PATCH # 092

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REMARKS: This PATCH provides updated instructions under Essential Requirements of the Survey, section K relating to acceptable water quality certificate provided during a plant survey. Updated information will be incorporated into the next revision of the Sanitation Manual.

Essential Requirements of the Survey

K. The plant must provide SCI Division an acceptable water quality certificate. Samples tested for water quality must be collected directly from a line within the facility, at the end of the facility's water system. Municipal water quality reports will not be accepted for fulfillment of this requirement. See your immediate supervisor if there is any question about the documentation provided.

United States Department of Agriculture

Marketing and Regulatory Programs

Agricultural Marketing Service

Fruit and Vegetable Program

Specialty Crops Inspection Division

AIM Inspection Series

Sanitation Manual

September 2013

SANITATION MANUAL

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INTRODUCTION

This manual is provided to Specialty Crops Inspection (SCI) Division personnel to promote uniformity in the performance of sanitation inspection procedures. Sanitation is an integral part of Division services. If needed, contact your immediate supervisor for any situation not addressed in this manual.

This manual contains links to various internal and external sources of information. For inspection personnel without internet or intranet access, please contact your immediate supervisor to obtain hard copies of documents as needed.

GUIDE FOR ELECTRONIC USAGE

The Administrative, Inspection, and Management (AIM) System of instructional manuals is available electronically in Adobe Acrobat Portable Document Format (PDF) at the following intranet address: http://agnis/sites/FV/PPB/AIM/default.aspx.

When accessed electronically, AIM materials have hyperlinks and hypertext (visible as underlined blue text) available to the PDF user. Clicking on a hyperlink takes the reader to a web site with information relating to the subject. Hypertext will link the reader to a different page within the current manual - or even a different manual - with information relating to the subject. For example, the hypertext in the Table of Contents allows a reader to go directly to the section of interest in the manual by clicking on the section title within the Table of Contents.

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IN-PLANT SANITATION

In-plant inspection is designed to give a processor the advantage of on-site, timely inspection of product quality, condition of raw materials, in-process control, availability of inspection reports, and sanitation inspection. These benefits can be realized to the fullest extent when good sanitary and good manufacturing procedures are practiced.

These instructions are designed to help the inspector make sound sanitation decisions, and to apply the same sanitary standards uniformly to all plants. Supervisors should be kept informed of any problem areas with which the inspector may need assistance.

Both the plant management and the inspector have specific sanitation responsibilities which should not be assumed by the other. Although supervisors and inspectors will work with plant management to maintain high standards of sanitation, plant management should not view the inspector as an additional foreman or sanitation supervisor.

A. Plant Management's Role in Sanitation

The plant management has the responsibility to produce a clean product, in a clean plant, under sanitary conditions.

Each plant or department must have a trained employee responsible for sanitation. This responsibility must include an inspection of the plant or department to insure proper and effective cleanup prior to the start of operations, and procedures to ensure that adequate cleanup is maintained throughout the shift. This depends on four things:

1. An effective cleanup procedure;

2. Trained, properly supervised personnel;

3. Appropriate cleanup equipment and materials; and

4. Time to properly accomplish the work.

B. Inspector's Role in Sanitation

Monitoring plant sanitation is one of the most important responsibilities of the in-plant inspector. The inspector must see that plant management follows through with their responsibilities to produce a clean product in a clean plant.

Inspectors must always remember that they are dealing with human food products. To be effective, inspectors must understand why good sanitation is essential; look and be personally clean; and be familiar with the plant and its operational procedures, including proper cleaning procedures.

Monitoring Plant Sanitation

The prerequisite for performing an efficient, thorough sanitation inspection is a comprehensive knowledge of the plant layout, premises, machinery, equipment, and processes.

A. General

Inspectors have the responsibility of evaluating management's plant sanitation program to assure that sanitation practices are satisfactory and effective. They must continually be on the alert to help management's representatives' spot conditions that might contribute to product contamination.

Inspectors must take the time necessary to perform thorough sanitation inspections, using plant sanitation history as a guide for checking problem areas. If other tasks pull the inspector away from this duty, the plant may need to contract for an additional inspector. Be sure the plant understands your responsibilities, and your supervisor knows your circumstances. If needed, schedule a meeting with you, your supervisor and plant management to resolve the situation.

Plants operating on an "around-the-clock" basis may be reluctant to use operating time for the purpose of cleanup. Proper sanitation cannot be maintained under these conditions. Plants under in-plant inspection must periodically cease operations for the length of time necessary to maintain proper sanitation. This time will depend on the size and efficiency of the cleanup crew and equipment, the size of the plant, the complexity and accessibility of processing equipment, and the kind of product being processed.

Shutdown for cleanup must be supplemented by "sustaining" cleanup during operations and production breaks. The "sustaining" cleanup includes emptying garbage containers, keeping floors hosed off during operations, and cleaning belts, fillers, cutters, and similar equipment and facilities during breaks.

The plant layout may permit alternate shutdowns on one or more lines for cleanup while other lines of the same product continue processing operations. This type of cleanup should not be permitted if there is danger of adulterating product lines that are still in operation.

B. Definition of Terms for Rating Conditions

1. **Minor Deficiencies** do not result in product contamination, but are not desirable.

2. **Major Deficiencies** may result in product contamination, or are highly objectionable.

3. **Critical Deficiencies** result in product contamination.

C. Correction of Sanitary Deficiencies

1. **Minor Deficiencies** should be corrected within 24 hours, or less if specified by the inspector.

2. **Major Deficiencies** must be corrected within the time specified by the inspector. This is normally between the time the deficiency is discovered and the next shift or end of the next cleaning period, depending on the probability of product contamination.

3. **Critical Deficiencies** must be corrected immediately. Contaminated product not immediately disposed of must be placed in a "hold" category pending disposition.

Note: FDA notification may be required in the case of critical deficiencies and uncorrected major deficiencies. Please see the Reporting Significant Food Safety Observations to the Food and Drug Administration and USDA Food Safety and Inspection Service section of this manual for additional instructions.

D. Coverage of Exempt Product Lines

Processing lines or facilities producing product not covered by the in-plant inspection contract are to be maintained in a clean, sanitary condition. Deficiencies in facilities or housekeeping which may pose a hazard to product safety must be corrected. The Inspector's concern will primarily be the general appearance of the facilities and operations as observed by a walk-through.

Note: FDA notification may be required in the case of critical deficiencies and uncorrected major deficiencies. Please see the Reporting Significant Food Safety Observations to the Food and Drug Administration and USDA Food Safety and Inspection Service section of this manual for additional instructions.

Reporting Sanitation Conditions

A. Oral Reports

The inspector will immediately make an oral report to the designated plant "sanitarian" on any major or critical deficiencies observed during the tour. Inspectors will also promptly notify plant management of situations which are in danger of deteriorating to an unsatisfactory condition. Oral reports are followed up in writing with appropriate sanitation score sheets.

Some facilities have the designated sanitarian accompany the inspector during the sanitation tour. This allows both people to simultaneously observe and discuss any issues of concern. As above, the inspector will follow up in writing with appropriate sanitation score sheets after the tour.

B. Written Reports, Sanitation Score Sheets

1. Procedure

Sanitation score sheets are used to record and report to plant management the inspector's evaluations of plant sanitation. These evaluations are made on a pre-operational basis and during processing operations for each production shift covered by an inspector. Sanitation score sheets (and a continuation sheet, if needed) clearly explain any deficiencies encountered and indicate when and what corrective action was taken. They provide a summary of conditions for that production day. These continuing evaluations and reports are extremely beneficial for quickly recognizing and correcting any troublesome areas. Current versions of approved sanitation score sheets may be found on the AMS Forms Catalog at the following intranet address: http://agnis/AMSFormsCatalog/Forms/AllItems.aspx.

The correct score sheet for (canned, frozen, citrus, olives, or raisins) is to be used in plants using our services.

As well as noting deficiencies, it is very important to include evaluations of a positive nature on sanitation score sheets. This will demonstrate to plant management SCI Division recognition of corrective measures, or any special efforts to improve the appearance or functionality of the plant.

2. Recording Deficiencies

Record deficiencies even when cleaned up immediately. Note on the sanitation score sheet that the corrective action was taken promptly.

Minor Conditions - Report as "**MN**" on the sanitation score sheet opposite the applicable item. If not corrected within the time specified by

the inspector (e.g., 24 hours), the condition is considered "Unsatisfactory", and shown as "U."

Major Conditions - Report as "**MJ**" on the sanitation score sheet opposite the applicable item. If corrective action is not taken within the time specified by the inspector (e.g., prior to the next shift or at the end of the next cleanup period), or it occurs repeatedly, it is considered "Unsatisfactory", and shown as "U."

Critical Conditions - Report as "**CR**" on the sanitation score sheet opposite the applicable item. Note what action is taken on the contaminated product.

3. Distribution of Sanitation Score Sheet

   a. Plant Management — original to the designated plant employee responsible for the sanitation program with copy(s) to upper-level management, as necessary.

   b. USDA Plant File — one copy.

   c. Area Field office — one copy when conditions are "Unsatisfactory" or unusual. 1/

   d. Regional office — one copy when conditions are "Unsatisfactory" or unusual. 1/

   e. National office — one copy when conditions are "Unsatisfactory" or unusual. 1/

   1/ The Area office will distribute these sanitation score sheets daily.

Note: FDA notification may be required in the case of critical deficiencies and uncorrected major deficiencies. Please see the Reporting Significant Food Safety Observations to the Food and Drug Administration and USDA Food Safety and Inspection Service section of this manual for additional instructions.

Example: Form FV-416-1, "Sanitation Score Sheet for Canned Food Processing Plants."

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U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE

"Unsatisfactory 1st Day"

SANITATION SCORE SHEET FOR CANNED FOOD PROCESSING PLANT

NAME OF PLANT	LOCATION	DATE	D.I.R. NO.
ABC PROCESSING COMPANY	*PROCESSVILLE, TN*	1/28/2011	129

RATING SYMBOLS
(√) Satisfactory
MN - Minor MJ - Major
CR - Critical U - Unsatisfactory

SIGNATURE OF USDA INSPECTOR *(Print and Sign)*
W. Fields, Conner Tibbetts, M. Jared
W. Fields, Conner Tibbetts, M. Jared

	TIME	1000	1300	1700	2100	0300	0500
	PREMISES						
	1. Outside Areas	*MN*	√	√		√	
A	2. Waste Disposal	√		MN	√	√	
	3.						
	RECEIVING DEPARTMENT						
	1. Boxes	√		√		√	
	2. Storage	√		√		√	
B	3. Dumpers & Conveyors	√		√		√	
	4. Floors, Gutters and Walls	√		√		√	
	5						
	PREPARATION DEPARTMENT						
	1. Washers and Flumes	MN		MJ		U	
	2. Belts and Elevators						
	3. Graders and Snippers						
	4. Cutters and Slicers	√		√		√	
C	5. Blanchers, Hoppers	√		√		√	
	6. Pulpers and Finishers	√		√		√	
	7. Floors, Gutters and Walls	√		√		√	
	8. De-waters, *Tanks*	√		√		√	
	9. *Chutes*	√		√		√	
	10.						
	CANNING DEPARTMENT						
	1. Belts	√	√	√	√	√	√
D	2. Fillers and Can Tables	√	√	√	√	√	√
	3. Floors, Gutters and Walls	√	√	√	√	√	√
	4.						
	5.						

	TIME	1000	1300	1700	2100	0300	0500
	COOK ROOM						
	1. Exhaust Box	√		√		√	
E	2. Syrupers	√		√		√	
	3. Seamers	√		√		√	
	4. Floors, Gutters and Walls	√		√		√	
	5.						
	SYRUP & EVAPORATION DEPARTMENT						
F	1. Tanks and Pipes	√		√		√	
	2. Vacuum Pans	√		√		√	
	3. Floors, Gutters and Walls	√		√		√	
	4.						
	WAREHOUSE						
G	1. General Housekeeping	√		√		√	
	2. Stacks	√		√		√	
	3. Condiment Room	MN		√			
	REST ROOMS						
H	1. Supplies	√		√		√	
	2. Wash Basins	√		√		√	
	3. Toilets and Urinals	√		√		√	
	4. Floors and Walls	√		√		√	
	5.						
	PERSONNEL						
I	1. Cleanliness	√		√		√	
	2. Head Covering	√		√		MJ	
	3. Smoking	√		√		√	
	4.						
	5.						

ITEM NO.	TIME	RATING SYMBOL	SANITATION DEFICIENCIES SHOW RATING, ITEM NO. AND DESCRIBE	TIME LIMIT	TIME CORR.
A1	*1000*	*MN*	*Ground area below ingredient hoist ---spilled spices, etc.*	*24 hrs*	*1300*
			on floor. Notified R. Benett.		
B	1000		*Receiving department is much improved since*		
			additional clean-up person was added.		
C1	1000	*MN*	*Product residue on underside of long wire grate on*	*1700*	
			whole peel line - between shift clean-up not effective -		
			will need attention prior to next shift. Notified R. Benett.		

FV-416-1 *Example*

Example: Form FV-416-5, "Sanitation Score Sheet for Processing Plants (Continuation Sheet)."

PAGE 2 OF 2

U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE

SANITATION SCORE SHEET FOR PROCESSING PLANTS (*Continuation Sheet*)

NAME OF PLANT	LOCATION	DATE	D.I.R. NO.
ABC PROCESSING COMPANY	*PROCESSVILLE, TN*	10/10/2010	129

RATING SYMBOLS
(√) Satisfactory
MN - Minor MJ - Major
CR - Critical U - unsatisfactory

SIGNATURE OF USDA INSPECTOR *(Print and Sign)*
W. Fields, Conner Tibbetts, M. Jared
W. Fields, Conner Tibbetts, M. Jared

ITEM NO.	TIME	RATING SYMBOL	SANITATION DEFICIENCIES SHOW RATING, ITEM NO. AND DESCRIBE	TIME LIMIT	TIME CORR.
G3	*1000*	*MN*	*Condiment room - spilled spices, etc.*	*24 hrs*	*1700*
A2	*1700*	*MN*	Offensive odor around cull hopper - Notified B. Stevens.	*24 hrs*	*2100*
C1	*1700*	*MJ*	Slime on underside of long wire grate on whole peel line - Notified B.Stevens. See C1 @ 1000.	*0030*	
C1	*0030*	*U*	*Same condition as 1700 - J. Byron stated that they are going down for general clean-up at 0700.*		
H	—	—	*Dockside men's room looks good since painting.*		
I2	*0030*	*MJ*	*Two graders on line 6 without hairnets- Notified J. Byron.*	*Immediately*	*Immediately*
			Overall sanitation rating		
			UNSATISFACTORY		
			account inadequate follow-up on		
			Major deficiency (See C1)		
			William Fields		
			Inspector-in Charge		

FV-416-5 *Example*

C. Problem Situations

The **Inspector** is responsible for informing the Officer-in-Charge, (OIC) of any sanitation problem situations in the plant, including instances of "no corrective action" or repeated occurrences of a sanitation deficiency.

The **OIC** is responsible for informing the Regional Section Head of any plant that has a definite or potential sanitation problem. The OIC will also initiate recommendations for withdrawal of service if the problem(s) cannot be resolved after discussion with plant management.

If the **Regional Section Head** concurs with the OIC, he or she will submit the recommendation of withdrawal to the Inspection Branch Chief. The withdrawal will proceed in accordance with 7 CFR, Part 50, "Rules of Practice Governing Withdrawal of Inspection and Grading Service under the Agricultural Marketing Act of 1946," which may be found at the following internet address: http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

Note: FDA notification may be required in the case of critical deficiencies and uncorrected major deficiencies. Please see the Reporting Significant Food Safety Observations to the Food and Drug Administration and USDA Food Safety and Inspection Service section of this manual for additional instructions.

D. Recommendations for Handling Unsatisfactory Sanitation Conditions

1. The inspector should be certain that all sanitation score sheets are distributed to the plant person(s) responsible for the sanitation program. The lines of communication must be kept open and clear to allow any unsatisfactory rating to be discussed in detail.

2. If there are unsatisfactory sanitation reports for three successive days, or three within one week, the inspector shall contact their immediate supervisor. The supervisor shall contact the appropriate plant management either by telephone or personal visit, and discuss arrangements for corrective action of the unsatisfactory plant conditions. **Pertinent points of all discussions are to be confirmed in writing. Distribute confirmation to the responsible plant personnel, the Regional Section Head, and the Inspection Branch Chief.**

3. If it is not possible to gain cooperation in correcting a definite sanitation problem, the OIC should contact the Regional Section Head. Together they should arrange for a meeting with top plant management, and thoroughly review all previous conversations and actions. During this meeting, plant management should be warned that further unsatisfactory reports will require a

recommendation for withdrawal of service. **Confirm the warning to management in writing, with a copy to the Inspection Branch Chief.**

4. If the Regional Section Head is unsuccessful in making progress, the Regional Section Head should discuss the situation with the Inspection Branch Chief. A memorandum should be prepared showing the efforts made to resolve the problem(s), including all necessary supporting documents. This memorandum should contain a recommendation to the Inspection Branch Chief for withdrawal of service.

Note: FDA notification may be required in the case of critical deficiencies and uncorrected major deficiencies. Please see the Reporting Significant Food Safety Observations to the Food and Drug Administration and USDA Food Safety and Inspection Service section of this manual for additional instructions.

Sanitation Deficiencies - Examples in Processed Fruit and Vegetable Plants

A. Premises-Waste or Garbage Areas-Receiving Areas-Dumping Areas

1. Minor Conditions

a. Overflow or spillage that adversely affects operations

b. Accumulation of freshly spilled product

c. Dusty roads or muddy areas

d. Insect "concentration" and/or harborage

e. Waste not removed in a timely manner

f. Litter, or paper and trash

g. Dirty raw product containers

h. Overflow or backup of waste disposal

i. Improperly handled old, decaying, or moldy products

j. Offensive, odorous conditions

k. Evidence of rodents and/or harborage conditions (grass, weeds, old equipment, junk, and other similar materials)

l. Slime on equipment, floors, or paving

B. Preparation and Processing Areas

1. Minor Conditions

a. Overflow or excessive water on floors

b. Product on floor after cleaning

c. A few insects in area

d. Fresh product, or product residue, on equipment after cleaning

e. Dirty walls, windows, ledges

f. Excessive product on floors during operations

2. Major Conditions

a. Dirty, decaying, or discolored product on parts of equipment that may contaminate the product

b. Slime on equipment

c. Insects in areas near vulnerable product

d. Loose rust, flaking paint, dust, cobwebs, or mold on overhead areas, or dirt on part of equipment that may come in contact with or contaminate the product while it is vulnerable. This includes overhead areas, underside of drip pans, motor mounts, walkways, and crossovers

e. Offensive, odorous conditions

f. Product containers that are rusty, dirty, or that contain cleanup water or sediment

g. Product holding containers (bins, tubs, pans) nested after having been in contact with unsanitary situations

h. Container cleaners not operating properly

i. Misuse of empty product containers such as drinking cups, waste receptacles

3. Critical Conditions during Operations

a. Vulnerable product that has been in contact with an insanitary condition (such as floors) returned to line or packaged for use

b. Dirty containers or equipment brought in contact with product

c. Insects in or on product or product contact surfaces

d. Condensate from dirty surfaces dripping on product

e. Filled, open containers stacked in such a manner as to contaminate the product

f. Dirty ice in product

g. Maintenance or repair work done in such a manner as to contaminate the product

h. Sediment or foreign material in packing media, fillers, or holding tanks

C. Warehouse and Shop Areas

1. Minor Conditions

a. Litter, trash, cigarette butts, and other materials on floor

b. Untidy, dirty, or wet storage conditions for containers, and/or other materials and supplies

2. Major Conditions

Overall storage conditions that are attracting insects, birds, rodents, and/or animals which may contaminate the product

D. Rest Rooms

1. Minor Conditions

a. Room not clean; presents a poor general appearance

b. Toilets or sinks not properly cleaned

c. Excessive water on floor

2. Major Conditions

a. Absence of toilet tissue, suitable hand-cleaning soap or detergents, paper towels, and any other essential supplies

b. Very dirty or non- functional toilet or sinks

c. No hot water available for washing hands

d. No hand washing signs (bilingual as appropriate)

E. Personal Hygiene 1/

1. Minor Conditions

a. Wearing unsecured jewelry

b. Chewing gum or eating except in authorized areas

c. Wearing improper clothes for work, such as sleeveless shirts

d. Personal items on unused equipment

1/ Although it will be monitored by USDA, this part of the plant sanitation program should be controlled by management. For it to be effective, management must provide adequate training on good personal hygiene practices. These practices and rules should be conspicuously posted throughout the plant.

2. Major Conditions

a. Smoking or spitting in plant processing area

b. Uncovered, or improperly covered hair (no hat, hairnet, or beard cover)

c. Wearing very dirty clothes

d. Starting or returning to work without washing or sanitizing hands and/or gloves

e. Using unhygienic practices

3. Critical Conditions

a. Production line employees having uncovered infections or cuts

b. Direct contamination of product by sneezing or coughing

F. Lunchroom Area

1. Minor Conditions

a. Untidy areas and facilities

b. Presence of a few flies

G. Freezer Facilities

1. Minor Conditions

a. Buildup of frozen spilled product from broken or leaking product containers

2. Major and/or Critical Conditions

a. Grease, oil, or dirt contamination of product on belts in freezing tunnels

PLANT SURVEY

The plant sanitation survey form includes the following:

A. Plant organization, management;

B. Plant facilities, equipment, and environmental factors;

C. Plant operational conditions; and

D. Survey evaluation and review.

The plant survey is a facility assessment to determine compliance with government and/or private buyer sanitation requirements and current Good Manufacturing Practices (GMPs). For processors who have contracts on a continuing basis, a plant survey is performed annually, prior to the anniversary date of the previous survey ensuring a continuous record of GMP compliance. For new applicants - processors that have never had a contract service agreement, or those without a contract for the previous processing season - a plant survey is performed prior to starting inspection.

Prior to implementing any inspection service, plant survey items A, B, and D above must be completed. Item C (the operational portion of the survey) may also be evaluated at this time if the plant is operating. When survey requirements are considered acceptable, the applicable contract service form will be completed and distributed according to Division instructions.

When it is not possible to evaluate the operational part of the survey before granting service, the survey form will be held until this is done. However, this will not delay distribution of the

application and contract of agreement for inspection/grading service. The contract form is accompanied by a memo stating that the plant is approved for service and that operational conditions will be evaluated within ten days after processing begins. When the survey is completed, an e-mail notification will be promptly sent to the appropriate regional office.

For other than new applicants, plants should be surveyed at least once a year. This applies to both seasonal and year-round plant contracts. For in-plant assignments, an experienced inspector may assist the supervisor by completing a "preliminary survey" which must be approved by the supervisor. All final surveys shall be completed by the OIC, Assistant OIC, sub-area supervisor, or approved inspection staff as soon as practical after a plant begins processing, normally within a period of ten days. The plant survey shall be distributed as follows:

1. Original to plant management, optional electronic delivery is acceptable if requested by the applicant;

2. Enter survey into Plant Survey database in Lotus Notes;

    a. All additional documentation relating to the survey e.g. cover letters, water potability, follow-up correspondence shall be added as attachments in Lotus Notes. Save the documents in a manner enabling retrieval as follows:

        i. Save the survey documents on your computer;

        ii. Select the “Attachment” tab in the survey you are working on in Lotus Notes;

        iii. Select the down arrow “v” on the right of the T.

        iv. Select “Attachments”;

        v. Select the “paperclip” icon. That will open “My Documents” on your computer;

        vi. Highlight the document to attach; and

        vii. Select “Create” and your document will be listed.

3. Copy to plant inspector's file; and

4. Copy maintained at the area field office. Hard copy delivery to the National office and Regions is no longer required.

For plants under consideration for continuous inspection approval, follow the survey procedures for this type of agreement. (See the AIM Management Site at the following intranet address: http://agnis/sites/FV/PPB/AIM/Manage/default.aspx.) The actual survey is performed and distributed in the same way as other types of contracts and agreements.

All plant survey reports and attachments shall be legible. Each section shall be completed in detail, particularly the evaluation and review section. Recommendations should be definite and understandable. Documents shall be dated and signed in the appropriate places.

On the front page of all plant surveys and related attachments, indicate the type of contract or service involved, i.e., Continuous, Pack Certification, Letter Agreement, request from applicants for potential government contracts. Also indicate the products being processed at the time of the survey. The plant should be evaluated as acceptable, conditionally acceptable, or unacceptable based on the results of the survey. Conditional approval is assigned if corrections are mandatory in order to approve the plant. The plant is unacceptable if conditions are present which would result in product contamination, or the plant is unwilling or unable to meet the essential requirements. Indicate if the plant is approved, not approved, or conditionally approved at the bottom of the survey front page.

Deficiencies are rated as minor, major, or critical. Each deficiency will be described, and the date the plant intends to correct the deficiency noted.

Survey results are to be discussed with responsible plant management. The inspector on duty should be present, if available. There should be complete understanding regarding the correction of all deficiencies.

Essential Requirements of the Survey

Many of the questions and statements on the plant survey are points of information and/or recommendation. They become a requirement only when an incident becomes serious enough to cause an unsanitary condition.

There are, however, certain essential requirements included in the plant survey. Unless these requirements are satisfied, the plant will not be approved and the Division will not enter into a contract for in-plant inspection. The requirements are as follows:

A. Parking lots and drives are to be surfaced or treated to control dust and dirt;

B. All exterior openings of the preparation and packaging rooms are to be enclosed or screened (metal or effective air screens) to protect finished product from birds, insects, rodents, and other vermin;

C. Screened, vented toilet facilities are to be designed so they do not open directly into rooms where products are handled;

D. Can cleaners (steam, air, or water) are to be installed on each line for glass, tin and semi rigid containers;

E. Non-wood, non-corrosive material is to be used on all product contact surfaces where the product is exposed, i.e. when the product has been pitted, peeled, cut, during and after blanching, or is in such a form as to be subject to contamination.

The surfaces of corrosive material must be kept clean, free of rust or flaking paint and other foreign material in order to avoid product contamination;

F. Lights above all product lines are to be shielded or shatterproof;

G. Floors and gutters are to be constructed to drain well, and be free of pitting or cracks which prevent proper cleaning. Wide, deep cracks and extremely rough sections that are difficult to clean must be repaired or replaced;

H. The cleanup program uses the proper equipment and adequate time to effectively sanitize - rather than rinse - processing lines during and between shifts;

I. Manufacturing practices that prevent product contamination shall be followed. This includes but is not limited to keeping overhead areas free from flaking paint, dust, condensate, mold, dirt;

J. Waste material is removed frequently, and on a timely basis; and

K. The plant provides SCI Division an acceptable water quality certificate. See your immediate supervisor if there is any question about the documentation provided.

Survey Follow-up

If conditional approval was granted, required changes will be listed on the final page of the survey. Deficiencies such as manufacturing practices are to be corrected immediately and noted in the date corrected column.

Other deficiencies should be corrected in accordance with realistic and reasonable timetables reached in agreement with the processor. The area OIC will confirm these dates in writing, listing each deficiency along with the correction dateline. Copies of this confirmation letter shall be sent to the Regional Section Head and the Division Director. If deficiencies are not corrected within the specified time, the area supervisor will contact the processor in writing, stating what action will be taken if the deficiencies are not corrected.

As corrective action is taken on each deficiency, the correction date is noted in the appropriate column of the follow-up summary sheet for deficiencies. Assisted by the plant inspector, the area supervisor is responsible for keeping this sheet up to date and checked against agreed correction datelines. Distribution of the follow-up summary sheet for deficiencies is the same as for the plant survey.

Example of Plant Survey Confirmation Letter

(Current Official Letterhead)

(Date)

(Plant Contact Information
Name, Title
Address
City, State Zip Code)

Dear (Insert Name):

It is the policy of the United States Department of Agriculture (USDA) to conduct an annual Plant Survey to ensure compliance with good commercial manufacturing practices. This year the survey for your facility located in (Insert facility location) was completed on (Insert date of survey).

The following deficiencies were noted during the plant survey:

(List deficiencies and agreed correction dates, if available)

(Insert food defense survey results as appropriate. i.e. The Food Defense System Survey is included. No deficiencies were found, etc.)

I would like to thank you for the cooperation given to us by you and your staff. If you have any questions or if there is any way we can improve our service to you to further meet your needs, please contact me at (insert appropriate SCI telephone number).

A copy of the Plant Survey and Food Defense System Survey is enclosed for your records. (As appropriate)

Sincerely,

Signature
Name
Title

Enclosure

CC:
(Insert Name), Division Director
(Insert Name), Regional Section Head
(Insert Name), Officer-in-Charge
USDA Inspector (If appropriate)
File

SCI DIVISION SANITATION POLICY

It is SCI Division policy to encourage essential sanitation requirements, seek positive alternatives with regard to problem areas, and advocate a continuing cooperative effort and working relationship with the industry.

In plant inspectors should strive to create and maintain a good working relationship with plant management. To support their efforts to achieve high sanitation standards and establish effective lines of communication, meeting with the processor prior to the packing season and again shortly after the season is over is recommended.

A. Pre-Season Meeting

1. Review in detail any sanitation problems which persisted throughout the previous season;

2. Recommend that a competent plant employee be assigned the responsibility for sanitation;

3. Define USDA and plant management sanitation responsibilities. Review our sanitation policies and procedures so that there is a complete understanding of our requirements and inspection coverage;

4. Determine that all necessary corrections of deficiencies in plant facilities and equipment have been made by the agreed date(s). Verify if the plant is ready to begin operation; and

5. Solicit comments and suggestions from plant management regarding improvements in the program.

B. Post-Season Meeting

1. Review the effectiveness of the overall sanitation program during the past season;

2. Discuss in detail all sanitation problem situations of the past year or season. Use the sanitation score sheets as a basis for discussion;

3. Make a list of the plant facilities and equipment that will need improvement. A reasonable corrective action date should be agreed upon. Most of the corrections can be made during the "off-season."

4. Often processors using our services make many improvements to plant facilities. During the meeting, be sure to recognize any effective sanitation improvements added over the course of the season.

Reporting Significant Food Safety Observations to the Food and Drug Administration and USDA Food Safety and Inspection Service

The purpose of this procedure is to facilitate the uniform reporting of significant food safety observations made by Specialty Crops Inspection (SCI) Division inspectors during the course of their normal duties (e.g., inspection, daily sanitation, Plant Surveys, etc.) to the Food and Drug Administration (FDA) or to USDA's Food Safety and Inspection Service (FSIS), as applicable. This procedure implements a component of USDA's commitment to continually improve procedures to notify FDA regarding potential food safety issues as outlined in a September 2010 letter from Agriculture Secretary Vilsack to Health and Human Services Secretary Sebelius and FDA Commissioner Hamburg. In addition, this procedure implements FDA-USDA guidance on reporting significant food safety observations as distributed on DVD in August 2011.

These guidelines apply to the SCI Division procedure for reporting significant food safety observations to FDA and FSIS. All applicable Division employees are responsible for ensuring the uniform application of these reporting procedures.

Reporting Procedure

A. When SCI is at a facility **less than once a week:**

This covers observations made during SCI Division inspection activities including Lot Sampling and Inspection, Plant Surveys, Plant Systems Audits (PSA), Qualified Through Verification (QTV) audits, and Domestic Origin Verification (DOV) audits. The steps in the process are as follows:

1. Inspector observes significant food safety observation (see Attachment 1), and documents the observation on Plant Survey, PSA, QTV checklist, or other appropriate document. If applicable, the inspector establishes and records a time frame for the facility to take corrective action.

2. Inspector reports significant food safety observation to the Officer-In-Charge (OIC).

3. OIC notifies the Regional Office. With the Regional Office's concurrence, the OIC (or the IIC, if designated by the OIC) informs the facility that FDA or FSIS will be notified. The OIC contacts the local FDA office or FSIS representative and reports the observation verbally, with supplemental e-mail, fax, or written correspondence if needed.

4. OIC inputs information about the observation into their Regional Office's SharePoint FDA Notification template at one of the following SharePoint sites:

For Eastern Region: http://agnis/sites/FV/PPB/East/Lists/FDANotifications/AllItems.aspx
For Western Region: http://agnis/sites/FV/PPB/West/Lists/FDANotifications/AllItems.aspx

5. The OIC alerts the Regional Office once the information about the observation has been entered into the SharePoint FDA Notification template.

6. The Regional Office reviews the information entered into the SharePoint FDA Notification template, makes editorial changes as needed, and alerts the National Office reviewer that the information is ready for review.

7. The National Office reviewer makes editorial changes as needed and finalizes the text. The National Office reviewer transfers the contents of the SharePoint template to the Interagency Referral Report internet website at: http://www.accessdata.fda.gov/scripts/IRF/. (In this report, the OIC will be the "Employee Reporting the Incident," and the National Office reviewer will be the "Employee Completing the Report.") The report includes the following in the "Additional Emails for the Report to be Sent" block:

   - Erin.morris@ams.usda.gov
   - KerryR.smith@ams.usda.gov
   - Regional Section Head
   - Assistant Regional Section Head
   - Officer-in-Charge
   - National Office reviewer

8. The National Office reviewer submits the report to the Interagency Referral Report internet website.

9. FDA or FSIS provides feedback to SCI regarding any FDA or FSIS actions and recommendations for SCI Division actions.

10. SCI Division follows-up as necessary.

B. When SCI Division is at the facility **at least once a week**

This covers observations made during SCI Division inspection activities including in-plant inspection duties or observations made at facilities visited frequently (i.e., at least once a week). These procedures apply to FDA-regulated products. For FSIS-regulated products covered under in-plant services, such as in Operational Rations plants, inspectors and OICs should continue to use existing channels of communication for reporting observations to FSIS. The steps in the process for reporting to FDA are as follows:

1. In-plant inspector makes a significant food safety observation (see Attachment 1), and documents the observation on the SCI Division sanitation score sheet. Inspector establishes and records a time frame for facility's corrective action.

2. In-plant Inspector-in-Charge (IIC) reports significant food safety observation to OIC.

3. OIC evaluates severity of the violation to determine whether it requires immediate reporting to FDA or FSIS (see Attachment 1).

4. If violation severity **does not require immediate reporting to FDA:**

   a. In-plant inspector monitors condition and facility's corrective action.

   b. If plant executes effective corrective action within the time frame required, the inspector documents the corrective action, time, and date on sanitation score sheet. No further SCI Division action is required.

   c. If plant does not execute effective corrective action within the time frame required, inspector documents status, and time and date on the sanitation score sheet and the IIC reports the uncorrected sanitation deficiency to the OIC. The OIC evaluates the observation to determine whether FDA should be notified (See Attachment 1). If yes, OIC follows step 5 below. If no, OIC takes no further steps to notify FDA, and stays in communication with IIC to monitor situation.

5. If violation severity **does require immediate reporting to FDA:**

   a. The OIC notifies the Regional Office. With the Regional Office's concurrence, the OIC (or IIC, if designated by the OIC) informs the plant that FDA will be notified. OIC calls local FDA office and reports observation verbally, with supplemental e-mail, fax, or written correspondence if needed.

   b. The OIC inputs information about the observation into their Regional Office's SharePoint FDA Notification template at one of the following SharePoint sites:

For Eastern Region: http://agnis/sites/FV/PPB/East/Lists/FDANotifications/AllItems.aspx
For Western Region: http://agnis/sites/FV/PPB/West/Lists/FDANotifications/AllItems.aspx

   c. The OIC alerts the Regional Office once the information about the observation has been entered into the SharePoint FDA Notification template.

   d. The Regional Office reviews the information entered into the SharePoint FDA Notification template, makes editorial changes as needed, and alerts the National Office reviewer that the information is ready for review.

e. The National Office reviewer makes editorial changes as needed and finalizes the text. The National Office reviewer transfers the contents of the SharePoint template to the Interagency Referral Report internet website at: http://www.accessdata.fda.gov/scripts/IRF/. (In this report, the OIC will be the "Employee Reporting the Incident," and the National Office reviewer will be the "Employee Completing the Report.") The report includes the following in the "Additional Emails for the Report to be Sent" block:

- Erin.morris@ams.usda.gov
- KerryR.smith@ams.usda.gov
- Regional Section Head
- Assistant Regional Section Head
- Officer-in-Charge
- National Office reviewer

f. The National Office reviewer submits the report to the Interagency Referral Report internet website.

g. FDA provides feedback to SCI regarding any FDA actions and recommendations for SCI actions.

h. SCI Division takes steps as appropriate.

The following Attachments are included for use and reference for these procedures:

Attachment 1: General guidance for assessing a food safety-related observation and determining whether it should be reported to FDA or FSIS

Attachment 2: Example of a completed Interagency Referral Report

Attachment 3: September 15, 2010, letter from USDA Secretary Vilsack to HHS Secretary Sebelius and FDA Commissioner Hamburg

Attachment 4: June 30, 2011, memorandum from Acting Branch Chief Randle Macon regarding Reporting Significant Food Safety Deficiencies

Attachment 5: September 28, 2011, memorandum from Acting Division Director Randle Macon regarding Guidance on Reporting Significant Food Safety Deficiencies

Attachment 6: September 22, 2011, Notice to the Trade regarding SCI Reporting Significant Food Safety Deficiencies

Reporting Significant Food Safety Observations to the Food and Drug Administration (FDA) and USDA Food Safety and Inspection Service (FSIS)

ATTACHMENT 1

The following provides general guidance for assessing a food safety-related observation and determining whether it should be reported to FDA or FSIS using this reporting protocol.

I. Reporting to FDA

A. An observation that Specialty Crops Inspection Division (SCI) procedures would classify as a Critical (CR) Sanitation Deficiency (i.e., a condition which results in product contamination) should be reported to FDA upon first occurrence, regardless of any corrective action the facility may take. This reporting of CR deficiencies is applicable to in-plant situations (e.g., continuous, year-round, less than year round, Quality Assurance Program (QAP), etc.) and non in-plant situations (e.g., Plant Survey, Plant Systems Audit (PSA), Qualified Through Verification (QTV) audit, Domestic Origin Verification (DOV) audit, or lot sampling, etc.).

B. In addition, FDA has identified certain additional conditions that if observed, should be reported upon first occurrence regardless of any corrective action the facility may take. Examples of these conditions include:

- Failure to protect ready-to-eat foods, such as fresh-cut produce from contamination;
- Obvious signs of pest damage to food;
- Obvious and significant pest infestation;
- Improper handling or labeling of food allergens (i.e., peanuts, soy, milk ingredients, eggs, fish, crustacean shellfish, tree nuts, wheat);
- Indication of possible problem(s) with contamination by gases (e.g., ammonia system leak);
- Improper cooling of potentially hazardous foods;
- Temperature of foods in refrigerators or freezers maintained above 41 degrees F or 10 degrees F, respectively; and
- Exposure of food to human blood.

C. For an observation that SCI procedures would classify as a Major (MJ) Sanitation Deficiency (i.e., a condition which may result in product contamination or is highly objectionable), the following guidelines apply:

1. If the MJ is observed while SCI is providing service at a facility that SCI visits less than once a week (such as during a Plant Survey, PSA audit, QTV audit, DOV audit, or lot sampling, etc.), the observation should be reported on first occurrence, regardless of any corrective action taken by the facility.

2. If the MJ is observed while SCI is providing service at a facility that SCI visits once a week or more frequently (such as an in-plant assignment), the observation should only be reported if the facility does not take effective corrective action within the required time frame. (For example, a MJ observation should be reported if SCI observes the condition uncorrected after informing the facility of the condition, and after the established time frame for correction has passed). In addition, if a particular MJ deficiency is observed repeatedly, even if it is corrected effectively by the facility each time within the required time frame, the observation should be reported to FDA.

II. Reporting to FSIS

A. If a significant observation is made during in-plant inspection of an FSIS-regulated product (such as a meat entrée at an Operational Rations plant), inspectors and OICs should continue to use existing channels of communication for reporting observations to FSIS.

B. If a CR or MJ observation is made regarding an FSIS-regulated product at a facility that SCI visits less than weekly (such as during a Plant Systems Audit), the deficiency should be reported to FSIS using the process described on page one of the "Reporting Significant Food Safety Observations to the Food and Drug Administration and USDA Food Safety and Inspection Service" section of the AIM Inspection Series, Sanitation and Safety manual under "Reporting Procedure, A. When SCI is at a facility less than once a week.

FOOD AND DRUG ADMINISTRATION REGULATORY VISITS

A. Purpose

Food and Drug Administration (FDA) inspectors visit processing plants for various reasons in connection with their overall regulatory responsibilities. Ordinarily, the purpose of these visits is as follows:

1. To perform a sanitation inspection, including the condition of raw materials;

2. To collect a routine sample, e.g., pesticide analyses; or

3. To check a processing compliance procedure for low acid products.

Our primary interest is in the sanitation inspection aspects of the FDA review.

Action by Inspectors

A. Agreement with Federal Food and Drug Administration

The March 4, 2011, Memorandum of Understanding (MOU) between AMS and FDA Concerning Information Sharing and Other Activities Related to the Auditing, Inspection, and Grading of Food Products, is an agreement between the Agricultural Marketing Service (AMS) and the FDA outlines the authority or basis for cooperative efforts between these two agencies. Inspectors should carefully review this agreement.

Although this instruction deals directly with FDA–USDA relationships under the agreement, the same basic philosophy applies to state, county, and other regulatory agencies. Whenever possible we cooperate with such agencies. However, since we have no agreement with them, they are not obligated to cooperate with us.

B. Plant Visits

The inspector should notify his/her supervisor as soon as the inspector becomes aware that FDA will be, or is, making a plant visit. FDA inspectors must always contact plant management and announce the intended purpose of their visit when they enter the plant, so the plant is aware of their presence and can accompany FDA on the tour.

If not contacted in the early stages of the visit, the SCI Division inspector may introduce him or herself to the FDA inspector and tactfully ask to be present during the tour. However, SCI Division inspectors should not spend more time on the tour than they can spare. If the FDA visit extends over a considerable

length of time, ask to be advised at the end of the visit to take the opportunity to review and receive a copy of the FDA report documenting their visit.

In many instances, the FDA inspector's purpose is to gather information concerning the condition of the raw and finished products, and observe packing practices and facilities. If encountered, unsanitary conditions or practices may later be associated with analyses of samples drawn at the time of inspection, or from trade channels before any seizure action is taken. During the inspection tour, the FDA inspector may or may not comment on conditions that might lead to seizures at some later date.

As indicated in the MOU between FDA and AMS, AMS will "when requested by FDA, provide assistance necessary to facilitate investigations required to ensure public health;" and "furnish to FDA upon request any pertinent reports AMS generates that include general information on deficiencies in current good manufacturing practice or good agricultural practice."

The SCI Division inspector should create and encourage a relationship of cooperation with the FDA inspectors. If FDA seeks plant documents, these can be provided by the plant or, if necessary from the SCI Division inspector, if in SCI Division possession for the execution of our services.

1. SCI Division Responsibilities

   a. If invited by FDA, the SCI Division inspector will make every effort to join in for at least part of the tour;

   b. When asked by the FDA inspector, the SCI Division inspector will comment only on the facts of any particular sanitation deficiency about which the SCI Division inspector is knowledgeable;

   c. SCI Division inspectors shall document the FDA inspector's visit on form FV-425. This form is to be used to document visits by all regulatory agencies, such as Occupational Safety and Health Administration, Environmental Protection Agency, state, county, or city health agencies, and may be found on the AMS Forms Catalog at the following intranet address: http://agnis/AMSFormsCatalog/Forms/AllItems.aspx.
   Any discrepancies noted between the SCI Division inspector's assessments and those of the Regulatory inspector should be fully explained in the "Remarks" section of the form, with enough detail to allow supervisory personnel to accurately evaluate the conditions. Retain one copy with the daily inspection report or sanitation score sheet. Send the original with a copy of the sanitation score sheet, and Food and Drug Form 483 or other documentation issued by FDA regarding the visit to the area field office, and the regional office for distribution to the Division Director.

Example of FV-425

Reproduce Locally. Include form number and edition date of all reproductions.

USDA Agricultural Marketing Service Fruit and Vegetable Program Specialty Crops Inspection Division **REPORT OF REGULATORY AGENCY INSPECTION**	NAME OF PLANT	DIR NO.
	LOCATION OF PLANT *(City and State)*	
	PLANT TOUR BY REGULATORY INSPECTOR(S)	
	BEGINNING DATE AND HOUR	ENDING DATE AND HOUR

INSTRUCTIONS: *Complete in triplicate. Retain copy. Send original to Washington and copy to Regional Office. Attach copy of sanitation scoresheet(s) and copy of regulatory agency report.*

NAME(S) OF REGULATORY INSPECTOR(S)	**AGENCY REPRESENTED**		
	FEDERAL FOOD AND DRUG	STATE FOOD AND DRUG	OTHER *(Specify)*

PRODUCTS BEING PROCESSED

	YES	NO
Did USDA inspector accompany regulatory inspector(s) on tour? *(If "No" explain under "Remarks")*		
Were the comments (oral or written) of the regulatory inspector(s) in substantial agreement with USDA reports or opinions? *(If "No" indicate discrepancies under "Remarks")*		
Did plant management make required or recommended corrections? *(Give details under "Remarks")*		

REMARKS

DATE OF REPORT	INSPECTOR IN CHARGE *(Signature)*

FV-425 (*Example*)

Action by Supervisors

If substantial disagreements are reported between the FDA and SCI Division inspectors in evaluating conditions of the plant, raw materials, or other pertinent factors, and the SCI supervisor is unable to resolve these differences, or there are numerous deficiencies, a report shall be made at once to the Regional Section Head and the National office concerning further steps to take. The OIC will report to the local FDA office as required in the Memorandum of Understanding, paragraph 5, under "The Agricultural Marketing Service will:"

Action by National Office

All actions under the agreement other than that specified above will be handled by the National office. This includes supplying information with respect to lots of product being considered for regulatory action by FDA.

Inspection of products under seizure by a Regulatory Agency

Refer to AIM Inspection Series, Sampling Manual, "Inspection of Products under Seizure by Regulatory Agencies" section for Division policy regarding products under seizure or quarantine by regulatory agencies on Federal, State, County, or City levels, or in an instance in which it may not be to the best interest of the government to perform such inspection.

Memorandum of Understanding between the Agricultural Marketing Service and the Food and Drug Administration concerning the inspection and grading of food products

MOU 225-72-2009 may be found at the following internet address:
http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/default.htm

SANITATION REQUIREMENTS

General

Although the Division refers specifically to the Food and Drug Administration regulations as our sanitary requirements, this does not excuse plant management from complying with any state, local, or contract requirements that also apply.

Regulations applying to plant sanitation requirements are issued under section 402 (a) (4) and 701 (a) of the Federal Food, Drug, and Cosmetic Act and now appear in Title 21, Part 110 of the Code of Federal Regulations published by the Food and Drug Administration, Department of Health and Human Services which may be found at the following internet address: http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR**.**

The following pages contain an example of the SCI Division Plant Survey.

APPENDIX A

United States Department of Agriculture
Agricultural Marketing Service
Fruit and Vegetable Program
Specialty Crops Inspection Division

PLANT SURVEY

PLANT FACILITIES, EQUIPMENT, ENVIRONMENT, MANAGEMENT AND OPERATIONS

NAME OF PLANT

LOCATION OF PLANT

AREA FIELD OFFICE

TYPE OF CONTRACT OR SERVICE

PRODUCT(S) PACKED DURING SURVEY

ANNUAL SURVEY (FINAL) COMPLETED BY DATE

OVERALL SANITATION LEVEL ☐ ACCEPTABLE ☐ UNACCEPTABLE

RECOMMENDED APPROVAL ☐ YES ☐ NO ☐ CONDITIONAL

LOCATION OF MAIN OFFICE (Complete mailing address, including Zip Code) ,	LOCATION OF PLANT COVERED BY THIS REPORT (Complete mailing address including Zip Code) ,
STATUS OF PROPRIETORSHIP ☐ INDIVIDUALLY OWNED ☐ PARTNERSHIP ☐ CORPORATION ☐ COOPERATIVE	☐ OTHER

OWNERS OR OFFICERS

NAME	TITLE

MANAGERS, SUPERINTENDENT, OR RESPONSIBLE FOREMAN

NAME	TITLE

AUTHORIZED PERSON RESPONSIBLE FOR SANITATION

NAME	TITLE

TO WHOM DO THEY REPORT?

PERSON WITH WHOM THE USDA INSPECTOR IS TO DEAL

NAME	TITLE

CODING SYSTEM - CODE MARKING SYSTEM INCORPORATES

☐ COMMODITY	☐ TYPE	☐ GRADE	☐ OTHER (SPECIFY)
☐ DATE	☐ STYLE	☐ SYRUP	
☐ SHIFT	☐ SIZE	☐ PLANT	
		☐ PERIOD	

INSPECTION SERVICE

WHAT IS THE REASON FOR THIS COMPANY APPLYING FOR INSPECTION SERVICE?

DOES THIS COMPANY INTEND TO USE SHIELDED LABELS OR OTHER APPROVED IDENTIFICATION OF CONTAINERS?

☐ NONE ☐ LIMITED ☐ EXTENSIVELY

FILL IN THE FOLLOWING INFORMATION REGARDING PRODUCTS PACKED BY THIS PLANT

COMMODITY	SEASON	COMMODITY	SEASON

DEFICIENCIES
DEFINITION OF TERMS
RATING

MINOR (MN) - Do not result in product contamination but are not desirable .

MAJOR (MJ) - May result in product contamination or are highly objectionable .

CRITICAL (CR) - Result in product contamination .

OVERALL SANITATION LEVEL

ACCEPTABLE - No critical or major defects that would have a significant impact on product contamination .

UNACCEPTABLE - Plant practices or operations present that result in product contamination or potential product contamination .

A. SANITATION CONTROLS

		YES	NO	RATING
1.	Is there a planned sanitation program that includes an educational training program for personnel hygiene and plant sanitation?			
2.	Does the plant have an authorized person charged with the responsibility to administer an effective sanitation program?			
3.	Does the plant maintain or utilize a bacteriological laboratory?			
4.	Does the plant maintain or utilize a pesticide residue laboratory?			
5.	Is there an adequate program to prevent rodents, birds or animals on the premises, in the receiving area, and/or warehouse? *			
6.	Is there an adequate program to control insects on the premises, in the receiving area, processing area, and/or warehouse? *			
7.	Does the plant contract for a commercial exterminator?			

DEFICIENCIES

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation'

B. PREMISES

Parking Lot and Yard Surfaces ☐ PAVED ☐ BLACKTOP ☐ DIRT ☐ GRAVEL

		YES	NO	RATING
1.	Are there significant deficiencies in the general appearance of the premises?			
2.	Are weeds, trash, rubbish, unused machinery or "junk" a problem?			
3.	Are there conditions on adjacent properties that could cause sanitation problems?			
4.	Is there evidence of rodent/insect harborage?			
5.	Are there offensive odors? *			
6.	Is there a dust or soot problem? *			
7.	Is there a drainage problem? *			

DEFICIENCIES

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

C. RECEIVING AREA

		YES	NO	RATING
1.	Is the general appearance satisfactory?			
2.	Is the area designed to facilitate cleanup?			
3.	Does there appear to be adequate cleanup equipment available?			
4.	Is the area free from offensive odors? *			
5.	Is debris and product refuse removed on a timely basis? *			
6.	Are there sufficient facilities for handling raw materials in an efficient and expeditious manner? *			
7.	Do raw material storage and handling practices preclude contamination by environmental hazards such as rodents, birds and insects? *			
8.	Are raw product containers cleaned and stored satisfactorily? *			
9.	Are holding tanks, holding bins, conveying equipment and devices adequately cleaned? *			

DEFICIENCIES

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

D. PLANT CONSTRUCTION AND DESIGN

		YES	NO	RATING
1.	Is the general appearance, construction and condition of the buildings satisfactory?			
2.	Are all exterior openings (including doors, windows, and wall openings) equipped with screens in good condition or otherwise protected?			
3.	Are exterior screen doors self-closing and/or air screens operating satisfactorily?			
4.	Are floors constructed of materials which can be well cleaned?			
5.	Are walls and ceilings in good condition and of the type that can be kept clean?			
6.	Are lights shatterproof or equipped with protective shields?			
7.	Is there an in-line chlorination or other sanitizing system?			
8.	Are there sufficient facilities including steam and water outlets throughout the plant for cleanup?			
9.	Is there a rodent-proof storage area for salt, sugar, and other product ingredients?			
10.	Is there proper locked storage for chemicals, cleaning compounds, and similar materials separate from product ingredients and container storage?			
11.	Is there sufficient lighting to permit efficient operations and cleaning? *			
12.	Do floors, gutters or drains have sufficient slope and outlets to drain adequately? *			
13.	Are buildings adequately ventilated so that all areas are kept reasonably free from excessive heat, steam, condensation, vapors, smoke, or fumes? *			
14.	Are there leaks in the roof? *			
15.	Are there leaking pipes or valves? *			
16.	Is the tool shop neat, orderly and well maintained? *			

DEFICIENCIES

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

E. PROCESSING AREA, EQUIPMENT AND FACILITIES

		YES	NO	RATING
1.	Is the general appearance satisfactory?			
2.	Are the equipment and area structures free from flaking paint and rust?			
3.	Are all product contact surfaces of equipment, containers and utensils made of non-absorbent corrosion resistant material that will not affect the product by chemical or physical contact?			
4.	Is the equipment constructed and located so that product contact surfaces are accessible for cleaning, maintenance and inspection?			
5.	Are equipment, containers, and utensils in good condition?			
6.	Is idle or unused processing equipment clean and located or arranged so as not interfere with cleanup?			
7.	Are equipment, containers and utensils constructed of wood? *(If so, for what purpose and what is the condition. Show in Remarks.)*			
8.	Are product contact brushes in good condition?			
9.	Are motors, conveyor belts and drive mechanisms located and protected so that oil or grease will not contaminate the product?			
10.	Are cross belts adequately protected?			
11.	Are catwalks and stiles properly constructed and located to prevent product contamination?			
12.	Is the area free from offensive odors? *			
13.	Are containers and utensils used in handling the product cleaned, stored, and utilized in such a manner as to preclude an insanitary condition? *			
14.	Are can cleaners (steam, air or water) on each line for glass, tin and semirigid containers?			
15.	Is the can cleaning system adequate for cleaning containers?			
16.	Are product belts clean and in good condition? *			
17.	Are gutters and drains in good repair, functioning satisfactorily, and properly fitted with grates and screens?			
18.	Are plant facilities and equipment satisfactory with respect to absence of slime and/or mold buildup? *			
19.	Are cleanup procedures adequate and supported by: *			
	a. proper equipment and materials?			
	b. trained and well supervised personnel?			
	c. sufficient time to accomplish the work?			
20.	Are blending tanks, product ingredient pipelines, pumps, and valves cleaned frequently (including dismantling if necessary)? *			
21.	When overflow sirup and brine are used, are they properly handled to avoid contaminating the products? *			
22.	Are window ledges, wall plates, beams, equipment, etc., free from lunch boxes, tools, and personal gear? *			

* Answer when plant is in operation

E. PROCESSING AREA, EQUIPMENT AND FACILITIES (continued)

DEFICIENCIES

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

F. WATER SUPPLY

☐ MUNICIPAL ☐ PRIVATE ☐ BOTH

		YES	NO	RATING
1.	Is the plant's water supply approved by a state, municipal or private authority?			
2.	If yes, name the authority.			

DEFICIENCIES

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

G. TOILET FACILITIES

		YES	NO	RATING
1.	Is there an adequate number of toilet facilities?			
2.	Do toilet rooms have independent outside ventilation?			
3.	Are toilet rooms designed so that they do not open directly into rooms or compartments in which processed products are being handled?			
4.	Are toilet rooms equipped with self-closing doors?			
5.	Are toilet rooms well lighted?			
6.	Are there sufficient and proper waste receptacles?			
7.	Are there signs posted indicating the importance of hand washing (multilingual if appropriate)?			
8.	Do hand washing facilities include hot and cold water, soap, and individual towels or forced air hand dryers?			
9.	Are toilet rooms clean, dry and of good general appearance? *			
10.	Are all toilets, sinks, and faucets in good working condition? *			
11.	Are waste receptacles emptied as necessary? *			

DEFICIENCIES

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when the plant is in operation

H. WAREHOUSE AND STORAGE FACILITIES

		YES	NO	RATING
1.	Is the warehouse in good repair?			
2.	Are the packaging, labeling, and storage areas neat and orderly?			
3.	Are empty containers protected from dust and other sources of contamination?			
4.	Are materials and supplies stacked in a manner to permit sanitation inspection?			
5.	Is the condition of storage areas adequate to protect the finished product, materials, and supplies from the elements?			
6.	Are there adequate facilities to cool and maintain the raw product when necessary?			
7.	Are there adequate facilities to refrigerate or freeze the finished product as required?			
8.	Are there temperature-recording devices located in the freezer facilities?			

DEFICIENCIES

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when the plant is in operation

I. WASTE DISPOSAL
(refers to waste areas in the plant and on plant premises)

		YES	NO	RATING
1.	Is there an adequate number of waste disposal containers and are they made of materials suitable for the intended use?			
2.	Are waste containers in good condition?			
3.	Is the general appearance of collecting area satisfactory? *			
4.	Is the frequency or removal of the waste timely? *			
5.	Is drainage suitable in all area(s) *			
6.	Are waste disposal containers cleaned regularly? *			

DEFICIENCIES

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

J. LABORATORY FACILITIES

		YES	NO	RATING
1.	Is the location, size, heating, cooling, and ventilation of the laboratory sufficient to provide a good working environment for the inspectors?			
2.	Is the USDA-approved lighting available for color scoring?			
3.	Is adequate space and inspection equipment available (including microscope and other appropriate specialized equipment)?			
4.	Does the laboratory meet basic safety requirements?			
5.	Are properly equipped grading stations available for line checks?			
6.	Is the laboratory used only by USDA and quality control personnel?			

DEFICIENCIES

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

K. PERSONNEL

		YES	NO	RATING
1.	Do employees wear suitable clothing, including effective head coverage? *			
2.	Are employees working in the processing area free from unsecured jewelry (bracelets, dangling earrings, etc.)? *			
3.	Are employees working in direct contact with food, free from infected lesions or skin diseases? *			
4.	Is gum chewing and all uses of tobacco limited to designated areas away from the processing areas? *			
5.	Are other personal habits such that they will preclude contamination of the food? *			
6.	Does plant management provide for personal comfort and assistance, such as: *			
	a. A lunchroom?			
	b. A first-aid station?			
	c. Suitable working condition of temperature and humidity?			

DEFICIENCIES

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

* Answer when plant is in operation

DEFICIENCIES (CONTINUATION SHEET)

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

This continuation sheet may be used for any section of the plant survey.

MANDATORY CHANGES REQUIRED IF CONDITIONAL APPROVAL WAS GRANTED

ITEM Letter and Number	DEFICIENCIES

CONTINUATION SHEET FOR:
MANDATORY CHANGES REQUIRED IF CONDITIONAL APPROVAL WAS GRANTED

ITEM Letter and Number	DEFICIENCIES

ANNUAL SURVEY (Preliminary)

CONDUCTED BY:		APPROVED BY:	
INSPECTOR'S SIGNATURE	DATE	SUPERVISOR'S SIGNATURE	DATE

ANNUAL SURVEY (Final)

CONDUCTED BY:		APPROVED BY:	
SUPERVISOR'S SIGNATURE	DATE	OFFICER'S-IN-CHARGE SIGNATURE	DATE

Auditor

FOLLOW-UP SUMMARY SHEET FOR DEFICIENCIES

(List deficiencies noted on previous survey. If corrected, note date corrected)

ITEM Letter and Number	DESCRIPTION	PROPOSED CORRECTIVE ACTION DATE	DATE CORRECTED

CONTINUATION SHEET FOR:
FOLLOW-UP SUMMARY SHEET FOR DEFICIENCIES

(List deficiencies noted on previous survey. If corrected, note date corrected)

ITEM Letter and	DESCRIPTION	PROPOSED CORRECTIVE	DATE CORRECTED

Number		ACTION DATE	

FOOD DEFENSE SYSTEM SURVEY

This survey is **optional** and can be used in conjunction with the plant survey to address Food Defense issues as identified in the FDA publication Guidance for Industry, Food Producers, Processors, and Transporters: Food Security Preventative Measures Guidance. This Food Defense survey meets the requirements of the Fruit and Vegetable Programs, Commodity Procurement Division, USDA Purchase Programs, and other programs requiring a Plant Survey and Food Defense System Survey. This survey may be used for any processing facility, storage, or offsite warehouse facility. The guidelines and rating elements listed should be used to determine facility ratings. A copy of this survey can also be found at the Fruit and Vegetable Programs, Specialty Crops Inspection Division website at the following internet address: http://www.ams.usda.gov/AMSv1.0/SCIHome. Under the "SCI Division Processed Services" block click on the "Audit Services" link, then under "Available Services" click on the "Food Defense System Survey" link.

Guidelines For Evaluation Elements

	Evaluation Elements	Guidance
1.	Does management have a Food Defense Plan that is implemented, and reassessed by management to assure it remains relevant to the operation?	▪ Procedures documented defining a food defense program. Food defense plan does not need to be formal (i.e., elements of a food defense plan may exist and be written in other company documentation; e.g., a recall plan). ▪ There is evidence that the Food Defense Plan is being followed. ▪ Plan identifies management responsibilities and frequency of review. ▪ Food Defense Plan is reassessed at least annually to assure it remains relevant to the operation.
2.	Does the Food Defense Plan address preventive measures relative to product tampering and deliberate contamination at the facility and during transport in commerce?	▪ Includes description of policy and preventive measures to reduce the risk of product tampering. ▪ Measures separately address food defense issues for product whether at the facility or in transport (both incoming and outgoing).
3.	Do written defense practices list management contacts and procedures for notifying appropriate authorities in the case of an emergency or security issue?	▪ Plan identifies management names and telephone numbers. ▪ Contacts for local authorities (police, fire, and rescue) are provided. ▪ Procedures describe steps involved in the notification process. These procedures may be verified in a documented recall program – if one exists.
4.	Do company personnel hiring practices include screening all potential employees?	▪ Review personnel files to verify security screening. Acceptable screening includes at least one of the following: 1. Employee references obtained and verified. 2. Employee immigration status checked (INS Form I-9). 3. Criminal background checks for employees, as needed (FBI Investigation watch list).

5.	After hiring, are photo identification or other measures employed to restrict access to the facility?	▪ Verify identification practices through observations. ▪ Verify measures used to restrict access.
6.	Have employees received training in Food Defense, and is the Food Defense training documented?	▪ ▪ Verify food defense training records for employees.
7.	Do supplier delivery personnel, contract workers, and visitors have restricted access to vulnerable product areas of the facility, and are they accompanied by a company representative?	▪ Security policy defines restricted access areas. ▪ Verify policy practices and procedures through observation.
8.	Are the outside premises of the facility secure with limited access to vulnerable areas?	<u>The following guidance is for questions 8-10</u>: ▪ Restricted access points to grounds and facility are defined and identified. ▪ Security monitored manually or mechanically as demonstrated by documentation. ▪ Verify the presence of posted signs or other measures used to secure and limit access to vulnerable areas. ▪ Policy describes procedures/frequency and responsibility.
9.	Are the grounds and facility monitored for suspicious activity and unauthorized entry?	
10.	Are "No Trespassing" signs visible along the perimeter of the facility, or are other measures being taken to secure and limit access to vulnerable areas?	
11.	Are assurances concerning food defense practices provided by suppliers of direct or indirect ingredients, product and equipment cleaning and sanitizing compounds, and packaging materials? This may include the use of tamper evident packaging for raw materials, sealing of trailers, and locking of bulk ingredient receiving ports.	▪ Review written assurances from suppliers. ▪ When possible, verify described assurances through observation.
12.	Is the security of water and utilities within the facility's control addressed in the Food Defense Plan, and does the plan define limited access by designated company representatives?	▪ Review plan for procedures, management responsibilities, and designated personnel. ▪ When applicable (company well or water reservoir included), verify limited access through observation.
13.	Does the processing plant have a manufacturer processor registration number (MPN), a Food and Drug Administration (FDA) food facility registration number issued to the manufacturer/processor by FDA?	▪ Affidavit or FDA correspondence verifies registration under the FDA Public Health Security and Bioterrorism and Response A of 2002. ▪ Verify company documents demonstrate registration of the facility with FDA.

Rating Elements Of The Food Defense System Survey

Question	Rating	Objective Evidence
1	Critical	If the facility does not have a documented food defense plan.
1	Critical	If the facility has a documented food defense plan but it is not implemented.
1	Minor	If the facility has a documented food defense plan but it has not been reviewed and verified, annually.
2	Major	If the plan does not include preventive measures relative to product tampering and deliberate contamination at the processing facility and during transport in commerce.
3	Major	If the plan does not include written defense practices listing management contacts and procedures for notifying appropriate authorities in the case of an emergency or security issue.
4	Major	If the plan does not include practices to include screening all potential employees.
5	Major	If after discussing this section with management, you find that they do not have adequate procedures according to their plan (No Identification Method or Restrictions) and/or you get an agreement that they need to improve this area.
6	Major	If the facility states they have not trained their employees in food defense and/ or cannot provide any documentation of training their employees in food defense.
6	Major	If employees of the facility have received training in food defense and/or documentation of this training cannot be provided.
7	Major	If you find that supplier delivery personnel, contract workers, and visitors are not restricted access to vulnerable product areas of processing and storage.
8	Major	If the plan states that the outside public has restricted access but you find the facility is not following their procedures which restrict access.
9	Major	After walking around the grounds and processing facility you find them not monitored for suspicious activity or unauthorized entry.
10	Major	If you find that the outside premises is secure, but areas inside the processing facility and/or off-site warehouse facility are not secure, or measures are not being taken to secure and limit access to vulnerable areas.
11	Major	If the plan does not include procedures for assurances concerning food defense practices from suppliers of direct or indirect ingredients, product and equipment cleaning and sanitizing compounds, and packaging materials.
11	Major	If you look at the operations section of the plan and it indicates that all raw materials, incoming vehicles, containers, or rail cars must be sealed, but you observe one that is not sealed.
12	Major	If the water and utilities that are under the control of the facility are not addressed in the plan to have limited access.
13	Critical	If the facility has not registered with FDA to obtain a manufacturer processor registration number.

ACCEPTABLE - No critical or major deficiencies.

UNACCEPTABLE – One or more major or critical deficiencies, practices or operations present that result in critical Food Defense Issues.

FOOD DEFENSE SYSTEM SURVEY

Food Defense questions listed below are to be evaluated at the processing and offsite warehousing facilities using the following key and column below: (P) Processing Facility (B) Both Processing and Warehousing Facility. Numbers 1-11 are applicable if evaluating the (W) Warehousing Facility only.			YES	NO	RATING
1.	B	Does management have a Food Defense Plan that is implemented, and reassessed by management to assure it remains relevant to the operation?			
2.	B	Does the Food Defense Plan address preventive measures relative to product tampering and deliberate contamination at the facility and during transport in commerce?			
3.	B	Do written defense practices list management contacts and procedures for notifying appropriate authorities in the case of an emergency or security issue?			
4.	B	Do company personnel hiring practices include screening all potential employees?			
5.	B	After hiring, are photo identification or other measures employed to restrict access to the facility?			
6.	B	Have employees received training in Food Defense, and is the Food Defense training documented?			
7.	B	Do supplier delivery personnel, contract workers, and visitors have restricted access to vulnerable product areas of the facility and are they accompanied by a company representative?			
8.	B	Are the outside premises of the facility secure with limited access to vulnerable areas?			
9.	B	Are the grounds and facility monitored for suspicious activity and unauthorized entry?			
10.	B	Are “No Trespassing” signs visible along the perimeter of the facility, or are other measures being taken to secure and limit access to vulnerable areas?			
11.	B	Are assurances concerning food defense practices provided by suppliers of direct or indirect ingredients, product and equipment cleaning and sanitizing compounds, and packaging materials? This may include the use of tamper evident packaging for raw materials, sealing of trailers, and locking of bulk ingredient receiving ports.			
12.	P	Is the security of water and utilities within the facility’s control addressed in the Food Security Plan, and does the plan define limited access by designated company representatives?			
13.	P	Does the processing plant have a manufacturer processor registration number (MPN), a Food and Drug Administration (FDA) food facility registration number issued to the manufacturer/processor by FDA?			

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ITEM NUMBER	**DESCRIPTION**	**PROPOSED CORRECTIVE ACTION DATE**	**DATE CORRECTED**

GOOD MANUFACTURING PRACTICES (GMPs)

SCI Division policy for sanitary procedures are the same as the Food and Drug Administration's (FDA) Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, 21 CFR 110. These regulations are published by Food and Drug Administration, Department of Health and Human Services, and amended under the authority of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. SCI Division employees are instructed to use these health, safety and sanitation guidelines whenever and wherever they are performing official Division business. These regulations may be found at the following internet address: http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

Food safety concerns have increased the request for inspection staff to read, fill out, and certify visitor hygiene, health and confidentiality agreements before being allowed to enter an applicant's facilities. Generally these policy statements cover visitor food safety policies that we must abide by while on-site. However, some visitor policy statements include health and/or confidentiality statements which we cannot sign. See the AIM General Procedures manual for instructions on employee signature of a firm's hygiene, health and confidentiality statements.

SCI Division employees must practice Division and FDA GMPs at all times while performing official duties. This includes ensuring that personal hygiene, safe work habits, personal appearance, equipment upkeep, and workstation housekeeping are maintained.

When performing inspection services other than in-plant inspection (such as lot inspection, checkloading, case stamping, etc...), SCI Division employees shall document and report any noted sanitation deficiency that may lead to product contamination.

SCI Division employees performing inspection services at public or private work sites shall also meet or exceed sanitation practices established by the company's health and safety policies. To meet GMPs, the assignment may require that a particular piece of equipment be brought from the field office in clean, sanitary condition. Before leaving for the assignment, consult your supervisor if there is any question about equipment needs specific to the inspection.

Above all, SCI Division employees should use common sense when dealing with health, safety and sanitation issues on the job. All employees should be concerned for the safety and health of their co-workers, industry counterparts, and others around them. Each employee's work habits and personal hygiene should reflect this concern. All employees shall take reasonable measures and precautions to ensure the following:

A. Sampling and Grading Equipment and Utensils

Any equipment, utensils, and/or tools used in the sampling, grading, or handling of the food product must be designed and constructed so that it can be easily taken apart for regular cleaning and inspection. All food contact surfaces for these items must be kept in good repair. If the contact surface cannot be repaired, then the item should be removed from service. Food contact surfaces must be cleaned to remove dirt and debris, and then sanitized prior to use and storage. Sanitizing without cleaning is insufficient. Equipment and utensils must be cleaned and sanitized during use as needed to prevent product contamination.

B. Laboratories and Grading Facilities

An effective cleaning and sanitizing operation is vital to plant operations. Food contact surfaces are the first priority, but improper cleaning of non-food contact surfaces can cause adulteration or contamination through indirect means. Good housekeeping of all areas is necessary, including locker rooms and restrooms.

Food contact surfaces (such as counters and containers) must be properly cleaned and sanitized before use. Sanitizing without cleaning is insufficient.

Non-product contact areas (such as walls, ceilings, floors, and other room areas as well as equipment) must also be cleaned regularly. Sanitizing is not required.

Note: Employees must take care to use cleaning and sanitization methods that will not adulterate or contaminate the food product.

Sanitizing Food Contact Surfaces

When sampling or grading product, it is necessary to clean and sanitize equipment. A sanitizing solution can be made from ordinary household bleach (sodium hypochlorite). Mix one tablespoon (one-half fluid ounce) of liquid bleach with one gallon of water to make the solution. To ensure that all surfaces of the equipment are sanitized, the equipment must be kept in contact with the sanitizing solution for a minimum of 2 minutes, and left to air dry without rinsing.

Note: Do not make the solution weaker or stronger than indicated. A solution that is too weak will not have the proper sanitizing effect, and a solution that is too strong will be no more effective, and could introduce excess chlorine to the product.

The sanitizing solution must be used on sampling equipment after cleaning but prior to use, prior to storage, and as necessary while sampling. Apply the solution to all surfaces of the equipment that may come in contact with the product, such as thermometers, chisels, scoops, honey thiefs, etc. After sanitizing, the equipment must be stored to prevent contamination, for example in a sealed plastic bag. Keep all sampling equipment as clean as possible between samples by resting equipment on a clean surface such as a plastic bag. If the equipment becomes contaminated during the sampling process, it must be cleaned and sanitized again prior to further use. After sampling completion, the equipment must again be cleaned and sanitized prior to storage.

Grading equipment and other food contact surfaces (such as grading tables) must also be cleaned and sanitized. If product that is graded is to be donated to a charitable organization or returned to the applicant, grading trays, screens, spoons, thermometers, etc. must be sanitized prior to use. If this equipment has not been cleaned and sanitized before use, the product must be destroyed after grading. Additionally, at the end of the day or the end of a shift, all grading equipment and other food contact surfaces must be cleaned and sanitized, then left to air dry.

Hazard Analysis and Critical Control Point (HACCP) Verification Survey

This is an optional survey used to assess if a facility has a HACCP food safety plan in place. It is not intended to assess the effectiveness of the plan. See compliance guidelines for key points to check. A YES response to all survey questions verifies the use of a HACCP plan at the facility.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) VERIFICATION SURVEY

The questions on HACCP listed below are to be evaluated based on the facility's HACCP plan. For a facility to pass this survey, all questions must have a "YES" response. Any "NO" response results in a "Critical" rating.			YES	NO	RATING: If "No" rate as Critical.
1.		Does management have a written HACCP plan?			
	1a.	Is the HACCP plan implemented?			
	1b.	Is there evidence of management commitment and are the appropriate personnel aware of their responsibilities for the implementation and maintenance of the company's HACCP plan?			
2.		Does the HACCP plan have a written hazard analysis which lists and evaluates the hazards associated with the commodity and process under consideration by this survey?			
3.		Does the HACCP plan address the application of one or more critical control point(s) (CCP) which is/are essential to prevent, eliminate, or reduce each identified potential food safety hazard?			
4.		Does the HACCP plan address the establishment of critical limits within which CCP(s) must be controlled to prevent, eliminate, or reduce each identified potential food safety hazard?			
5.		Does the HACCP plan address the application of monitoring procedures to assess whether CCP(s) is/are under control to prevent, eliminate, or reduce each identified potential food safety hazard?			
	5a.	Are monitoring procedures followed?			
6.		Does the HACCP plan address the establishment of corrective action(s)?			
	6a.	Are corrective actions taken when there is a deviation from established critical limits?			
7.		Does the HACCP plan address the application of verification procedures to confirm that the systems are operating according to the plan?			
	7a.	Are verification procedures followed?			
8.		Does the HACCP plan address the establishment of record-keeping and documentation procedures for the HACCP plan?			
9.		Are applicable "Good Manufacturing Practices" (GMP) and prerequisite programs addressed by management?			
	9a.	Are documented Standard Sanitation Operating Procedures (SSOPs) addressed?			
	9b.	Are documented supplier control procedures addressed?			
	9c.	Are documented specifications for ingredients, products, and packaging materials addressed?			
	9d.	Are documented receiving, storage, and shipping procedures addressed?			
	9e.	Are documented pest control program and procedures addressed?			
	9f.	Are documented traceability and recall procedures addressed?			
	9g.	Are documented chemical control procedures addressed?			
	9h.	Are documented personal hygiene procedures addressed?			
	9i.	Are documented employee training program for GMPs, HACCP, and sanitation addressed?			

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QUESTION NUMBER	**DESCRIPTION**	**PROPOSED CORRECTIVE ACTION DATE**	**DATE CORRECTED**

Compliance Guidelines for Hazard Analysis and Critical Control Point (HACCP) Verification Survey

NOTE – Apply compliance guidelines to determine appropriate response to the questions.

Reference Number	Questions	Compliance Guidelines
1.	Does management have a written HACCP plan?	Review HACCP plan documentation which should, at least, include the following: ▪ Organizational chart with assigned responsibilities; ▪ Summary of hazard analysis; ▪ Description of product, its distribution, intended use, etc.; ▪ Product flow diagram; ▪ HACCP plan which identifies hazard(s), and describes the critical control points, critical limits, monitoring procedures, corrective actions, verification procedures, record-keeping and documentation procedures; ▪ HACCP plan summary table; ▪ Support documentation such as validation records; and ▪ Records generated by implementation of the HACCP plan.
1a.	Has the HACCP plan been implemented?	Implementation involves the continual application of the monitoring, record-keeping, corrective action, verification procedures, and other activities described in the HACCP plan. Observe plant activity and review records for evidence of this.
1b.	Is there evidence of management commitment and are the appropriate personnel aware of their responsibilities for the implementation and maintenance of the company's HACCP plan?	HACCP plan implementation is facilitated by commitment from top management. This commitment provides facility personnel with a sense of the importance of producing safe product. Observe plant activity and review records for evidence of this. Interviewing certain plant personnel may be necessary.
2.	Does the HACCP plan have a written hazard analysis which lists and evaluates the hazards associated with the commodity and process under consideration by this survey?	Review the written hazard analysis to determine if it addresses the product and process designated for consideration by this survey.
3.	Does the HACCP plan address the application of one or more critical control point(s) (CCP) which is/are essential to prevent, eliminate, or reduce each identified potential food safety hazard?	Review written HACCP plan to determine if CCPs are identified.
4.	Does the HACCP plan address the application of critical limits which must be controlled at a CCP(s) to prevent, eliminate, or reduce each potential food safety hazard?	Review written HACCP plan to determine if critical limits are established.
5.	Does the HACCP plan address the application of monitoring procedures to assess whether CCP(s) is/are under control to prevent, eliminate, or reduce each potential food safety hazard?	Review written HACCP plan to determine if monitoring procedures for each CCP are identified and described.

5a.	Are monitoring procedures followed?	Review written HACCP plan and the appropriate records to determine if monitoring procedures are followed. Also observe plant activity for evidence of this.
6.	Does the HACCP plan address the establishment of corrective actions?	Review written HACCP plan to determine if corrective actions are established and described.
6a.	Are corrective actions taken when there is a deviation from established critical limits?	Review written HACCP plan and the appropriate records to determine if corrective actions were taken as described in the plan. Also observe plant activity for evidence of this.
7.	Does the HACCP plan address the application of verification procedures to confirm that the systems are operating according to the plan?	Review written HACCP plan to determine if verification procedures are identified and described.
7a.	Are verification procedures followed?	Review written HACCP plan and the appropriate records to determine if verification procedures are followed.
8.	Does the HACCP plan address the establishment of record-keeping and documentation procedures for the HACCP plan?	Review written HACCP plan to determine if record-keeping and documentation procedures are identified and described.
9.	Are applicable "Good manufacturing Practices" (GMP) and prerequisite programs addressed by management?	Obtain information from management, review appropriate documents, and observe operations to assess whether the GMPs and prerequisite programs are addressed by management.
9a.	Are documented Standard Sanitation Operating Procedures (SSOPs) addressed?	Review written applicable HACCP plan and facility documentation to determine if SSOPs are identified and described.
9b.	Are documented Supplier Control Procedures (SCPs) addressed?	Review written applicable HACCP plan and facility documentation to determine if SCPs are identified and described.
9c.	Are documented specifications for ingredients, products, and packaging materials addressed?	Review written applicable HACCP plan and facility documentation to determine if applicable specifications for ingredients, products, and packaging materials are identified and described.
9d.	Are documented receiving, storage, and shipping procedures addressed?	Review written applicable HACCP plan and facility documentation to determine if procedures are identified and described for receiving, storage, and shipping procedures.
9e.	Are documented pest control program and procedures addressed?	Review written applicable HACCP plan and facility documentation to determine if applicable pest control program and procedures are identified and described.
9f.	Are documented traceability and recall procedures addressed?	Review written applicable HACCP plan and facility documentation to determine if traceability and recall procedures are identified and described.
9g.	Are documented chemical control procedures addressed?	Review written applicable HACCP plan and facility documentation to determine if chemical control procedures are identified and described.
9h.	Are documented personal hygiene procedures addressed?	Review written applicable HACCP plan and facility documentation to determine if personal hygiene procedures are identified and described.
9i.	Are documented employee training programs for GMPs, HACCP, and sanitation addressed?	Review written applicable HACCP plan and facility documentation to determine if the applicable training programs are identified and described.

Sanitary Practices for Fresh Produce Inspection

Protecting the safety of the U. S. food supply requires a coordinated effort throughout food production, distribution, transportation, marketing, and consumption channels. The responsibility to safeguard our food supply is shared by everyone, from the grower to the consumer. It is important that everyone handling fresh produce understand the importance of personnel cleanliness and sanitary practices with respect to food safety. Individuals at each step along the farm-to-table chain have a responsibility to help ensure the safety of our food supply and prevent food safety hazards. As USDA representatives we must lead by example.

These guidelines provide practices that Specialty Crops Inspection (SCI) Division employees and Federal-State Inspection Program (FSIP) cooperators must use while performing fresh produce inspection and related activities.

Employee Responsibilities

SCI Division employees and FSIP cooperators shall follow sanitary practices when they are performing SCI Division business. All employees should take appropriate measures and precautions to prevent food safety hazards, including the following steps:

- Wash hands thoroughly:
  - Before starting work;
  - Before and after eating;
  - Before and after treating a cut or wound;
  - After using the rest room;
  - After touching an animal, animal feed, or animal waste; and
  - After contact with a source that could cause contamination.

Hand washing is one of the most effective ways to prevent the spread of many types of infection and illness. Hand washing is the act of thoroughly cleansing hands by applying soap and water, rubbing them together vigorously for at least 20 seconds, then rinsing them with clean water, and thoroughly drying using single use towels or forced air. The use of gloves in no way lessens the need or importance of hand washing and proper hygienic practices. If gloves are used, they must also be maintained in a sanitary manner.

- The use of hand sanitizers is not a substitute for hand washing. If hand sanitizers are used they MUST be used as a supplement, not a substitute, for hand washing.

- Maintain adequate personal cleanliness including clean clothes and hair.

- Inspection equipment including, but not limited to, knives, thermometers, scales, sizing rings, inspection tables, clip boards, and laptops, etc., should be clean prior to use on any given day.

- Writing instruments should not be placed behind an ear.

- Eating food, chewing gum, drinking beverages, or using tobacco are confined to designated areas separate from where produce is handled while performing official SCI Division business.

- No spitting where inspections and/or audit activities are conducted.

- Product and/or product packaging/cartons/bags should not be placed directly on the floor or ground, or other surfaces which result in similar exposure to contamination.

- Inspection samples and specimens probed with a thermometer or cut open should not be returned to the lot. Disposition of these samples should be coordinated with the applicant such that they do not return to product destined for consumption.

- Comply with firm's employee and visitor hygiene/sanitation policies (i.e., use of hair, beard or head coverings, no jewelry, and wear coveralls, protective clothing and boots).

SCI Division employees and FSIP cooperators should practice food safety procedures and take appropriate steps to prevent food safety hazards. Thank you for staying alert and vigilant regarding food safety issues and concerns.

Employee Signature of a Firm's Hygiene, Health and Confidentiality Statements

SCI Division employees and FSIP cooperators while performing inspection and audit activities must comply with a firm's employee and visitor hygiene/sanitation policies (i.e., use of hair, beard or head coverings, no jewelry, and wear coveralls or protective clothing and boots as required). If required, you may read, fill out, and certify a firm's visitor hygiene/sanitation/safety policy statement.

We have been informed through our general counsel that we are not to complete questionnaires or sign releases for health information. SCI Division policy regarding personnel is in accordance with the Food and Drug Administration, current Good Manufacturing Practices, 21 CFR 110:

Disease Control

Any person who by medical examination or supervisory observation is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food packaging material becoming contaminated shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

SCI Division employees should not sign confidentiality statements from applicants. We are not in a position to commit the government to confidentiality statements. SCI Division has an

established history of providing inspection service and audit programs that have maintained the confidentiality of an applicant's information. Federal employees are generally prohibited from disclosing confidential information by "United States Code: Title 18 – Crimes and Criminal Procedure: Part 1 – Crimes; Chapter 93-Public Officers and Employees; Section 1905, Disclosure of Confidential Information Generally. The penalties for not adhering to this regulation are imprisonment, monetary fines and removal from service."

SCI Division policy is that company plans and relevant company documents reviewed during the audit will not be removed from the facility. Also documents sent to SCI Division for review are to be stamped as "CONFIDENTIAL" and remain the property of the company. When the stated purpose of the document has been fulfilled, the company can request that the documents be returned or destroyed.

Attachments

Version Date
(Printed for distribution)

☐ **7 CFR 52.50:** _____
http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR.

☐ **21 CFR 110:** _____
http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR

☐ **29 CFR 1910.146:** _____
http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR

☐ **Optional Plant Safety Manual:** _____
http://agnis/sites/FV/PPB/Safety/default.aspx.

☐ **FDA AMS MOU 225-72-2009:** _____
http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/default.htm.

☐ **Report of Regulatory Agency Inspection, FV-425:** _____
http://agnis/AMSFormsCatalog/Forms/AllItems.aspx.

☐ **Sanitation Score Sheets, FV- 416-1, 2, 3, 5, 6, 7, 8, 9:** _____
http://agnis/AMSFormsCatalog/Forms/AllItems.aspx.

Checked Materials have been printed from the links in this Manual and included for reference.