Scientific Certification Systems
Food Safety Management Program Certification Standards

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Scientific Certification Systems is a multi-disciplinary scientific testing organization
founded in 1984. SCS associates and inspectors have extensive experience
in the food industry and a thorough knowledge of USDA/FDA regulations.
SCS's certification programs provide confidence in market claims to consumers and industry.

These Standards were peer reviewed by
recognized experts in the industry and in relevant academic fields.

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Introduction

To provide a mechanism for companies to communicate their high sanitation standards to industry and the consuming public, Scientific Certification Systems (SCS) developed certification standards for food safety management programs (FSMPs). SCS's Food Safety Management Program Certification Standards define the required elements of a program, the certification process and the evaluation criteria. They are based on the principles of the Hazard Analysis and Critical Control Point System and its basic prerequisite programs, as well as the U.S. Food and Drug Administration's Good Manufacturing Practices. These standards are applicable to all food industries, including producers, processors, packers, shippers, distributors, grocery retailers, and restaurants.

While recognizing that reducing the risk of foodborne illness to zero is impossible, certification indicates that a company maintains, monitors, and documents safe and sanitary practices. Certification also indicates that a company meets or exceeds applicable local food safety and sanitation related governmental regulations and the requirements set forth in these standards. A company with a certified FSMP demonstrates due diligence in providing the safest food possible.

Certification allows a company to make claims about their FSMP. The *Food Safety Management Program Certification Agreement* describes in detail allowable claims and advertising restrictions. This agreement is signed by a company after certification is achieved.

The first step to achieving certification is documenting the required elements of a FSMP. The documentation or manual, which describes the required elements, is referred to as a FSMP description. Required elements include a description of the steps taken to establish the program, sanitation standard operating procedures, and a food safety management plan. A food safety management plan details the preliminary steps for conducting the hazard analysis, the results of the hazard analysis, and the Critical Control Point Management Summary, often referred to as the Hazard Analysis and Critical Control Point (HACCP) Plan. See Section I for more details.

Submission of an *Application for Certification of a Food Safety Management Program* begins the application process for certification. The application process includes a review and evaluation of the FSMP Description, monitoring records and other records associated with the execution of the FSMP, followed by an on-site inspection. Determination of certification is based on the number and severity of deficiencies found. See Sections II and V for more details.

If SCS determines that a FSMP meets the requirements of these standards, SCS will issue a Certified Food Protection Program certificate. The certificate indicates an effective date, which is valid as long as a company continues to meet the requirements of these standards. Certification may apply to an operation or facility within a company, or portion thereof, and/or to specific products. The certificate will identify the operation or facility and specific products which are certified.

After certification is achieved, SCS will establish a schedule of maintenance audits. Maintenance audits are a combination of records audits and on-site inspections. Continuation of certification is based on the number and severity of deficiencies found. See Sections III and V for more details.

SCS may revoke certification if there is reason to believe the integrity of a FSMP is or may be compromised. See Section IV for more details.

Deficiencies found during records audits and on-site inspections are rated as minor, major, and critical. See Section V for more details.

A company may appeal a decision made by SCS. The appeals process is described in Section VI.

Terms and acronyms used in this document are defined in the Glossary.

I. Required Elements

A. BASIC COMPONENTS. A company shall demonstrate the following components are documented in the Food Safety Management Program (FSMP) Description and/or are in place.

1. Compliance with applicable local food safety and sanitation related governmental regulations.

2. Management Commitment. Food safety should become a company priority. This is demonstrated most effectively by assigning management personnel to the Food Safety Management Team who have the authority and resources to carry out the FSMP.

The FSMP Description shall include a mission statement signed by management. Distribution of this mission statement to all employees is yet another way to demonstrate management's commitment to the FSMP and encourage full participation by employees.

3. Food Safety Manager and Management Team. A Food Safety Manager and Management Team are responsible for development and implementation of the FSMP Description. They assure that it accurately reflects actual procedures and update it as needed. If a FSMP encompasses various products and/or processes, it may be necessary to have a manager and/or team for each.

The Food Safety Management Team should consist of individuals with different specialties, including employees who are directly involved with daily operations and employees at various levels of management. For example, a grower operation should include personnel from maintenance and field production; a processing plant should include personnel responsible for daily procedures and for monitoring quality control; and a retailer or distributor should include buyers, in-store staff, and their supervisors. In addition, the Team may seek information from other resources or experts, or the company may contract with an outside source to develop and assist in implementing their FSMP.

4. Training and Education System Description. Personnel at all levels shall be trained in food safety procedures (sanitation and proper hygiene) and/or Hazard Analysis and Critical Control Point (HACCP) principles, as appropriate to job function.

a. The Training and Education System Description shall describe how training and education will be achieved, either from within the company or by another organization. It must indicate how continuing training and education will be addressed, so that prolonged periods of time do not elapse without exposure to food safety procedures and principles.

b. The Training and Education System Description shall describe the training and education courses provided to employees. SCS requires, at a minimum, three primary levels of training and education. The level required depends on an employee's responsibilities.

1) **College Level.** Evidence of training and education at this level are demonstrated by completion of a college level course on Food Safety and HACCP Principles. The following are considered acceptable:

   - General HACCP (U.S. Food and Drug Administration)
   - Scientific Certification Systems HACCP-based Food Safety Training Course
   - Seafood HACCP (U.S. Association of Food and Drug Officials)
   - Other Courses. SCS will review the content of other courses and make a determination on their adequacy.
   - Evidence of training and education may also be demonstrated by experience. SCS will review curriculum vitae and may waive the requirement of participation in a training course.

   This level of training and education is required of the Food Safety Manager and other facility managers, so that staffing allows for someone at this level to be available or *on call* during operating hours.

2) **Basic Level.** Evidence of training and education at this level are demonstrated by completion of a basic food handling course or individualized training by a manager who has completed one of the courses listed in item 4.b.1 above. SCS will review the content of courses and/or individualized training and make a determination on their adequacy. Training must impart the principles of HACCP.

   This level of training and education is required of personnel responsible for documenting compliance with and verifying established critical control points.

   Personnel shall receive this training, within at least six months of employment or within at least six months of implementation of the FSMP. SCS may impose stricter time periods for completion of training.

3) **General Level.** Evidence of training and education at this level are demonstrated by inclusion of food safety procedures (sanitation and proper hygiene) as a part of new employee orientation.

   This level of training and education is required of all food handlers and personnel who have responsibilities in or near the area where food is handled.

   Employee Orientation is required prior to handling food or working in or near where food is handled.

5. Organizational Chart and Description of Responsibilities.

a. Organizational Chart. This shall include names and titles of personnel involved in the production of the product beginning with the president of the company. All

members of the Food Safety Management Team shall be indicated on the chart.

b. Description of Responsibilities. This shall include a short description of each position listed on the organizational chart.

6. Floor Plan and/or Map.

a. Floor Plan. Packers, shippers, distributors, processors, retailers, food service and other facilities performing procedures in an enclosed building or other physical structure shall have a floor plan of each building/structure. At a minimum, floor plans shall include placement and/or description of:

- receiving area
- shipping area
- production lines
- storage
- vents, windows, doors and entries
- water source
- plumbing
- adjacent land use

b. Map. Grower operations shall have a map. At a minimum, maps shall include placement and/or description of:

- fields and/or greenhouses
- buildings/structures
- landmarks which define the property
- adjacent land use
- water source and irrigation, including: drainage, tailwater, return system, sumps, and pumps.

7. Sanitation Standard Operating Procedures (SSOPs). An SSOP details procedures, record keeping and record review or verification requirements for sanitation. If record keeping requirements are applicable, a blank copy of the record shall be attached to the SSOP. SSOPs are required which outline the following:

a. Personnel Practices.

1) Disease Control. This section of the SSOP describes procedures to avoid having personnel work while ill or not in an appropriate condition for work.

2) Procedures for Maintaining Cleanliness. This includes a description of:

- required apparel
- maintenance of apparel
- restricted items
- personal hygiene requirements (hand washing/sanitizing procedure)
- proper product handling to protect food from contamination

- specific areas for non-work related activities (for example, eating, drinking, gum chewing, smoking and storing personal belongings)

3) **Supervision/Enforcement.** This section of the SSOP describes specific staffing requirements (for example, supervisory personnel, indicated by job title, who need to be present during operating hours).

b. Training and Education.

1) Level of training and education required for each job title.

2) Time period in which training and education must be received.

3) Description of training records and procedures for maintaining them.

c. Facility and Grounds Maintenance.

1) Storage of equipment.

2) Waste removal/treatment.

3) General maintenance of grounds (yards, roads, parking lots).

4) Exclusion of contaminants.

d. Cleaning, Sanitizing and Maintenance Procedures for Food Contact Surfaces (for example, pack lines, tables, carts, utensils).

1) **Procedures.** Description of cleaning, sanitizing and maintenance procedures shall also include cleaning and sanitizing materials identified by brand name or active ingredient.

2) Storage procedures for portable equipment (carts, utensils).

3) Schedule for cleaning, sanitizing and maintenance.

e. Cleaning, Sanitizing and Maintenance Procedures for Non-Food Contact Surfaces. For example, walls, floors, drains, or cooling units.

1) **Procedures.** Description of cleaning, sanitizing and maintenance procedures shall also include cleaning and sanitizing materials identified by brand name or active ingredient.

2) Schedule for cleaning, sanitizing and maintenance

f. Cleaning, Sanitizing and Maintenance Procedures for Sanitary Facilities.

1) **Description of hand washing and sanitizing system.** For example, sinks, hand dip stations, or sanitizer dispensers.

- Hand washing material identified by brand name or active ingredient
- Sanitizing material identified by brand name or active ingredient

2) **Cleaning, sanitizing and maintenance of hand washing and sanitizing system.**

- Procedures. Description of cleaning, sanitizing and maintenance procedures shall also include cleaning and sanitizing materials identified by brand name or active ingredient.
- Schedule for cleaning and sanitizing.
- Schedule for maintenance (check that supplies are available).

3) **Cleaning, sanitizing and maintenance of toilets/bathrooms.**

- Procedures. Description of cleaning, sanitizing and maintenance procedures shall also include cleaning and sanitizing materials identified by brand name or active ingredient.
- Schedule for cleaning and sanitizing
- Schedule for maintenance (check that supplies are available)

g. Operations and Procedures Identified during the Hazard Analysis. Steps in the process which prevent, eliminate, or reduce a hazard, but are not defined as Critical Control Points, shall be described in SSOPs. Examples of SSOPs which address the prevention, elimination and reduction of hazards may be:

- Procedures to prevent cross contamination. For example, not handling raw and cooked product in the same area.
- Procedures for assuring pre-harvest intervals of fertilizers and pesticides are met.
- Protection from adulterants. For example, not cleaning and sanitizing when food is present.
- Labeling, storage and use of toxic compounds.
- Maintenance and storage of cleaning tools, such as towels, mops, brushes, buckets and equipment.
- Storage of the product. For example, temperature requirements established and monitoring procedures described.
- Distribution of the product. For example, checking that trucks are cleaned prior to loading.

h. Pest Control Procedures.

1) **Description and schedule for conducting the following:**

- Exclusion practices, description of how harborage for pests is avoided.
- Population control methods.
- Monitoring procedures.

2) **Procedures to protect product from chemical contamination during pesticide applications.**

i. Maintenance of a Safe Water Supply and Plumbing.

1) **Monitoring procedures.** How often and from what points in the system samples of water will be collected and analyzed to ensure a safe water supply.

2) **Schedule of maintenance checks for plumbing.**

3) **Specific procedures.** For example, chlorinating system maintenance.

j. Creation and Maintenance of SSOPs.

1) **Format.** SSOPs shall follow a consistent format. This format shall be defined, including a place for approval signatures by management and attachment of a blank copy of a check list or monitoring form, if required.

2) **System for distribution.** SSOPs shall be accessible to all employees and outdated SSOPs shall be removed from circulation.

3) **Development of new SSOPs.** The need for new SSOPs shall be reviewed and when a new SSOP is written it shall be accounted for and distributed.

4) **Modification of existing SSOPs.** The need to modify an existing SSOP shall be reviewed and when an SSOP is modified it shall be accounted for and distributed.

5) **Periodic review.** All SSOPs shall be reviewed annually to ensure they are current and reflect actual procedures. All sets of SSOPs shall be checked to ensure they correspond with those in the FSMP Description.

8. Recall Procedures. A company shall be able to identify, locate and retrieve products. This may include having a descriptive product identification and coding system. It is recommended that a company conduct mock recalls or some other test of the system to evaluate their procedures.

B. FOOD SAFETY MANAGEMENT PLAN. A food safety management plan shall be specific to each item, process, and facility. The following items shall be included in a food safety management plan.

1. Description of the Product. A brief description of the product, which addresses the items listed below, is required.

- Description of the finished product.
- Raw materials, additives, or ingredients used. This should include a description of any variability in the raw materials, additives, or ingredients (for example, change in source of materials due to seasonal changes, different growing area, etc.).

- Processing/handling procedures.
- Processing aids.
- Packaging used.
- Storage.
- Distribution.
- Intended use of the product (for example, consumed without further cooking, heat-and-serve, or to be cooked).
- Target Consumer (for example, general public, infants, or elderly).

2. **Description of the Process.** Previous government inspections and current monitoring practices should be considered when documenting the Process-Flow Diagram and Process-Flow Description. The diagram and description shall be clear and complete so that people unfamiliar with the process can quickly comprehend the production stages.

   a. **Process-Flow Diagram.** This shall show in simple block or symbol form the steps required to manufacture, store and distribute the product.

   b. **Process-Flow Description.** This shall include a brief description of each step including:

      - Information on where raw materials are purchased
      - Title of the person, if applicable, responsible for completing the step
      - Process parameters, when applicable (for example, times, temperatures or chlorine levels).

3. **Hazard Analysis and Identification of Control Measures.** A Hazard Analysis Worksheet shall identify potential biological, chemical, and physical hazards that may be introduced, controlled, or enhanced at each step in the process-flow diagram. Factors that are beyond the immediate control of the company should also be considered, for example distribution. Information on what happens to the product after leaving a facility may influence how the food is handled or packaged. The risk and severity of each hazard should be evaluated. The estimate of risk and severity should be based on scientific publications, epidemiological data, information provided by consultants and experts, and if applicable, consumer complaints. If a hazard is determined to be significant, control measures shall be defined to prevent or eliminate the hazard, or reduce it.

   a. **Identification of Critical Control Points (CCP).** A critical control point is a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. For each hazard identified as significant in the Hazard Analysis, it shall be decided if that step will be a CCP or if the hazard can be addressed at a later step in the process.

   b. **Identification of Other Monitoring Requirements.** Control measures not associated with Critical Control Points shall be defined in SSOPs.

4. **Critical Control Point Management Summary (or *HACCP Plan*).** This should describe how critical control points will be managed. The following items shall

be addressed for each CCP.

a. Determination of Critical Limits and Operating Limits. A critical limit is a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard. Critical limits shall be based on one or more of the following: scientific publications, regulatory guidelines, experimental studies, information provided by consultants and experts, variability of the monitoring equipment, or tests designed to establish the critical control limits. The rationale and reference material shall be maintained as support documentation to the food safety management plan.

Operating limits are criteria that are more stringent than the critical limits and are used by an operator to reduce the risk of a deviation. Operating limits are recommended, but are not required. Operating limits are useful, in that they may help avoid violating a critical limit. For example, if monitoring shows a trend toward lack of control at a CCP, operators may take action to bring the CCP under control before the criterion of a critical limit is violated. An operator, who makes a process adjustment in order to avoid violating the criterion of a critical limit, need not document a corrective action. Corrective action is only required when the criterion of a critical limit is not met.

b. Description of Monitoring Requirements. Monitoring means to conduct a planned sequence of observations or measurements to assess whether a CCP is under control. The Critical Control Point Management Summary shall indicate what will be monitored, how it will be monitored, the frequency of monitoring, and who will be responsible for monitoring. When possible, monitoring procedures will be validated with a statistically established method.

c. Description of Record Keeping Requirements. The Critical Control Point Management Summary shall describe the format in which the monitoring records will be kept. For example, printouts from data collection devices may be maintained in a log book.

Monitoring records shall include the following information.

- Form title, indicating what is observed or measured.
- Facility name and location.
- Product identification (including product description, processing line, and product code, where applicable)
- Time and date of each observation or measurement.
- Critical limits.
- Operating limits (if applicable).
- Operator’s signature or initials and date for all entries and/or each periodic review.
- Reviewer’s signature or initials and date for each verification review.

d. Definition of Corrective Actions for Critical Limit Deviations. A corrective action is the set of steps followed when the criterion of a critical limit is

not met. The Critical Control Point Management Summary should provide some guidance on corrective action procedures, for example, placing suspect lots on hold for further evaluation. Predetermined corrective action procedures are useful, but not necessary.

Whenever the criterion of a critical limit is not met, a corrective action record shall be completed which indicates how an operator identified and segregated the affected lots, if necessary, and how he/she brought the CCP back under control. Corrective actions may also include what occurred to the affected lots. Each corrective action record shall be reviewed and signed by the Food Safety Manager.

e. Verification Procedures. Verification activities ensure that the control procedures described in the Critical Control Point Management Summary are working as intended. Verification activities shall be documented and records maintained. The following verification criteria shall be identified for each CCP.

1) Calibration of equipment and instruments used in monitoring a CCP. Calibration procedures provided in the operation manual of the instrument shall be followed and a recognized standard shall be used. Calibration shall be done at a frequency to ensure accuracy of measurement.

2) Calibration record review. Calibration records shall be maintained. Dates, methods, and results of calibration shall be reviewed. The review shall be done at a frequency to ensure equipment and instruments are providing reliable results.

3) CCP monitoring record review. A review of the monitoring record shall be done at a frequency to ensure the criterion of a critical limit is met. The Critical Control Point Management Summary shall indicate who will be responsible and how often reviews will be done.

f. Signature by Senior Management. The Critical Control Point Management Summary shall be signed by a member of the senior management.

C. DESCRIPTION OF VERIFICATION PROCEDURES FOR THE FSMP.

1. Periodic Review. The FSMP Description shall identify the time schedule for a periodic review of the entire FSMP Description. A periodic review should be done at least annually. The person or team of people responsible for conducting the periodic review shall be identified.

The basic components and each food safety management plan should be reviewed to assess whether they accurately reflect actual procedures. The review should include an assessment of whether execution of the FSMP represents due diligence in providing the safest food possible. Documentation of the review shall be maintained.

2. Targeted Sampling and Testing to Verify CCP Control Measures and SSOPs. The FSMP Description shall describe the type and frequency of sampling and testing. This may involve measurements, analyses or observations of equipment, the

final product, or of the product at different stages along the production process. Sampling and testing may also include swab samples of product contact surfaces. Sampling and testing shall be done at a frequency to provide confidence in the established critical limits and in the procedures outlined in SSOPs.

Results from verification sampling and testing shall be documented. Appropriate action should be taken and documented when results indicate that procedures are not adequately controlling potential hazards.

D. **MAINTENANCE OF RECORDS.** Records and documents related to the FSMP shall be maintained for at least five years (electronically stored data is acceptable). The following is a summary of record keeping requirements.

1. Support Documentation. Support documentation includes the following:

- A summary of preliminary steps taken in the development of the food safety management plan.
- Data used to establish the adequacy of operating (if applicable) and critical limits.
- Data used to establish any other procedures related to the production of an item.
- Data used to assess risk and severity of hazards (for example, scientific publications, epidemiological data, or information from consultants and experts).

2. Documents and Records which demonstrate the *Basic Components* have been met. See items described in I.A.

3. Food Safety Management Plan. See items described in I.B.

4. All Monitoring Records.

5. Corrective Action Records.

6. Records of Verification Activities. Verification documents shall include results of SCS audits or other inspections, calibration records, results of equipment or product verification testing and sampling, and documentation of the periodic review of the FSMP.

A company interested in certification shall submit to SCS an *Application for Certification of a Food Safety Management Program*. In the application SCS requires submission of the documents which describe the FSMP. A company shall specify in the application the products/processes and sites of all facilities which are included in their FSMP.

A. MINIMUM TIME PERIOD FOR OPERATING UNDER A FSMP. A company with a FSMP which requires CCPs shall have executed the FSMP for a minimum of 60 days. For a company with a FSMP which does not require CCPs, there is no minimum operating time period. Instead, the company must demonstrate in their application and during their initial on-site inspection that the FSMP is executed adequately.

If the minimum time period has not been met, a company may still apply for certification. SCS will review the FSMP Description and make recommendations. The company can then make the suggested changes prior to implementing the FSMP. When the minimum time period is met, the certification process may proceed.

B.

C.

B. APPLICATION REVIEW AND EVALUATION.

1. **Review and Evaluation.** SCS will conduct an application review and evaluation. The application and the FSMP Description will be reviewed for completeness, adequacy and compliance with these standards. Copies of monitoring records will also be reviewed.

2. **Report of Findings.** SCS will provide a written report of deficiencies and recommendations.

3. **Company's Response to the Report of Findings.** The company must respond to each item in the Report of Findings, submit corrections to the FSMP Description, and if requested submit additional monitoring records. After a review of the company's response and additional submissions, SCS will determine if the company is ready for an initial on-site inspection. The initial on-site inspection will not be scheduled until all elements of the FSMP Description are complete and deficiencies indicated in the Report of Findings are addressed.

D. INITIAL ON-SITE INSPECTION.

1. **Scheduling.** When it is determined that the company is ready for an initial on-site

inspection, the company will be notified of the inspection date. For a company with facilities at multiple sites, initial on-site inspections will be scheduled for each site.

2. **Initial On-Site Inspection.** The initial on-site inspection includes an audit of records and documents related to the FSMP, such as CCP and SSOP monitoring records, corrective action records, calibration records, training records and verification documentation that were not reviewed during the application review and evaluation. The initial on-site inspection also consists of an evaluation and observation of the facility and FSMP procedures during production and interviews with management and personnel.

E. DETERMINATION OF CERTIFICATION. Following the initial on-site inspection, SCS will send a Report of Findings, which will describe the deficiencies found in the FSMP or execution of the FSMP, as well as recommendations for correction. The Report of Findings will indicate the certification status.

Deficiencies are rated as described in Section V. The number of deficiencies of each rating are totaled and the final count adjusted according to the following:

6 MINORs = 1 MAJOR
6 MAJORs = 1 CRITICAL

That is, any six (6) minor deficiencies are counted as one (1) major deficiency. Any six (6) major deficiencies are counted as one (1) critical deficiency.

1. **Certification Denied.** If a critical deficiency was assessed by the accumulation of six (6) major deficiencies or is assessed on a single item, certification will not be granted.

2. **Achieving Certification after Initial Denial.** If certification was denied, a company may achieve certification by indicating in writing what steps will be taken to correct each item in the Report of Findings and if appropriate, including documentation which supports these steps. SCS may make specific requirements regarding data submission.

   A company with continuous production has 30 days to respond to the Report of Findings. For a company with seasonal production, the response time period will be determined on a case-by-case basis. If a company does not reply within the 30-day time period, or sooner if required, and has not conveyed to SCS a satisfactory reason for their delay, it will be assumed that the company is no longer interested in certification.

   SCS will reevaluate the FSMP based on the written response and supporting documentation and determine if certification will be granted or denied.

3. **Certification Denied after Reevaluation of the FSMP based on Responses to the Report of Findings.** If SCS determines the steps outlined in the response to the Report of Findings are inadequate or cannot be confirmed by the documents submitted, certification will not be granted.

4. **Certification Granted.** If no critical deficiency was assessed and the number of major deficiencies (including those attained by the accumulation of six (6) minor deficiencies) does not exceed five (5), then certification will be granted.

   If certification was denied, but responses to the Report of Findings and submitted records adequately demonstrate that steps have been taken to correct each item, then certification will be granted.

F. **CERTIFICATION OF A COMPANY WITH FACILITIES AT MULTIPLE SITES.** For a company with facilities at multiple sites, all facilities must attain certification in order for the entire company to be certified and thus be able to make company-wide certification claims. If all operations or facilities do not achieve certification, then certification may be granted on an individual basis, and claims may be made specific to that operation or facility.

G. **ISSUING CERTIFICATE.** After certification is granted, the company shall sign a Food Safety Management Program Certification Agreement. The agreement includes contractual information about maintenance audits, payment, allowable claims, and advertising restrictions. SCS will issue a Certified Food Protection Program certificate after receiving the signed agreement.

The certificate indicates an effective date, which is valid as long as the company continues to meet the requirements of these standards. Certification may apply to an operation or facility within a company, or portion thereof, and/or to specific products. The certificate will identify the operation or facility and specific products which are certified.

Certification is not considered complete until the certificate is issued.

H. **REAPPLYING AFTER CERTIFICATION IS DENIED.** If certification was denied, and a company does not proceed as described above in E. 2 above, or certification was denied after reevaluation of responses to the Report of Findings (E.3, above), a company may reapply after the deficiency(ies) is corrected. The company shall meet the same minimum time period for operating under the revised FSMP as stated in the application process, see item II.A. SCS will consider the company to be a first time applicant, and the steps in the application process will be followed.

III. Maintenance of Certification

A company maintains certification by continuing to comply with the procedures outlined in their FSMP Description, replying to Reports of Findings, participating in scheduled maintenance audits, and avoiding actions that result in revocation of certification.

Certification maintenance audits are a combination of records audits and on-site inspections. Audit frequency is based on the successful execution of the FSMP as assessed during audits.

A. Maintenance of Certification during the First Year.

1. **Certification Denied, but later Granted based on Responses to the Report of Findings from the Initial On-Site Inspection.** A company maintains certification by complying with any data submission requirements established by SCS to monitor the area(s) of concern. Any indication that the steps described in the response to the Report of Findings are not being carried out is cause for SCS to revoke certification, see section IV.

   The facility will be scheduled for an on-site inspection within 3 months, as indicated below in the schedule of maintenance audits.

2. **Certification Granted after Initial On-Site Inspection.** A company maintains certification by indicating in writing what steps will be taken to correct each item in the Report of Findings and if appropriate, including documentation which supports these steps.

   A company with continuous production has 30 days to respond to the Report of Findings. For a company with seasonal production, the response time period will be determined on a case-by-case basis. If a company does not reply within the 30-day time period, or sooner if required, and has not conveyed to SCS a satisfactory reason for their delay, it will be assumed that the company is no longer interested in certification. SCS will revoke the certification, see section IV.

   SCS will evaluate the responses to the Report of Findings. SCS may request follow-up actions, for example submission of data on a periodic basis, or request a company to amend their response. Failure to comply with SCS's request is cause for SCS to revoke certification, see section IV.

   The facility will be scheduled for an on-site inspection or records audit within 3 months, as indicated below in the schedule of maintenance audits.

3. **Schedule of Maintenance Audits.** The following schedule is for a company with continuous production. For a company with seasonal production, the schedule is adjusted based on the length of the season, with a minimum of at least one audit per quarter.

   a. **Audit Schedule A.** If no critical deficiencies were issued during the initial on-site inspection of a facility and corrections to any major deficiencies can be confirmed in

a records audit, the facility's maintenance audits will follow this schedule, during the first year:

- two records audits
- one on-site inspection (in addition to the initial on-site inspection)

These audits may occur in any order. Generally audits occur on a three-month basis, but the schedule of audits are at SCS's discretion and may be unannounced.

b. Audit Schedule B. If certification was denied, but later granted based on responses to the Report of Findings from the initial on-site inspection, or if certification was granted but corrections to major deficiencies cannot be confirmed in a records audit, the facility's maintenance audits will follow the schedule below during the first year:

- an on-site inspection within at least three months of the initial on-site inspection

A facility will remain on audit schedule B or be placed on audit schedule B, if during a previous audit a critical deficiency is issued or if corrections to major deficiencies cannot be confirmed in a records audit. In this case, SCS will continue to require an on-site inspection within at least three months of the previous on-site inspection. Continuation on audit schedule B may be cause for SCS to revoke certification (See item IV.A.2)

B. MAINTENANCE OF CERTIFICATION DURING THE FOLLOWING YEARS.

1. Schedule of Maintenance Audits. The following schedule is for a company with continuous production. For a company with seasonal production, the schedule is adjusted based on the length of the season, with a minimum of at least one audit per quarter.

a. Audit Schedule A. If no critical deficiencies were issued during the previous maintenance audit and corrections to any major deficiencies can be confirmed in a records audit, the facility's maintenance audits will follow this schedule:

- three records audits per year
- one on-site inspection per year

These audits may occur in any order. Generally audits occur on a three-month basis, but the schedule of audits are at SCS's discretion and may be unannounced.

b. Audit Schedule B. If a critical deficiency was issued during the previous maintenance audit or corrections to any major deficiencies cannot be confirmed in a records audit, the facility's maintenance audits will follow this schedule:

- an on-site inspection within at least three months of the previous inspection

A facility will continue on this schedule if a critical deficiency is issued or if

corrections to major deficiencies cannot be confirmed in a records audit. In this case, SCS will continue to require an on-site inspection within at least three months of the previous on-site inspection. Continuation on audit schedule B may be cause for SCS to revoke certification (See item IV.A.2)

C. Definition of Maintenance Audits

1. **Records Audit.** A records audit includes an audit of records and documents related to the FSMP, such as CCP and SSOP monitoring records, corrective action records, and verification documentation. Records audits generally are completed off-site.

2. **On-site Inspection.** An on-site inspection includes an audit of records and documents related to the FSMP, such as CCP and SSOP monitoring records, corrective action records, calibration records, training records and verification documentation that are not reviewed during off-site records audits. The on-site inspection also consists of an evaluation and observation of the facility and FSMP procedures during production, and interviews with management and personnel. On-site inspections may or may not take place when production is in progress.

D. Determination of Certification after a Maintenance Audit.

Following a maintenance audit, SCS will send a Report of Findings, which will describe the deficiencies found in the FSMP or execution of the FSMP, as well as recommendations for correction. The Report of Findings will indicate whether the company's certification status is in good or conditional standing.

Deficiencies found during a records audit and/or on-site inspection are rated as described in Section V. The number of deficiencies of each rating are totaled and the final count adjusted according to the following:

6 MINORs = 1 MAJOR
6 MAJORs = 1 CRITICAL

That is, any six (6) minor deficiencies are counted as one (1) major deficiency. Any six (6) major deficiencies are counted as one (1) critical deficiency.

1. **Certification in Conditional Standing.** If a critical deficiency was assessed or corrections to any major deficiency cannot be confirmed in a records audit, the status of certification will be considered conditional.

   A company maintains certification by indicating in writing what steps will be taken to correct each item in the Report of Findings and if appropriate, including documentation which supports these steps.

   A company with continuous production has 30 days to respond to the Report of Findings. For a company with seasonal production, the response time period will be determined on a case-by-case basis. If a company does not reply within the 30-day time period, or sooner if required, and has not conveyed to SCS a satisfactory reason for their delay, it will be assumed that the company is no longer interested in certification.

SCS will revoke the certification, see section IV.

SCS will evaluate the responses to the Report of Findings. SCS may request follow-up actions, for example submission of data on periodic basis, or request a company to amend their response. Failure to comply with SCS's request is cause for SCS to revoke certification, see section IV.

The facility will be scheduled for an on-site inspection within 3 months, as indicated above in the schedule of maintenance audits.

2. **Certification in Good Standing.** If no critical deficiency was assessed and corrections to any major deficiency can be confirmed in a records audit, the status of certification will be considered good.

A company maintains certification by indicating in writing what steps will be taken to correct each item in the Report of Findings and if appropriate, including documentation which supports these steps.

A company with continuous production has 30 days to respond to the Report of Findings. For a company with seasonal production, the response time period will be determined on a case-by-case basis. If a company does not reply within the 30-day time period, or sooner if required, and has not conveyed to SCS a satisfactory reason for their delay, it will be assumed that the company is no longer interested in certification. SCS will revoke the certification, see section IV.

SCS will evaluate the responses to the Report of Findings. SCS may request follow-up actions, for example submission of data on periodic basis, or request a company to amend their response. Failure to comply with SCS's request is cause for SCS to revoke certification, see section IV.

The facility will be scheduled for an on-site inspection or records audit within 3 months, as indicated above in the schedule of maintenance audits.

E. CERTIFICATION OF A COMPANY WITH FACILITIES AT MULTIPLE SITES. For a company with facilities at multiple sites, maintaining certification will be based on the performance of individual facilities. The audit schedule above will be used for each facility within a company.

1. **Ten or More Facilities.** For a company with ten or more facilities, if at any time greater than 10% of the facilities have their certification revoked, the company's certification is revoked. Facilities that remain in good or conditional standing may maintain their certification on an individual basis.

2. **Less than Ten Facilities.** For a company with less than ten facilities, if at any time one of the facilities have their certification revoked, the company's certification is revoked. Facilities that remain in good or conditional standing may maintain their certification on an individual basis.

IV. Revocation of Certification

A. Reasons Why Certification May Be Revoked.

1. **No Response to a Report of Findings.** If a company does not reply to a Report of Findings within 30 days, or sooner if required, and has not conveyed to SCS a satisfactory reason for their delay.

2. **The Same Critical Deficiency Is Noted on Three Consecutive Audits.** If a facility has two consecutive critical deficiencies for the same item, certification will be revoked if that same deficiency is noted upon the third consecutive audit of that facility.

3. **Imminent Public Safety Issue Exists.** If SCS discovers or is made aware of an imminent public safety issue, SCS reserves the right to revoke certification.

4. **Failure to Take Appropriate Action.** If at any time SCS becomes aware of the following:

   a. Company fails to initiate a recall procedure within 24 hours after a significant hazard in the finished product is confirmed. Or, if a company chose not to initiate recall procedures, failure to report the finding and to provide a substantiated reason for the decision to SCS within 24 hours by certified mail of a confirmed finding.

   b. Company fails to comply with requests for information within 72 business hours. For example, submission of data in a timely fashion as requested by SCS.

   c. Company fails to allow SCS to conduct an unannounced on-site inspection.

   d. Company fails to notify SCS of a change in the product/process, food safety management plan, or execution of the food safety management plan prior to a product being released for sale.

   e. Company fails to agree with SCS upon a change or a time period to enact a change in the FSMP or execution of the FSMP.

   f. Company fails to agree with SCS on an adequate response or steps to be taken to correct an item in a Report of Findings.

   g. Company fails to adequately demonstrate steps have been taken to correct an item in a Report of Findings.

   h. Company fails to notify SCS of a food safety management change within 72 hours. For example, the Food Safety Manager or General Manager is replaced.

B. Procedures for Revocation of Certification.

1. **Notification by SCS.** SCS will notify the company that certification is revoked in a Notice of Certification Revocation via certified mail within 24 hours of confirming a cause for revocation. The effective date of the revocation is the date on the Notice.

2. **Company Notification of Vendors.** A company shall notify all vendors within 24 hours of receiving the Notice of Certification Revocation and provide SCS with documentation of these notifications within 48 hours.

3. **Cease Using Market Claims and Stickers.** A company may no longer make market claims about certification or use stickers which include SCS's name or logo.

C. Application for Re-Certification.

After certification is revoked, a company may reapply after the deficiency(ies) is corrected or the process leading to the deficiency(ies) is reevaluated. The company shall meet the same minimum time period for operating under the revised FSMP as stated in the application process, see item II.A. SCS will consider the company to be a first time applicant, and the steps in the application process will be followed.

A company with facilities at multiple sites which has had certification revoked must achieve certification for all facilities. Only the facilities which had certification revoked need to re-apply, but all facilities must again achieve certification in order to make a company-wide claim of certification.

A. **SEVERITY OF DEFICIENCIES.** Deficiencies found during a records audit and/or on-site inspection will be rated as minor, major, or critical, depending on their severity.

1. **Minor.** A minor deficiency is the least severe rating. A minor deficiency indicates an error in execution that does not directly or immediately compromise the safety of the product.

2. **Major.** A major deficiency is the rating that indicates a severity greater than a minor rating, but not as severe as a critical rating. A major deficiency indicates that a FSMP is not being executed or managed properly, but the safety of the product is not directly or immediately compromised. A major deficiency that is not addressed promptly may eventually lead to the safety of the product being compromised.

3. **Critical.** A critical deficiency is the most severe rating. A critical deficiency indicates that a FSMP is not being executed or managed properly and the safety of the product may be compromised.

B. **TYPES AND RATING OF DEFICIENCIES.**

1. **Deficiencies in Training Records.** The SCS inspector will audit the training records of a minimum of ten percent of the total number of employees. The percentage of errors found in the audit sample will be calculated in the following way:

$$\frac{\text{number of employees with a training record error} \times 100}{\text{total number of employees reviewed}}$$

A training record error is:
- Failure to receive adequate training within the time period specified in the SSOP
- Failure to document training that was received.
- A record that is unavailable, illegible, or incomplete.

Based on the percentage of error, the following rating systems ill be used:

greater than 10% in error	MAJOR
greater than 0% but less than or equal to 10% in error	MINOR
Incomplete training and education for managers. (Staffing requirement of a HACCP-trained manager at each facility not met.)	MAJOR

2. **Deficiencies in Monitoring Records.** *For each* of the monitoring records detailed in the Critical Control Point Management Summary or in SSOPs, the SCS inspector will audit a minimum of ten percent of the total number of recordings which were to be

taken during the time period specified. The percentage of errors found in the audit sample will be calculated in the following way:

$$\frac{\text{number of recording errors}}{\text{total number of recordings reviewed}} \times 100$$

A recording error is:
- Any individual observation which is unavailable, illegible, incomplete or inaccurate, *and* which was not corrected during the periodic verification procedure.
- Use of pencil

- Use of colored ink other than blue or black
- Erasures or use of white-out. (Corrections to entries should be lined out and footnoted with an explanation, signature and date.)
- Failure to document a signature and date of a record review.

The SCS inspector may increase the sampling size at his/her discretion.

Based on the percentage of error and the type of record, the following rating system will be used:

a. CCP Monitoring Record.

greater than 10% in error	CRITICAL
from 2% to 10% in error	MAJOR
greater than 0% but less than 2% in error	MINOR
any single error or combination of errors, which jeopardize the safety of the product	CRITICAL

b. SSOP Monitoring Record.

greater than 10% in error	MAJOR
greater than 0% but less than or equal to 10% in error	MINOR

c. SSOP and CCP Verification Record.
(Includes targeted sampling or testing records and calibration records)

greater than 10% in error	MAJOR
greater than 0% but less than or equal to 10% in error	MINOR

For example, if a CCP requires that temperatures of a product be taken four times daily, and the audit covers a 60 day time period, the total number of recordings is equal to 240. The inspector will select a minimum of 24 recordings to review. If the inspector found that 2 of the 24 recordings contained errors, the percentage in error

would be 8.3%. The facility would be given a MAJOR deficiency.

3. Failure to conduct/document Periodic Review of FSMP. MINOR or MAJOR

4. Deficiencies in Corrective Action Records. MAJOR or CRITICAL

Deficiencies in Corrective Action Records are defined as any portion of a record that is unavailable, illegible, incomplete or inaccurate or if Corrective Action was not properly taken. Deficiencies are assessed on the severity of the error.

5. Falsification of any Record. CRITICAL

Falsification is defined as changing an entry to reflect a value that was not the value measured or observed with the intent and full knowledge of hiding the actual measurement or observation. Falsification is also defined as any instance where an entry was made without a measurement being taken.

Incidents of falsification which are addressed during the company's internal verification procedures will be investigated to determine if there are procedural problems which might affect the safety of a food product. These incidents may be identified as a deficiency (see item 6.g below).

6. Deficiencies noted during on-site inspections.

a. Inability to adequately demonstrate recall procedures — MAJOR or CRITICAL

b. Failure to follow SSOP procedure — MINOR, MAJOR or CRITICAL

c. Failure to implement a defined CCP — CRITICAL

d. Failure to include a CCP in a food safety management plan — CRITICAL

e. Improper monitoring of a CCP — MINOR, MAJOR or CRITICAL

f. Not having a trained Food Safety Manger or other facility manager available or on call during operating hours — MAJOR

g. Procedural problems or structural items which may affect the safety of the food product — MINOR, MAJOR or CRITICAL

7. Recurring Deficiency. MINOR, MAJOR or CRITICAL

If deficiencies are noted for the same item from a previous audit, the severity of a deficiency may be increased or additional deficiencies may be added on to the total count of deficiencies for the current audit.

8. Failure to Take Appropriate Action. If at anytime SCS becomes aware of the following:

a. Failure to notify SCS within 24 hours by certified mail of initiation of recall procedures.	CRITICAL
b. Failure to notify SCS within 72 hours by certified mail of government inspections which reveal adverse findings.	CRITICAL
c. Failure to address verification testing results which indicate that procedures are not adequately controlling potential hazards.	MAJOR or CRITICAL

VI. Appeals

A. **Participant Appeals.** Every participant has a right to appeal an SCS decision. The burden of establishing the invalidity of a certification decision rests with the filing participant. All requests and notices of appeal must be made in writing and accompanied by supporting documentation. A written appeal must be submitted within 30 days of receipt of a Report of Findings or Notice of Certification Revocation.

If the matter is not resolved after reviewing the appeal, an appeal hearing will be scheduled. A telephone conference may be convened in order to contain costs. The hearing shall include the inspector(s), other appropriate SCS personnel (i.e., FSMP Director and Chief Operations Officer), and a representative from the company making the appeal. The appeal decision is rendered by the Chief Operations Officer of SCS, as acting Appeals Officer. The decision will be supported by a written report.

B. **Arbitration.** The appellant has the right to carry the grievance to arbitration through the Office of the American Arbitration Association.

Glossary

Application Review and Evaluation The Application for Certification of a Food Safety Management Program and the FSMP Description are reviewed for completeness, adequacy and compliance with these standards. Copies of monitoring records are also reviewed.

CCP see Critical Control Point

Company Company refers to the entity which submitted the application for certification and is responsible for overseeing the execution of the FSMP.

Control Measure A control measure is any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

Corrective Action Corrective action is the set of steps followed when the criterion of a critical limit is not met.

Corrective Action Record A corrective action record is documentation which indicates what steps were taken when the criterion of the critical limit was not met. It indicates how an operator identified and segregated the affected lots, if necessary, and how he/she brought the CCP back under control. A corrective action record may also indicate what occurred to the affected lots. Each corrective action record shall be reviewed and signed by the Food Safety Manager.

Critical Control Point (CCP) A critical control point is a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Control Point Management Summary The CCP Management Summary describes how critical control points will be managed. It is also referred to as the HACCP Plan.

Critical Limit A critical limit is a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

Deficiency A deficiency is a problem found in the FSMP or execution of the FSMP during a records audit or on-site inspection.

Deviation of a Critical Limit A deviation of a critical limit is the failure to meet the criterion of the critical limit defined for a critical control point.

Facility Facility is the entity which executes the FSMP on a daily basis.

Food Safety Management Plan A Food Safety Management Plan is the document which describes the product and process, identifies hazards, and details procedures to be taken to prevent, eliminate, or reduce hazards.

Food Safety Management Program A FSMP is a system of control procedures designed to prevent and control food safety hazards associated with food from the time a facility receives raw material through production and distribution to the consumer.

Food Safety Management Program Description A FSMP Description is the document which describes the elements of a FSMP, including the food safety management plan(s).

Food Safety Management Team A food safety management team consists of individuals with different specialties, including employees who are directly involved with the daily operations and employees at various levels of management. The team is responsible for development and implementation of the FSMP Description. They assure that it accurately reflects actual procedures and update it as needed.

Food Safety Manager A food safety manager works closely with the Food Safety Management Team, is responsible for maintaining the FSMP Description, and oversees the FSMP operations.

FSMP see Food Safety Management Program

GMP see Good Manufacturing Practices

Good Manufacturing Practices (GMP) Good Manufacturing Practices are the procedures for manufacturing, packing or holding human food described in the Code of Federal Regulations (United States), section 21, part 110.

HACCP Plan see Critical Control Point Management Summary.

HACCP Principles see Hazard Analysis Critical Control Point Principles.

Hazard A hazard is a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the Critical Control Point Management Summary.

Hazard Analysis Critical Control Point Principles (HACCP Principles) The concept of HACCP was pioneered by Pillsbury Co. in the early 1960s during its efforts to supply food for the U.S. space program. The National Advisory Committee on Microbiological Criteria for Foods later standardized the seven principles used by industry and regulatory authorities. The seven principles are:

1. Conduct hazard analysis and identify control measures.
2. Identify critical control points.
3. Establish critical limits.
4. Monitor each CCP.
5. Establish corrective action to be taken when a critical limit deviation occurs.
6. Establish a record-keeping system.

7. Establish verification procedures.

Initial On-Site Inspection The initial on-site inspection includes an audit of records and documents related to the FSMP, such as CCP monitoring records, corrective action records, calibration records, training records and verification documentation that were not reviewed during the application review and evaluation. The initial on-site inspection also consists of an evaluation and observation of the facility and FSMP procedures during production and interviews with management and personnel.

Hazard Analysis Worksheet The Hazard Analysis Worksheet is the component of the food safety management plan which documents the identification of hazards, the determination of risk for hazards, control measures, and identification of critical control points or SSOPs for each step in the production of a product.

Limits Limits are criteria that are used to reduce the risk of a deviation on a critical control point.

Monitoring Monitoring means to conduct a planned sequence of observations or measurements to assess whether control measures keep hazards under control.

Monitoring Record A monitoring record: 1) allows for process adjustments in order to maintain control, 2) identifies when there is a loss of control, and 3) provides written documentation of the process to be used in verification of the FSMP.

On-Site Inspection An on-site inspection includes an audit of records and documents related to the FSMP, such as CCP and SSOP monitoring records, corrective action records, calibration records, training records and verification documentation that are not reviewed during off-site records audits. The on-site inspection also consists of an evaluation and observation of the facility and FSMP procedures during production and interviews with management and personnel. On-site inspections may or may not take place when production is in progress.

Operating Limits Operating limits are criteria that are more stringent than a critical limit and that are used by an operator to reduce the risk of a deviation on a critical control point.

Periodic Review A Periodic Review is conducted to verify the procedures described in the FSMP Description. It includes a review of the basic components and each food safety management plan. It includes an assessment of whether procedures in the FSMP Description accurately reflect actual procedures and whether execution of the FSMP represents due diligence in providing the safest food possible. Required corrections or updates to the FSMP Description should be made immediately.

Process-Flow Description A Process-Flow Description includes a brief description of, the title of the person responsible for, and the time it takes to complete each step indicated in the Process-Flow Diagram.

Process-Flow Diagram A Process-Flow Diagram shows in simple block or symbol form the steps required to manufacture, store and distribute a food product.

Recall A recall is the retrieval of a product after it is in the channels of trade.

Record Keeping Requirement A record keeping requirement is any documentation required by an SSOP or any documentation related to monitoring requirements described in the food safety management plan.

Records Audit A Records Audit includes an audit of records and documents related to the FSMP, such as CCP and SSOP monitoring records, corrective action documentation, and verification documentation. It is conducted by an SCS inspector, and is generally completed off-site.

Records Review A Records Review is a review of CCP or SSOP monitoring records to ensure record keeping requirements are documented adequately, critical limits are not exceeded, and appropriate corrective action was taken if the criterion of a critical limit was exceeded. It is required for all monitoring records and is conducted on a periodic basis by assigned personnel at a facility.

Report of Findings A Report of Findings is a written report of deficiencies and recommendations noted during the application review and evaluation, initial on-site inspection, or maintenance audits. A company is required to respond to each item in the Report of Findings.

Risk Risk is an estimate of the likely occurrence of a hazard.

Sanitation Standard Operating Procedure (SSOP) A Sanitation Standard Operating Procedure is a special Standard Operating Procedure, which is specific to sanitation procedures.

Severity Severity is the seriousness of a hazard or deficiency.

Standard Operating Procedure (SOP) A Standard Operating Procedure is a document which describes in a step by step manner 1) how to operate a piece of equipment, 2) how to perform a particular phase of an operation, 3) general practices to be followed, and 4) record keeping and record review requirements.

SOP see Standard Operating Procedure.

SSOP see Sanitation Standard Operating Procedure.