or written statement that the food was destroyed or reconditioned. As the following table shows, in 49 of 77 recalls where verification did not take place, a class I or class II recall[1] was involved.

---

[1]Recall classification is the numerical designation, i.e., class I, II, or III, assigned to a particular product recall to indicate the relative degree of health hazard involved. Class I recalls involve products that could cause serious adverse health consequences or death; class II, products that may cause temporary or medically reversible adverse health consequences; and class III, violations that are not likely to cause adverse health problems.

Destruction or Reconditioning of Recalled Products Verified by FDA

Destruction/reconditioning	Recall classification Class I	II	III	Total	Percent
Verified[a]	0	33	48	81	50
Not verified or limited verification[b]	18	31	28	77	47
Not known[c]	0	3	2	5	3
Total	18	67	78	163	100

[a]We considered that verification took place if FDA recall files contained information on FDA's verification of the destruction/reconditioning of all recalled products or if the file contained data on third-party verification, such as receipts or signed statements from third parties that such actions occurred.

[b]We considered limited verification to have taken place if FDA witnessed only a portion of the destruction/reconditioning process.

[c]In five recalls, the case file contained no information on FDA's verification of the destruction or reconditioning of the product.

FDA officials in two districts told us that verification of the destruction or reconditioning of recalled food depends on several factors, including (1) the reputation of the firm and its location, (2) resources available to FDA at the time the process is being conducted, (3) the amount and type of the product to be destroyed or reconditioned, and (4) the reason the product was being recalled.

Officials in the district explained that it is sometimes difficult for FDA to verify the destruction or reconditioning process because of actions taken by the firm. The officials said that, because of national distribution, a product may be destroyed by retail stores or the firm may not notify FDA of the destruction or reconditioning of recalled food until after the process is complete.

For example, in 6 of the 18 class I recalls where verification did not take place, the recalled product had been distributed nationally, and the cognizant FDA district director informed us that it was destroyed by retail stores. Because several

thousand retailers were involved, FDA did not verify the destruction. In addition, we found that the firm responsible for the product being recalled in another three class I recalls, where verification did not take place, did not notify FDA of the recalls or the destruction of the recalled products until after the actions were completed. In these cases FDA could not verify the destruction of the recalled food. In the other nine class I recalls, FDA witnessed the reconditioning process only on a periodic spot-check basis.

Because FDA did not verify the destruction or reconditioning of recalled food, it could not be certain that adulterated food was not being remarketed. We identified three examples of class I recalls where recalled food was later remarketed without being reconditioned.

--For example, in two 1982 recalls, canned salmon was sold before it was reprocessed in accordance with an agreement between FDA and the recalling firms. These recalls were triggered because a Belgian man died from botulism after eating salmon from a defective can. No other case of botulism was reported. FDA learned that equipment which formed the can punctured a small hole in it and that other firms were using the same equipment. As a result, it was believed that other cans of salmon could have the same defect.

  Nine Alaskan canneries later recalled about 23 million cans of salmon from markets in the United States and overseas. FDA estimates that it spent about $9 million and 220 staff years supervising the recall.

  Because the recalls were due to defective cans, the recalling firms agreed to a reconditioning process which involved examining each recalled can for defects, including removing the label and visually inspecting each can. FDA verified the process on a periodic spot-check basis.

  In our review of FDA files, we noted two instances where some firms did not perform the visual inspection step of the reconditioning process. This may have led to the redistribution of some adulterated products. Over a 4-month period, one firm distributed 140 cases of recalled salmon that had not been visually inspected. The firm was able to recover 66 of the cases. However, the other 74 cases had been distributed to retail districts. We were unable to determine if any of this salmon was recovered.

In another instance, one of the firms made shipments of recalled salmon to a foreign country without visually examining the cans for defects. The foreign country found defective cans in the shipments and returned the salmon to the United States.

Officials of the firm that made the shipments stated that the cans were not visually inspected because they believed that this requirement did not apply to salmon being exported. However, the foreign government advised FDA that further shipments of canned salmon from the firm would be refused entry into the country until FDA confirmed that it was satisfied that the firm was complying with FDA's examination criteria.

--In addition to the salmon case, we noted an instance in 1980 where canned mushrooms recalled because some of the cans contained C. botulinum toxin[2] were returned to the market for resale without being reconditioned. The firm was subsequently prosecuted. FDA spent about $731,000 assisting the firm in its recall efforts.

FDA and the firm had agreed to a plan for reconditioning the product which included heat reprocessing (cooking) of the mushrooms to kill the botulinum toxin. According to court records, the firm correctly reconditioned the product only when an FDA inspector was present. When the inspector left the plant, the firm shipped the adulterated mushrooms without the proper heat reprocessing treatment.

In another instance, FDA verified the destruction or reconditioning of only a limited amount of the recalled product.

--For example, a firm conducted a recall of 2 weeks' production of corn chips after FDA initiated seizure action. The chips were recalled because aflatoxin (a potent carcinogen produced by a fungus found primarily on corn and peanuts) exceeded FDA guidelines.

The firm had its route salesman remove all stock being recalled during its normal deliveries. The recalled stock was returned and destroyed at the manufacturing plant. An FDA investigator stated that he witnessed the destruction

---

[2]C. botulinum toxin is a poison which, if consumed, could cause death or serious health consequences.

of only a few bags of the chips. Later, the general manager called the FDA district office to advise the officials that 10,772 bags and 19 bulk boxes of the chips were destroyed.

In reviewing the verification statistics we had developed, one district director stated that FDA's current practice is to allow district officials to evaluate each recall situation individually and take the action they believe to be most appropriate. The director said that district officials consider all the factors in the recall (firm involved, nature of the problem, scope and level of distribution, and where the product will be destroyed), and determine if it is the best use of FDA's resources to verify the destruction or reconditioning of the product. The director said that additional guidance to districts should still permit directors to use their best judgment in this regard.

An FDA headquarters official stated that providing guidelines to the districts would help to ensure that verification is performed by FDA when needed. However, the official said that the guidelines should be flexible enough to permit district directors to use their judgment in any situation.

CONCLUSIONS

FDA needs authority to examine production and shipping records of food firms to effectively protect the consumer from adulterated products. When firms do not cooperate with FDA to identify such products, FDA must attempt to seek out the adulterated products through more time-consuming means. Additional authority to review production and shipping records would permit FDA, in recall or seizure situations, to more quickly determine what caused the problem, how long the problem has existed, and how widely the product has been distributed. We believe that firms should be able to provide such information to FDA and that any proprietary data contained therein could be appropriately identified and safeguarded.

In addition, we believe that FDA should develop guidelines regarding verification of the destruction or reconditioning of recalled food that presents a potential health hazard. Normally, this would include food products involved in class I and II recalls. For these recalls, the firm should have a clear understanding that FDA intends to verify this process. We recognize that there are instances when the adulterated product has been distributed nationally and the recalling firm decides to have the product destroyed by the retail stores. In these situations, visual verification by FDA investigators of the destruction or reconditioning process may not be possible. Guidelines could

state FDA's policy concerning minimum verification efforts needed to ensure the proper destruction or reconditioning of products involved in class I and II recalls. Guidelines should address such factors as the firm's reputation, FDA's resources, the type of product being recalled, and the reason for the recall and specify the type and extent of documentation food manufacturers should submit to FDA to support the disposition of recalled products. In some instances, FDA may be able to rely on observations by independent state and local agency officials.

MATTER FOR CONSIDERATION BY THE CONGRESS

The Congress should consider amending the FD&C Act to give FDA authority to review production and shipping records after it has found that a firm is producing adulterated food products.

RECOMMENDATION TO THE SECRETARY OF HHS

We recommend that the Secretary direct the Commissioner of FDA to develop guidelines specifying required verification procedures, considering the factors discussed above, to ensure that the destruction and reconditioning of recalled foods is adequately verified directly by FDA or through some alternative means, such as appropriate state or local officials.

AGENCY COMMENTS

HHS agreed with the recommendation and stated that FDA will develop guidelines to assist district managers regarding verification of reconditioning or destruction of recalled products. HHS added that the guidelines must be flexible enough, however, to allow district managers to exercise their best judgment as to the degree of verification needed and how to achieve it within available resources and competing demands.

We agree that decisions regarding verification procedures should take into account such matters as available resources. HHS guidelines should explicitly address the various factors which would affect the verification process.

CHAPTER 4

HIGHER FINES NEEDED TO DEAL WITH FIRMS THAT DO NOT COMPLY WITH THE FD&C ACT

Criminal prosecutions of food firms and individuals do not always bring about compliance with the FD&C Act, and resulting fines have been small considering that some of the firms prosecuted have been operating under insanitary conditions for a number of years and have estimated sales in excess of several hundred thousands of dollars.

During fiscal years 1980-82, FDA inspection reports showed that 5 of the 19 firms prosecuted for the first time for insanitary conditions did not correct FDA-noted violations that led to the prosecutions. FDA inspected these five firms 19 times after the prosecution with 17 inspections showing insanitary conditions. Fines assessed averaged about $500 per violation or about $3,000 per prosecution for 19 first-time offenders. Three additional firms, prosecuted a second time, were fined about $4,200 per violation or about $12,700 per prosecution.

Fines are small because (1) the maximum fine for any person or firm violating a provision of the act was established in 1938 and never increased and (2) charges are frequently negotiated through plea bargaining to facilitate out-of-court settlement of cases. Currently, fines up to $1,000 per violation on the first conviction and $10,000 per violation on the second conviction can be assessed. (See p. 2.) Considering inflation, a comparable fine for the first conviction in 1983 would be about $7,500.

Bills have been introduced which included proposals to raise the maximum fine for FDA food prosecutions. Three attempts to raise the maximum fine were included as part of omnibus legislation to amend the act introduced during the 93rd, 94th, and 96th Congresses. These bills were never enacted (see p. 9).

PROSECUTIONS DO NOT ALWAYS BRING ABOUT COMPLIANCE WITH THE FD&C ACT

FDA is selective in seeking court action and generally recommends that U.S. attorneys prosecute only firms that have a continued history of insanitary conditions. During fiscal years 1980-82, 22 firms were prosecuted. (See app. I for a list of the prosecutions reviewed.) For five firms the prosecution appeared to have little impact. Generally these firms failed to

correct or had conditions that were similar to the insanitary conditions that were identified by FDA before the prosecution. Three other firms were being prosecuted for the second time.

An Assistant U.S. attorney and an FDA attorney stated that the current fines do not act as a deterrent and that the maximum fine of $1,000 should be increased. FDA headquarters officials believe that greater fines should be available to the courts in prosecution cases. However, FDA is concerned that attempts to raise the fines might result in attempts to change other provisions of the law, such as the strict liability provision.[1] Under this provision, FDA does not have to prove that the defendant intended to violate the law. FDA believes this provision is essential to its enforcement authority.

When the 1938 law was passed, the Congress also believed that penalties higher than those in existence at that time were needed

> ". . . to bring about substantial compliance with the law on the part of those manufacturers who regard an occasional small fine as an inexpensive license to carry on their illicit operations."[2]

Of the 22 prosecutions reviewed, 19 firms and/or individuals were being prosecuted for the first time. Five firms continued to operate under insanitary conditions after prosecution. FDA inspected these five firms 19 times after prosecution with 17 inspections showing insanitary conditions. FDA inspection reports noted that some products had to be destroyed or that rodent or insect infestation was found in food storage areas. Three of the five firms were sent Notice of Adverse Findings letters,[3] another had products seized because of severe bird infestation, and the other firm voluntarily destroyed products on four occasions. For example:

---

[1]Section 303(a) of the FD&C Act does not require that consideration be given to the fact that the defendant did not know the law was being violated or was ignorant of the existence of the law.

[2]See S. Rep. No. 361, 75th Cong., 3d Sess., 27 (1935).

[3]Notice of Adverse Findings letters are used by FDA to advise regulated firms of potentially adulterated products, practices, or conditions, or of violations requiring correction and are a way of providing prior warning to responsible officials of possible criminal action.

--One company had an extended history of preparing and packing crabmeat under insanitary conditions which could lead to bacterial contamination of fresh crabmeat. FDA inspected this company 13 times between 1969 and 1980. FDA inspectors found objectionable conditions, including structural defects, in the form of ill fitting doors allowing entryways for rodents and insects, live flies outside and inside the plant and on the crabmeat, and retrieval of the product from the floor. Following an October 1979 inspection, about 3,600 pounds of crabmeat was seized at four locations. On August 18, 1980, FDA recommended that the U.S. attorney prosecute the firm's owner. The U.S. attorney filed the case in district court on September 26, 1980. The defendant was found guilty of seven violations, and on January 20, 1981, received a $3,500 fine, a 1-year suspended prison term, and 2 years of probation.

Three inspections after the prosecution, conducted in July 1981 and June and August 1983, resulted in FDA sending the firm two Notice of Adverse Findings letters. FDA inspectors noted numerous flies in and around the crabmeat, no quality control program for monitoring raw material, and poor employee health practices, such as the failure of employees to wash hands and retrieving crab claws from the floor and returning them to the processing table. The 1983 inspections stated that the insanitary conditions could lead to product contamination with filth and bacteria.

Three of the 22 firms were prosecuted a second time.

--One of three firms prosecuted a second time stored a wide variety of foods, including cornmeal, bread mix, flour, and popcorn, which were distributed to independent grocers, bakers, and other small manufacturers and retailers. FDA originally prosecuted the owner of the firm in 1977 due to the presence of rodent contaminated foods. The owner was found guilty on two violations and fined $1,200 on February 2, 1977. After the 1977 prosecution, FDA conducted four additional inspections, in May 1977, January 1978 and 1979, and June 1979. The May 1977 and January 1978 inspections revealed rodent habitation, the presence of rodent excreta, broken windows, defective doors which permitted pest entry, and scattered debris throughout the warehouse.

FDA recommended a second prosecution based on a January 1979 inspection. FDA investigators found live rodents and rodent excreta throughout the storage areas on the floors and on the surfaces of bagged food products. On March 14, 1979, U.S. marshals seized about $1,300 worth of goods, including yellow cornmeal, sweet bread mix, flour, and unpopped corn. A June 1979 inspection disclosed various openings for bird entry, pigeon excreta on bagged bakery products, and pigeons roosting in the rafters. FDA recommended prosecution and sent the case to the U.S. attorney on February 29, 1980, who filed the case in district court on that same date. The defendant pleaded guilty to two violations on August 25, 1980, and was fined $15,000.[4]

FD&C ACT FINES ARE SMALL

A maximum fine of up to $1,000 per violation (or count) and/or up to 1 year's imprisonment can be assessed on the first conviction against any person or firm who violates a provision of the act. Small fines are assessed against most defendants. An FDA attorney stated that one person has been imprisoned as a result of a food sanitation prosecution case. In 19 cases, individuals or corporations prosecuted for the first time were found guilty on an average of six violations. These cases resulted in an average fine of about $500 per violation or $3,000 per prosecution.

By the time a recommended prosecution case is forwarded to a U.S. attorney, FDA has usually invested many hours of investigative, analytical, and legal time developing the case. Time is spent collecting and analyzing samples of suspected adulterated foods, obtaining concurrence in the recommended action at the district office and headquarters level, and conducting follow-up inspections and a hearing to allow the prospective defendants an opportunity to present their views. The 22 cases prosecuted, on the average, had six inspections where FDA noted insanitary conditions before prosecution. In some prosecutions, firms were inspected more frequently. For example:

--a food warehouse was inspected 12 times and insanitary conditions found over a 14-year period;

--a second warehouse was inspected 12 times and found with insanitary conditions over a 9-year period; and

---

[4]Fines of up to $10,000 per violation and/or up to 3 years' imprisonment can be assessed for second convictions.

--a packing company that prepared, packed, and shipped cooked crabmeat was inspected 13 times and insanitary conditions found over an 11-year period.

FDA estimates that it takes about 400 staff hours or $8,000 to $10,000 to develop a prosecution case. Cases that go to trial may cost FDA an additional $8,000 to $10,000. An assistant U.S. attorney stated that although cost information is not kept, a case without a grand jury where the defendant admits negligence probably costs the Department of Justice about $30,000.

Fines are also small when compared to the estimated annual sales volume of the firms being prosecuted. Information available at FDA headquarters for 16 of the 19 prosecutions showed that the firms prosecuted the first time had estimated sales ranging from $100,000 to $50 million and over. Of the 100 charges brought against individuals and firms in these 16 cases, 70 charges resulted in fines of $500 or less. Fines assessed were as low as $50 per violation per individual and $100 per violation per firm. For example:

--A $50 per violation fine was assessed against the general manager of a large commissary that stored a variety of foods for human consumption, such as sugar, flour, cornmeal, wafers, rice, and candy. The firm distributed such foods to restaurants, schools, nursing homes, hospitals, and cafeterias. Six inspections before prosecution revealed serious insanitary conditions, including bags of rice stained with rodent urine and excreta, bags of donut mix covered with rodent excreta, a live mouse inside one of several rodent-gnawed flour bags, and innumerable fresh and old rodent excreta pellets on flour, pallets, and various food lots in the warehouse. A U.S. marshal, on one occasion, seized and later destroyed five lots of foods due to rodent contamination. On other occasions the firm's management either destroyed or reconditioned food products. Although the firm's management attended FDA workshops on how to maintain sanitary facilities, conditions still did not improve. FDA concluded that although corrections were repeatedly promised, the record clearly showed that the firm and its management did not take actions to correct problems and store food under sanitary conditions. The firm and its vice president were fined $500 each for one count; the firm's general manager was fined $300--$50 for each of six counts. This firm had estimated annual sales in excess of $5 million.

--Another firm and its president were fined $100 on each of three counts. This firm was a distributing company that sold flour, rice, salt, and breakfast cereals to restaurants and other food outlets. Before the prosecution, foods were seized or voluntarily destroyed by the firm's management. FDA noted that the firm had a long history of insanitary conditions that extended over a 14-year period and 12 FDA inspections. Four inspections in 1978 revealed problems with rodent and bird filth and extensive insect infestation in damaged merchandise stored on the premises. The firm and its president were fined $600, an insignificant amount considering that the firm had estimated annual sales in excess of $5 million.

Charges may be dropped or reduced through plea bargaining

Firms and individuals are seldom charged with all the violations developed by FDA. Charges may be dropped by U.S. attorneys to facilitate prosecution or to obtain pretrial settlements. An FDA official stated that usually it is too costly in terms of time and dollars to get convictions on three or more counts, and the cases become too complicated. An assistant U.S. attorney commented that the burden of proof increases with each count. Charges may be further reduced through plea bargaining. An assistant U.S. attorney stated that a preindictment plea is usually sought, whereby the defendant admits guilt in exchange for a reduced sentence. Nearly 90 percent of FDA-recommended prosecutions are plea bargained, which reduces the time needed to resolve the case.

In five prosecutions FDA charges against defendants were dropped or plea bargained by about 33 percent, from 36 to 24 violations. If firms and individuals had received the maximum fine on all violations, fines would have totaled $72,000. However, fines of $23,850 were assessed. In addition, the maximum fine is not always assessed largely because of plea bargaining. In 19 cases, 116 counts were brought against individuals and firms. While fines of $116,000 could have been assessed, firms and individuals were fined $57,000.

PENALTIES AVAILABLE TO OTHER FEDERAL CONSUMER PROTECTION AGENCIES ARE LARGER

Other federal agencies responsible for protecting the consumer against harmful products have authority to assess higher fines. For example, under Environmental Protection Agency legislation, violators of the law (7 U.S.C. 136(l)), such as wholesalers and retailers, can be prosecuted and fined up to $5,000 for marketing illegal pesticides and up to $25,000 if the sale

is willful. The Consumer Product Safety Commission can prosecute and request fines of $2,000 for each consumer product that violates the law up to a $500,000 maximum (15 U.S.C. 2068 (a)(5)). If a firm knowingly and willfully violates Commission legislation, it can be prosecuted and fined up to $50,000 for each violation.

During the last 10 years several bills have been introduced in the Congress which included proposals to increase the fines associated with criminal prosecution. The proposed maximum fines have ranged from $10,000 to $25,000 for the first conviction for individuals and $50,000 for the second conviction. Some bills also recommended higher fines for "other than individual" (i.e., the firm) of $25,000 to $50,000 for the first conviction and not more than $100,000 for the second conviction. None of the bills were passed by the Congress (see p. 9.)

CONCLUSIONS

Fines associated with criminal prosecutions should be increased. Such monetary penalties were established over 45 years ago and are small considering inflation and the sales volume of the firms prosecuted. The fines levied on some firms do not appear to be a major factor in getting them to correct violations of the FD&C Act. Although most firms comply with the act, some firms previously prosecuted do not correct insanitary conditions and must continually be inspected by FDA.

We believe that increased fines would be a greater deterrent for violating the FD&C Act and give the federal government more flexibility in assessing penalities since nearly all prosecutions are settled out of court. Fines available to other federal regulatory agencies, previously introduced legislation, and the effect of inflation on existing fines should provide the Congress some guidance for determining appropriate penalties for violations of the FD&C Act.

MATTER FOR CONSIDERATION BY THE CONGRESS

The Congress should consider amending section 303(a) of the FD&C Act to increase the amount of the fine authorized for criminal prosecutions.

AGENCY COMMENTS AND OUR EVALUATION

Justice commented that it believed the report criticizes the plea bargaining process and the resultant smaller fines levied against firms and individuals. Justice stated that the decision to reduce or drop charges is based on the prosecutors'

judgment as to the merits of each case and an evaluation of all the evidence. Justice added that the cooperation of an otherwise law-abiding and responsible criminal defendant must be weighed in determining the appropriate prosecutorial action to be taken. Justice stated that the volume of criminal activity is so great and resources so limited that U.S. attorneys must, of necessity, give priority to the most significant criminal offenses which are brought to their attention.

We are not criticizing or questioning Justice's use of the plea bargaining process or the prosecutors' judgment to drop charges. We agree that each case requires an evaluation of all the evidence presented in arriving at prosecutorial decisions. However, in view of the small fines being assessed against firms and individuals, we believe raising the maximum fine would provide a higher base for the government to begin negotiating from when the plea bargaining process is used.

FOOD PROSECUTION CASES SETTLED IN FISCAL YEARS 1980-82

Case number	I/C[a]	Number of violations	Amount of fine	Fine/ violation	Prior FDA inspections in which insanitary conditions were found[b]	Annual sales volume (000 omitted)[c]
1	I	4	$4,000	$1,000	4	$50,000 & over
	I	4	4,000	1,000		
	I	4	4,000	1,000		
2	I	2	1,000	500	12	50,000 & over
	I	2	1,000	500		
	C	2	2,000	1,000		
3	I	1	500	500	5	d
	C	6	3,000	500		
4	C	3	3,000	1,000	7	1,000-4,999
5	C	5	1,250	250	3	d
6	I	1	500	500	11	5,000-9,999
	I	1	1,000	1,000		
	C	1	1,000	1,000		
7	I	2	1,000	500	2	1,000-4,999
	I	2	1,000	500		
	C	2	1,000	500		
8	I	2	1,000	500	2	d
	C	2	1,000	500		

APPENDIX I

Case number	I/C[a]	Number of violations	Amount of fine	Fine/ violation	Prior FDA inspections in which insanitary conditions were found[b]	Annual sales volume (000 omitted)[c]
9	I	7	3,500	500	13	$ 1,000-4,999
10	I	1	250	250	9	500-999
	C	2	500	250		
11	I	3	300	100	12	10,000-24,999
	C	3	300	100		
12	I	7	2,800	400	7	1,000-4,999
	C	7	2,800	400		
13	I	2	0	0	3	100-499
	C	2	0	0		
14	I	1	500	500	2	1,000-4,999
	I	2	1,000	500		
	C	3	2,000	667		
15	I	2	750	375	4	100-499
	C	2	750	375		
16	I	5	500	100	2	100-499
	C	5	500	100		
17	I	2	2,000	1,000	6	1,000-4,999
	I	2	2,000	1,000		
	C	2	2,000	1,000		
18	I	2	2,000	1,000	4	100-499

APPENDIX I

Case number	I/C[a]	Number of violations	Amount of fine	Fine/ violation	Prior FDA inspections in which insanitary conditions were found[b]	Annual sales volume (000 omitted)[c]
19	I	1	500	500	6	$5,000-9,999
	I	6	300	50		
	C	1	500	500		
20[e]	I	1	1,000	1,000	1	5,000-9,999
	C	1	10,000	10,000		
21[e]	I	2	15,000	7,500	4	5,000-9,999
22[e]	I	2	2,000	1,000	3	5,000-9,999
	C	3	10,000	3,333		

SUMMARY

Defendants prosecuted for the first time-- 19 cases		Defendants prosecuted a second time-- 3 cases	
Total number of violations charged	116	Total number of violations charged	9
Total fines	$57,000	Total fines	$38,000
Average fine per violation	491	Average fine per violation	4,222
Average fine per violation/individual	521	Average fine per violation/individual	3,600
Average fine per violation/corporation	450	Average fine per violation/corporation	5,000
Average fine per case	3,000	Average fine per case	12,667

APPENDIX I

[a]Denotes whether a responsible corporation individual (I) or a corporation (C) was fined.

[b]Conditions found generally include rodent urine and excreta, or bird excreta on food products or on floors, and insect infestation. FDA gave firms verbal or written warnings regarding these conditions through discussions with management and Notices of Adverse Findings. Some firms destroyed the contaminated food, reconditioned it, or FDA seized it.

[c]Amounts obtained from FDA inspection reports.

[d]Information not available in FDA headquarters files.

[e]Defendants in these cases were previously prosecuted.

APPENDIX I

FDA'S DETENTION AUTHORITY FOR OTHER PRODUCTS

FDA has the authority to administratively detain and refuse admission into the United States a wide variety of products both under the FD&C Act and statutes administered in cooperation with other agencies, but it does not have such authority for nearly all of the food products produced in the United States.

Section 304(g) of the FD&C Act (21 U.S.C. 334) provides that during an inspection of a facility, FDA may detain a medical device that is believed to be adulterated or misbranded. The detention period cannot exceed 20 days. (During that period the device may not be used, moved, altered, or transferred unless authorized by FDA or the device is released by FDA.)

This section also provides that if a longer period of detention is required to institute seizure or injunction action, the device may be detained for no more than 30 days. Presently, FDA's implementing regulations apply only to devices intended for human use.

Section 801 of the FD&C Act (21 U.S.C. 381) authorizes FDA to refuse admission of any food, drug (including biological products), device, and cosmetic which is being imported into the United States, if FDA determines that the product is misbranded or adulterated. This section provides that such misbranded or adulterated products are to be destroyed, reexported, or in appropriate cases, allowed admission if relabeling or other action can bring the product into compliance with the FD&C Act.

In addition to its authority under the FD&C Act, FDA has detention authority and authority to refuse admission of products offered for import into the United States under several other statutes. These include:

--Section 360(a) of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263h(a)) authorizes FDA to refuse admission of any radiation-emitting equipment, such as microwave ovens, which are being imported into the United States, if it determines that the product certification is false or misleading. This section provides that such noncomplying electronic products are to be destroyed, reexported, or in appropriate cases, allowed admission if the product can be brought into compliance with the applicable standards.

--Sections 402 and 409(b) of the Federal Meat Inspection Act (21 U.S.C. 672 and 679(b)) authorize FDA to detain meat products found outside any premises where an inspection is being maintained under the Meat Inspection Act for purposes of enforcement of the FD&C Act.

--Sections 19 and 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467a and 467f) authorize FDA to detain poultry products found outside any official establishment for purposes of enforcement of the FD&C Act.

--Sections 19 and 23(d) of the Egg Products Inspection Act (21 U.S.C. 1048 and 1052(d)) authorize FDA to detain egg products found at other than the inspected facility, if it believes the products are in violation of the Egg Products Inspection Act.

Under the latter three statutes, detention is for a period of up to 20 days, and the products cannot be moved from the place of detention until authorized by FDA.

THE RECALL PROCESS

Recalls are a firm's voluntary removal or correction of a marketed product that is considered by FDA to violate the FD&C Act. Recalls may be undertaken at any time by a firm to carry out its responsibility to protect consumers from adulterated products or in response to a formal request by FDA. According to FDA guidelines, once a decision is made to recall an adulterated product, FDA's role is primarily one of monitoring the firm's effectiveness in recalling the product. FDA accomplishes much of its monitoring through audit checks.[1] Most of the responsibility for conducting the recall rests with the recalling firm. FDA spent an estimated $17 million during fiscal year 1982 monitoring and assisting firms in their recall efforts.

A recall begins when a firm notifies FDA that an adulterated product has been distributed or when FDA, through laboratory analysis, determines that a product is adulterated. The FDA district that will have primary responsibility for monitoring the recall and reporting the results to FDA headquarters will immediately begin an investigation of the problem. The information obtained along with the district's analysis of the information is sent to the Center for Food Safety and Applied Nutrition.

An ad hoc committee of FDA scientists (referred to as the Health Hazard Committee) within the Center for Food Safety and Applied Nutrition evaluates the information submitted by the district to determine the product's potential health hazard. FDA classifies recalls according to the level of health hazard involved. Class I recalls involve products that could cause serious adverse health consequences or death. Class II recalls involve products that may cause temporary or medically reversible adverse health consequences. Class III recalls--shortweight in products, some filth, or defective containers--involve those products not likely to cause adverse health problems.

Once the Center for Food Safety and Applied Nutrition has established the recall classification and strategy, the recalling firm, in consultation with FDA, develops a plan to implement the strategy. The plan identifies how the firm will contact consignees, the number of effectiveness checks the firm will make, and the corrective action to be taken on the recalled product.

---

[1]FDA audit checks are made to determine the adequacy of the firm's performance in assuring that all holders of the adulterated product have received notification of the recall and are taking appropriate action.

The recall plan should address such issues as:

--whether the firm must notify wholesalers, its retailers, or the consumer (including the need for public warnings);

--the percentage of sales accounts the firm should contact to verify that the firms were properly notified of the recall; and

--the percentage of the recalling firm's accounts that FDA district officials must contact to verify awareness of the recall and adequacy of the corrective action taken.

Because lot numbers or package codes used to identify the specific product being recalled are generally not recorded on sales transactions, it is often difficult and sometimes impossible to isolate those food establishments that receive the adulterated food products. As a result, the recalling firm may have to contact hundreds of independent wholesalers, distributors, and retailers if the product has been widely distributed.

APPENDIX IV

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

JUL - 5 1984

Mr. Richard L. Fogel
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Fogel:

The Secretary asked that I respond to your request for the Department's comments on your draft report "Legislative Changes and Administrative Improvements Should Be Considered for FDA to Better Protect the Public from Adulterated Food Products." 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,

Richard P. Kusserow
Inspector General

Enclosure

APPENDIX IV

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT, "LEGISLATIVE CHANGES AND ADMINISTRATIVE IMPROVEMENTS SHOULD BE CONSIDERED FOR FDA TO BETTER PROTECT THE PUBLIC FROM ADULTERATED FOOD PRODUCTS," REPORT NO. HRD-84-61, DATED JUNE 7, 1984

We appreciate the opportunity to review the draft report and comment on it. In general, we believe the report has identified and appropriately delineated issues of significant concern to the Food and Drug Administration (FDA).

GAO Recommendation

We recommend that the Secretary of HHS direct the Commissioner of FDA to:

1. —Develop guidelines to process more seizures through direct reference criteria and improve the timeliness of routine seizure actions by permitting district directors after concurrence of FDA's General Counsel to present routine seizure recommendations directly to U.S. attorneys.

Department Comment

We agree that to the extent possible, district directors, with the General Counsel's concurrence, should refer routine seizure recommendations directly to the U.S. Attorneys. To date, FDA has developed guidelines for direct reference seizures covering some 82 routine violative situations that FDA headquarters personnel do not review. FDA will determine whether additional products qualify for direct reference seizure actions and include those that do qualify in guidelines issued to district directors.

GAO Recommendation

2. —Develop guidelines specifying required verification procedures to ensure that the destruction and reconditioning of recalled foods is adequately verified.

Department Comment

We agree. FDA's policy in the past has been to allow district managers broad discretion in determining what, if any, verification procedures to use for destruction or reconditioning of recalled products because of the many and varied factors associated with recalls. These factors

APPENDIX IV

include: FDA's experience with the firm or firms involved, the size of the recall, the product involved, the nature of the problem, the level of distribution of the product prior to the recall, and availability of resources required for verification.

FDA will develop guidelines to assist district managers regarding verification of reconditioning or destruction of recalled products. The guidelines must be flexible enough, however, to allow district managers to exercise their best judgment as to the degree of verification needed and how to achieve it within available resources and competing demands.

APPENDIX V

U.S. Department of Justice

Washington, D.C. 20530

8 564

Mr. William J. Anderson
Director
General Government Division
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Anderson:

This letter responds to your request to the Attorney General for the comments of the Department of Justice (Department) on your draft report entitled "Legislative Changes and Administrative Improvements Should Be Considered for FDA to Better Protect the Public from Adulterated Food Products."

The draft report has been reviewed by organizational components within the Department having an interest in the subject matter of the report. The Department has only two general comments on the draft report.

[See GAO note.] Pages iv-vi, 8-9, and 15-22 of the draft report comment on the average time frame for processing seizure requests, with 24 of the 65-day average allocated to the Department. The report notes that the 24-day period is the average length of time for processing such cases and that the actual length of time for processing these cases by the Department varied from one to 150 days. By emphasizing the average, the draft report may convey the mistaken implication that the Department and its United States Attorneys do not consider these cases to be very serious. In fact, it should be emphasized that the Department considers adulterated food product cases that pose a serious threat to health and safety to be very important, and stands ready to take expedited action to to obtain judicial authority to proceed in those cases where the serious and emminent threat to health and safety is brought to the attention of the United States Attorneys. Moreover, after the warrant is issued, the United States Marshal must seize and make arrangements to secure and/or destroy the items in question, a process which cannot always be completed as rapidly as the Department would like.

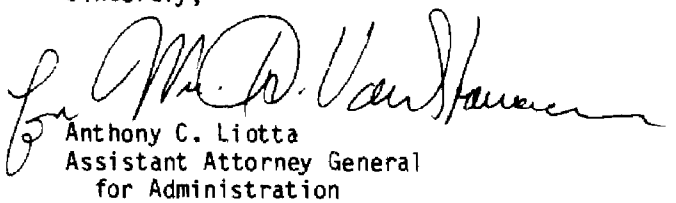
[See GAO note.] Secondly, pages 41-42 of the draft report criticize the process of plea bargaining and the resultant smaller fines levied against firms and individuals. The decision to reduce or drop charges is based on the prosecutor's judgment as to the merits of each case. Each case requires an evaluation of all the evidence presented to the United States Attorney and the Civil Division Attorney(s) working with the United States Attorney. Moreover, the cooperation of an otherwise law-abiding and responsible criminal defendant must be weighed in determining the appropriate prosecutorial action to be taken. Finally, the volume of criminal activity is so great and resources so limited that United States Attorneys must, of necessity, give priority to the most significant criminal offenses which are

GAO note: Page numbers do not correspond to the page numbers in the final report.

brought to their attention, and to make prosecutorial decisions within the Principles of Federal Prosecution issued by the Department. Consequently, these decisions are not always readily quantifiable on an emphirical basis.

We appreciate the opportunity to comment on the report while it is in draft form.

Sincerely,



Anthony C. Liotta
Assistant Attorney General
for Administration

(108854)