UNITED STATES GENERAL ACCOUNTING OFFICE
WASHINGTON, D C 20548

HUMAN RESOURCES
DIVISION

April 11, 1978

The Honorable Donald Kennedy
Commissioner, Food and Drug
Administration
Department of Health, Education,
and Welfare

Dear Dr Kennedy

Our recent survey to evaluate the sanitary conditions in selected food industries was a followup to our previous reports on (1) sanitary conditions in the food manufacturing industry (B-164031(2), April 18, 1972), (2) protecting the consumer from potentially harmful shellfish (B-164031(2), March 29, 1973) and (3) sanitary conditions in restaurants (B-164031(2), December 8, 1975, MWD-76-42)

Our work was done at the Food and Drug Administration's (FDA's) Boston and headquarters offices For a number of establishments, we compared recent FDA inspection results with those that were used as the basis for the conclusions and recommendations contained in our earlier reports We also obtained information from Massachusetts State officials responsible for sanitary conditions in the shellfish and restaurant industries

On the basis of our survey, we believe that·

--FDA's current strategy for inspecting food manufacturing plants has resulted in improved surveillance of food manufacturing firms

--Sanitary conditions in the shellfish manufacturing industry have not improved appreciably since our previous report

--Although FDA officials believe sanitary conditions of restaurants may be improving, FDA has little evidence to support this contention

IMPROVED SURVEILLANCE OF FOOD MANUFACTURING INDUSTRY

Since our previous review, FDA has increased its staff and has redirected or initiated compliance programs

to more effectively monitor conditions in the food manufacturing industry In addition, data obtained from FDA compliance progam evaluations indicates that there have been improvements in the sanitary conditions of the food manufacturing industry

For instance, the preliminary results of the Super Measure-Act-Measure compliance program indicate that the number and percentage of firms with violative conditions has declined significantly The objective of this program was to measure the compliance rate of a statistical sample of manufacturers in seven commodity groups, to take regulatory action against firms that were found violative, and to remeasure the compliance rate of firms that either were identified as being violative during the first inspection or were inspected as part of a second statistical sample of the same commodity groups FDA inspections under this compliance program were conducted in fiscal years 1974 and 1976 and were directed toward determining the sanitary conditions under which food is manufactured, processed or stored

The results of the fiscal year 1974 inspections indicated that of tne 1,528 firms inspected about 15 6 percent were violative The fiscal year 1976 inspection results indicated that only 8 5 percent of the 1,778 firms FDA inspected were found violative While more detailed analysis of the Super Measure-Act-Measure program is continuing, these initial results appear to indicate improvement in the sanitary conditions of the firms manufacturing the seven commodities that were the subject of the study

FDA has also formalized an inspection strategy that establishes inspection priorities according to (1) the potential health hazards or risk associated with various food commodities, (2) previous inspection results, (3) time periods since the last inspection, and (4) comprehensiveness of the inspection Inspections of the food industry had previously been directed primarily to sanitation considerations and to an in-depth review of a firm's processing practices on a given day.

Also, Region I officials told us FDA has (1) reduced the average length of time between food establishment inspections and (2) improved the accuracy and completeness of its official food establishment inventory.

For 18 firms we reviewed in Region I during our recent survey, the average time between the last two food safety inspections was about 17 5 months In our 1972 report on sanitary conditions in the food manufacturing industry, we pointed out that many food firms with insanitary conditions had not been inspected for 2 years or more and that according to FDA its resources would only permit it to inspect the food establishments in its inventory on the average of once every 5 to 7 years

Our 1972 report also stated that FDA's official establishment inventory (OEI) for the six districts we reviewed was inaccurate because about 35 percent of the food manufacturing firms were either out of business, misclassified as food manufacturers, or not an FDA responsibility FDA contracted with a private organization to exchange inventory listings of manufacturing firms in order to improve the OEI An FDA Region I official estimated that its OEI was 90 percent accurate based on information received from Region I inspectors about firms that are out of business Another FDA regional official told us that without a legislative requirement that food firms register their establishments and products with FDA it is virtually impossible to insure a complete inventory Legislation introduced in the 95th Congress (H R 10358 and S 2540) would require each food processor to register with the Secretary of the Department of Health, Education, and Welfare (HEW)

UNSUCCESSFUL ATTEMPTS TO IMPROVE THE SHELLFISH SANITATION PROGRAM

In June 1975, as a result of our report and FDA's own surveys, FDA proposed comprehensive regulations that related to all aspects of shellfish sanitation covered by the National Shellfish Sanitation Program (NSSP). The objective of these regulations was to formalize the procedures under which the cooperative Federal-State-industry national program had been operating

Industry officials testifying at congressional hearings in November 1975 argued that the regulations, if implemented, would have a devastating economic impact on the industry Industry and State officials also commented that the proposed codification of the NSSP with stronger FDA enforcement authority violated the traditional voluntary nature of the program

Subsequently, amendments to the Coastal Zone Management Act of 1976 imposed restrictions that prohibited the Secretary, FEW, from promulgating final regulations concerning shellfish safety before June 1977 At least 60 days prior to the promulgation of the final regulations, the Secretary of HEW, in consultation with the Secretary of Commerce, must publish an analysis of (1) the economic impact of such regulations on the domestic shellfish industry, and (2) the cost of such national shellfish safety program relative to the benefits that it is expected to achieve

The act also required the Secretary of the Department of Commerce to make a study and report to the Congress on all aspects of the molluscan shellfish industry including (1) the environmental, socio-economic, technical and public health issues associated with the growing, harvesting, processing and marketing of shellfish products and (2) how Federal laws concerning water quality affect molluscan shellfish

The Department of Commerce report was issued to the Congress in September 1977 The report identified a complex array of problems facing the molluscan shellfish industry including overregulation, a lack of coordinated Government research and service programs, a decreasing resource base largely due to inadequate protection of shellfish growing areas, and the need for new technology and market development The report did not specifically address the NSSP because it was under revision by FDA

FDA is in the process of revising the regulations it proposed in 1975 for shellfish sanitation so that they will have less financial impact on the shellfish industry An FDA official said that the revised proposed regulations are expected to be submitted to you for review and approval in the near future

While the development of revised regulations for the NSSP is continuing, FDA is relying on State regulatory agencies to enforce the provisions of the voluntary national program We believe, however, that the results of recent FDA evaluations of State programs in Maine, Massachusetts, and New Hampshire raise questions as to the extent to which FDA can rely on the States These evaluations showed that

--One State was conducting only about 40 percent of the required number of shellfish plant inspections

--State inspectors' ratings of firms were significantly higher than FDA's ratings of the same firms

--Some State growing area surveys and patrol coverage were infrequent or incomplete.

An FDA Region I official told us that none of the New England States meet all the NSSP guidelines For the State of Maine, the FDA Region I shellfish specialist thought that Maine's program did not meet minimum national program guidelines and recommended that FDA withdraw its endorsement of the program. Under the NSSP member States must refuse shellfish shipments from States which lose endorsement. However, because FDA considers this sanction impractical, and because there are no enforceable regulations, FDA no longer considers withdrawal of a State's endorsement as a practicable means of obtaining compliance with program requirements Maine's endorsement was not withdrawn

Our survey results also indicated that sanitation conditions of shellfish processors have not improved appreciably since our last report when we found that 12 of 30 plants had insanitary conditions that posed a potential for product adulteration.

We selected a sample of 13 shellfish processors in Region I and found that according to the most recent FDA inspections, 7 of the processors were not in compliance Although provisions of the NSSP permit States to remove firms that do not maintain satisfactory sanitation conditions from FDA's list of Interstate Certified Shellfish Shippers, an FDA official told us that States are reluctant to remove a firm's certification. A firm's removal from the Shellfish Shippers List is supposed to put food control officials--persons who process and distribute shellfish--and others who purchase shellfish on notice that a firm is not complying with the provisions of the NSSP.

A Massachusetts Division of Food and Drug official told us that Massachusetts has not withdrawn a certificate from a shellfish plant in the last 5 or 6 years This official told us that actions against violative firms generally involve reinspection or other types of enforcement action rather than witndrawal of a firm's certification. An FDA official said that FDA relies completely on States to take action against shellfish firms with violative conditions.

We recommend that FDA take prompt action to reissue proposed shellfish sanitation regulations that will insure that only safe and wholesome shellfish processed under sanitary conditions are available to consumers

LITTLE EVIDENCE TO SUPPORT IMPROVEMENT IN RESTAURANT SANITATION

FDA has responsibility for insuring the safety and wholesomeness of food served in public eating establishments However, it has traditionally relied on State and local governments to inspect the approximately 600,000 food service establishments in the United States FDA's effort to establish uniform requirements for food service sanitation by proposing Federal regulations was unsuccessful Proposed regulations were withdrawn in March 1977 after State and local governments raised objections that the proposal violated the long-term understanding between State and Federal governments regarding the regulation of the food service industry

With respect to restaurant sanitation, FDA continues to perform an advisory function that includes activities such as (1) training and certifying State officials that conduct inspections, (2) developing a management information system for use by the States, (3) developing a model food service sanitation ordinance, (4) periodically evaluating State programs, and (5) developing and supporting vocational education related to food safety State and local governments continue to assume primary responsibility for inspecting and regulating restaurants

Since our report on sanitary conditions in restaurants was issued in December 1975, FDA has not conducted specific evaluations of State restaurant sanitation programs in Region I However, in fiscal year 1976 FDA conducted a national survey of the administrative practices of each State's primary food service regulatory agency so that it could establish future policy and plans for providing assistance on food service sanitation matters to States Preliminary results of this survey showed that.

--State programs were often fragmented and duplicative

--Many State programs were understaffed with inadequate resources to operate effectively

--State programs often suffered from poor planning and insufficient use of administrative and legal sanctions to obtain compliance

Based on the administrative survey data collected from the States in Region I, FDA regional officials believe that some of these States have made improvements in the management of their food service sanitation programs However, they told us that there was little data available showing that the sanitary conditions of restaurants have actually improved

Because a State's commitment to insuring restaurant sanitation is largely dependent on its ability, interest, and available resources, and because it is unlikely that FDA can provide States and local governments with much more than technical assistance on food service sanitation matters, we believe FDA should more vigorously (1) encourage State and local governments to adopt the provisions contained in the model food service sanitation ordinance, (2) identify deficiencies in States' programs, and (3) develop innovative methods that result in improved administration of State and local programs

FDA should also periodically assess the sanitary conditions of restaurants in various States or municipalities to determine the impact, if any, of FDA's efforts to provide technical assistance to these jurisdictions

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We plan no further reporting on the results of our survey work We appreciate the cooperation and courtesy extended to us by FDA personnel during our survey and we would appreciate being advised of your views with regard to the matters discussed in this report

Sincerely yours,

Albert B Jojokian
Assistant Director