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Agricultural Marketing Service

Federal Grain Inspection Service

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Sanitation and Food Defense Handbook

Rice, Beans, Peas, Lentils, and Processed Commodities

United States Department of Agriculture Agricultural Marketing Service Federal Grain Inspection Service

Program Handbook

September 09, 2020

Sanitation and Food Defense Handbook

Foreword

The information contained in this handbook is applicable to the Federal Grain Inspection Service (FGIS) field offices and to delegated and designated agencies. FGIS provides plant sanitation inspections under the authority of the Agricultural Marketing Act of 1946 (AMA), as amended, and under <u>FGIS Directive 9060.2</u>, "Implementation of the FGIS-FDA Memorandum of Understanding."

The Sanitation Handbook provides policies and procedures for this service. This handbook is revised to authorize field office managers to delegate licensees or samplers to perform sanitation inspections at certain locations, clarify some procedures, and make minor editorial changes.

Trade names are used solely to provide specific information. The mention of trade names does not constitute a guarantee or warranty of the product by the U.S. Department of Agriculture or an endorsement by the Department over other products not mentioned.

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CHAPTER 1: COOPERATION WITH OTHER AGENCIES

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1.1 MEMORANDUM OF UNDERSTANDING¹

The Food and Drug Administration (FDA), Department of Health and Human Services (HHS), and the Federal Grain Inspection Service (FGIS), Agricultural Marketing Service (AMS), Department of Agriculture, have certain related objectives in carrying out their respective regulatory and service functions. In order to assure the most effective discharge of their responsibilities and that their activities are fully responsive to the public interest, the two agencies entered into a Memorandum of Understanding (MOU) concerning the inspection and grading of various products or commodities.

- a. <u>Purpose</u>. <u>FGIS Directive 9060.2</u>, "Implementation of the FGIS-FDA Memorandum of Understanding," sets forth the working arrangements between FGIS and FDA regarding their respective responsibilities in the inspection and standardization of grain, rice, pulses, and food products.
- b. <u>Statutes Relating to the Agreement.</u>
 - (1) FDA enforces the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (Act). In fulfilling its responsibilities under the Act, FDA ensures that foods, including animal feed, are safe and wholesome and are labeled in a truthful, informative manner. FDA accomplishes this, in part, by inspecting facilities that process, hold, and distribute grain, rice, pulses, and similar food. FDA also examines samples of inspected food to determine whether the food is adulterated or misbranded within the meaning of the Act. FDA also promulgates, under the Act, standards of identity, quality, and fill of container for food products.
 - (2) FGIS, under the authority of the <u>Agricultural Marketing Act of 1946</u> (7 U.S.C. 1621 et seq.) (AMA) and the regulations thereunder (7 CFR Part 868), performs voluntary inspection and weighing services, upon request, to aid in the efficient marketing of agricultural products.
- c. <u>Services</u>. Services include developing specifications and standards. providing inspection, grading, and weighing services; and issuing certificates of quantity, quality, and condition to producers, processors, shippers, buyers, and other interested parties.

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¹ This agreement applies only to those commodities assigned to FGIS by the Secretary of Agriculture.

1.2 FDA RESPONSIBILITIES

During inspection of a facility that processes, packs, or holds agricultural products, FDA may perform the following:

- a. Request the FGIS inspector/licensee stationed at a facility to accompany the FDA inspector during the inspection. The FDA inspector and the FGIS inspector/licensee will discuss any conditions that they believe may result in violations of the Act.
- b. Request FGIS to furnish information concerning quality determinations of specific lots of products against which FDA has taken or may take action. When involved in such an action, FDA will consider the results of official FGIS inspections and other available data, provided the information is relevant to the current condition of the product and the nature of the violation charged.

When an FDA action is to be based on an analysis by the FGIS inspector/licensee and FDA has not received the results of an appeal analysis, FDA through its appropriate field office will contact the designated FGIS field liaison person, confirm that an appeal analysis is being conducted, and request an oral report of the results of the analysis as soon as possible.

- c. Notify FGIS concerning details of objectionable conditions found to exist in processing plants, packing plants, grain elevators, or any other facilities where FGIS provides official services.
- d. Notify FGIS of the criteria FDA uses to determine when FDA should consider action under the Act against an agricultural product. Notification will ensure that FGIS does not classify an objectionable commodity as acceptable.
- e. Upon request of FGIS, review for possible conflict with the misbranding provisions of the Act (e.g., the labels, legends, stamps, and other marks on products that are packed under the various official services).

1.3 FGIS RESPONSIBILITIES

When performing functions under the AMA and regulations administered by FGIS that relate to agricultural products, FGIS will perform the following:

- a. Promptly notify FDA of the facilities that are subject to withholding of service, termination of contract, or denial of official FGIS services because of insanitary conditions or other processing deficiencies. Notification is not necessary if the plant management is cooperating in correcting the insanitary condition(s).
- b. Investigate any report of objectionable conditions found by FDA that a processor, packer, merchandiser, or facility operator, using official FGIS services, has not corrected. Upon completion of the investigation, initiate appropriate action and notify FDA of the action taken.
- c. Refuse to inspect products which have been seized by FDA or which are known to be involved in formal FDA actions. This does not preclude official retest and appeal of authorized samples if the FDA action involves products which have been officially inspected.
- d. Promptly report to FDA the results of any inspection or analysis (including results of any appeal analysis, when available) for any product that may be actionable under the Act. Report to the appropriate FDA field office by telephone within 24 hours of the receipt of information that a specific lot of product is considered adulterated or in noncompliance by reason of failing to comply with FDA requirements. Immediately follow up with written notification using the appropriate format (refer to section 1.5, "FDA Written Notification Follow-Up Example").
- e. Furnish FDA, upon request, any pertinent information concerning the grade or quality of FGIS inspected specific lots of products against which FDA has taken or may take action.

1.4 MUTUAL AGREEMENTS

The following is mutually agreed upon:

- Field liaison will be maintained between FDA district offices and FGIS designated field persons. General matters involving the MOU may be referred to the agencies' liaison officers.
- b. Proposed regulations initiated by either agency which affect, establish, or amend food standards or other products covered by the MOU will be referred to the other agency for review and comment before the proposed regulations are published for broader comment.
- c. Both agencies will cooperate with industries in improving sanitation and food handling practices in processing plants, packing plants, or other facilities.
- d. Both agencies will exchange data and cooperate in developing sampling plans, methodology, and guidelines for determining natural and unavoidable defects common to products officially inspected.
- e. In order to avoid duplication of effort and to keep the disruption of plant operations to a minimum, inspection personnel will cooperate with Federal, State, and local agencies performing comparable sanitation inspection services.
- f. Where feasible, before performing a sanitation inspection, inspection personnel should inquire of plant management as to when the plant last received a sanitation inspection. If another agency performed a sanitation inspection within the past 3 months, contact that agency and request a copy of their inspection report. Review the report and determine if there were any problem sanitation areas. Inquire of plant management as to the action taken to correct the problems and make a general observation of the problem areas. If it appears that the problems still exist and that little, if any, effort has been made to correct the problems, then make a thorough examination and conduct a complete sanitation inspection of the plant. If it has been more than 3 months since the last sanitation inspection, or if the agency performing the inspection will not supply a copy of the inspection report, make a complete sanitation inspection.

- g. Name and addresses of liaison officers:
 - (1) For the Food and Drug Administration:

Director, Field Programs
Center for Food Safety and Applied Nutrition (HFS-009)
5001 Campus Drive, College Park, MD 20740-3835
Ph. 888-723-3366

(2) For the Agricultural Marketing Service, Federal Grain Inspection Service:

Director, Field Management Division Federal Grain Inspection Service 1400 Independence Ave, SW, STOP 3630 Washington, D.C. 20250 Ph. 202-720-0291

It is FGIS policy that if any dispute arises concerning an interpretation as to an insanitary condition(s) in a plant, FDA must be requested to examine the condition(s) in dispute and advise FGIS as to whether or not an insanitary condition(s) exists. FDA's decision is final and FGIS will be guided accordingly. If FDA is unable to make an examination, upon request, FGIS' decision is final.

If a Federal, State, or local agency requests that an FGIS inspector accompany and assist them in making a sanitation inspection of a plant, the inspector must cooperate whenever and wherever possible.

1.5 FDA WRITTEN NOTIFICATION FOLLOW-UP EXAMPLE

[Date] TO: FDA Field Office FGIS Field Office Manager FGIS Field Office FROM: Confirmation of Telephone Report SUBJECT: This will confirm our telephone report of [date] about the following inferior commodity lot of [product]: Commodity: Contract No: Car No: Lot No: Sampling Date: Mill: Location: Amount: Destination: Contamination per 50 grams: Other Conditions:

CHAPTER 2: INSPECTION RESPONSIBILITIES

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2.1 FGIS INSPECTOR'S DUTIES

It is an inspector's duty is to ensure that products are processed, stored, and handled in a sanitary manner. However, both the plant management and the inspector have specific sanitation responsibilities which should not be assumed by the other. The plant management should not view the inspector as an additional foreman, sanitation supervisor, or quality control supervisor. Likewise, the inspector should not minimize the value of his/her presence and influence in those plants or situations where a good sanitation program exists. The inspector should work with plant management to ensure that management assumes its responsibilities to produce a clean product in a clean plant, utilizing sound hygienic procedures.

In circuits where plant locations are scattered over a wide area, Field Office Managers (FOM's) are authorized to delegate other personnel (licensees or contract samplers) to perform plant sanitation inspections; provided, in the judgment of the FOM, the person is qualified to perform the inspection and the plant has a good approval record. The delegated inspector is supervised periodically at the FOM's discretion.

The following are required competencies of an inspector in order to be effective in performing inspections:

 a. <u>Knowledge</u>. The more knowledge an inspector has, the more effective he or she can be.

Having a basic understanding of why good sanitation is vital. Being prepared and able to explain the "whys" of sanitation go a long way toward being an effective inspector. The inspector should know the industry and its operational procedures. This includes the cleaning procedures used on equipment within the plant. The better an inspector knows the industry, the easier the job will be. It is important to know not only what can be done but also what cannot be done.

Standards and requirements change as new knowledge and procedures are introduced. Inspectors must receive ongoing training to keep current with standards and requirements.

In many mass production situations, workers can easily lose sight of the end result or purpose of their work. In the case of food processing, the worker may no longer view the product being handled as an article of human food. This is a dangerous attitude that can lead to a complete breakdown of sanitation standards. The inspector must not only guard against this attitude but must serve as an example of the best in personal hygiene, dress, and methods of handling food products.

- b. <u>Attitude</u>. The inspector should have a courteous, considerate, and patient approach but be firm in insisting that the plant comply with sanitation requirements. The inspector should be consistent from day-to-day and from plant-to-plant. The same sanitary standards must be applied with equal fairness to all plants.
- c. <u>Judgment</u>. Judgment is the ability to choose a just or wise action based on conclusions made from the circumstances presented. No matter how they are defined, *good judgment* and *common sense* are essential elements of good inspection. There are few clear-cut formulas or universal standards to go by; therefore, inspectors must cultivate and develop the ability to make decisions based on the potential for product contamination, good judgment, common sense, and sound reasoning.

2.2 PLANT MANAGEMENT DUTIES

When a processor enters into a contract that requires a product to be inspected or graded by USDA, the responsibility is to produce a clean product in a clean plant under hygienic conditions and in accordance with USDA regulations and FDA's Good Manufacturing Practice Regulations. This also includes cooperating with the inspector and providing information and assistance necessary for the inspector to do a proper sanitation inspection.

Plant management duties include the following:

- a. Assigning a competent individual(s) (depending upon the size of the plant) the responsibility for plant sanitation.
- b. Ensuring that no person affected with a communicable disease or while afflicted with boils, sores, infected wounds, or other abnormal sources of microorganism contamination works or visits in any areas of the establishment where there is likelihood of disease transmission or food ingredient contamination.
- c. Reporting promptly to local health authorities all known or suspected cases of communicable disease among their employees.
- d. Training plant employees in proper food handling techniques and food protection principles, as well as providing them the necessary equipment/supplies for compliance (e.g., gloves, hairnets). Employees must be alert to the dangers of poor personal hygiene and insanitary practices.
 - The area of personal cleanliness is a most difficult one in which to obtain effective action. Rigid rules of personal hygiene and practice must be instituted.
- e. Setting standards in sanitation at a high level and striving to develop attitudes in personnel consistent with the responsibility and obligation to achieve and maintain a sanitary food processing operation.

2.3 PERSONAL HYGIENE

The facility and equipment may be essentially clean and free from any contaminants, but the product is still not considered processed under sanitary conditions if individuals located at the plant do not maintain a high degree of personal hygiene. For more information, refer to 21 CFR Part 110, "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food."

Dirty or contaminated hands or clothing present a serious potential source of contamination to products. Clean hands, clean clothing, and hygienic practices reduce the likelihood of contamination of the product and product-contact surfaces of equipment, utensils, and packaging materials.

- a. <u>Disease Control</u>. Boils, infected cuts, and sore throats are sources of organisms which cause staphylococcal food intoxication, the most frequently reported type of foodborne illness in the United States. A wide range of communicable diseases and infections may be transmitted by food handlers to other employees and consumers through contaminated food products and careless handling practices.
- b. <u>Clothing and Personal Equipment</u>. All persons handling commodities, ingredients, or their contact surfaces must wear clean outer garments.

All persons must wear caps, hats, hairnets, or other effective hair restraints (including facial hair restraints) where exposed product is handled to prevent hair from falling into product.

All loose or insecure jewelry, such as rings, wrist watches, etc., that might serve as a source of product contamination during work periods in which food or food components are manipulated by hand must be removed. Plastic or rubber gloves should be worn by all personnel who touch or manipulate processed food products by hand. If gloves are used in food handling, they should be maintained in a clean and sanitary condition. Such gloves should be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.

c. <u>Cleanliness</u>. To avoid product contamination, all persons who handle any product must keep their hands clean. Fingernails should be neatly trimmed and kept clean at all times.

After visiting the toilet rooms or urinals or at other times when the hands have become soiled or contaminated, hands must be washed with soap and water before handling any product or implements used in the preparation of the product.

Necessary care should be taken to prevent contamination of product with substances such as perspiration, hair, cosmetics, tobacco, chemicals, and medicants.

Do not use tobacco in any form while engaged in food handling. When permitted by local law or ordinance, designated locations may be approved for smoking provided no contamination hazards will result.

Spitting on the floor is prohibited. Insanitary and unsightly personal practices, such as scratching the head, placing the fingers in or about the mouth or nose, or indiscriminate and uncovered sneezing or coughing should be avoided. The mouth must not be used to temporarily hold tags, pins, cards, or other objects that will directly or indirectly contact the product. Wetting of the fingers by the mouth in order to better grip or grasp containers or other items that come in the food product is prohibited.

CHAPTER 3: PLANT FACILITY

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3.1 GROUNDS

The sanitation of the outside grounds of a plant can have a significant effect on the sanitation inside the plant. Food products, as they are processed or handled in the plant, may become exposed to the outside elements through loading docks, doorways, open windows, and the passage of workers and visitors in and out of the plant. For more information, refer to 21 CFR Part 110, "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food."

- a. <u>Maintenance</u>. A disorderly, haphazard accumulation of useless materials, such as plant refuse, discarded equipment, scrap metal, and lumber, provides a refuge and breeding place for flies, rats, and other vermin.
 - Suitable containers or facilities must be provided for routine accumulation of such materials. Appropriate routine removal of the useless materials is also essential. In addition, all outside grounds should be policed periodically, and vegetation should be kept under control.
- b. <u>Burning of Waste Materials</u>. Outside burning of plant refuse, such as paper towels, cartons, labeling materials, and office waste, should be done in appropriate incineration facilities so ash, smoke, and partially burned materials will not be carried by the wind into the plant and around the docks. Indiscriminate ground surface burning of refuse should not be permitted.
- c. <u>Roadway Surfaces</u>. All roadways and railroad sidings on plant grounds should be paved or otherwise rendered dust proof to prevent product contamination by blowing dust.
- d. <u>Outside Storage</u>. When useful materials and equipment are stored on the outside grounds, the materials and equipment should be placed in an orderly manner on elevated racks at least 12 inches high. This will permit the routine cleanup of waste and debris from all ground surfaces.
- e. <u>Drainage</u>. Surface and runoff water is usually contaminated and, if allowed to accumulate in pools or puddles, may produce offensive odors and serve as a breeding place for insects. The plant grounds should promote the quick runoff of all water around the plant and on the grounds.

3.2 PLANTS

For more information, refer to <u>21 CFR Part 110</u>, "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food."

- a. <u>General Maintenance</u>. Buildings, fixtures, and other physical facilities of the plant must be maintained in a sanitary condition.
- b. <u>Plant Construction</u>. Plant buildings and structures should be designed and constructed to facilitate maintenance and sanitary operations.
 - (1) <u>Fixtures, Ducts, and Pipes</u>. Fixtures, including ducts, pipes, and conveyor lines, suspended over working areas should not permit drips, condensate, dirt, metal fragments, glass, or other foreign materials to contaminate foods, raw materials, packaging materials, or equipment. Space over such working areas should be substantially free of possible contamination sources.
 - (2) Floors. Floors are ideal places in which food may lodge, decompose, and support the growth of insects or the development of undesirable organisms. Floors should be maintained to eliminate all open cracks and crevices. Wet spots or areas present a safety hazard and permit tracking contaminants from one place to another. Depressions or low areas that would accumulate moisture should be corrected.
 - Containers used for holding reclaimed product and holding floor sweepings, dirty product, and trash should be labeled accordingly to ensure the quality of the product is maintained.
 - (3) Walls and Ceilings. Walls and ceilings can be a source of product contamination as scale and loose paint are ideal breeding places for insects. Walls and ceilings must be maintained free of scaling and loose paint, dust, and condensate.

(4) Lighting. Effective cleanup procedures, sanitary processing and handling of products, as well as sanitary practices in all areas of the plant are difficult unless adequate lighting is available. Such lighting must be provided to all areas where food or food ingredients are processed, examined, or stored; where equipment and utensils are washed; and to hand-washing areas, dressing and locker rooms, and toilet rooms. The overall intensity of artificial illumination in workrooms should not be less than 20-foot candles when measured at the work surface area. The illumination should not be less than 50-foot candles when measured at the work surface areas at all places where product or container inspections or examinations are made by the inspector.

Since broken glass is a serious contaminant, light bulbs, fixtures, skylights, or other glass suspended over food in any stage of preparation should be of the safety type or otherwise protected to prevent food contamination in case of breakage.

(5) Screens, Insect Control, and Rodent Proofing. The presence of birds, dogs, cats, and vermin creates a serious sanitation problem in a food processing plant. The plant must provide adequate screening and other protection to exclude birds, dogs, cats, and vermin (including, but not limited to, insects and rodents). Efforts to control the entry of pests must afford safe egress and not impair life safety.

All windows, doorways, and other openings that could admit insects or rodents should be equipped with effective insect and rodent screens or barriers. Air curtains or plastic strip doors may be used in some openings as barriers to pests. Effectively designed and installed "fly chaser" fans and ducts should be provided over doorways in outside walls of food handling areas used for shipping or receiving.

(6) <u>Ventilation</u>. Objectionable vapors, odors, dust, smoke, etc., can be absorbed by exposed products. Adequate and properly designed ventilation facilities and equipment are closely related to good plant sanitation.

Fresh air intakes should be located so that air is not contaminated with odors, dust, smoke, etc. Ventilators or exhaust fans should be of sufficient capacity and located so that they promptly remove objectionable odors and vapors.

c. Animal and Vermin Control. All insects and rodents are capable of transmitting a number of diseases to man through contamination of food. Their presence in a plant creates a potential public health hazard. The only way to guard against this is by effective vermin control. Elimination and destruction of insects and rodents in and around plants are vital to good sanitation. Two principles should be followed: Prevent their breeding and prevent their entrance into the plant.

In most instances, the owners of adjoining properties and the local health authorities will cooperate in developing a program for insect and rodent control. The management should be encouraged to obtain such cooperation.

- (1) Any place that will afford food, water, and a hiding place is a potential source of pests. The most common places are trash piles, piles of product spillage, and garbage dumps.
- (2) Buildings and equipment that harbor pests should be repaired or replaced so as to eliminate breeding and hiding places. Walls, floors, and ceilings that have been tunneled by rodents should be repaired or replaced with rodent-proof material, such as concrete or brick. Tunnels may be blocked with glass, metal, or other rodent-proof material. An 18-inch space, painted white, should be left along walls to aid in a good pest control and inspection program.
- (3) Stone and brick walls should have the joints pointed up flush and smooth; and all cracks, crevices, and openings around pipes, etc., should be sealed tight. Walls, ceilings, and partitions should be of tight-fitting material to prevent insects and other pests from entering and hiding.
- (4) Floor drain strainers should be in good repair and should remain in place so as to prevent the entrance of rats through drainage lines.
- (5) Dry storage rooms should be kept neat and clean. The stored material should be arranged so that as the supplies are moved the areas can be thoroughly cleaned. Most dry stores can be placed on racks having a clearance of at least 12 inches from the floor and be arranged so the floor beneath the racks can be readily cleaned. If racks are not used, the dry stores should be closely piled to eliminate any possibility of runways or harborage for rodents. All openings that may admit rodents, birds, flies, and other pests should be effectively screened.

If pests do gain entrance to plants, this is an indication that the preventive measures have not been entirely successful and the management and inspectors should determine where preventive methods have failed and act to prevent a recurrence.

(6) Pesticide/rodenticides should be used as a last resort. Because these chemicals may contaminate food, they should be regulated, stored properly, and only used by certified personnel.

It takes ingenuity to cope with all of the various kinds of insects and rodents. The goal of complete eradication of pests in plants is definitely possible and should be attained.

3.3 EQUIPMENT AND UTENSILS

Since there is extensive contact of product with equipment surfaces, this is a prime area for potential hazards to product sanitation and cleanliness. For more information, refer to <u>21 CFR Part 110</u>, "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food."

- a. <u>Equipment</u>. Equipment should be constructed, installed, and maintained so that it can be easily kept clean. All surfaces contacting the product must be free of scale, oil, grease, or other foreign substances. Surfaces should be nonporous and free from pits or rough spots, crevices, seams, or joints in which food may lodge, decompose, and support the growth of organisms.
- b. <u>Utensils</u>. All utensils and sampling equipment used in processing and handling of food products must be thoroughly washed or cleaned prior to use each day. Utensils must be constructed and maintained so that they are easily kept clean. Also, utensils should not be placed on unclean surfaces while in use. In addition, all utensils should be thoroughly washed and cleaned if for any reason they became contaminated during use.

Utensils constructed of certain types of materials, such as copper, bronze, or brass, should not be used in processing operations or for sampling or storage of samples of oils, shortenings, or margarine. In addition, due to the high risk of chipping, utensils made of enamelware or porcelain are not acceptable for use in the handling, processing, or sampling of products.

- c. <u>Sanitation of Equipment and Utensils</u>. There are some general precautions that should be observed by plant management to ensure the proper sanitation of equipment and utensils.
 - (1) The building, rooms, equipment, and other physical facilities of the plant should be kept in good repair and be maintained in an orderly sanitary condition at all times.
 - (2) Cleaning operations are to be conducted to minimize the danger of contamination of food and food-contact surfaces.
 - (3) Properly located facilities and equipment for cleaning equipment and utensils should be provided.

- (4) When an inspector determines that any equipment or utensils are unclean, these should not be used again until properly cleaned.
- (5) Sanitizing agents must not be used as a substitute for thorough and effective cleaning. Sanitizing residues must be removed from edible product equipment and utensils by thoroughly rinsing with clean water before the equipment or utensils are used again for handling products.
- (6) Supplies which might contact edible products must be handled and stored under sanitary condition. Adequate measures should be taken to prevent dust collection, contamination from footwear, insects, rodents, or other sources.
- (7) Staples from metal stitching machines represent a source of potential contamination of food products from bits and pieces of the metal staples. Operation of machines near open containers or in close proximity to the processing lines should not be permitted if there is any possibility of product contamination. In addition, metal-stapled cartons and wire-bound boxes should be opened with great care if they are in the vicinity of open containers or the processing line.
- d. Storage and Handling of Cleaned Portable Equipment and Utensils.

 Processing and sampling equipment and utensils, after cleaning, should be stored and maintained in such a manner as to be protected from any sources of contamination. If there is any question as to the cleanliness of these items, they should be rewashed and cleaned prior to their use.

3.4 SANITARY FACILITIES AND CONTROLS

For more information, refer to <u>21 CFR Part 110</u>, "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food."

a. <u>Potable Water</u>. An adequate supply of fresh, clean water is of primary importance in sanitation programs and plant operations. The first requirement is that the water supply in the plant be "potable." This simply means drinkable or safe for human consumption without further treatment, such as boiling or adding chemicals.

Potability requirements consist of the following general considerations:

- (1) <u>Physical Characteristics</u>. Water should contain no impurity which would cause offense to the sense of sight, taste, or smell.
- (2) <u>Microbiological Quality</u>. Water should not contain any microorganisms that would be a potential threat to human health.
- (3) <u>Chemical Characteristics</u>. Water should not contain any chemical impurities in concentrations which may be hazardous to the health of consumers.
- (4) <u>Radioactivity</u>. Exposure of humans to radiation is harmful; therefore, water should not contain radioactive materials.
- b. Nonpotable Water Supply. At a minimum, the plant water supply must pass the tests prescribed for potability in the "Drinking Water Standards" issued by the Public Health Service of Health and Human Services. Water from any source not approved and certified as potable must be deemed nonpotable.

In some plants, the supply of potable water is limited and costly and a nonpotable supply from a river, lake, or unapproved well is made available. This water may be used in certain restricted areas, but special attention must be given that no cross connection exists between the potable and nonpotable water supplies. Nonpotable water is permitted only in those parts of the plant where no edible product is handled or prepared. Then it is only for limited purposes, such as on ammonia condensers not connected with the potable water supply, in connection with washing equipment used for other than production of edible products, and in sewer lines for moving heavy solids in the sewage.

Nonpotable water is not permitted for washing floors or other areas or equipment involved in moving materials to and from edible product departments.

In all cases, nonpotable water lines must be clearly identified and must not be cross connected with the potable water supply lines.

Arrangements can be made for emergency fire-fighting connections between the potable and nonpotable systems, but a complete break in the piping must routinely exist. Valves alone cannot be used as the means of separations, as they may leak or be opened accidentally. In each case, such emergency fire-fighting connections must be approved by local authorities.

c. Reuse of Water. There are certain situations where potable water may be reused for the identical, original purpose within a plant. Reuse of water may be approved for such purposes as in vapor lines leading from deodorizers used in preparation of shortening and similar edible products and in equipment used for chilling of canned products.

All pipelines, reservoirs, tanks, cooling towers, and like equipment employed in handling the reused water must be constructed and installed so as to facilitate their cleaning and inspection. Supply lines for potable water must be installed so as to prevent back siphonage. (Back siphonage is the backflow of used, contaminated, or polluted water from a plumbing fixture, equipment, or other source into a water supply pipe due to a negative pressure in such pipe or supply system.)

Complete draining and disposal of the reused water, effective cleaning of the equipment, and renewal with fresh potable water must be accomplished frequently enough to ensure an acceptable supply of water for the purpose intended.

d. <u>Sewage Disposal</u>. The sewage disposal facilities utilized by the plant must be acceptable to the local authorities having jurisdiction over such matters. If the inspector suspects that the sewage disposal facilities are not acceptable for any reason, he or she should check with the local authorities responsible for the approval of the plant's sewage system to determine that the system has been approved.

e. Plumbing. Plumbing is a particularly important consideration in food plants. If plumbing is improperly installed or maintained, a variety of public health hazards, such as cross connections, back siphonage, drainage system stoppage, or overhead leakage may occur. Any of these conditions can result in serious contamination of the water supply, product, equipment, or utensils or create obnoxious odors or other nuisances.

In general, all plumbing should be sized, installed, and maintained in accordance with applicable state and local plumbing laws, ordinances, and regulations. If an inspector suspects that any part of the plumbing system does not meet with local requirements, the plant management should be requested to furnish evidence that the questionable system meets all local requirements.

f. Toilet Facilities. Toilet facilities must meet the requirements of the Occupational Safety and Health Act of 1970 and the FDA's Good Manufacturing Practice Regulations of 1969 (21 CFR, Part 110.37). The facilities must be maintained in a sanitary condition and kept in good repair at all times. Restroom facilities must be so constructed that they do not open directly into rooms or areas where ingredients or products are handled, processed, or stored. Entrance through an intervening dressing room or ventilated restroom vestibule is permissible. Restroom facilities and vestibules must have self-closing doors completely filling the openings.

Adequate ventilation of restrooms is also critical because of the possibility of objectionable odors entering production areas. Restroom facilities without air conditioning should be effectively ventilated mechanically by means of an exhaust fan with a duct conveying the foul air to the outside. Conveniently located wall-mounted tissue dispensers must be provided and maintained so they remain functional and contain an adequate supply of tissue. It is important that tissue be available without the user being required to handle the tissue roll.

Rigid standards of sanitation must be maintained in the restrooms. Special attention must be given to ensure that toilets and urinals are clean and functional at all times. Blockage of toilets or urinals dictates immediate attention by plant management. If the floors become contaminated with human wastes, the entire room must be declared unfit for use until repairs are made and a thorough cleaning and sanitizing of the floor is accomplished.

When making an inspection of toilet facilities, arrangements should be made with plant management for entrance and examination of the toilet facilities used by the opposite sex.

Signs must be posted directing employees to wash their hands with cleaning soap or detergent immediately after using toilets.

g. <u>Hand-Washing Facilities</u>. Hands often become soiled in the performance of routine duties in and about the plant, so convenient location of hand-washing facilities is desirable.

Pedal-operated, hand-washing facilities are desirable so that touching knobs or levers that have been contaminated by unwashed hands is not required. Facilities must have tepid water and soap for hand washing, sanitary towel service or suitable drying devices, and, where appropriate, easily cleanable waste receptacles.

h. Rubbish Disposal. In food processing plants, control and disposal of wastes is a major concern. In most instances, the plant's waste represents most of the contaminants and filth that the sanitation program has eliminated from actual or potential contact with edible products. It is essential that this material be disposed of in a manner that does not pose a further threat to edible products or human health. Disposal of trash by burning should be performed according to local ordinances only.

In addition, plant wastes by their very nature have a high nuisance potential. Rubbish, such as used paper towels, cartons, office waste, labeling materials, floor sweepings, etc., frequently can be a sanitation problem. Suitable containers or trash cans, with tight-fitting lids, must be conveniently located throughout the plant. These should be emptied frequently so that the accumulation of rubbish prior to its removal does not cause a sanitation problem.

CHAPTER 4: SANITATION INSPECTIONS

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4.1 SAFETY²

Generally, official personnel should follow the below guidelines:

- a. Comply with all pertinent <u>Occupational Safety and Health</u> <u>Administration</u> 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 must 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 inspections are performed when plants:
 - (1) Have not had a previous contract for which FGIS had inspection responsibility;
 - (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;
 - (3) May have been renovated or otherwise altered significantly since the last inspection; and
 - (4) Are planning to produce a significantly different type of product than the type they normally produce.

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² The requirements in this section are mandatory for FGIS employees. All others are strongly encouraged to also follow the guidelines.

- b. <u>Plant Visits</u>. During these visits official personnel must:
 - (1) Determine the capability of the plant to produce a sound, wholesome product of consistent quality and quantity (e.g., conduct a sanitation inspection, determine the plant's quality control points);
 - (2) Establish or maintain contact with appropriate plant personnel so that good relations and communications may be effected;
 - (3) Determine the most efficient, reliable, and economical means of conducting official inspection services;
 - (4) Ensure that the plant understands the contractual requirements; and
 - (5) Ensure that the plant understands FGIS procedures (i.e., inspection, request for service, billing, subsequent inspections).

If it is impractical to visit a plant prior to performing inspection services, FOMs or cooperator managers must contact the appropriate plant personnel by telephone to determine as much of the above information as possible. In this situation, visit the plant as soon as possible after inspection begins. Unresolved differences or difficulties should be reported to the Office of the Director for assistance.

- c. Subsequent plant sanitation inspections are performed:
 - (1) In accordance with the following schedules:
 - (a) <u>Processed Commodities and Rice</u>. (Refer to <u>FGIS-952</u>.)
 - In 6 months, if the plant received a <u>Sanitation</u> <u>Inspection Report</u> (SIR) score of 0-30 on the last sanitation inspection.
 - In 2 months, if the plant received an SIR score of 31-75 on the last sanitation inspection.

- 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 Technology and Science Division (TSD) according to the Processed Commodities Handbook.
- 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. (Refer to FGIS 952-1.)
 - In 6 months, if the plant received an SIR score of 0-20 on the last sanitation inspection.
 - In 2 months, if the plant received an SIR score of 21-45 on the last sanitation inspection.
- (c) Overpacker. (Refer to FGIS 952-2.)
 - In 6 months, if the plant received an SIR score of 0-8 on the last sanitation inspection.
 - 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. <u>General</u>. 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. <u>Inspection Priorities</u>. 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) <u>Direct Product Contamination</u>. 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).

These areas must be clean before operations involving their use begin. "Clean" in this instance is defined as free from all foreign material (e.g., rust, dust, lubricating grease, cleaning compounds, scale). 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). 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).

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 PREPARATION³

Sanitation is not limited to those who have USDA or plant responsibility. 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.)
- 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 FOM informed. It is very advantageous for the FOM to have advance information when a plant protest or complaint is likely to occur. This will enable the inspector and the FOM to work as a team in obtaining the cooperation of plant management in correcting problem areas.

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

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³ Refer to section 4.8, "Equipment and Utensils," for list of needed equipment and utensils.

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 SIR lists the areas reviewed and compiles the defects received from a plant examination in order to properly assess and score the sanitary or insanitary plant conditions, according to the instructions provided. The appropriate SIR must be completed for each sanitation inspection performed, and the results will determine any necessary follow-up actions, as indicated on the report and outlined below.

The SIR for processed products (<u>FGIS-952</u>) must be used for all processed product and rice processing plants. SIRs that are specifically designated for bean, pea, and lentil processors, as well as military overpackers, must be used when making sanitation inspections of these activities (<u>FGIS 952-1</u> and <u>FGIS 952-2</u>). An overpacker is a facility where small containers are put into larger containers. These forms are available, upon request, from the Policies, Procedures, and Market Analysis Branch.

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

a. <u>Defect Points</u>. 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 the inspector's best judgement 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 could be improved upon, 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. <u>Critical Items</u>. 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. <u>Sanitary Rating</u>. 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 <u>FGIS-952</u> 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 must 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 must 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

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

a. <u>Inspector</u>. 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 FOM.
- b. <u>Field Office Manager/Cooperator</u>. 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 <u>FGIS Directive 9060.2</u>, "Implementation of the FGIS-FDA Memorandum of Understanding." If services are withheld, FDA should be notified.

4.8 EQUIPMENT AND UTENSILS

- a. <u>Required</u>. In order to perform a proper sanitation inspection, it is necessary to use certain equipment, while others are optional. The following are required:
 - (1) Hard hat and hair net.
 - (2) Rubber/plastic gloves.
 - (3) Flashlight.
 - (4) Clipboard.
 - (5) Small paper or plastic containers for exhibits of insects, rodent evidence, or other conditions.
 - (6) Putty knife or other instrument for probing into crevices and corners.
- b. <u>Optional</u>. In order to perform a proper sanitation inspection, it is necessary to use certain equipment, while others are optional. The following are optional:
 - (1) Flour slick for dry commodities (or similar instrument) used to smooth out samples of the product for examination.
 - (2) Boot trier used to remove samples from boots of legs carrying the different stages of a commodity.
 - (3) Hand sieve (No. 24 or 2-1/2" x 64") and bottom pan. (After obtaining commodity samples for examination, sieve them to determine if dead insects or rodent excreta is present.)
 - (4) Light meter (refer to Equipment Handbook).
 - (5) Attaché or briefcase in which to carry equipment.
 - (6) Other aids could include such items as a portable black light and camera. Do not use a conventional flash camera or any type of light without permission (refer to Equipment Handbook).

ATTACHMENT 1: FGIS 952 - SANITATION INSPECTION REPORT (PROCESSED PRODUCTS)

	SANITATION INSPECTION	REP	ORT (,	FGIS	952
SAN	SANITARY INSPECTION OF (Name and Address of Plant)				PECTOR TE INSPECTED		
PLA	NT OWNED BY (Company or Individual)				PECTOR ACCOMPANIED BY (Name and Title)		
	SANITARY DEFECTS	Assigned Defect Points	Inspr's Defect Points		SANITARY DEFECTS	Assigned Defect Points	Inspr's Defect Points
l.	PREMISES			٧.	VENTILATION		
Α.	Outside premises not well drained	3		C.	Areas where steam or hot air vapors are predominant and not effectively exhaust ventilated.	3	
B.	Outside premises not free of weeds, clutter, unused equipment or other materials.	3		D.	Cooling and air-conditioning units not equipped with filtering devices; filter not changed or cleans when necessary.	3	
C.	Waste not properly stored or contained.	3		E.	Window opening to the outside not screened with 14-mesh or finer screen (during presence of flies or other flying insects).	3	
D.	Outside premises not free of harborage or breeding places for insects, rodents, birds, or other animals.	4		F.	Exhaust fans not screened or equipped with self-closing louvers.	3	
E.	Approaches to docks not clean or treated to minimize dust.	3		VI.	WATER SUPPLY		
II. A.	RAW MATERIALS Raw materials used in the product not handled in a sanitary manner that would prevent adulteration of finished product.	Critical		A. B.	Lack of satisfactory evidence that the water supply is potable. Presence of a cross-connection between water lines and sewage system (not allowed).	Critical Critical	
III. A.	CONSTRUCTION OF BUILDING Plant construction does not excluded probable entrance of insects, rodents, birds, or other animals.	5		VII. A.	DISPOSAL OF WASTES Garbage, trash, and dry waste materials, inside or outside the building, not satisfactorily contained.	4	
B.	Walls, partitions, ceilings, and exposed structural supports in poor repair.	3		B.	Waste is not disposed of frequently enough to prevent unsightliness or undesirable odors.	4	
C.	Floors not smooth and readily cleanable.	3		VIII.	TOILET, HAND-WASHING, AND DRESSING ROOM FACILITIES		
D.	Floors that frequently get wet not constructed to prevent pooling or are not kept dry.	3		A.	Toilet facilities not provided for each sex.	4	
E.	Exposed, unprotected overhead sewer lines present in product area.	Critical		В.	Toilets and urinals not water-flushed.	3	
F.	Wooden floors, where present, not coated with a suitable floor seal that effectively minimizes cracks and crevices.	5		C.	Toilet room(s) not equipped with self-closing doors.	3	
G.	Walls not sealed at juncture with floor.	3		D.	Toilet rooms open directly into a processing or food storage room where food is exposed.	Critical	
H.	Walls and ceilings not free of flaked paint, nor in good repair.	3		E.	Cold and hot, warm, or tepid water not provided at wash basins.	3	
I.	Windows not intact.	3		F.	Hand cleaner and towels not provided at or near basin.	3	
J.	Entrance ways to production rooms not equipped with self- closing doors, nor provided with other effective means to prevent entrance of vermin.	3		G.	Adequate hand-washing signs not provided.	3	
K.	Screen doors, where present, not self-closing.	3		H.	Adequate dry waste receptacles not provided.	3	
L.	Utility rooms of areas, including boiler rooms and maintenance ship, not isolated enough or separated from production rooms.	4		l.	Toilet facilities not working.	5	
IV.	LIGHTING			J.	Toilet and locker room not satisfactorily ventilated.	4	
A.	Production rooms not adequately lighted (20-foot candles).	3		K.	Toilet and dressing rooms not kept in a clean orderly condition.	5	
B.	Places where detailed inspection of the product or ingredients is required not adequately lighted (50-foot candles).	4		IX.	CONSTRUCTION AND REPAIR OF EQUIPEMNT		
C.	Places where detailed inspection of the processes or operations is required not adequately lighted (50-foot candles).	3		A.	Equipment product contact surfaces not constructed of smooth nontoxic, corrosion-resistant, odorless materials; wood, where used, not fine, close grained, high-density type.	5	
D.	Storage areas not adequately lighted (20-foot candles).	3		В.	Equipment product zone surfaces not free of cracks, crevices, pits, or other imperfections (such as knots, in wood).	5	
E.	Toilets and dressing rooms not adequately lighted (20-foot candles).	3		C.	Adequate space not allowed around equipment for cleaning and inspection purposes.	4	
F.	Light bulbs, fixtures, skylights, or other glass suspended over food in any stage of preparation not of a safety type or otherwise protects where essential to prevent contamination of the product during production.	5		D.	Equipment not designed to protect the product zone against contamination and extraneous materials.	5	
V.	VENTILATION			E.	Equipment not free of parts or areas inaccessible for cleaning and sanitary inspections.	4	
A.	Plant not reasonably free of undesirable odors, hot air vapors or dust.	3		F.	Electrical system not constructed or positioned to prevent insect harborage.	3	
B.	Evidence or presence of excessive condensate on walls, ceilings, equipment, or pipelines.	4		G.	Equipment not kept in good repair.	2 for each item not in good repair	

	SANITARY DEFECTS	Assigned Defect Points	Inspr's Defect Points		SANITARY DEFECTS	Assigned Defect Points	Inspr's Defect Points
Х.	CLEANING	r onns	FUIIIS	ΥIII	STORING AND STORAGE FACILITIES	FUILIS	FOILIS
	Equipment not cleaned at frequencies necessary to prevent contamination of the product.	Critical		A.	Supplies and products not adequately protected from contaminations or frim becoming spoiled.	5	
B.	A dust free method of cleaning not used wherever possible.	3		B.	Storage areas not well ventilated and free from objectionable odors.	3	
XI. A.	CONTROL OF INSECTS AND ANIMALS Presence or evidence of any rodents in plant.	_		C. D.	Storage areas not clean and dry. Materials not stored in an orderly manner in suitable, covered	3	
B.	Presence of any birds or any other animals including domestic	5		E.	or closed containers. Supplies and product not protected against unfavorable	3	
C.	types in plant. Presence of live insects in processing or product storage	Critical		F.	temperatures and humidity. Adequate skids or pallets not used where needed.	3	
D.	areas (two or more). Presence of dead insects in processing equipment (two or	Critical		XIV.	PERSONNEL	3	
E.	more). Presence of live or dead insects in other plant areas (three or	5		A.	Employees not wearing garments suitable for work being	4	
F.	more). Rodenticides, insecticides, and other control or eradication material including applicatory equipment not used in a safe	Critical		В.	performed. Personnel in contact with unwrapped product or ingredients not using proper headwear, including protection from facial hair.	4	
G.	acceptable manner. Evidence that effective pest control not exercised where needed.	3		C.	Fingernail polish, costume jewelry, and wrist watches worn by	3	
H.	Type of insecticides and rodenticides not in compliance with Federal Food and Drug Administration regulations.	4		D.	plant personnel working on production line. Gloves, if worn, not kept in a sanitary condition.	3	
l. XII.	Poisoned baits, if used, not adequately secured. COOLING AND REFRIGERATION FACILITIES	5		E. F.	Storage of employees personal effects in production room. Employees not washing hands after contamination.	3 Critical	
	Perishable supplies and products not adequately protected from contamination or from becoming spoiled.	5		G.	Failure of employees to be hygienically clean; fingernails not kept clean and trimmed.	4	
B.	Storage areas not free of visible mold and objectionable odors.	3		H.	Employees affected with or a carrier of a communicable or infectious disease not excluded from product areas.	Critical	
C.	Storage areas not reasonably clean.	3		l.	Plant employees having an infectious wound, sore, or lesion on hands, arms, or other exposed parts of the body, not excluded from contacting ingredients, products, or product zones.	5	
D.	Where required refrigeration facilities not properly cooling and keeping perishable supplies and products at temperatures not exceeding 45° F.	5		J.	Plant personnel not instructed in acceptable hygienic practices and proper sanitary rules of food handling.	5	
E.	Adequate skids or pallets not used when needed.	3		K.	Personnel not prohibited from expectorating, eating or smoking in product areas.	5	
F.	Items not stored in an orderly, easily accessible manner in suitable, covered, or closed containers.	3					
		TOTAL					
REM	MARKS		DF 76 OF				
SIGN	NATURE OF INSPECTOR					DATE	
	FORM FGIS 952 (Reverse)					L	

ATTACHMENT 2: FGIS 952-1 – SANITATION INSPECTION REPORT (BEANS, PEAS, AND LENTILS)

SAN	SANITATION INSPECTION F NITARY INSPECTION OF (Name and Address of Plant)	'FI. OL	, , (DE		PECTOR	FGIS	JJZ-
SAI	NTART INSPECTION OF (Name and Address of Plant)				TE INSPECTED		
LΑ	ANT OWNED BY (Company or Individual)			INSI	PECTOR ACCOMPANIED BY (Name and Title)		
	SANITARY DEFECTS	Assigned Defect Points	Inspr's Defect Points		SANITARY DEFECTS	Assigned Defect Points	Insp Def Poi
	PREMISES			VI.	WATER SUPPLY		
١.	Outside premises not well drained	3		Α.	Lack of satisfactory evidence that the water supply is potable.	Critical	
١.	Outside premises not free of weeds, clutter, unused equipment or other materials.	3		B.	Presence of a cross-connection between water lines and sewage system (not allowed).	Critical	
) .	Waste not properly stored or contained.	3		VII.	DISPOSAL OF WASTES		
).	Outside premises not free of harborage or breeding places for insects, rodents, birds, or other animals.	4		A.	Garbage, trash, and dry waste materials, inside or outside the building, not satisfactorily contained.	4	
l.	RAW MATERIALS			B.	Waste is not disposed of frequently enough to prevent unsightliness or undesirable odors.	4	
١.	Beans, peas, and lentils not handled in a sanitary manner that would prevent adulteration.	Critical		VIII.	TOILET, HAND-WASHING, AND DRESSING ROOM FACILITIES		
I.	CONSTRUCTION OF BUILDING			Α.	Toilet facilities not provided for each sex.	3	
١.	Plant construction does not excluded probable entrance of insects, rodents, birds, or other animals.	3		B.	Toilets and urinals not water-flushed.	3	
3.	Walls, partitions, ceilings, and exposed structural supports in poor repair.	3		C.	Toilet room(s) not equipped with self-closing doors.	3	
Э.	Floors not smooth and readily cleanable or impervious under normal usage.	3		D.	Toilet rooms open directly into a processing or food storage room where food is exposed.	Critical	
).	Floors that frequently get wet not constructed to prevent pooling or are not kept dry.	3		E.	Cold and hot, warm, or tepid water not provided at wash basins.	3	
	Exposed, unprotected overhead sewer lines present in product area.	Critical		F.	Hand cleaner and towels not provided at or near basin.	3	
	Walls not sealed at juncture with floor.	3		G.	Adequate hand-washing signs not provided.	3	
.	Walls and ceilings not free of flaked paint, nor in good repair.	3		H.	Adequate dry waste receptacles not provided.	3	
ł.	Windows not intact.	3		I.	Toilet facilities not working.	5	
	Entrance ways to production rooms not equipped with self- closing doors, nor provided with other effective means to prevent entrance of vermin.	3		J.	Toilet and locker room not satisfactorily ventilated.	4	
l.	Screen doors, where present, not self-closing.	3		K.	Toilet and dressing rooms not kept in a clean orderly condition.	5	
٧.	LIGHTING			IX.	CONSTRUCTION AND REPAIR OF EQUIPEMNT		
١.	Production rooms not adequately lighted (20-foot candles).	3		A.	Adequate space not allowed around equipment for cleaning and inspection purposes.	4	
3.	Places where detailed inspection of the product or ingredients is required not adequately lighted (50-foot candles).	4		В.	Equipment not designed to protect the product zone against contamination and extraneous materials.	5	
).	Places where detailed inspection of the processes or operations is required not adequately lighted (50-foot candles).	4		C.	Equipment not free of parts or areas inaccessible for cleaning and sanitary inspections.	4	
).	Storage areas not adequately lighted (20-foot candles).	3		х.	CLEANING AND SANITIZING TREATMENT		
	Toilets and dressing rooms not adequately lighted (20-foot candles).	3		A.	Equipment not cleaned at frequencies necessary to prevent contamination of the product.	Critical	
	Protective shields for lights not present in areas where essential to protect the product during production.	5		XI.	CONTROL OF INSECTS AND ANIMALS		
	VENTILATION			A.	Presence or evidence of any rodents in plant.	5	
١.	Plant not reasonably free of undesirable odors.	3		В.	Presence of any birds or any other animals including domestic types in plant.	5	
3.	Evidence or presence of excessive condensate on walls, ceilings, equipment, or pipelines.	4		C.	Presence of live insects in processing or product storage areas (two or more).	Critical	
).	Window opening to the outside not screened with 14-mesh or finer screen (during presence of flies or other flying insects).	3		D.	Presence of dead insects in processing equipment (two or more).	Critical	
).	Exhaust fans not screened or equipped with self-closing louvers.	3		E.	Presence of live or dead insects in other plant areas (three or more).	5	
	1			F.	Rodenticides, insecticides, and other control or eradication material including applicatory equipment not used in a safe acceptable manner.	Critical	

SANITARY DEFECTS		Assigned Defect Points	Inspr's Defect Points	SANITARY DEFECTS		Assigned Defect Points	Inspr's Defect Points
XI.	CONTROL OF INSECTS AND ANIMALS (Cont.)	1 Olliko		XII.	PERSONNEL (Cont.)	. 61116	1 On its
G.	Evidence that effective pest control not exercised where needed.	3		F.	Failure of employees to be hygienically clean; fingernails not kept clean and trimmed.	4	
XII.	PERSONNEL			G.	Employees affected with or a carrier of a communicable or infectious disease not excluded from product areas.	Critical	
Α.	Employees not wearing garments suitable for work being performed.	4		H.	Plant employees having an infectious wound, sore, or lesion on hands, arms, or other exposed parts of the body, not excluded from contacting ingredients, products, or product zones.	5	
В.	Personnel in contact with unwrapped product or ingredients not using proper headwear, including protection from facial hair.	4		l.	Plant personnel not instructed in acceptable hygienic practices and proper sanitary rules of food handling.	5	
C.	Gloves, if worn, not kept in a sanitary condition.	3		J.	Personnel not prohibited from expectorating, eating or smoking in product areas.	5	
D.	Storage of employees personal effects in production room.	3					
E.	Employees not washing hands after contamination.	Critical					
		TOTAL					
PLA	NT OPERATIONS ARE CONSIDERED TO BE INSANITARY		R MORE		TICAL DEFECTS ARE FOUND OR IF THE PLANT RECEIVE	S AN SIR S	SCORE
SIGN	IATURE OF INSPECTOR					DATE	

FORM FGIS 952-1 (Reverse)

ATTACHMENT 3: FGIS 952-2 - SANITATION INSPECTION REPORT (OVERPACKER)

SANITATION INSPECTION REPO					T (OVERPACKER)	FGIS	952-2
1AS	NITARY INSPECTION OF (Name and Address of Plant)						
			ONE NO OF DIANT				
		PHONE NO. OF PLANT					
				INS	PECTOR		
PLA	NT OWNED BY (Company or Individual)			DA [*]	TE INSPECTED		
-							
OF!	NREAL TYPES OF ITEMS INSPECTED			INS	PECTOR ACCOMPANIED BY (Name and Title)		
GEI	NREAL TYPES OF TIEMS INSPECTED						
		۸ : ا				A :	la a a ala
	SANITARY DEFECTS	Assigned Defect	Defect		SANITARY DEFECTS	Assigned Defect	Defect
I.	PACKING MATERIAL	Points	Points	IV.	TOILET AND HAND-WASHING FACILITIES (Cont.)	Points	Points
Α.	Not free from adulteration.			D.	Absence of hot or cold water, soap, or hand-drying facilities.		
"	The three heart additional on the state of t	Critical			The state of the s	5	
B.	Shows evidence of insanitary conditions or deterioration.	5		E.	Toilet rooms not properly vented to the outside.	5	
		3					
C.	Not stored under sanitary conditions.			٧.	CONTROL OF INSECTS, BIRDS, AND ANIMALS		
		5					
II.	LIGHTING			Α.	Rodent harborages or insect-breeding places present.		
						4	
Α.	Insufficient lighting in areas where inspection and examination			В.	Insects, birds, or animals present in plant.		
	are performed (50-foot candles).	4				5	
<u></u>	DISPOSAL OF WASTES			C.	Insecticides or rodenticides are handled so as to contaminate		
	DIO GOAL OF WASTES			0.	the product.	Critical	
L							
A.	Floor drains not functional nor properly trapped.	3		VI.	STORAGE FACILITIES		
		ŭ					
B.	Dry wastes not collected in suitable containers conveniently located throughout the plant.			A.	Storing methods do not minimize deterioration nor contamination.		
		3					
C.	All waste not collected and disposed of at frequent intervals nor			В.	Storage facilities not clean, sanitary, nor in good repair.		
	in a sanitary condition.	4				4	
IV.	TOILET AND HAND-WASHING FACILITIES			C.	Shelves, cabinets, or dunnage not used where necessary to		
					prevent contamination or deterioration.	4	
Α.	Toilet room opens directly into packing or storage area.						
ľ.,	puoling of storage area.	5					
				1			
B.	Doors not self-closing and tight fitting.	3					
		L	L				
C.	Absence of sign directing employees to wash hands.						
		3					
	I .						

	SANITARY DEFECTS	Assigned			SANITARY DEFECTS	Assigned	
		Defect Points	Defect Points			Defect Points	Defect Points
VII.	PERSONNEL			VII.	PERSONNEL (Cont.)		
Α.	Not free fo communicable nor infectious desease.			В.	Not free of infected cuts, open sores, or other lesions on		
		Critical			exposed parts of the body.	Critical	
		TOTAL					
PL/	ANT OPERATIONS ARE CONSIDERED TO BE INSANITARY		R MORE OF 21 OF			S AN SIR S	SCORE
RFI	MARKS						
SIG	NATURE OF INSPECTOR					DATE	
	FORM FGIS 952-2 (Reverse)					<u> </u>	

CHAPTER 5 FOOD DEFENSE SYSTEM SURVEY

CONTENTS

5.1	INTRODUCTION	.5-2
5.2	WHO WOULD USE THE FOOD DEFENSE SYSTEM SURVEY?	.5-2
5.3	RESOURCES	.5-3

5.1 INTRODUCTION

The Specialty Crops Inspection (SCI) Division of AMS developed the "Food Defense System Survey" (FDSS) (pdf) as a means of verifying an organization's Food Defense systems. These are measures that operators of food establishments may take to minimize the risk of tampering or other malicious criminal actions against the food under their control. Operators of food establishments are encouraged to review their current procedures, controls, and work to mitigate the potential for tampering. A FDSS may be performed at any processing facility, storage, or offsite warehouse facility handling processed fruits, vegetables and/or related products at the request of the processing facility management.

5.2 WHO WOULD USE THE FOOD DEFENSE SYSTEM SURVEY?

- a. Companies with the following interests would use the Food Defense System Survey:
 - (1) Companies interested in demonstrating to customers that they have effective food defense procedures in place.
 - (2) Companies who want an analysis of their Food Defense System in accordance with measures identified in the FDA's, "Guidance for Industry Food Producers, Processors, and Transporters:

 Food Security Preventative Measures Guidance."
 - (3) Companies who want to demonstrate that their facility meets the Food Defense requirements of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Specialty Crops Program, Commodity Procurement Branch, Purchase Programs and other programs requiring a FDSS.
- b. <u>Benefits</u>. The benefits of passing the survey are an independent 3rd-party USDA verification that specified Food Defense measures/criteria are met in accordance with FDA guidelines; and Demonstration of compliance with USDA/AMS/FV Purchase Program requirements.

5.3 RESOURCES

a. Food Defense Contact Information.

Specialty Crops Inspection Division scaudits@ams.usda.gov
202-720-5021

b. Additional Resources.

(1) Food Defense System Survey (FDSS) Checklist: <u>FDSS Checklist</u> (pdf).

This checklist provides questions which are evaluated at the processing and offsite warehousing facilities.

(2) Food Defense System Survey (FDSS) Guidelines: <u>FDSS</u> <u>Guidelines (pdf)</u>

This document provides guidelines for evaluation elements listed in the FDSS Checklist, referenced above. The guidance is most helpful to better understand the expectations of each question on the survey checklist. The FDSS Guidelines also provide a list of rating elements (Minor, Major, and Critical), alongside a description of the objective evidence, gathered from the survey.

CHAPTER 6 REVISION HISTORY

CONTENTS

CHANGE NO. 2:	SEPTEMBER 09, 2020	6-2
CHANGE NO. 1:	MARCH 28, 1997	6-2

The Sanitation and Food Defense Handbook, formerly known as the 'Sanitation Handbook,' was revised to incorporate policy and procedural changes, namely the introduction of the Food Defense Survey, as well as re-formatting and editorial updates to maintain in compliance with <u>FGIS Administrative Directive</u> 3010.2, "Policies, Procedures, and Guidance Issuance."

Since the previous date of revision, a new chapter was added (Chapter 5, Food Defense System Survey), and the handbook title was changed accordingly. Additionally, guidance from Policy Bulletin, Reference #228, "Limiting Analysis of Lots Containing Deleterious Substances, and Testing Plant Environmental Material Collected During Plant Sanitation Inspection," was incorporated in Chapter 4, Sanitation Inspections.

For all substantive revisions, updated hyperlinks were embedded within the text to link directly to both internal and external content wherever possible. When the entire contents of an applicable resource, such as an FGIS Program Directive, are able to be incorporated within the handbook text, then no link or reference will be provided—once all of the applicable content is incorporated as necessary in the respective handbook updates, FGIS will likely remove the directive, program notice, etc. from its active inventory. Guidance from FGIS Directive 9100.2, "Preinspection Plant Visits," was incorporated in its entirety in section 4.2, "Frequency of Inspections."

Change No. 1: March 28, 1997

This handbook is revised to authorize field office managers to delegate licensees or samplers to perform sanitation inspections at certain locations, clarify some procedures, put in new format, and make minor editorial changes.