Distribution Center Food Safety, Quality, and Good Manufacturing Practices Audit Expectations Manual

February 2011
# CONTENTS

- **Introduction** .......................................................... 5
- **Definitions** ............................................................. 5

## I. Pest Control ............................................................ 6
- Quality Systems ......................................................... 6
- Rework ........................................................................ 6
- Single/isolated ............................................................ 6
- Standard Operating Procedure (SOP) ............................... 6
- Traceability ................................................................. 6
- Transport vehicle ....................................................... 6

## II. Sanitation .................................................................. 7
- A. Sanitation Standard Operating Procedures .................. 7
- B. Cleaning Equipment and Chemicals ............................. 7
- C. Cleaning, Sanitation and Housekeeping Procedures .... 7
- D. Facilities .................................................................... 7
- E. Training ...................................................................... 7

## III. Facility and Equipment ............................................. 8
- A. Grounds ..................................................................... 8
- B. Facilities ..................................................................... 8

## IV. Product Protection .................................................... 8
- A. Product Storage, Receiving, Shipping ......................... 8
- B. Temperature Control .................................................. 9
- C. Employee Hygiene Practices ...................................... 9

## V. Quality Systems .......................................................... 10
- A. Training ............................................................... 10
- B. Food Safety/Quality Program .................................... 10
- C. Product Recovery/Traceability ................................. 10
- D. Customer Complaints ............................................... 10
- E. Maintenance ........................................................... 10
- F. Miscellaneous .......................................................... 11

## VI. Food Defense ........................................................... 11
- A. Program ................................................................... 11
- B. Records ................................................................. 11

**Silliker-eSTAR – Real-Time Information** ............................ 12

**Automatic Failure Questions** ........................................... 12

**Resources:** .................................................................. 13

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Introduction

Silliker Standards for Food Safety, Good Manufacturing Practices Requirements for Distribution Centers were developed for food distribution centers to use in the development and assessment of their food safety and quality programs. These standards contain the criteria and scoring method utilized during a Silliker distribution center audit. The criteria are a combination of Good Manufacturing and Distribution Practices, good management principles, recommendations from the National Advisory Committee for Microbiological Criteria in Foods and the Federal Food Drug and Cosmetic Act. Also included in the criteria are recommendations that many US food companies require of their distributors.

All information obtained by Silliker during the audit will be treated as confidential between Silliker and the client. Except as required by law, Silliker will not release any information or report of the inspection to a third party without written authorization by the client.

Silliker recognizes that audit consistency is very important in the food industry today. Our auditors undergo thorough training in best audit practices, the latest requirements from top US companies, and calibration visits from our senior audit staff. In addition, audit reports are reviewed by a member of our senior audit staff. If you have any questions or comments, please call our Audit Services staff at +1 312 938 5151.

Silliker is the leading international network of accredited food testing and consulting laboratories specializing in helping food and feed industry professionals ensure the safety, quality and nutritional value of their products. In addition to audits, our broad range of capabilities include microbiological and chemical analysis, custom designed research studies, such as shelf-life and challenge studies, risk management services, including technical consulting, short courses and training videos, vendor certification, environmental monitoring, and Hazard Analysis and Critical Control Point (HACCP) programs.

Definitions

Allergen
A protein or compound that elicits an adverse reaction in a segment of the population. The nationally recognized listing of allergens includes wheat, soy, eggs, shellfish, milk, fin fish, tree nuts, and peanuts. In Canada, sulfites and sesame seeds are also considered allergens.

Attribute
A microbiological, physical or chemical test, analysis, or evaluation that is used to determine the safety or quality properties of a food product.

Calibration
The verifying and adjustment of equipment performance against a recognized standard to ensure accuracy of the equipment.

Certificate of Analysis
A document that is provided with the receipt of a product that verifies that certain microbiological, chemical, or physical analyses were conducted on the delivered product, and the product performed within the established criteria.

Corrective Action
Action that is taken when product or conditions are found to be below prescribed evaluation criteria. They should include the deviation from the criteria, the actions to be taken to bring the situation into compliance, and verification that the actions have been followed through.

Good Laboratory Practices (GLP)
Guidelines that are established to ensure the accuracy and precision of results from described evaluations.

Good Manufacturing Practices
Guidelines that have been established by the Food and Drug Administration to assist food manufacturers in the production of unadulterated food products. Title 21, Code of Federal Regulations, part 110.

Guidelines
Policies or procedures on specific tasks that may or may not be documented.

Hold
Product that has been placed in a “do not use” area and is awaiting disposition.

Instance
One issue noted for a particular question.

Issues
A deviation from the prescribed standards.

Numerous
Three or more instances or issues noted.

Pest control operator
A certified, licensed individual or company that applies any pesticides used at a food production or distribution facility and also manages the pest control program.

Primary package
The packaging material that comes in direct contact with the food product.

Product Recall
An activity that recovers all shipped suspect product from the manufacturer of a product to the customers of the manufacturer, usually the final consumer of the product, the retail level.

Product Withdrawal
An activity that recovers all shipped suspect product that has only reached distribution (first customer) and has not yet entered the retail market.

Program
Documented policies, procedures, tasks, or activities that describe specific functions within the facility.

Quality Systems
Programs that are designed to monitor and improve the quality and safety of a food product.

Rework
Product that has been recovered or rejected from normal production, and has been reprocessed, relabeled, or reformatted into the finished product.
I. Pest Control

Each food distribution center must have a documented pest control program. It must include a designated pest control operator, scheduled frequency of service, as well as the following documentation:

- A current, dated map of the facility, which shows all pest control devices both inside and outside the facility. These include glueboards, insect light traps, tin cats, mechanical traps, pheromone traps, etc. The devices should be numbered so that activity and service can be tracked. The map should be updated annually. The locations of the interior and exterior traps must correspond to the map.
- Service records showing description of service rendered including types and amounts any chemicals used, the method of application, EPA or other regulatory agency registration number for chemicals used, locations treated, targeted pests, any signs of pest activity, corrective action due to activity noted, , and signature of pest control operator.
- If a third party is performing service, then current business license and proof of indemnity insurance must be available at time of review.
- A current certification for all persons who are applying chemicals for pest control activities at the facility.
- Any pesticide used at the facility must be approved by the appropriate regulatory agency approved for use in an industrial food distribution center. A sample label and matching MSDS sheet must also be available.
- Service labels must be kept on the interior of all pest control devices. These labels must contain the date of service and the initials of the PCO who performed the service. Punch cards may be used if the PCO who punches the card signs it. Bar codes can be used as long as there is proof that all devices have been scanned in appropriately.

Any pesticides stored at the facility must be in a segregated, secured area. To be secured, the storage area must be locked.

On the interior of the facility, there must be pest control devices around the interior perimeter of the facility, spaced approximately 25 to 40 feet apart. This includes any locker room, break room, dry storage area or, cooler that shares an outside wall. All dry storage areas need pest control devices placed appropriately. On each side of all exterior doors, there must be a pest control device within 10 feet of the door. All devices must be located so as not to contaminate products, packaging materials, or equipment. No bait is to be used inside the facility. All devices should be functioning properly and in good condition. Glueboards may be used in the center as an alternative to mechanical traps, except around exterior doors.

Insect light traps, if used, must be properly located so as not to contaminate products. These traps must be installed according to manufacturers instructions. When no instructions are available, they must be at least 4 feet off the ground. If the low voltage type is utilized, then they must not be stored directly above exposed product. If the high voltage type is used, then insect light traps must not be used within 30 feet of exposed product, or within 10 feet of packaged product. This includes all shipping and receiving areas. The bulbs must be changed at least annually and be protected from shattering. These devices must be scheduled for appropriate cleaning and maintenance. If sticky traps are used with these devices, they must be scheduled for replacing the sticky pads.

All interior pest control devices should be checked by a PCO or designated employees at least twice per month. There should be no decomposed rodents found in the devices. There should be no signs of pest activity inside the facility, especially around food products or packaging materials. There should be no evidence of insects, spiders, rodents or birds on (or in) any food product or packaging materials.

On the exterior of the facility, there needs to be tamper-resistant bait stations positioned approximately every 25 to 50 feet around the exterior perimeter of the facility. In public areas or areas where traps are not allowed to contain pesticides by local ordinance, no pest control stations are required. However, bait stations must be utilized in all other areas. The stations must be secured in place at the ground/building junction. Attaching the bait station to a patio block, chaining to the building, or anchoring to the ground are all acceptable means of securing the station. Tamper-resistant means that a tool must be used to open the station. Bait inside the station must be protected from shattering. These traps must be installed according to manufacturers instructions. When no instructions are available, they must be at least 4 feet off the ground. If the low voltage type is utilized, then they must not be stored directly above exposed product. If the high voltage type is used, then insect light traps must not be used within 30 feet of exposed product, or within 10 feet of packaged product. This includes all shipping and receiving areas. The bulbs must be changed at least annually and be protected from shattering. These devices must be scheduled for appropriate cleaning and maintenance. If sticky traps are used with these devices, they must be scheduled for replacing the sticky pads.

There should be no pest activity on the exterior of the building. Activity includes bird nests, heavy insect activity in close proximity to the building, burrowing, excessive pellets in stations, and heavily chewed or missing bait.
II. Sanitation

A. Sanitation Standard Operating Procedures
Each distribution center must have a master cleaning schedule that details tasks to be done by the sanitation personnel on a periodic, regular basis. The sanitation schedule should include all areas of the facility, including interior and exterior. Standard operating procedures for completing sanitation activities, including management verification, must be developed and implemented. The SSOPs must include the task to be completed, the responsible party, the chemicals and equipment necessary, the method used, the frequency, and records that must be completed once task is complete. Appropriate documentation for all tasks completed must be kept. SSOPs must include all refrigerated raw product storage and address the separate use and storage of dedicated raw product cleaning and sanitizing equipment.

B. Cleaning Equipment and Chemicals
All chemicals used for cleaning and sanitizing must have appropriate regulatory approval for use in an industrial food distribution center. MSDS must be maintained for all products used and must be easily accessible. Any chemical not in its original container must contain an appropriate, permanent label. All chemicals must be stored in a secured, segregated location when not in use.

Equipment, containers, and brushes used for cleaning and sanitizing are color coded or labeled to appropriately identify them for their intended use. Cleaning equipment must be made of nonporous material, clean, and properly stored when not in use. This storage is not in food storage areas. Power floor scrubbers must be stored empty of chemicals or in a secured area.

C. Cleaning, Sanitation and Housekeeping Procedures
Cleanliness must be maintained in all areas of the center. There should be no evidence of aged spills in receiving or storage areas. No aged ice should be present in the freezer section. Dock shelters, levelers, and bumpers are also clean and in good repair. Excessive moisture and condensation are removed promptly. Floors are free of standing water. Coolers are free of condensation.

If trailer washing is done in the distribution center, the area must be free of aged debris. Drains must be clear and operational (water capturing systems are acceptable), and dock shelters and bumpers must be clean. If the trailer wash area is off-site, then the area is not evaluated in the audit.

D. Facilities
Inbound and outbound trailers must be inspected to ensure they are clean, sanitary and free from debris and any infestations. Doors must be maintained and good fitting. All dry storage racking, pipes, overhead structures, electrical boxes and fans are free from dust.

E. Training
A program for conducting ongoing training for cleaning and sanitation procedures and safe handling of chemicals has been established. The training is for employees completing sanitation tasks. Training documentation includes the date(s) given, topics covered, name of trainer, and is part of the employee’s records. The training must be conducted annually.

III. Facility and Equipment

A. Grounds
Within 20 feet of the building, all parking lots and grounds are well maintained with no harborage areas for pests. All exterior trash receptacles must be covered and periodically emptied. This outside area must be free of litter and all weeds and landscape vegetation must neatly kept to prevent pest harborage areas. All equipment that is stored within 20 feet must be at least 6 inches off the ground. Any tube or piping must have the ends sealed to prevent harborage sites. No standing water is found within 20 feet of the building.

The dumpster area is clean, with no litter overflowing onto the ground. The lids on the dumpsters are closed. All loading dock and shipping areas are well maintained. All dock levers, dock shelters and bumpers are clean and in good repair.

B. Facilities
The distribution center is structurally sound with no roof leaks. Floors, walls, and ceilings are well maintained and properly designed. All outer openings are protected to prevent pest entry. No opening exists that is greater then 1/4 inch. The interior of the facility should have an 18 inch perimeter (where no product or materials are stored or kept) for sanitation and pest control. All doors must be closed when not in use.

All glass and brittle plastics must be shielded and protected against breakage. This includes lights in storage, shipping, and receiving areas (including all emergency lighting, dock lights, and fork truck lights). The center should have a glass and brittle plastics containment policy in the event that glass or brittle plastics breakage occurs. All areas of the facility should have adequate lighting to perform all tasks.

All break rooms, restrooms and locker rooms are clean and maintained in an orderly manner. Hand wash stations have hot and cold running water, hand wash soap, appropriate single use hand drying devices, and trash receptacles. All women’s restrooms or unisex restrooms must have a covered trash container for sanitary waste. All fixtures and drains must be clean and in good repair. Adequate ventilation must be in place to remove odors.
All center equipment must be designed for proper sanitation. They must be easily cleanable, non-porous and easily accessible. Equipment should be used only for the task for which it was intended. All food products and food stuffs must be stored on racks or pallets. No food items can be stored on the floor. Forklifts/floor scrubbers/vacuums are well maintained, clean, and stored properly. Floor scrubbers must be stored empty. Idle equipment and spare parts are properly cleaned and stored. Battery storage areas must be clean and away from product storage areas.

All maintenance activities must be conducted to protect the food products from contamination. No repairs are to be made with inappropriate materials such as tape, plastic, cardboard, or wood. Only food grade lubricants are to be used on racking or equipment that is in direct contact with food.

Doors and curtains are evident at all refrigeration/freezer storage areas. Doors must be in good working order, strip curtains should be clean so that personnel can see through them. Mold and frost removal practices are expected to occur on a routine basis.

Dock levelers must have appropriate brushes and gaskets in place. All exterior drains (except roof drains) must be screened to prevent pest entrance.

**IV. Product Protection**

**A. Product Storage, Receiving, Shipping**

Guidelines must be in place to protect products while in transit or in storage. When raw meat products are handled by the distribution center, they should be physically separated from packaged product while in storage, receipt, shipping, or distribution. At a minimum, a significant spacing must be present between raw meat products and packaged product or packaging materials. There must not be any contamination of packaged product or packaging by any raw meat product. Containers that carry raw meat must be destroyed or cleaned and sanitized prior to reuse.

Products must be held in the appropriate locations within the distribution center. Dry products must be held in dry storage; frozen products in freezer; and perishable products in the cooler. Only non-temperature/sensitive products should be stored on cool docks. A cool dock is any storage area that is temperature controlled and has outside dock doors. Only staging should occur on the cool dock. Staging of product is generally defined to be pallets that are picked from within one hour of placement on the cool dock. Pallets that sit for more than one hour on the cool dock are considered stored on the cool dock. No crushed or torn cases should be in active pick slots or storage.

Centers must establish product loading and receiving guidelines. Loading guidelines should be established to protect the product from damage as well as temperature abuse. All trailers of temperature sensitive product must be pre-cooled prior to loading. Documentation of trailer temperatures at time of loading must be kept. Appropriate pre-cooling includes reefer on with doors closed, or reefer on with doors open and a bulk head in place approximately 1/3 into trailer.

Receiving procedures need to be developed to include:

- Inspection of inbound trailer
- Product inspection for integrity of load
- Documentation of receipt date on pallet
- Code date of product
- Temperature of product (if applicable)

Documentation needs to be kept on all inbound inspections. If a trailer of many products is taken, then integrity and temperature checks need to be taken at the front, middle, and back of the trailer.

**B. Temperature Control**

Distribution centers must have established procedures to ensure that at no time during the storage, receiving, shipping, or distribution, the product deviates from established temperature parameters. These procedures should detail who will monitor the temperatures of all temperature controlled products and how the product temperatures will be monitored. These procedures should also explain the upper and lower cooler, freezer and cool dock settings, the target settings for each storage area, alarm settings, and appropriate monitoring activities of ambient and product temperature. All manual ambient air temperatures should be taken twice daily and product temperatures taken daily seven days a week. Recommended temperature ranges are 34-40°F for coolers, < 45°F for cool docks, and < 0°F for freezers. Note: temperatures for some items such as tomatoes and potatoes can be above 40°F and the center temperature standards should explain these criteria. Corrective actions should be documented when monitoring records show that temperature criteria were not met. All hand-held temperature recording devices need to be calibrated weekly, or as described by the manufacturer. All activities must have accompanying documentation. There should be a detailed plan outlining the procedures to follow in the event of a power outage where
temperatures could not be maintained for some time. Procedures might include use of generators or third party storage facilities or trailers to store product while temperature holding devices are being repaired.

If a third party is utilized to carry product by the distribution center, then controls must be in place to assure product temperature is maintained at all times during distribution. All carriers of perishable food products should have clean, temperature controlled transport vehicles and equipment to ensure temperature of frozen product (dry ice, blankets, and coolers). Centers should have procedures for inspecting all third party transport vehicle to ensure compliance.

V. Quality Systems

A. Training
Training must be conducted for all employees of the distribution center. This must include orientation for new employees, as well as regular training for established employees. This on-going training must occur at least annually. The types of training that are required include:

- Food safety training – An awareness of how foodborne illness occurs, and the role of employees in the transmission of microorganisms that can cause outbreaks and/or recalls.
- GMP training – All employees should have GMP training on the specific GMP program for the facility. This should be presented and available in languages other than English when appropriate.
- Sanitation – Any employee that is involved in sanitation tasks must have documented training that is specific to his/her job function. This should include specific SOPs for cleaning equipment as well as proper chemical handling, mixing and storage. If an outside company is hired to perform sanitation tasks, then their training program must be documented and available.

Documentation of all training must be kept. This should include the agenda for the training, the date that the training took place, who conducted the training, and who attended.

B. Food Safety/Quality Program
All distribution centers need to have a quality program established that identifies key points in the distribution chain that ensures product safety and quality. Employees in the areas where key food safety and quality points have been identified are familiar with those key points, and are trained in the criteria established at each point. Employees also are aware of appropriate action to be taken when key points have not been met. Corrective action is documented and maintained.

Procedures and criteria exist for a hold and release program. This program is designed for product that has been returned, does not meet quality checks, is damaged or is short on shelf-life. A hold and release program should include the following attributes:

- A designated area that is for “on-hold” product only. This area is clearly marked and is well known by employees that products in the area are not to be used. A computer system that would prevent shipment of product or use of ingredients would be sufficient.

C. Employee Hygiene Practices
Centers must have good employee hygiene practices (GMPs) programs established. Employees must comply with GMPs at all times. No eating, drinking, smoking, tobacco use or gum chewing are allowed in any receiving, shipping, or storage area. Employees are following proper personal hygiene practices. Medical problems from employees must not be a source of contamination. Appropriate signs should be posted reminding employees and advising visitors of employee hygiene practices for the center. Signs should be posted in all restrooms advising all employees to wash hands prior to returning to work. All personal employee items are stored in lockers or personal storage areas, away from center product storage areas.

A. Training
B. Food Safety/Quality Program
C. Product Recovery/Traceability
D. Customer Complaints
E. Maintenance
F. Miscellaneous

- A system for identification of product that is on hold. This can include tags, color coding, or signs. Any system of identification should include the identification of the product (code date, lot number, etc.), date of the hold, and declare that the item is not to be used or distributed.
- A log book or record of all holds within the facility. This should include the hold number, the product identification, the reason for the hold, the date of the hold and the product disposition. This log book should be reconciled frequently to ensure an accurate representation of all held product.

C. Product Recovery/Traceability
A formal product recovery program is required to be in place in order to recover shipped product in the event of a recall or product withdrawal.

The following elements need to be included in a product withdrawal and recovery program:

- A current 24 hour/ 7 day a week availability list of key personnel and customer contacts
- Procedures on how to conduct a product recall. This should include how to identify product, how to determine the amount of product in question, the amount of product shipped, where it was shipped, and the amount of product still within the facility (if applicable). Procedures should also include the reconciliation of documented product found versus actual product received and shipped.
- A worksheet to aid in the completion of the recall. Mock recalls should include all appropriate documentation (recall summary, shipping documents, and recall worksheet). A guideline to follow is that all product (100%) should be identified to the first customer within 2 hours. An actual recall should not take the place of a mock recall. Any portion of a mock recall that is found to be deficient should be tested again. A mock recall must include product that has actually left the distribution center. A product withdrawal is
VI. Food Defense

A. Program
- A Food Defense team should be established with members from different areas (multi-disciplinary) of the facility to address food defense issues for the facility. The team should have completed a documented food vulnerability assessment. The team must develop a reduction strategy for any identified risks. The team should meet annually to review all issues concerning the protection of product from intentional contamination.
- There should be a detailed food defense plan available for review. This plan should cover all aspects of the operations within this facility.
- The plan must address the screening of new employees, prior to hiring to reduce the risk of intentional contamination to product. Screening includes reference checks for all employees and basic felony background checks for supervisors and above. Employees must be trained on how to report and react to any suspicious activities.
- A visitor policy must be in place that supports the facility program. The policy must be posted or provided to all visitors.
- The facility plan must address any restricted areas and the management of those areas including employee and access control.
- The plan must include procedures to verify that non-company drivers actually work for the expected transportation company (e.g. the company name and the name on the driver’s ID matches the shipping documents). This is important when new drivers or unexpected drivers arrive to deliver or pick-up a shipment. Facility personnel should contact the shipping company when there are questions or suspicious situations surrounding the driver for a shipment.
- The facility plan shall include procedures to control access (non-company drivers, visitors, etc) to products and to any hazardous substances at the facility. This includes procedures to control access to products while on trailers.
- All shipments (in or outbound) should be either locked or sealed while away from the dock. This includes the use of locks and seals and the documentation of these locks and seals. All used seals should be documented on accompanying shipping or receiving documents. Full loads must be sealed. Procedures for handling Less than full loads (LTLs) must be documented. At a minimum all LTLs must be locked and documented as being locked on the shipping documents (such as Bill of Lading or invoice).
- The food defense plan can been incorporated into the monthly self-audit program where area access, product security and personnel management aspects of food defense are checked during self-audits.

B. Records
- All outbound and inbound shipments should be checked for product security (use of locks and seals) and these checks must be documented.
- All employees should be trained on food defense. This training should be documented. Personnel should know what suspicious activity is and who to report suspicious activity to. Personnel should challenge all unescorted, non-company personnel found around or within the facility to lower the risk of intentional contamination to products.
## Automatic Failure Questions

<table>
<thead>
<tr>
<th>Question #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.A.1</td>
<td>Documented pest control program has not been established.</td>
</tr>
<tr>
<td>1.A.10</td>
<td>There is no evidence of decomposed rodents anywhere in the interior of the facility, including pest control devices.</td>
</tr>
<tr>
<td>1.A.11</td>
<td>There is no evidence of insects, spiders, rodents or birds on or in any food ingredients, products or packaging materials.</td>
</tr>
<tr>
<td>4.A.2</td>
<td>No actual product contamination is observed.</td>
</tr>
<tr>
<td>4.A.12</td>
<td>No expired product is found ready for distribution in a pick slot or on a pallet ready for loading.</td>
</tr>
<tr>
<td>4.A.14</td>
<td>Corrective actions must be taken for deviations in the center's temperature controls.</td>
</tr>
<tr>
<td>4.14</td>
<td>Facility temperature control corrective actions are not followed.</td>
</tr>
<tr>
<td>4.A.16</td>
<td>Product temperature checks are not within required temperature ranges. Auditor to measure of a minimum of 1 product per storage unit.</td>
</tr>
<tr>
<td>4.A.17</td>
<td>Corrective actions must be taken for deviations in maintaining proper product temperatures.</td>
</tr>
<tr>
<td>4.A.19</td>
<td>Frozen and refrigerated products staged on the cool dock during loading and receiving processes must meet customer or facility (if customer has not established specifications) temperature specifications.</td>
</tr>
<tr>
<td>4.A.23</td>
<td>Employee personal hygiene practices are sanitary. Medical problems are not a source of contamination. No cross contamination or cross-contact practices are observed.</td>
</tr>
<tr>
<td>5.A.1</td>
<td>A documented GMP program has been established. It complies with all applicable regulations.</td>
</tr>
</tbody>
</table>

## Silliker-eSTAR – Real-Time Information

24/7/365 access to information is crucial in business today. Through Silliker-eSTAR.com, our secure test / auditing results website, you can access your confidential auditing data at the plant or on the road. With Silliker-eSTAR.com, you can retrieve data through a variety of options and even track the status of your suppliers’ corrective action plans for audit deviations. This powerful data management allows you to resolve critical issues and make informed decisions about your product.

[www.silliker-estar.com](http://www.silliker-estar.com)
Resources:

Additional information can be obtained by referring to the sites listed below.

HACCP
http://www.haccpalliance.org/
http://www.cfsan.fda.gov/~lrd/haccp.html

Recall Procedures
FDA/ORA Regulatory Procedures Manual Chapter 7 Recall & Emergency Procedures

Food Allergens
Compliance Policy Guide Sec. 555.250 Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens
http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-250.htm

Food Defense
Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL107-188)
http://www.cfsan.fda.gov/~dms/sec-ltr.html
Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance
http://www.cfsan.fda.gov/~dms/secguid.html

Good Manufacturing Practices
Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food

Good Laboratory Practices
Proficiency testing information: http://www.aoac.org/proficiencytesting/proficiency.html

Sanitation

Pest Control
http://www.nrcs.usda.gov/technical/ECS/pest/pest_policy.doc

General
21 CFR 110 http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr110_02.html

Quality Systems
Food Processing Industry Quality System Guidelines, ASQ Food, Drug, and Cosmetic Division;
www.asq.org