CHAPTER 4

SANITATION INSPECTIONS

4.1 SAFETY 1/

Generally, official personnel shall:

a. Comply with all pertinent Occupational Safety and Health Administration requirements (e.g., 29 CFR 1910-60).

b. Obey all posted warning signs and wear appropriate protective equipment when conditions warrant; e.g., hard hats, dust masks when necessary, ear protection when the noise level in the plant is high, and eye protection.

c. Ensure that adequate first aid and rescue equipment is available and identify the individual responsible for this equipment so that quick access to the equipment can be made in case of an emergency.

4.2 FREQUENCY OF INSPECTIONS

Initial and subsequent sanitation inspections shall be performed in plants that are processing or intend to process products requiring USDA inspection for quality or grade when (1) the product inspected is processed under a contract with Federal, State, or local governments, (2) the product inspected is processed under a contract requiring sanitation inspection or conformance with FDA regulations, or (3) the plant requests a sanitation inspection.

a. Initial plant sanitation inspection shall be performed when plants:

(1) Have not had a previous contract for which FGIS had inspection responsibility; and

(2) Have not been inspected and found to be in a sanitary condition by USDA, FDA, or State or local authorities within the past 3 months.

1/ The requirements in this section are mandatory for FGIS employees. All others are strongly encouraged to also follow the guidelines.

b. Subsequent plant sanitation inspections shall be performed:

(1) In accordance with the following schedules:

(a) Processed commodities and rice. (See attachment 1.)

1 In 6 months, if the plant received a Sanitation Inspection Report (SIR) score (see chapter 4, section 4.5, for explanation of the SIR score) of 0-30 on the last sanitation inspection.

2 In 2 months, if the plant received an SIR score of 31-75 on the last sanitation inspection.

3 In 3 months, if the plant is producing products that require Salmonella testing under government contracts, unless conditions are such that more frequent inspections are necessary. Environmental material samples must be obtained and forwarded to the Commodity Testing Laboratory according to chapter 3, section 3.16 b, of the Processed Commodities Handbook."

4 When Section XII, Cooling and Refrigeration Facilities, is not applicable, perform subsequent inspections in 6 months if the SIR score on last visit was 0-21; in 2 months if the SIR score was 22-53.

(b) Beans, peas, and lentils. (See attachment 2.)

1 In 6 months, if the plant received an SIR score of 0-20 on the last sanitation inspection.

2 In 2 months, if the plant received an SIR score of 21-45 on the last sanitation inspection.

(c) Overpacker. (See attachment 3.)

1 In 6 months, if the plant received an SIR score of 0-8 on the last sanitation inspection.

2 In 2 months, if the plant received an SIR score of 9-20 on the last sanitation inspection.

(2) When plant operations have been shut down for a period of 2 weeks or

longer.

(3) When plants have been renovated or otherwise altered significantly since the last inspection.

(4) As frequently as may be warranted because of unusual or special circumstances, such as flood, fire, strike, or an unexpected deterioration in plant sanitation.

4.3 INSPECTION AREAS AND PRIORITIES

a. General. Sanitation examination consists of three general areas:

(1) Product handling which includes such items as sanitary processing, equipment and utensils sanitation, hand washing, etc.

(2) Plant housekeeping, such as floor cleaning, trash removal, control of smoking and spitting, prevention of unnecessary accumulation of spills and broken containers, insect and rodent control, etc.

(3) Problem detecting, such as identifying potential problems that will need attention before the next operation begins or the need for scheduling for cleaning, repair, maintenance, or replacement.

b. Inspection Priorities. The chief concern of sanitation is the protection of the product from contamination; therefore, give the product primary consideration. Establish priorities based on the relative importance of different types of contamination.

The following categories are given as general guidelines which should be helpful to all who are concerned with the production of clean products.

(1) Direct Product Contamination. This is the most critical category and involves situations that result in direct product contamination. These situations require immediate and effective correction. In inspecting equipment, the most critical surfaces are those that routinely contact the product, directly or indirectly, during the normal course of operation (e.g., table tops, inside surfaces of carts, processing equipment, workers' hands, surfaces handled by workers who alternately handle product, etc.).

These areas must be clean before operations involving their use begin. "Clean" in this instance is defined as free from all foreign material, such as rust, dust, lubricating grease, cleaning compounds, scale, etc. It must look clean, feel clean, and smell clean. Although no microbiological standards have been established for equipment surfaces directly contacting the product, these surfaces should be cleaned by procedures designed to reduce to a minimum or eliminate bacterial contamination. The presence of any visible debris can reasonably be assumed to be a source of bacterial contamination.

(2) Possible Product Contamination. Included in this category are areas or surfaces which have a reasonable possibility of product contact through the course of normal operations. Some examples include sampling devices; workers' clothing; outside surfaces of buckets, ladles, or containers; wiping or cleaning cloths; etc.

(3) Potential Product Contamination. These are areas or surfaces that, while not normally in direct contact with the product, could potentially contact the product directly or indirectly, usually through accidental happenings. Some examples include floors, certain walls, scales, tables, platforms, etc. Usually, these are the areas that can be identified and cleaned before the next day's operation and programmed for periodic maintenance and cleaning.

(4) Remote Product Contamination. These are areas or surfaces unlikely to constitute a direct hazard to the product but nonetheless must be cleaned (i.e., the wall behind a large piece of equipment, stairways, etc.). These problems can and should be corrected through a long-range sanitation program of established periodic cleaning and maintenance (e.g., window cleaning, floor sweeping, stairway cleaning, etc.).

The above categories are relative and not absolute. The degree of uncleanliness is very important. A grossly dirty item in the last category could become the first category of importance.

For example, window screens can become so dirty and dusty they become a

source of direct product contamination, but it must be remembered they did not get that way overnight and should have been detected as a potential problem and corrected through the long- or medium-ranged cleaning and maintenance programs.

Screens, as well as any other areas in the plant, must be scheduled for maintenance and cleaning as often as necessary to provide adequate product protection, whether this be on a daily, weekly, monthly, or other routine schedule.

Good sanitation eliminates all sources of direct product contamination and most, if not all, sources of possible contamination. Daily, weekly, or other periodic cleaning should be programmed for potential sources of contamination. Sources of remote contamination should be programmed for correction on a long-term basis.

Since the inspector cannot observe the operations all of the time, some means must be developed to ensure that good sanitation continues when the inspector is absent.

4.4 INSPECTION PREPARATION 1/

Sanitation is everybody's job and is not limited to those who have USDA or plant responsibility. All inspectors whose work involves plant assignments are sanitation inspectors. All inspectors and samplers on duty are responsible for being constantly alert to sanitary conditions while processing operations are in progress.

When making a sanitation inspection, the inspector should:

a. Review previous sanitation inspection reports for the plant involved in order to identify specific problem areas that should have been corrected. (Check these areas closely.)

1/ See attachment 1 for list of needed equipment and utensils.

b. Arrive at the plant unannounced.

c. Immediately contact the plant manager or other responsible plant personnel and explain the purpose of the visit.

d. Invite the plant manager or other plant representatives to accompany and witness the inspection of the plant. It is highly desirable that at least one plant employee who is in a responsible position accompany the inspector on the tour of the plant.

It is the duty of each inspector to keep the field office manager informed. It is very advantageous for the field office manager to have advance information when a plant protest or complaint is likely to occur. This will enable the inspector and the field office manager to work as a team in obtaining the cooperation of plant management in correcting problem areas.

The field office manager should be contacted when there are areas of doubt or problems with which the inspector may need assistance. The field office manager is also interested in problems that may have significance in other plants, as well as situations where the inspector has achieved unusually good results.

The inspector should plan the inspection and avoid the haphazard approach. The inspector should keep in mind that areas hardest for them to reach and inspect are likewise the most difficult for cleanup personnel to reach. Also, the inspector's effectiveness can be increased by avoiding set patterns and definite time schedules. He should be thoroughly familiar with the appropriate Sanitation Inspection Report (SIR) used in performing the inspection. However, if the inspector is unfamiliar with the type of operation conducted at the plant, the inspector should start with the beginning of the product flow; that is, the receipt of the raw ingredients and work through the natural flow to the finished product.

4.5 SANITATION INSPECTION REPORT (SIR)

The appropriate SIR shall be completed for each sanitation inspection performed.

The SIR for processed products (FGIS-952, attachment 1) shall be used for all processed product and rice processing plants. SIRs specifically designed for bean, pea, and lentil processors and military overpackers shall be used when making sanitation inspections of these activities (FGIS-952-1 and FGIS-952-2, attachments 2 and 3 respectively). An overpacker is a facility where small containers are put into larger containers. These forms are available, upon request, from the Standards and Procedures Branch.

The SIR shall be completed and signed in the appropriate place by the inspector performing the sanitation inspection. Immediately upon completion of the SIR, a copy shall be given to the plant representative. This copy will be the plant's written notification of the conditions found by the inspector.

a. Defect Points. Individual defects are listed on the SIR. The range of points assigned is based on the importance of the defect item to the maintenance of good sanitation in the plant. For example, the defect item "Presence or evidence of rodents in plant," is assigned a point range of 0 to 5; whereas, "Waste not properly stored or contained," is assigned a point range of 0 to 3.

In performing a sanitation inspection, rate the defect item based on your opinion as to the relative potential for product contamination. If the item is clean and presents no sanitation problem, assign 0 defect points to the item. If the item is relatively clean but not perfect, assign 1 or 2 defect points to the item. If the item is insanitary or presents a clear hazard to sanitary operations, assign the maximum defect points possible for that item.

All items assigned maximum defect points should be corrected within the time specified by the inspector. This is normally between the time the insanitary condition is discovered and the next shift or end of the next cleaning period, depending on the potential for product contamination.

b. Critical Items. The most serious defects have not been assigned defect points but are listed as "critical." Sanitary defects listed as critical are scored on a "pass" or "fail" basis. For example, the item "Presence of live insects in processing or product storage areas (two or more)" is a critical item. When **any type** of insect is present in the number indicated, it is a critical defect. Explain critical defects in the "Remarks" section of the SIR so as to clearly describe the conditions observed.

Critical items scored "fail" require immediate action by plant management. The action taken is determined by the nature of the critical item. For example, if employees are not washing their hands after contamination, this defect can be corrected immediately without disruption or discontinuing processing. If raw materials are handled in such a way as to become contaminated, this may cause a temporary delay in production until the problem has been corrected and the contaminated product removed or adequately cleaned. However, if two or more

live insects are found in the processing area, this may require a shutdown of operations and a general cleanup and fumigation that would result in a discontinuation of processing for several days.

In all of the above instances, request the cooperation of plant management in correcting the problems. If it is necessary to discontinue processing operations, make every effort to have plant management take this action on a voluntary basis. However, if plant management refuses to cooperate and will not take remedial action on critical sanitation problems, then take the necessary steps to withhold inspection services as outlined in this chapter.

c. Sanitary Rating. Some plants may not have an affirmative finding on any critical items and yet their overall sanitary condition is so poor that the plant should discontinue processing and have a general cleanup or maintenance program initiated. Plants in this condition can be evaluated on the basis of their total SIR score.

When completing FGIS-952 and section XII, Cooling and Refrigeration Facilities, is not applicable, delete the assigned defect points (22) from the total overall score of 76 or higher and use 54 or higher as the defect limit.

Inspectors should total the defect points in the SIR; and, if the score reaches or exceeds the score level indicated, plant operations are considered to be insanitary and constitute a serious sanitation problem. When a plant exceeds the allowable score, make every effort to have plant management voluntarily discontinue processing operations and initiate corrective actions. If plant management will not cooperate, take the necessary steps to withhold inspection services as outlined in this chapter.

4.6 FOLLOW-UP INSPECTIONS

If a plant has voluntarily discontinued operations, or if inspection services have been withheld by notification from FGIS, it shall be the responsibility of plant management to notify the appropriate FGIS field office when the condition(s) has been corrected. As soon thereafter as possible, an inspector shall inspect the problem area(s) and determine whether the condition(s) has been corrected. If the condition(s) has been corrected, the plant may resume processing operations immediately.

4.7 CONDITIONAL WITHHOLDING OF INSPECTION SERVICES

Section 868.24 of the regulations under the AMA provides for the conditional withholding of inspection services for a correctable cause, such as insanitary plant conditions.

a. Inspector. If upon completion of a sanitation inspection, the inspector finds that the plant fails the sanitation inspection because of a critical defect or because of a score exceeding the acceptable limit, a decision must be made as to whether the lot being inspected has been adversely affected by the insanitary conditions to the extent that a noncompliance certificate or dismissal is warranted.

The inspector should take the following action:

(1) Notify a responsible plant employee, both orally and in writing, by means of a copy of the SIR.

(2) Request that the plant immediately correct the insanitary condition(s).

(3) If necessary, request that they voluntarily discontinue processing operations on the contract.

(4) If the plant fails to take action or refuses to discontinue operations, immediately notify the field office manager.

b. Field Office Manager/Cooperator. Upon receiving notification from an inspector that a plant has failed the sanitation inspection, take the following action:

(1) Review and discuss with the inspector his findings and the action taken with respect to notifying the plant.

(2) Determine that the inspector has taken all necessary steps to obtain plant cooperation.

If it is concluded that a withdrawal action is necessary, notify the applicant, in writing, of the proposed dismissal of service in accordance with FGIS Program Directive 910.3, "Withholding and Withdrawal of AMA Inspection Services." If services are withheld, FDA should be notified per chapter 1, section 1.3.