

Food Supply Chain Handbook





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The information in this handbook should not be considered legal advice. For advice regarding the legal requirements applicable to supply-chain management, please consult your legal counsel.

Introduction

Today's food industry relies upon a web of inter-company relationships. Successful interactions among ingredient vendors, food contact packaging providers, re-packers, co-manufacturers, brokers and other suppliers are the precursors to effective food safety management. Resources devoted to knowing and building relationships with a company's suppliers represent sound investments.

Preventing the production and shipment of contaminated or adulterated food is heavily favored over reliance on corrective action plans once contaminated goods have entered distribution channels and subsequently the food supply. One responsible approach to ensuring the production of safe foods is to engage suppliers capable of providing ingredients, food contact packaging materials, and services that complement a company's food safety goals.

To aid companies in selecting valued business partners capable of supplying ingredients, food contact packaging and services that help to ensure the safety of foods, the Grocery Manufacturers Association (GMA) has provided this publication: *Food Supply Chain Handbook*. This reference manual represents a "tool chest" for companies in search of examples of successful management practices for suppliers. Not every example will be applicable for all suppliers. Companies should always implement those practices that will best serve the production of safe foods in their individual operations.

Food Supply Chain Handbook follows a typical procurement process by focusing on the critical aspects of selecting a preferred supplier.

Scope

The *Food Supply Chain Handbook* was developed for ingredient suppliers and service providers to the food industry in the United States. These practices could be applied internationally, but the focus of this information resource is on meeting U.S. regulatory requirements. Many of the provisions could apply to transporters, warehouses and brokers. Suppliers may want to consider the food safety programs referenced in this document as the foundation for a successful system designed to minimize the potential for product adulteration and contamination.



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Definitions

Broker: An agent that facilitates transactions between a buyer and seller. The broker may or may not take legal title to such items. It may purchase goods from producers or other brokers and re-sell them to US processors or other brokers.

Co-manufacturer: A co-manufacturer transforms food products but does not own the brand name, processes and/or specifications applied to the product. It is a supplier of finished goods typically on a contract agreement.

Customer: The receiving firm or company that will further process or redistribute into commerce. Also known as the *buyer*.

Distribution channel: A chain of intermediaries, each passing the product through the chain to the next organization, before it finally reaches the consumer or end-user.

Distributor: A company or individual who arranges transfer of goods between parties but does not produce food, feed or food-contact packaging.

Food Safety: Food that will not cause harm to the consumer when it is prepared and/or eaten according to its intended purpose.

Ingredients: For the purpose of this document, ingredients are considered to be food components. Ingredients also encompass the term “raw materials”.

Manufacturer: A manufacturer produces food products and owns the brand name, processes and/or specifications applied to the product.

Market Withdrawal: The removal from distribution of products that do not meet a company’s own quality standards or specifications, or in a technical but minor way violate federal or state law. Such products would not be subject to legal action by regulatory agencies.

Recall: The removal and/or correction of marketed products that are in violation of federal or state laws. If a company does not act to remove such products from the marketplace, regulatory agencies may take legal action to stop further movement of product into commercial channels.

Regulatory Agencies: Government agencies in the United States that have legal jurisdiction over foods. At the federal level the primary agencies are the United States Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA). State and local agencies may also have jurisdiction over foods in the individual locales where they are produced, stored and distributed.



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Re-packer: A business that re-packs products manufactured elsewhere.

Shipper: The party that institutes transportation of the product. The shipper is often identified on freight bills or bills of lading by terms such as “shipped by.” The shipper may or may not be the manufacturer, and can be a third party, especially in the case of broker transactions. The shipper may or may not be the transporter.

Supplier: A company that provides materials or products to another company. A supplier may include the producer, co-manufacturer, re-packer etc., of a food or food component.

Supply Chain: The system of organizations, people, activities, information and resources involved in producing and/or moving a food product to the customer.

Transporter, 3rd party: An entity who transports food, feed, feed ingredients or food-contact packaging from one place to another and is not owned by the producing or storage firm. Common modes of transport are truck, rail and ship. The transporter does not take ownership of the goods; it simply moves them from one location to another.

Acronyms

AOAC: Formerly known as the Association of Official Analytical Chemists, the organization is currently known as AOAC International.

APC: Aerobic Plate Count

BAM: Bacteriological Analytical Manual (FDA)

BOL: Bill of Lading

BT Act: Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (also known as “The Bioterrorism Act”)

CDC: Centers for Disease Control and Prevention (United States)

COA: Certificate of Analysis

COC: Certificate of Compliance

CFR: Code of Federal Regulations (United States)

FALCPA: The Food Allergen Labeling and Consumer Protection Act

FBI: Federal Bureau of Investigation (United States)



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FDA: Food and Drug Administration (United States)

FSIS: Food Safety and Inspection Service (United States)

GAPs: Good Agricultural Practices

GAqPs: Good Aquaculture Practices

GLPs: Good Laboratory Practices

GMA: Grocery Manufacturers Association

GMPs: Good Manufacturing Practices

LACF: Low-Acid Canned Foods

LOG: Letter of Guarantee

MLG: Microbiology Laboratory Guidebook (USDA FSIS)

MSDS: Material Safety Data Sheet

RTE: Ready-to-eat

TPC: Total plate count

USDA: United States Department of Agriculture

WIP: Work-in-process



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Supplier management

Today's food industry must strategically place greater emphasis on preventive measures for food safety and food defense. These measures will promote improved food protection capabilities throughout the food supply chain. Prevention requires that food safety be built in from the beginning generally via close interaction with suppliers, growers, manufacturers, distributors, service providers, and importers. The Food and Drug Administration (FDA) promotes companies implementing their own preventive approaches and to similarly require preventive measures of their suppliers.

In no area is the concept of a food chain more visible than in supplier management. Being able to identify a supplying firm's food safety strengths and weaknesses is an admirable achievement. However the value of this accomplishment is highly diminished if that firm has no knowledge of their supplier's food safety programs back through the chain. This chain, like all others, is only as strong as its weakest link.

With very few exceptions, supplying companies procure their ingredients from outside sources. All suppliers throughout the food chain may want to consider approval programs for their own suppliers consisting of a collection of appropriate programs, specifications, policies and procedures. Examples of such programs are described in this document.

Supplier Pre-assessment and Review

Prior to doing business with any supplier, it is often beneficial for companies to perform an initial supplier assessment and food safety programs review. Suppliers, co-manufacturers/re-packers and other members of the supply web should think about having programs in place to ensure compliance with customer food safety requirements. Nothing in these programs should supersede any requirements imposed by federal, state or local regulatory agencies. At their discretion customers may have requirements that are more stringent than those set forth by government agencies.

In conducting a pre-assessment, customers have a variety of methods at their disposal of which they may use one or all. Supplier inspection surveys, facility audits, product testing, and evaluation and review of product specification compliance are but a few of the approaches that could be employed. Whatever tactics are utilized, the assessment should be designed to provide a level of knowledge that programs are, or are not, present, effective and operating at a level that will ensure food safety, regulatory compliance and other quality assurance attributes. Many of these programs, which will be discussed in greater detail in other locations within this document, could include:



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Food safety and sanitation

- Evaluation of hazards, identification of control measures and monitoring for food safety controls
- Sanitation programs, including sanitation standard operating procedures (SSOPs), master cleaning schedules, pest control, and sanitation verification and validation
- Good manufacturing practices (GMPs), and documented work practices related to food safety not covered by regulations
- Environmental monitoring programs
- Foreign material control such as metal detectors, screens, filters, sieves and magnets
- Allergen control programs, including label design and label compliance

Preventative procedures

- Programs for controlling non-conforming product (hold and release)
- Recall programs facilitated by lot coding and product and ingredient tracing
- Food defense program
- Crisis management program
- Management of re-worked and returned product(s)

Other

- Supplier management
- Development of and compliance to specifications
- Processes developed by recognized process authorities for low-acid canned foods (LACF) and acidified canned foods
- Product testing of incoming goods, work-in-process (WIP), and finished goods.
- Documentation and records management.
- Procedures dealing with visits by regulatory agents
- Employee training

Change Control

Change control aims to ensure that all changes are assessed and approved by management before their implementation. Change control attempts to ensure that standardized methods and procedures are used for efficient and prompt handling of all changes to the food safety system, in order to minimize the impact of any related modifications to supplied items.



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Suppliers may want to consider notifying customers of any proposed changes in formulation, ingredients, production facilities or processes and supply sources that could affect the food safety or regulatory compliance of the ingredients provided to customers. Suppliers may want to look into having multiple avenues of communication with customers available in order to facilitate this objective (e.g., appropriate phone numbers, alternate contacts, cell phone numbers, emails, and home phone numbers).

Relatively simple changes in ingredients can often have major changes in operations. If not managed and promptly communicated between suppliers and customers, major consequences can ensue. For example:

- Ingredients sourced from different countries may be subject to:
 - Different standards for allergen labeling (e.g., sesame in Canada)
 - Different standards of adulteration (e.g., citric acid in fruit juice concentrates)
 - LACF process authorities not recognized in the U.S.
 - Different standards for chemical residues or pesticides
- A change in an ingredient supplier could result in an item being sourced from a factory with marginal food safety programs versus exemplary ones
- Changes in process machinery or methods could affect sanitation procedures for new machinery that may not be validated for elimination of microorganisms or allergenic residues
- Changes in ingredients could affect:
 - Heat penetration and commercial sterility (starches)
 - Water activity (brines, solids content)
- Required changes in finished product country-of-origin labeling (juices)

The level of notification needed for change control can vary from supplier to supplier. Items such as level of trust, food safety implications of the particular ingredient, and past or recent history of the ingredient, among other issues, can affect the requirements for notification.



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Documentation and Recordkeeping

Documentation is needed to substantiate all appropriate food safety and quality programs. Programs should be well defined; responsibilities and authorities should be designated and assigned to appropriate individuals. Suppliers may want to periodically review program documentation to ensure that it reflects current practices. The language of each document should be appropriate for the end user.

Suppliers should consider employing formal, written procedures to control all documents and data. Companies may want to have obsolete information suitably identified, archived, and retained according to current supplier procedures. Another effective procedure is having documents reviewed and approved for adequacy by authorized personnel prior to issue, and having such document updates indicate the version and effective date. Ongoing change logs are also an option. Having a written record retention policy in place for food safety documents, both records and supporting documentation is another useful procedural tool. Suppliers may consider retaining records for at least the market life of the product or as mandated by regulation.

Generally, companies may want to consider having food safety processing records reviewed before any product represented by those documents has left the manufacturer's control. Having the records reviewed promptly, signed or initialed, and dated is an effective protocol. Companies may want to consider having the persons reviewing records receive or possess appropriate training to understand the food safety implications of the data contained in the records. Records and documentation should generally be available for review and audit upon request by regulatory agencies or the customer.

Supplier Documentation (Letters of Guarantee, Certificates of Analysis, etc.)

At times, suppliers may find it necessary to issue timely documentation to customers. Common documents at times requested by customers to maintain food safety programs with suppliers are a Letter of Guarantee (LOG), also known as a Continuing Commodity Guarantee, a Certificate of Analysis (COA) and a Certificate of Compliance (COC).

LOGs are often required of suppliers prior to doing business with a customer. The LOG typically states that products provided to the customers meet all governmental requirements as mandated by the Federal Food Drug and Cosmetic Act, including the current Good Manufacturing Practices (21 CFR 110), the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act, as appropriate. Individual customers may require additional language to cover the labeling, safety, general wholesomeness and sanitary conditions under which the products were produced.



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Another form of documentation often required of suppliers is a COA. These documents address major analytical parameters for the specific foods, or lots, contained in a specific shipment, or other analytical information needed by the customer. COAs are often required prior to product arrival at a customer's facility.

COCs often state that the goods were manufactured in compliance with specific regulations, that control points and/or prerequisite programs were satisfied, a customer's specification was met, or that no deviations from required parameters occurred when the products were produced

Suppliers may be asked to meet customer requirements for LOGs, COAs and COCs. Accordingly, suppliers may want to have programs in place to address specific parameters designated by customers as required in a COA/COC in a timely manner, and consider developing procedures for ensuring results that are meaningful, accurate and representative of lot quality. Recognized analytical methods and statistically valid sampling plans are recommended. In some cases, customers may require approval of outside labs and analytical methods. While requirements will depend on the material involved, its specification(s), site-specific procedures, and specific customers, information included on a COA could include amongst other specifics:

- Full description of the commodity
- Name of supplier
- Lot number(s) for products in the shipment
- Customer's specification number
- Date of production
- Whether testing was done in-house or by an outside lab
- Date product was shipped
- Quantity of product covered by the COA (e.g., 40 cases at 70 lbs. each)
- The specification to be met
- Results of chemical, physical, and/or microbiological analyses
- Methods of analysis (method number from AOAC, FDA BAM, FSIS MLG, etc.)
- Descriptions of sampling plans used to generate results contained on the COA
- Signature of analyst or person issuing the COA

Customers, in turn, are not required to immediately accept an LOG, COA or COC at face value. Confidence in the accuracy of such documents should be developed over time. Utilization of many of the items discussed in this text can be used by customers over time to authenticate documentation furnished by the supplier.



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Auditing

Internal (Self) Audits: Suppliers may want to contemplate having a formal, documented internal audit program designed to constantly monitor/improve its operations by identifying food protection issues (safety/defense) and sanitation deficiencies. These self-assessments can be performed by internal personnel or by a hired first party auditor. If internal personnel are utilized, the employee should probably not work in the particular area he/she is assessing. Suppliers may want to consider having self-assessments be performed by trained employees and said training could be documented to allow for verification. Not only could the self-assessment be documented so as to provide verification that they are being performed, but it may also be helpful to have any and all corrective actions that are performed for non-compliances discovered during a plant's self-assessment documented as well. Consider having the corrective action contain information showing who was responsible for performing the corrective action and who verified that the corrective action was performed.

These systematic, regularly scheduled audits might consist of both GMP inspections and quality system checks. Self-assessments could include the following areas at a frequency based on risk and history of compliance:

- Quality and food safety system effectiveness reviews
- Reliability of reporting and documentation systems
- Plant inspections against GMPs

Responses by management to self-assessments can be assessed during a second or a third party audit. Identified, open issues that have no rationale for remaining open can affect a plant's outcome during a customer audit.

External (second/third party audits) Many customers may choose to audit a supplier by using an employee of the company (second party auditing) or a qualified third party auditing firm (independent auditor). Third party auditors do not work for the supplier or the customer; they are independent, hence the term "third party." Moreover, a supplier may choose to voluntarily undertake a detailed third party audit of their own accord.

If third party auditing firms are used, one may request an auditor experienced with the food commodity item that the supplier produces. It is beneficial if the individual auditor and the certification body (audit company) are certified according to a recognized international standard. A supplier interested in selecting a reputable third party audit company should consider making sure that said company has the following elements in place:

- Quality systems programs and reviews
 - Shadow audits by a seasoned auditor with the particular expertise in the product/process the auditor is inspecting



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- Review reports
- Follow-up surveys
- Review programs
- Auditor Competency and Other Considerations
 - Education/experience
 - Verification of expertise
 - Continuous improvement/education
 - Lead auditor assessor training
 - Advanced HACCP training
 - Minimum 120 hours of auditing within expertise per year
 - Listens to suppliers and customers
 - Adjusts to new issues rapidly

When customers require a third party audit, the supplier generally ensures that the third party auditing firm and the specific auditor are acceptable to the customer.

Whether the audit is internal or external, suppliers should attempt to promptly respond to audit findings, especially those that impact the safety of the product. Customers will likely expect documented corrective action plans and preventive measures to any identified issue(s) made during the audit.

Regulatory Compliance

A supplier's regulatory compliance programs should be designed to demonstrate the ability to meet all federal state and local requirements, for products destined for the U.S. commercial markets.

Suppliers should strive to be able to provide documentation that all appropriate registrations have been completed and are current; for example, the US registration requirement defined in the Bioterrorism Act (see Food Defense) and any other necessary registrations, such as for LACF and acidified canned foods.

Suppliers may consider establishing procedures for handling regulatory inspections. These procedures could address which specific person(s) are to be delegated to accompany regulatory personnel. Company policy regarding photographs, copying of records and the taking of samples is generally spelled out in these type of policies.

Food Defense

Suppliers should be able to provide written confirmation of facility registration as required by the U.S. Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the BT Act). Facilities regulated exclusively throughout the entire facility by the USDA are exempt from registering. Additional information on the BT Act, including



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requirements for prior notice of imported foods and FDA administrative detention of foods, can be found at <http://www.fda.gov/oc/bioterrorism/bioact.html>. On-line registration can be done at <http://www.cfsan.fda.gov/~furls/ovffreg.html>.

In addition to compliance with the BT Act, suppliers may want to have documented, established food defense plans to ensure that their manufacturing site(s), grounds, employees, record keeping, and inbound and outbound traffic are in compliance with guidance from FDA and USDA:

USDA FSIS Security Guidelines for Food Processors

(<http://www.fsis.usda.gov/OA/topics/SecurityGuide.pdf>)

FDA Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance (<http://www.cfsan.fda.gov/~dms/secgui14.html>)

FDA and USDA have embraced the CARVER assessment in addressing food defense and emergency response. This document can be viewed at <http://www.cfsan.fda.gov/~dms/carver.html>

Suppliers and transporters shipping goods across borders into the US should consider becoming C-TPAT (Customs-Trade Partnership Against Terrorism) certified. C-TPAT is a joint government-business initiative to build cooperative relationships that strengthen overall supply chain and border security.

http://www.cbp.gov/xp/cgov/import/commercial_enforcement/ctpat/

Foundation programs for a comprehensive food defense program, where appropriate, could include:

- A documented, comprehensive food defense assessment conducted for each facility using at least one of the above publications as a guide. This assessment is repeated at a frequency sufficient to maintain the integrity of the food defense program.
- The food defense plan requires that security breaches be reported to upper management.
- Protection of data systems using passwords, firewalls and effective back-up systems.
- Routine, documented food security inspections.
- Inbound and outbound trucks, tankers and railcars are sealed. The seal numbers, where applicable, are recorded on shipping documents.
- Procedures to restrict employee access to the facility in general, or to individual departments inside the facility.
- Programs to ensure the identification, segregation and security of products involved in the event of deliberate product contamination.
- Requiring advance notification for all ingredient deliveries.
- Procedures to identify and restrict access by visitors, contractors, service providers, truck drivers and other non-employee personnel.
- Restricted access to ports or pipelines used in the receipt of bulk ingredients.



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- Less-than-truckload shipments could be secured by use of seals or locks.
- Food defense tools such as picture IDs, guard service, cameras, exterior lighting, and self closing doors.
- Background checks on full time, part time, temporary and seasonal employees.
- Communication of food defense requirements to visitors.
- Documented corrective actions for food defense vulnerabilities when revealed through management assessments.
- Documentation of employee training in food defense.

Sanitation Programs

Suppliers should consider having a comprehensive, written sanitation program in place. Sanitary conditions assure the production of unadulterated and safe food, as well as enhance product quality and shelf life. As with many other programs, a strong commitment by management to sanitation and providing proper resources, including funding, personnel, materials and equipment assists in facilitating proper sanitation.

There are a number of sanitation regulations for food processors. Minimum sanitation requirements have been promulgated by FDA for food establishments in the current Good Manufacturing Practices (cGMPs; 21 CFR 110 <http://vm.cfsan.fda.gov/~lrd/cfr110.html>) and by USDA/FSIS for meat and poultry establishments (9 CFR 416; http://www.access.gpo.gov/nara/cfr/waisidx_07/9cfr416_07.html). Requirements for written sanitation standard operating procedures (SSOPs) and for sanitation monitoring have been issued as part of the requirements in conjunction with USDA/FSIS HACCP regulations for meat and poultry products (9 CFR 416.11 – 416.17). HACCP regulations by FDA for fish and fishery products (21 CFR 123.11) recommend written SSOPs. HACCP regulations for juice products (21 CFR 120.6) do not require written SSOPs, but do require sanitation monitoring. Suppliers should endeavor to be fully compliant with these regulations where they apply.

Sanitation is not limited to equipment cleaning. While clean facilities and equipment are essential for the production of safe and unadulterated foods, there are many other components necessary for a comprehensive sanitation program, which can be considered when creating written SSOPs. Some of these are:

- A safe supply of potable water
- Sanitary design of facilities and equipment
- Protection of food, packaging materials, and food contact surfaces from adulteration with lubricants, pesticides, cleaning agents and other non-food compounds
- Proper labeling, storage and use of cleaning compounds, pesticides and other potentially toxic chemicals
- Pest control



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- Pre-operational sanitation controls
- Operational sanitation procedures
- Prevention of cross contamination through defined traffic patterns, usage of different color smocks or utensils for certain areas, etc.
- Control of employee health conditions
- Proper personnel hygiene practices
- Corrective actions
- Documentation and record keeping
- Verification procedures such as environmental monitoring or ATP testing

Food Safety

Industry has the responsibility to prevent and control food safety issues that can negatively impact consumers. Enhancing consumer confidence can best be achieved through proper development and implementation of effective food safety programs. Food safety practices and procedures that concentrate on prevention and anticipation of problems can be designed to locate potential problems before they manifest themselves as finished product consequences. Avoiding the production and shipment of tainted goods is significantly preferred over reliance on remedial procedures once contaminated goods have entered distribution channels.

Ingredient suppliers and other members of the supply chain (co-manufacturers/re-packers, transporters, warehouses etc.) may want to consider having a risk-based food safety system implemented at their place of business. At the very minimum, these parties should contemplate providing written verification that a documented, comprehensive evaluation to identify potential biological, chemical, and physical hazards in the process stream has been conducted and that effective measures are in place to control them. By comprehensively reviewing food supply vulnerabilities and developing and implementing risk reduction measures, potential critical issues can be minimized.

Risk reduction tools could include:

- Hazard evaluation, control and documentation programs similar to, or including, HACCP.
- Control programs derived from the risk evaluation with scientifically validated limits, where possible.
- Compliance with these controls that are documented and routinely verified.
- Records substantiating the daily performance and the technical foundation of the food safety program that are maintained, reviewed regularly and readily available for examination.
- Compliance with critical processing parameters that are verified before the product leaves the supplier's control.
- Technical references could be made available to support the selection of control parameters.



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- Monitoring procedure frequencies that are logically justified as adequate to control targeted hazards.
- Suppliers could provide documentation showing that all pertinent personnel have received training in food safety system requirements.

In some cases customers may wish to ensure that food safety plans have been reviewed or validated by a qualified third party. If companies desire to employ third party auditing programs, they should know the specific auditor and his/her qualifications to conduct detailed food safety reviews. For further information on third party reviews, see the section on auditing above.

Employee training

A major portion of the success of food safety programs relies on programs that provide education and training of employees, including management, in the importance of understanding and following their assigned tasks. Without a complete understanding of the purpose of the programs and each individual's role, the programs are not likely to succeed. Training is particularly important in operations where personnel changes occur frequently.

Suppliers should consider having programs in place to ensure that all full time, part-time, contract and temporary employees have received appropriate food safety training. Management may want to recognize that cultural and educational differences could require specific training programs for divergent populations. For example, management training programs would be different from those programs used for minimally educated line workers with marginal English language skills.

Supervisors and managers in food production plants could be educated in each of the following key areas where applicable to the product:

- Food safety, including identification of hazards and successful management of programs to control those hazards
- Proper food handling, storage, and distribution
- Maintenance and sanitation of facilities and equipment
- Environmental monitoring
- Personal hygiene
- Temperature control
- Food allergens management
- Pathogen control
- GMPs applicable to certain agricultural operations
- HACCP, where applicable.



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Effective training needs the backing of management. Management may consider adequate resources, both financial and otherwise, for thorough education and training. Generally, personnel should be given refresher training on a regular basis. Training effectiveness can be verified through competency testing, job shadowing, self assessments, audits or other effective techniques.

Companies may consider having food processing employees trained in basic GMPs/food hygiene prior to beginning employment. Management may also consider having these employees receive refresher training on a regular basis. Other training requirements for non-management, non-supervisory employees could be established, implemented and maintained.

Food safety systems mandated through regulations often contain specific training requirements. HACCP regulations that stipulate the individual developing, reassessing and modifying the HACCP plan must have successfully completed a course of instruction in the application of HACCP principles include:

- 21 CFR 120.13 for juice products
- 21 CFR 123.10 for seafood products
- 9 CFR 417.7 for meat and poultry products

Operators of processing systems covered by the following regulations are required to be under the supervision of a person who has successfully completed a curriculum recognized by the regulatory agencies as being adequate that covers critical parameters for specific preservation technologies, including container closures. For further information see the personnel sections of these regulations.

- LACF (21 CFR 113) (FDA)
- Acidified foods (21 CFR 114) (FDA)
- USDA meat canning regulations (9 CFR 318, subpart G)
- USDA poultry canning regulations (9 CFR 381, subpart X)

Environmental monitoring

The purpose of an environmental monitoring program is to verify the effectiveness of overall sanitation and the effectiveness of programs in place to minimize the risk of post-processing contamination by pathogens. Any such control program should generally be commensurate with the risks presented by the product and the processing and packaging environment. Suppliers may want to consider assessing their individual processing situations to determine if environmental monitoring is appropriate and take the necessary steps to incorporate it in those situations where warranted. In addition to testing the environment for pathogens, evaluation of general sanitation effectiveness may include the use of techniques such as swab testing for indicator organisms such as total aerobic plate count (APC or TPC) or swab testing for organic residues such as ATP testing.



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Environmental monitoring may be used as an effective tool to verify programs targeting post-processing contamination with pathogens. For example, environmental monitoring can be used to verify the effectiveness of a *Listeria* control program in ready-to-eat (RTE) products that are exposed to the environment and will not receive additional lethality treatment before consumption. Contamination of cooked RTE foods with pathogens such as *Listeria monocytogenes* is largely a consequence of transfer from the processing environment rather than survival of the organism present in raw materials. Environmental monitoring also has been used to verify the effectiveness of programs to address the potential for recontamination of low moisture products from the processing environment with *Salmonella* (e.g., spray dried milk, dry cereal, peanut butter and other low moisture, low water activity foods) or *Enterobacter sakazakii* (e.g., powdered infant formula).

For products amenable to USDA/FSIS inspection, RTE products are subject to the requirements of 9 CFR 430.4, Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products (http://www.access.gpo.gov/nara/cfr/waisidx_07/9cfr430_07.html) Suppliers producing RTE meat and poultry products should review this regulation in considerable detail.

A written SOP can be developed for the environmental monitoring program(s), including sampling locations, frequency, sampling methods and corrective actions when positives or values in excess of pre-established thresholds are found. Maintaining appropriate records as necessary can assist in judging the effectiveness of the program, identifying the root cause of sanitation failures, and documenting corrective actions.

Allergen Control

Managing allergens during the processing of food products is an issue of great importance. Suppliers and transporters may want to consider having effective programs in place at each business location to prevent cross contact and the inadvertent inclusion of major allergenic proteins in food products where they are not labeled as present. Suppliers must be diligent in informing customers regarding the presence of regulated allergens in product formulations.

The list of allergens currently used by the FDA and USDA to prioritize regulatory enforcement actions contains milk, eggs, fish, crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts, peanuts, wheat, and soybeans. Suppliers to companies should consider being knowledgeable of, and having control programs to address, requirements for allergens as designated by the regulatory bodies at the point of ingredient use. Certain countries outside the U.S. have requirements for allergens that go beyond the eight substances listed above. Co-manufacturer/re-packers often have responsibility for legal label compliance regardless of who has provided them with labels. Suppliers must meet all regulatory requirements when labeling for allergens.



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Avoiding cross contact with allergens and proper labeling of foods that contain allergens are the two main goals of any allergen control program. Accordingly, it is important to establish appropriate policies and procedures as well as provide for an infrastructure that will facilitate management of allergens so there are no undeclared allergens in products. While each operation will have its own unique situations, components of successful allergen management programs typically can be classified in four categories: Controls to minimize the potential for cross contact, management of work-in-process (WIP) and rework, administrative and management functions, and label control programs. Each of these categories can contain many sub-components depending on the individual operation. For details regarding label controls, see the Label Control Program and Consumer Packaging section below. For further detail see GMA's "*Managing Allergens in Food Processing Establishments*." Other facets of a well-managed allergen control program could include:

- Standard operating procedures (SOPs) to address allergen control activities, including the staging, warehousing and scaling of allergenic ingredients to prevent cross contact with non-allergenic ingredients
- Lists or maps of allergenic ingredients, their locations and likely traffic patterns
- Validated "allergen-clean" sanitation and/or changeover procedures
- Control of factory air flow
- Sanitary design of equipment and facilities
- Avoidance of cross contact through physical barriers, control of traffic patterns and other means
- Traceability of rework and WIP components
- Use of rework only in "like to like" products, through use of a formula matrix
- Production scheduling to minimize changeovers and potential cross contact
- Monitoring and verification of allergen control procedures
- Documentation and record keeping

Foreign Material Control

A variety of devices appropriate to individual operations are available to suppliers to limit the presence of foreign materials. Suppliers may want to consider the use of these devices where appropriate and useful to minimize the potential for product to contain foreign material. Foreign material control devices should where necessary, be placed in the process flow in the location(s) where they will have maximum product protection and effectiveness. Control devices should be routinely calibrated and checked.

Foreign material control devices and guidelines for their effectiveness could include:

Metal detectors

- For end product testing or located as close as practical to end product packaging



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- With an automatic reject or conveyor stopping mechanism and an alarm where appropriate
- Calibrated for effective rejection of product containing metal the time of installation and tested during production to ensure rejection of appropriate test pieces

Magnets

- Of rare earth construction
- Tested for effective placement, coverage, and pull strength at the time of installation and routinely thereafter

Filters

- Checked for breakage and proper placement

Screen/Scalper/Sifters

- A mesh size that is the smallest possible that does not restrict product flow
- Inspections to assure their integrity

Other foreign material control devices could include:

- Cyclones
- Tilt tables
- Flotation or water tanks
- De-stoners
- Optical sorting equipment
- Strategically placed protective line covers
- Bottle/jar washers, inverters, rinsers and other pre-filling clean-out devices
- X-ray or other vision control systems

Operations packing in glass could have appropriate machinery identified above as well as adequate procedures in place to considerably limit the breakage of containers and the potential for contamination of products by glass fragments. Components of a thorough and comprehensive glass control program could include:

- Verification of incoming glass quality
- Proper design of conveyors and transfers to minimize pressure exerted on bottles and jars.
- Rinser validation studies
- SOPs for both accidental and intentional bottle/jar breaks (e.g., to clear a machinery jam)
- Employment of glass-free zones in manufacturing areas



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Label Control Programs and Consumer Packaging

Suppliers may have internal or external programs to deal with label development, label control and proper labeling during operations. Label controls include safeguards to ensure that each container has an accurate label that meets all applicable laws and regulations. Two important aspects of label management include controls for design and for inventory.

Design Controls

Suppliers of food labels and pre-printed packages may want to consider having procedures in place to ensure accurate fulfillment of label design orders from their customers. Procedures may include these elements:

- Orders in writing for art work and labeling copy
- Sufficient knowledge of regulatory requirements, including declaration of allergens, to ensure compliant label and package designs
- The use of commonly understood terms in consumer friendly language for all allergenic ingredient declarations (e.g. milk, not whey or casein).
- Design and copy proofreading
- Written approval of label and package proofs
- Identity coding (color and/or numerical) of printed labels and packages
- Shipping of labels and pre-printed packages that minimize co-mingling.

Suppliers may wish to discuss with customers about providing detailed written specifications for label and package art work and copy. Customers may want to make label content decisions before ordering label and package design services. Suppliers may request that customers transmit label copy to design services so that re-keying of the text is minimized.

Inventory Controls

Suppliers of food products in labeled or pre-printed packages should manage label and pre-printed package inventory to avoid product labeling errors. Label and package inventory control could include the following elements:

- Physical storage of labels and pre-printed packages that minimizes mixed label batches and co-mingling with other labels and packages
- Sufficient knowledge of regulatory requirements to ensure labels and pre-printed packages are compliant
- Procedures to check labels and pre-printed packages prior to and during production and labeling operations
- Procedures to ensure labels match products in production and/or labeling operations



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- Procedures to document label use and reconcile label and package inventory changes
- Procedures to isolate and destroy obsolete or non-compliant labels and pre-printed packages in a timely manner to eliminate the risk that they may be mistakenly applied to current production or diverted for use by a third party (counterfeit goods)

In the US, packaging materials, be they rigid, flexible, metal, glass, paper, plastic or other material, are considered “indirect food additives” by FDA and should be appropriate for the specific food product. If a food-contact packaging material imparts odor or taste to a specific food product it could be considered unfit under the Federal Food Drug and Cosmetic Act. Also, 21 CFR 174.5(a) (2) states “any substance used as a component of articles that contact food shall be of purity suitable for its intended use” (<http://www.cfsan.fda.gov/~lrd/FCF174.html>). Further information may also be found in sections 21 CFR 170.39 and 21 CFR 174.6

Labels controls for ingredient and industrial packaging

Ingredient containers should where required, be clearly marked with the name and address of the manufacturer, packer, or distributor; product labeling information such as declaration of ingredients and nutrition information; production lot code; net contents; date of processing; and identification of allergens present. The preferred manner of production date coding is a code in the format of a calendar (e.g., 07/15/08, 03 Dec 08, or similar), also known as an open date code. Bulk shipments should contain this information on the shipper’s Bill of Lading (BOL).

Product and ingredient tracing

At minimum, suppliers and transporters should consider their ability to trace back and track forward the movement of ingredients and finished goods through the supply chain. Being able to locate where all ingredients, including food contact packaging, came from and where all finished goods were sent may be useful in the event of a recall or crisis. The Bioterrorism Act mentioned above mandates that all members of the food chain shall be able to trace goods one step forward and one step backward, as well as know the shipper/transporter of the goods. Those who cannot perform these duties can be found in violation of the BT Act.

Despite the challenges associated with products and/or ingredients moving through a broker or other distribution channels, suppliers could attempt to define those who have had prior physical possession of the ingredients and/or products used in their manufacturing process. Specifically, as outlined in the Bioterrorism Act, when purchasing ingredients through a broker, suppliers shall have programs to define the physical location from which their ingredients were shipped as well as the shipper/transporter. Just knowing the name



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and the P.O. Box address of the brokerage that provided the ingredients would not be sufficient in this regard. Just knowing that the ingredients were shipped by truck, but not having the name and address of the trucking firm, would also be inadequate.

Companies may want to verify the similar programs exist at upstream suppliers to extend the traceability of product throughout the supply chain. Suppliers should also consider having programs in place to thoroughly trace rework and WIP through their processing system.

One method of facilitating proper and effective tracing is for suppliers to have a lot coding procedure for all finished goods. The lot code can identify the product and the date manufactured. Coding that breaks down the manufacturing information into smaller segments, e.g., time periods, may be a regulatory requirement (LACF, acidified foods, infant formula). Coding information, including lot codes and the number of units belonging to each lot code, may be included on the shipper's BOL. For bulk shipments, information including lot codes, the contents of the bulk shipper (including weight or gallons), manufacturer, shipper and point of origin should be included on the BOL.

Product Testing

Suppliers should consider having in place an analytical testing program designed to assure conformance to specifications, achieve regulatory compliance, and verify control programs. Analytical testing may be performed by the supplier's in-house laboratory or contracted to an outside testing laboratory. Testing programs, which can apply to ingredients, WIP and finished goods, can be risk-based and take into consideration how product will be ultimately used.

Laboratories conducting testing generally follow standard practices for sampling and testing and have controls in place, including equipment calibration as appropriate, to ensure the accuracy of their results. Testing may employ a recognized methodology, such as prescribed by AOAC (<http://www.aoac.org>), the FDA Bacteriological Analytical Manual (BAM, <http://www.cfsan.fda.gov/~ebam/bam-toc.html>), the FSIS Microbiology Laboratory Guidebook (MLG, http://www.fsis.usda.gov/Science/Microbiological_Lab_Guidebook/index.asp) or other recognized methodology. Laboratory activities should generally conform to standards for Good Laboratory Practices, (<http://www.nal.usda.gov/awic/legislat/21cfr97.htm>).

For in-plant laboratories, a strict set of controls to prevent cross contamination of pathogens from the lab to the processing environment should be considered. Ideally, laboratories for manufacturing facilities should not be located in the same building as processing activities. In cases where this is not practical, companies may want to consider having laboratories that:

- Have negative air flow and separate drainage
- Exclude processing employees



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- Not open directly into processing, staging or storage areas
- Maintain other controls as necessary to avoid jeopardizing product

Where laboratory personnel must enter the processing environment, e.g., to take samples, controls should be in place to ensure they do not serve as a source of contamination.

To ensure accuracy of testing methodologies, suppliers or their outside testing laboratories may want to participate in programs where a third party provides unknown samples to the supplier's laboratory. The laboratory analyzes the samples and returns the results, in confidence, to the administrative third party, who in turn informs the supplier whether the results generated are accurate or not.

All products associated with the testing of pathogens, either direct product testing or environmental monitoring of food contact surfaces, can be placed on hold until written confirmation of an acceptable result is received. Suppliers need to consider whether the testing impacts more than one lot of product as a result of the use of a common ingredient, rework or other factors.

Control of non-conforming product (hold and release)

Suppliers may want to consider having clear procedures for the segregation and control of non-conforming ingredients, WIP and finished products. These procedures could include a variety of detailed documentation, which may address:

- Complete description of the non-conformance: date, time, quantity, lot code(s)
- Reason for non-conformance
- Product disposition (when known)
- Corrective actions commensurate with the seriousness of potential risk
- Tracking of non-conforming product



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Consumer Complaints

A formalized written program for evaluating consumer complaints, particularly those related to adulteration, should be considered by all suppliers. The company may want to have a program with a protocol for determining when, what and how information should be disseminated. Complaint information and trends could be used to avoid recurrence and implement ongoing improvements to product safety and quality. Actions appropriate to the seriousness and frequency of complaint issues could then be carried out promptly and effectively.

Recalls and Market Withdrawals

Suppliers and transporters should consider having a written and effective recall program as evidenced by mock recalls and/or an actual recall. Timely communication is expected of any inherent product risk (up/down the supply chain). In the case of co-manufacturers/re-packers, the company who owns the product label should generally be notified immediately when a recall or withdrawal is to take place.

Recalling products from the marketplace is a complicated and detailed procedure. Having a written, detailed plan on how to handle such an event will be invaluable if the occasion arises when a recall must take place. Thorough and comprehensive recommendations can be found in GMA's "*Successfully Managing Product Recalls and Withdrawals*," other trade association publications, and government resources.

Recalls or market withdrawals can be necessary for a variety of reasons.

- Product contamination (biological, chemical or physical)
- Packaging defects
- Residues of illegal pesticides, drugs or color or food additives
- Product components containing an unlabeled ingredient, especially if that ingredient is an allergen or sensitizing agent (e.g., sulfites)
- Misbranding
- Illness identified by state health departments or the Centers for Disease Control and Prevention (CDC)

Mock or practice recalls can be considered as well. Mock recalls test both trace back and track forward scenarios. Management may consider holding follow-up meetings to assess the effectiveness of the practice recall and establish improvement goals to enhance future recall effectiveness. Records of these meetings could be documented for future use. A mock recall of an ingredient, including food contact packaging, from receiving through the first level of shipping in a processing plant, may aim for accounting of 100% of the target material in less than 4 hours.



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Regulations on FDA-related recalls are found in 21 CFR 7, http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr7_07.html. Further information on FDA recall policies can be found at <http://www.cfsan.fda.gov/~lrd/recall2.html> and guidance to the industry can be found at http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm. USDA Food Safety and Inspection Service (FSIS) recall guidelines are covered in FSIS Directive 8080.1, <http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4.pdf>

Crisis Management (other than recalls and market withdrawals)

For the purpose of this publication a crisis is defined as any unforeseen event that would render the product(s) unsafe or adulterated. Crisis management includes the assessment by the crisis management team of which potential crises could affect a facility, written and practiced procedures to deal with those crises, and availability of resources necessary to deal with a particular crisis at the time it occurs. Common contingency planning could include detailed plans, including disaster recovery plans, to deal with:

- Leak of ammonia refrigerant that could affect product
- Facility fire and subsequent smoke damage of product
- In-transit accidents that may result in product adulteration
- Destruction of facility due to hurricane, tornado, flood, or other weather-related disasters
- Discovery of carcinogenic compounds such as asbestos in a processing area
- Fire sprinkler system malfunction, resulting in water damage to product
- Threats, suspected sabotage or tampering threats, both internal and external
- Power failures

Successful components of a comprehensive crisis management program, where appropriate, could include:

- Management commitment of resources, monetary and otherwise
- Employee training, including practice drills
- Immediate communication with customers when conditions arise that may indicate necessary removal of a product from the marketplace and/or distribution channels
- Emergency contact numbers for:
 - The local Federal Bureau of Investigation (FBI)
 - Key service providers (e.g., refrigeration contractors, boiler service)
 - Key management personnel
 - Food regulatory agencies
 - Utility providers



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- Local fire, police and ambulances
- Specific first aid training to deal with identified potential crises

Suppliers are encouraged to have a system that would allow access to duplicate records within 24 hours when a crisis makes the originals inaccessible.

Other preventive control programs

Suppliers and transporters may find that their individual needs mandate requirements that are not mentioned previously. They should be at liberty to implement other preventive programs as they see fit. As with many of the other programs mentioned in this document, it is important that miscellaneous food safety programs be supported by management and be given adequate resources, be documented, be periodically reviewed to ensure they remain relevant, have appropriate record keeping procedures and have properly trained employees.

For foods sourced directly from farms, Good Agricultural Practices (GAPs) (<http://www.cfsan.fda.gov/~dms/prodguid.html>) offer guidance on microbial food safety hazards and other good agricultural and management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form. This voluntary, science-based guidance can be used by both domestic and foreign fresh fruit and vegetable producers to help ensure the safety of their produce. GAPs are revised periodically to reflect new information. Suppliers should attempt to follow the most recent recommended practices.

Additionally, commodity specific GAPs are also available for

- Tomatoes (<http://www.cfsan.fda.gov/~acrobat/tomatsup.pdf>),
- Melons (<http://postharvest.ucdavis.edu/datastorefiles/234-571.pdf>),
- Lettuce and leafy green vegetables <http://www.cfsan.fda.gov/~acrobat/lettsup.pdf> and (<http://www.caleafygreens.ca.gov/docs/resources.asp>)
- Sprouted seeds (<http://www.cfsan.fda.gov/~dms/sprougd1.html>).

All suppliers of agriculturally-based products may want to consider having a program in place that protects against the use of unapproved pesticides or excessive residues of approved pesticides on the products they supply. Components of a successful program could include:

- Grower/broker education as to the proper use of registered pesticides
- Applying pesticides by licensed applicators only
- Appropriate record keeping for pesticide applications, including pesticide applied, EPA registration number, formulation, amount, location, date, pre-harvest interval, target pest and applicator's name with certification number



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- Approved pesticide lists, including Material Safety Data Sheets (MSDS) or label information
- Verification of compliance through the use of pesticide testing on ingredients and finished goods
- Issuance of COAs to customers containing the results of pesticide testing (see sections on Supplier Documentation and Laboratory Control Programs)

Growing world demand for seafood will require the aquaculture industry to double in size by the year 2050. In order to achieve this growth, food safety needs to become an integral part of the aquaculture structure. Good Aquacultural Practices (GAQPs) are described at the following location: http://www.jifsan.umd.edu/gaqps_man.html. Suppliers of aquaculture-produced seafood should be familiar with these recommended practices.

Resources/References

Governmental Citations

9 CFR 318, Subpart G, beef canning regulations:
http://a257.g.akamaitech.net/7/257/2422/14feb20071500/edocket.access.gpo.gov/cfr_2007/janqtr/9cfr318.310.htm

9 CFR 381, Subpart X, poultry canning regulations:
http://www.access.gpo.gov/nara/cfr/waisidx_07/9cfr381_07.html

9 CFR 416, USDA Sanitation Performance Standards;
http://www.access.gpo.gov/nara/cfr/waisidx_07/9cfr416_07.html

9 CFR 417 Hazard Analysis and Critical Control Point systems, USDA:
http://www.access.gpo.gov/nara/cfr/waisidx_07/9cfr417_07.html

9 CFR 430.4, Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products (http://www.access.gpo.gov/nara/cfr/waisidx_07/9cfr430_07.html)

21 CFR 7, FDA related recalls,
http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr7_07.html

21 CFR 11, Electronic Records, Electronic Signatures:
http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr11_07.html

21 CFR 110 Current Good Manufacturing Practices;
<http://vm.cfsan.fda.gov/~lrd/cfr110.html>



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21 CFR 113, Low Acid Canned Food (LACF) regulations:

http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr113_07.html

21 CFR 114, Acidified Foods:

http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr114_07.html

21 CFR 120, Juice HACCP:

http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr120_07.html

21 CFR 123, Seafood HACCP:

http://www.access.gpo.gov/nara/cfr/waisidx_07/21cfr123_07.html

21 CFR 170.39 Threshold of regulation for substances used in food-contact articles.

<http://www.cfsan.fda.gov/~dms/opa-gg2.html>

21 CFR 174 Indirect Food Additives: <http://www.cfsan.fda.gov/~lrd/FCF174.html>

FDA Guidance for industry: Product Recalls, Including Removals and Corrections

(http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm)

FSIS Directive 8080.1, USDA Food Safety and Inspection Service recall guidelines

(<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev4.pdf>)

FSIS Directive 10,240.4, Verification Procedures for Consumer Safety Inspectors for the Listeria monocytogenes Regulation:

www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10240.4Rev1.pdf

Other Resources and References

AOAC International: <http://www.aoac.org>

Bacteriological Analytical Manual (BAM), (<http://www.cfsan.fda.gov/~ebam/bam-toc.html>)

The Bioterrorism Act (the BT Act or Public Health Security and Bioterrorism

Preparedness and Response Act of 2002) <http://www.fda.gov/oc/bioterrorism/bioact.html>

The Bioterrorism Act, on-line registration: <http://www.cfsan.fda.gov/~furls/ovffreg.html>

CARVER assessment in food defense and emergency response:

<http://www.cfsan.fda.gov/~dms/carver.html>



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Compliance Guidelines to Control *Listeria Monocytogenes* In Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products

http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-013F/Lm_Rule_Compliance_Guidelines_May_2006.pdf

C-TPAT (Customs-Trade Partnership Against Terrorism)

http://www.cbp.gov/xp/cgov/import/commercial_enforcement/ctpat/

Defect Action Levels for given commodities, complete with methods of analysis:

<http://vm.cfsan.fda.gov/~dms/dalbook.html>.

The Environmental Protection Agency (EPA) (www.epa.gov)

FDA Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance (<http://www.cfsan.fda.gov/~dms/secgui14.html>.)

FDA recall policies, further information: <http://www.cfsan.fda.gov/~lrd/recall2.html>

Federal Food, Drug and Cosmetic Act: <http://www.fda.gov/opacom/laws/fdcaact/fdctoc.htm>

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA):

<http://www.epa.gov/lawsregs/laws/fifra.html>

Food Allergen Labeling and Consumer Protection Act (FALCPA)

<http://www.cfsan.fda.gov/~dms/alrguid4.html>

GAP programs examples provided by the University of California at

Davis <http://ucgaps.ucdavis.edu/> and Cornell University <http://www.gaps.cornell.edu/>

GMA, “*Food Labeling Manual: Complying with FDA Requirements for the Labeling of Processed Foods*,” Second edition, 2004

GMA “*Managing Allergens in Food Processing Establishments*”

GMA “*Successfully Managing Product Recalls and Withdrawals*”

Good Aquaculture Practices: http://www.jifsan.umd.edu/gaqps_man.html

Good Laboratory Practices: <http://www.nal.usda.gov/awic/legislat/21cfr97.htm>

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, October 1998, <http://www.cfsan.fda.gov/~dms/prodguid.html>



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Katsuyama, A. M., 1993 *Principles of Food Processing Sanitation*, 2nd edition. The food Processors Institute

National Center for Agricultural Law Research and Information:
www.nationalaglawcenter.org **NOT A SUBSTITUTE FOR LEGAL ADVICE!**

Operational and Administrative System for Import Support (OASIS)
http://www.fda.gov/ora/import/oasis/home_page.html

Pesticide residues in food and feed, information regarding criteria:
http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg575-100.html

Recall information for FDA and USDA in one location <http://www.recalls.gov/food.html>

The Sanitary Food Transportation Act of 1990
(<http://www.fda.gov/opacom/laws/sftact.htm>)

Sanitary Design Principles (www.sanitarydesign.org)

Scott, V.N., 2005, M. Wiedmann, D. Hicks, R. Collette, M.L. Jahncke, K. Gall 2005
Guidelines for testing of environmental, raw product and finished product samples in
smoked seafood processing facilities *Food Protection Trends* 25:23 – 34.

State, county and territorial food and health agencies, a general listing:
http://www.fda.gov/ora/fed_state/directorytable.htm

Tompkin, R.B., V.N. Scott, D.T. Bernard, W.H. Sveum, K.S. Gombas 1999, Guidelines to
Prevent Post-Processing Contamination From *Listeria monocytogenes*, *Dairy, Food, Env.*
Sanitation 19: 551 -562

USDA FSIS Security Guidelines for Food Processors
(<http://www.fsis.usda.gov/OA/topics/SecurityGuide.pdf>)

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