2010

NATIONAL PEST MANAGEMENT ASSOCIATION

Pest Management Standards For Food Plants

NATIONAL PEST MANAGEMENT ASSOCIATION inc. International

Pest Management Standards For Food Plants

INTRODUCTION

We are pleased to release the 2010 Pest Management Standards for Food Plants, a cornerstone of NPMA's Commercial Division activities since 2007.

In 2009, NPMA witnessed the evolution of the allergen issue and issued a revised standard, 2.14. This is incorporated with 2009 changes into this version.

As always, hese standards also DO NOT preempt local, state, provincial, and/or federal regulations. Any service provided must comply with government regulations or statutes governing pest management, safety, and food protection. In addition, food plants may have requirements more stringent than these standards.

Pest management firms embracing the standards have raised the professionalism and technical abilities to secure the industry role as protectors of food. With the standards, a comprehensive testing site which provides all pertinent information at www.npmatesting.com, and the study guide as well as other resources noted in the standards, NPMA has provided the tools necessary to comply with the standards and to raise the level of competency of professionals servicing food plants.

As of the date of publication, well over 3,000 technicians have take the exam prepared as a companion to these standards. That is a credit to the industry's striving to provide the best possible service.

We hope that you find these standards a beneficial addition to your own company protocols and procedures. As protectors of food it is our obligation to exceed expectations and to see our role as a vital component to overall food safety.

Greg Baumann, Vice President
Technical Services, NPMA

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DEFINITIONS

For definition purposes,

"Company" means the pest management firm

"Contact" means the food plant contact person

"Employee" means pest management firm employee

"Good Manufacturing Practices" means the FDA's Current Good Manufacturing Practices in the United States, or equivalent outside of the US.

"Pest management product" means any lure, bait, monitoring product, pesticide, or any other formulated material used in performance of pest management activities.

"Plant" means a food manufacturing facility including associated warehousing and does not include restaurants or other food service facilities

"Rodent bait station" means any station used for placement of solid rodenticide bait

"Rodent management station" means any station used for monitoring or managing rodents. These include mechanical traps, rodent bait stations (see above), and other placed equipment for rodent management.

"Technician" means the pest management firm employee providing service

Section 1
Personnel

1.1 Employee Identification

Reasoning
This section sets forth minimum standards for company employee identification so that the plant has a clear understanding of which personnel are from the pest management firm to ensure that plant food safety and security are maintained.

Standard
All employees entering grounds of a food plant shall wear photo identification to include:
- employee name
- employee identification number (if issued by the company)
- company name
- company phone number
- employee photo
- date of issue

The identification shall be worn at all times while the employee is on site unless plant personnel practices set by the customer prohibit such badges. In addition, plants may require other identification and badges such as visitor badges and the employee must comply at all times with the visitor/contractor policies of the plant.

1.2 Uniforms

Reasoning
Uniforms are an important part of the plant safety and standards program. Criteria set are designed to comply with the majority of food plant requirements for uniforms.

Standard
All employees who perform service work in food plants shall wear uniforms meeting the plant's current requirements and at least the following criteria:
- Slip Resistant Sole Shoes (steel tips if required by plant)
- Socks
- Long Pants
- Shirt with sleeves (short or long) with company logo or name
- Bump cap if required by the plant

Uniform closures shall be in compliance with plant requirements.

A clean set of clothing shall be used in plants if the previous account visited has exposed the clothing to contaminants. These contaminants include but are not limited to chemical, microbiological, or allergens such as peanut products.

More stringent requirements may be in place for individual plants in addition to these standards and service personnel must comply with those standards.

1.3 Security and Criminal Background Checks

Reasoning
Security is a major concern at all food plants. This section is designed to ensure that personnel in food plants have had proper background checks and that they comply with plant rules.

Standard
Any newly hired employee, including management, entering a food plant shall have a criminal background check performed covering the previous five years prior to the date of hire. The checks shall be part of the records of the company and shall include all states or provinces in which the employee has lived and/or worked during the previous five years. Resulting action as a result of the check will be at the discretion of the company management. Some food plants may have specific requirements and companies must comply with these requirements in addition to the above. Reminder: Companies must comply with government regulations related to obtaining background checks.

Plants may also have policies regarding when an employee is permitted onsite and/or escorted. Companies should understand and comply with all plant policies and provide a written procedure to employees with a copy in the plant as to:

- Whether advanced notice must be given prior to arrival onsite
- Parking and vehicle use
- Substitute employees (technicians taking place of previous technicians may have to be on a roster provided to the plant)
- Sign in policies
- Hours of operation when employees may have access
- Visitor badge policies
- Escort policies
- Restricted areas

1.4 Customer Personnel Practices

Reasoning
It is imperative that all employees entering a food plant property understand and comply with the plant personnel practices. Besides being required by law, compliance is important as a part of food safety and also plant personnel morale.

Standard
All employees entering a food plant property must have reviewed and signed off on the standards of the plant in terms of personnel practices as outlined by the plant. If a special set of standards is in place for plant contractors, then the employee must comply with the standards. If any questions or conflicts arise, the employee must either notify their supervisor or the plant contact person.

A copy of the signed document shall be maintained in the plant files.

1.5 Vehicles

Reasoning
Plants have very specific requirements for vehicles both in terms of operations and in terms of security. This section sets the minimum for vehicle standards.

Standard
All vehicles used for service must:
- Be clearly marked with company name
- Be properly licensed
- Have a current inspection if required by the state or province.
- Have adequate insurance of at least $1 million aggregate bodily injury and property damage (U.S. and Canada only); for other countries, the minimum insurance required by law shall be obtained. If plant requires additional insurance, then the plant requirement must be met
- Be parked in properly assigned area
- Contain materials and equipment secured when unattended to restrict access.

Drivers
A five year motor vehicle background check must be completed for all new company employees who will drive on plant property.

All drivers must have viewed the NPMA Safe Driving Video or participate in an insurance industry approved program annually and the company must retain safe driving training records as required by the insurance company.

In addition, the vehicle must include at least the following equipment:
- First aid kit
- Spill control to cover all products on the vehicle
- Current labels and Material Safety Data Sheets
- Vehicle list (continued):
- Service Kit (carrying kit for small quantities of products and equipment)
- Change of clothing
- Coveralls
- Other equipment required by plant or label of products used in the plant.

1.6 Safety

Background
Safety is a vital part of any pest management program. The pest management company and the food plant both must maintain safe working environments.

Beyond just minimal regulatory requirements, policies must be in place to ensure a safe work environment.

Standard
Each company must have a Safety Plan and must document training of all employees working in food plants. Each company must also provide verification that food plant specific safety training has been completed. Safety plans must include but are not limited to:
- Respiratory protection training if a product is used requiring use of a respirator. Where a respirator is required, respirator training must be completed including the use of the NPMA Respiratory Safety Video or equivalent. The video is available from that National Pest Management Association. For contact information, visit www.npmapestworld.org.

- Pesticide safety including the proper understanding of all labels of products to be used in the food plant, proper use, and disposal of products and containers
- Proper storage of products and equipment
- Emergency Response in case of spills
- Safety of other personnel near pest management activities such as plant employees and consumers
- Ladder safety and transportation including tie down
- Use of fall prevention
- Lock out and tag out systems
- Pinch hazards
- Crushing hazards
- Shoe safety
- Personal protective equipment
- Definition of accident
- Reporting requirements including use of OSHA 300 (www.dol.gov)
- Fumigation plan if fumigation is to be performed (fumigation in general is not covered by these standards)
- Restricted areas in plant
- Confined space entry requirements
- Hazard communication

Note: An optional safety manual is available for sale through the NPMA Resource Center which addresses safety program compliance and will provide guidelines for developing a safety program. For more information go to www.npmapestworld.org.

1.7 Minimum Training Standards for Technicians

Background
Technicians performing pest management in food plants must be properly trained and verification of training specific to food plants must be shown.

Standard
Any technician performing pest management services in food plants must be trained. Certain proof of training must be available to the food plant contact.

These standards require pesticide enforcement regulatory agency certification or registration and verifiable training specific to food plant pest management including an exam regardless of whether an exam for the state or province has been passed for certification or registration of technicians.

Testing is conducted via the internet and is administered for a nominal fee by NPMA. Procedures and verification are the responsibility of NPMA.

NPMA has provided a testing site at www.npmatesting.com. A proctor designated by the company is required and the test is closed book. Each technician to be tested must establish his/her own account on the testing site and must select his/her own username and password. The login information is NOT the company's NPMA membership login.

There are fifty random questions on the exam and technicians must score 80% (40 correct) or better to pass. Technicians who do not pass may retake the exam at no additional cost.

An optional study guide is available through the NPMA Resource Center to provide education on food plant work and to help pass the exam. Not all questions are directly from the study guide. The testing site does provide advice on how to prepare for the exam at www.npmatesting.com.

1.8 Compliance with GMPs

Background
Federal agencies have established regulations to include basic food safety. This requirement is to ensure compliance with US Current Good Manufacturing Practices or equivalent in other countries.

Standard
All pest management programs must comply with Current Good Manufacturing Practices (GMPs). All technicians performing any type of work in food plants must be trained in requirements of GMPs and plant implementation. Also plants may have GMP-related requirements beyond GMPs and technicians must be trained in plant policies as well. Written verification must be on file in the plant and in the company office.

Section 2
Pest Management Plan

2.1 Rodent Program-Exterior Property Survey

Prior to developing a rodent management program at each plant site, a thorough inspection must be made of the entire property. The property should be inspected and the following observations at a minimum must be identified and documented using a diagram and/or notes:

- Areas of rodent infestation based upon sightings, harborages, or other evidence including all areas of the building including roofs
- Areas conducive to infestation of the property such as cluttered areas, open trash, standing water, potential or confirmed burrowing areas
- Dumpsters which are not on rigid cleanable areas such as concrete pads
- Open doors or gaps in building areas which could permit rodent entry
- Clutter or debris underneath load levelers
- Dock areas that have clutter or debris
- Off loading areas with clutter or debris
- Tall grass and vegetation on property, sidings, and adjacent to buildings
- Perimeter areas of buildings having less than 24" of clearance and areas not having gravel or other material which will reduce chances of rodent activity
- Neighboring properties which may have conditions leading to infestation

A summary of infestation observations and potential infestation must be documented and presented to the pest management contact of the plant.

2.2 Rodent Management Plan-Interior Survey

All areas of the plant interior shall be surveyed for rodents and conditions which may lead to rodent infestation. These areas shall include but are not limited to:

- Pallet storage
- Warehouse
- Incoming raw materials
- Packaging storage
- Processing
- Finished goods storage
- Returned goods area
- Waste disposal
- Workshop
- Sanitation area
- Offices areas
- Other areas

Any rodent management devices shall be mapped and recorded.

2.3 Rodent Program-Facility History

Prior to designing and implementing a rodent management program, a company representative shall interview plant contacts and review all available rodent history information. This will help develop an effective rodent management plan.

In the course of the inspection, maintenance issues such as but not limited to holes in walls, pipe chases, bulk feed lines, spilled food items, or open doors/windows shall be noted. Recommendations shall be made to the plant to reduce chances of future infestation.

Form NPMA-38 (Appendix A) may be used. As requested by members, optional supplies of pre-printed NPMA-38 forms in carbonless copy format are available for sale through the NPMA Resource Center.

2.4 Rodent Program-Depth Matrix & Frequency of Service

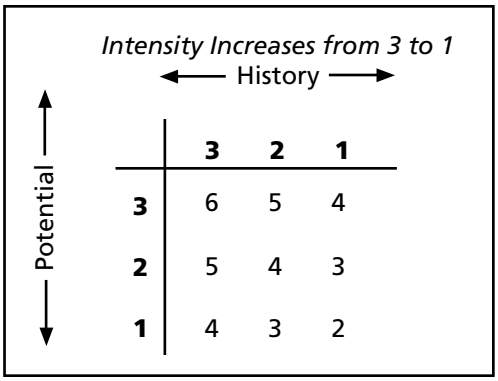
As a result of an initial inspection, examination of history, and discussions with plant personnel, the level of rodent management program area can be developed. This is history versus the potential. If the plant is totally sealed, and there is minimal chance of infestation by rodents, then the potential is reduced. If there is ample raw material exposed, or open doors on the building exterior, then the potential is much higher.

For history:
- Category 3 denotes no significant evidence or history in the building in the past year;
- Category 2 denotes no significant evidence or history in the past six months;
- Category 1 denotes significant evidence or history in the past six months. The following Matrix can determine the level of the management program necessary. The category assignment of 1 is most intense.

For Potential:
Potential is determined by plant maintenance such as holes, unsealed pipe chases, etc., and operations such as open doors, at grade loading docks, etc., and surrounding rodent pressure
- Category 3 denotes no significant potential for infestation due to plant maintenance and operations, and rodent pressure
- Category 2 denotes medium potential for infestation due to plant maintenance and operations, and rodent pressure
- Category 1 denotes high potential for infestation due to plant maintenance and operations, and rodent pressure

RODENT MANAGEMENT EXTERIOR PROGRAM-DEPTH MATRIX

Potential and History: Potential for Infestation (One is most intense, two is medium, and three is least intense)



The Potential score based upon the above criteria must be determined by and is at the sole discretion of the pest management company. The history score must also be determined as previously noted. They are then added together to get a matrix score, which is the italicized score on the matrix.

FREQUENCY OF SERVICE, EXTERIOR AREAS

For exterior of buildings: If the score is 2, 3, or 4, then the exterior service interval must be at least twice monthly. If the score is 5 or 6, the exterior service may be monthly. Results of the analysis and conclusions should be reviewed by and accepted by plant contact and may be reviewed and adjusted as necessary.

2.5 Rodent Program-Spacing of Rodent Management Stations

SPACING OF RODENT MANAGEMENT STATIONS

Special note for 2009: There is a trend towards needs-based placement of stations, either mechanical, bait, monitoring, or other devices, rather than assigning specific spacing. NPMA supports science based rodent management plans. When these Standards were conceived, many third party auditors required stations based solely upon spacing regardless of pest pressures. The Spacing of Stations section is an interim step between arbitrary placement without justification and implementing rodent management programs based upon real need supported by scientific evidence. This section will be modified when the scientific research leads the industry to the new philosophy of rodent management. NPMA will continue to monitor developments in rodent management in anticipation of shifting towards this new philosophy when it is ready for industry-wide adoption.

Note: any placement should be approved by plant contact to make sure that the program complies with plant corporate policies

Record of service verification such as stickers, cards, or bar codes shall be on the inside of the station, requiring the station to be opened to record data or to scan.

Proper care must be exercised to comply with the label in terms of access to children or non-target animals. If it is not possible to install stations in secure areas then glue boards or snap traps or other mechanical traps may be used inside of locked and anchored stations.

Monitoring stations may be used at any interval with a non-toxic block.

EXTERIOR PERIMETER

Property Perimeter: If an exterior property perimeter program is utilized, then based upon history only, rodent management equipment, such as but not limited to rodent bait stations or multiple-catch traps, shall be placed along property perimeter areas (e.g. fence lines or outer boundaries) at the rate of:

- For History Category 1: Spacing of not more than 50 feet
- For History Category 2: Spacing of 50-75 feet
- For History Category 3: Spacing of up to 100 feet

Exterior Building Areas (buildings at or near exterior walls of buildings on plant property) Based upon history, rodent bait stations shall be placed along building exterior areas at the rate of:

- For History Category 1: Spacing of not more than 25 feet
- For History Category 2: Spacing of between 25-50 feet
- For History Category 3: Spacing of up to 75 feet

Rodent management devices should be added adjacent to doors, docks, and ramps to the level of History Category 1 at least but may be placed adjacent to any exterior opening per company practices.

INTERIOR OF PLANT

The inside of any exterior wall should have multiple-catch traps or glueboards in stations at the rate of one per 20-40 feet. In areas of high traffic, stations should be placed directly against the wall and should be protected or covered if necessary to prevent forklift damage. Interior traps do not have to be anchored. Traps may be placed along interior walls at the discretion of the pest management company. Interior rodent management programs shall be monitored weekly.

Multiple-catch traps may be supplemented at a rate determined by the technician with snap traps in stations or glue boards added into PVC pipes. These traps may be used also on mezzanines where equipment is stored and in areas where using large traps may be cumbersome, such as in areas of heavy activity and dense storage areas. All stations must be recorded and numbered and records must reflect the placement.

Rodenticides shall not be used inside food plants in any area unless approved by the plant contact and permitted by label. Upon such a request, any action and reasoning must be documented and should be temporarily used when there is no exposed food product. Non-toxic monitoring blocks may be used if permitted by plant contact.

Plants should have an inspection aisle of at least 18 inches along walls. Commonly, this area is painted white in order to contrast with droppings or insects. Traps may be placed along these areas.

Due to concerns about allergens, no peanut butter or nut based attractants may be used inside a plant unless approved by plant contact.

2.6 Rodent Program-Monitoring

Adjustments to the program based upon observations may be made at any time. Use of "temporary" program changes are acceptable. All traps, bait stations, and other devices must be opened and inspected. Record of service verification or bar code shall be on the inside of the station requiring the station to be opened. Observations must be recorded as outlined in the Recordkeeping section.

A master map of all rodent control devices used on the property must be maintained and kept current.

Rodents must be disposed of in a sanitary method offsite per company policy. Rodents, droppings, and any urine deposits or residue must be handled using protective gear per company policy.

2.7 Insect Program

Inspection
A thorough inspection shall be conducted of the exterior of the building including raw material receiving, receiving docks, shipping docks, load levelers, waste disposal, entrances, roof areas, exterior storage such as silos, doors and windows, and ventilation intakes to investigate signs of infestation or possible signs of infestation by stored product insects.

A thorough inspection of the accessible components of the plant shall be conducted not less than monthly. The areas to be inspected includes but is not limited to floor/wall junctures, drop ceilings, equipment, processing areas, warehousing materials and racking, offices, locker rooms, mezzanines, raw material handling and processing, returned goods areas, sample areas, windows, ventilation, shop areas, packaging storage and equipment, laboratory areas, and cafeteria. See 2.10 for documentation.

In the course of the inspection, maintenance issues such as but not limited to holes in walls, pipe chases, bulk feed lines, spilled food items, or open doors/windows shall be noted. Recommendations shall be made to the plant to reduce chances of future infestation.

Stored Product Insects
Determination of the source of stored product pests must be completed prior to action. Sometimes, a certain lot of raw materials can be isolated as the source. If pests have spread into the plant, management measures must be performed.

Pheromones and pheromone traps may be used as part of the monitoring and management processes.

Non-Stored Product Insects and Occasional Invaders
Determination of source and entry point, real or potential, is necessary in developing a control/management program. Commonly, mechanical alterations on the exterior will be necessary such as filtering incoming air, sealing cracks, repairing door gaskets or self closing doors, etc.

Prevention and Management of Insects
Insects shall be managed using a product labeled for the site. These products may be residual or non-residual products.

Non-regulated/exempt products (including but not limited to essential oil products, limestone dusts, etc.) may be used according to the instructions and in a crack and crevice or spot method only.

Space treatment may be used to reduce adult populations. This may also include the use of insect growth regulators (IGRs).

General applications may be used only if the use of the product will not contaminate the food product.

Pests may also be managed by fumigation after coordination with the plant contact. These standards do not address fumigation specifically.

Insect bait stations may be used in areas not prone to heavy traffic or water accumulation.

Treatment of electrical panels and boxes must be done with extreme care per the label and liquids should not be used.

Insect Light Traps and Flying Insect Traps
Insect light traps (ILTs) may be installed to monitor and manage certain flying insects and to be used in the decision making process for adjusting the program for certain insects (e.g. Indianmeal moths, fruit flies, etc.). Findings and seasonal requirements will dictate frequency of inspection. Placement must be according to manufacturer's instructions and in compliance with any regulatory policies and guidelines. In absence of instructions, ILTs should be placed where plant operations will not interfere with the operation. Typically, ILTs should be placed not less than two feet but not more than five feet above floor level unless specified by manufacturer instructions or due to special circumstances such as targeting high flying insects. Any ILT must be recorded on the site layout or map and ILTs must have the same recordkeeping as other types of traps.

ILTs must be monitored based upon the contract and weekly monitoring is suggested for most cases unless the traps are in an area or at a time of year when there is no activity (e.g. unheated warehouse in winter in colder climates). The tray must be emptied. Insects in the tray must be examined and categorized according to:

- stored product insects
- flies
- occasional invaders

The technician should determine if the types and numbers of insects reveal a concern and if so, then the insect management program should be modified to address the issue.

Bulbs in ILTs must be changed according to manufacturer's recommendations but in any case at least annually. Shatter protection must be in place where food or packaging may become contaminated by glass.

Sticky type ILTs must be monitored at least monthly and the sticky board must be replaced if ineffective. Type of insects on the board must be recorded and categorized according to above.

Sticky type traps including pheromone sticky traps or other flying insect traps must be monitored at least monthly and the sticky material must be replaced at ineffective. Type of insects on the board must be recorded and categorized according to above.

The insect program must be reviewed with the plant contact at least annually and adjustments must be made as necessary. Any services may not contaminate nor potentially contaminate food, food contact surfaces, or food packaging.

2.8 Birds and Wildlife

Birds and wildlife can enter plants or plant areas and create contamination or potential contamination hazards.

In the course of the inspection, maintenance issues such as but not limited to holes in walls, pipe chases, bulk feed lines, spilled food items, or open doors/windows shall be noted. Recommendations shall be made to the plant to reduce chances of future infestation.

Bird Prevention/Management
Areas susceptible to infestation by birds shall be called to the attention of the plant contact. If the plant approves, bird prevention measures may be installed. These shall be any type of wire, net, device, or material to prevent roosting.
No restricted use pesticides designed for scaring of birds may be used inside any structure where food is exposed. Any such product use shall be in areas inaccessible to non-target species and plant personnel.

Any interior bird removal shall be by trapping and removal in accordance with regulations. Exterior infestations such as geese on grounds may be managed by scaring devices or repellents. Use must be in accordance with manufacturer's instructions. Use of protective gear shall be required for removal of nests and/or droppings

Plants should be encouraged to eliminate favorable conditions for bird infestation and observations by the technician shall be recorded in the log.
Within the confines of the above, additional information on bird management may be found in the NPMA Pest Management Library, available through the NPMA Resource Center (www.npmapestworld.org).

Wildlife Prevention/Management
Areas susceptible to infestation by wildlife shall be called to the attention of the plant contact. If the plant approves, wildlife prevention measures may be installed. These shall be any type of wire, net, device, or material to prevent entry, nesting, and/or roosting. This is usually beyond the scope of the original contract and a separate contract should be developed.

Any miscellaneous animal removal shall be by trapping and removal in accordance with local regulations. Exterior infestations such as prairie dogs on grounds may be managed by repellents or other method according to label or instructions. Use must be in accordance with manufacturer's instructions.

Plants should be encouraged to eliminate favorable conditions for wildlife infestation and observations by the technician shall be recorded in the log.

Within the confines of the above, additional information on wildlife biology and management may be found in the NPMA Pest Management Library.

2.9 Weed Management

Vegetation should not be planted against the buildings (exterior). An inspection band and clear zone adjacent to the building should be encouraged as part of the periodic audit. If the company performs weed management, ideally a vegetation free clear zone should be maintained.

This item shall be checked as part of the normal audit process during pest management service regardless of whether the company performs weed management. Any

vegetation around the building should be called to the attention of the plant contact for management in order to reduce the chances of infestation. Note: Certain types of vegetation/plantings may be more susceptible to pest harborage. These may be noted during the audit.

2.10 Pest Management Survey

At least monthly, the pest management company shall perform a survey to look at infestation by pests and the potential for infestation. Building maintenance, employee practices, physical conditions of the plant, incoming materials, processing, and shipping shall be evaluated. Recommendations shall be presented to the plant contact including results of plant documents such as incoming materials inspection and pest sightings, and technician observations.

The NPMA form NPMA 38 or equivalent shall be used to record observations and recommendations and a copy shall be disclosed to and signed by the plant contact.

All NPMA 38 or equivalent forms shall have one copy submitted to plant contact, one copy shall be filed with the pest management records and a copy shall be kept by the pest management firm unless the forms are filed and maintained electronically.

2.11 Quality Assurance

At least once per year, prior to the anniversary of the date on which the company began pest management services at the food plant, a supervisor, quality assurance staff person, or a manager from the pest management company shall review the entire program onsite. The QA audit shall look at the program, records, and frequency, as well as the monthly audits to make sure that all documentation is in order. In addition, labels and MSDS must be reviewed to make sure that all products used have current information. MSDS and labels of pest management products used at that facility must be filed either in hard copy or via electronic records.

Results of the quality assurance audit must be filed in the plant, with a copy in the pest management company office.

2.12 Annual Training

At least once per year, the pest management company shall offer to conduct an educational program for plant personnel. Date, content, and list of those who attend must be kept in the plant pest management records.

The following staff should be encouraged to participate:

- Management
- Supervisory staff
- Security
- Mechanics
- Production lead staff
- Warehousing staff
- Quality Assurance staff
- Plant contact
- HACCP committee, if applicable
- Others determined by the plant management

While the plant ultimately makes the decision as to who may attend, the content shall include:

- Review of the pest management program
- Product flow
- Vulnerable areas
- Practices which may reduce pest pressures
- Review of audits and monthly reports
- How to record a pest sighting

Review of FDA, state, provincial, local, and third party audits and inspections as related to pest management.

How plant personnel should interact with pest management tools and devices

2.13 Storage

All pesticides for use in pest management shall be stored off site or in a locked and secured storage area with adequate spill control and safety equipment for all materials stored. All storage must be in compliance with government regulations as well as the policies of the food plant. Any storage requirements listed on the label must also be addressed. If storage is in a locked cabinet, all room requirements must be met. Fumigants shall not be stored onsite unless storage requirements of the label are met.

Records must be stored in a secured area.

2.14 Compliance with Plant Food Allergen Control Program

Background
In recent years, there has been a great emphasis on food allergens, most notably, peanut products. Many consumers have acute reactions to food allergens. "Big Eight" allergens include: cow's milk, eggs, peanuts, tree nuts, soybean products, wheat, fish, and crustacean shellfish. Consequently, food plants must declare if there is a possibility of any of these products entering the food either as an ingredient or an incidental additive. Plant policies and third party auditor standards may require formal food allergen control programs and these might affect pest management practices.

Standard
The pest management company must comply with any plant food allergen control program as it relates to pest management practices.

Section 3
Communication

3.1 Reporting

All records and documents may be retained electronically.
All documents in the pest management filing system must be available to the plant within a reasonable time as determined by the plant. The plant has the option of requesting copies of all documents produced including service tickets for their files.
The pest management company must keep a backup copy of all documents at the pest management company office. The pest management company shall not surrender any copies of materials to any official without the express written permission of the plant contact or their substitute. If there is a regulatory audit of the pest management such as the state department of agriculture or other pesticide enforcement agency, the pest management company may surrender documents to the agency if required.

While paper backup information may be permitted, official documentation and reporting listed in these standards shall be retained in the following manner:

Reporting shall provide access to all service data

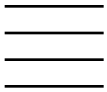
Record recovery shall be available on demand with the ability to be sorted by product used, area, pest, date, time, and shift.
Trends shall be determined at the interval of service.

Data onsite may be gathered by handheld electronic devices or manually or a combination of these methods

Trends may be used to modify the pest management program based upon observations.

All inspections reports such as, but not limited to the NPMA 38, may be available online

Section 4
Recordkeeping and Contracts



4.1 Contracts

Prior to completing any work in a food plant, a signed contract must be in place unless specifically waived by the food plant and must include:

- Name of Plant
- Plant contact person
- Frequency of visits
- Description of services
- Term of contract
- Fee
- Equipment storage and product storage specifications
- Scope of emergency calls
- Products which may be used
- Service records to be issued to the plant
- Requirement to notify plant of any new products used

4.2 Labels and MSDS

A copy of all EPA, PMRA (Canadian Pest Management Regulatory Authority), or other country product labels and Material Safety Data Sheets for pest management products used at the plant shall be maintained in the plant by the pest management company. Only labels and MSDS for products which may be used at the plant should be included in the "active" file. This may also be filed electronically or web-based. A label and MSDS shall be added for any new products used.

4.3 Pest Sighting Log

Each pest management company shall provide a Pest Sighting Log to be maintained in a plant office which may be the pest management area. The log shall include dates, times, locations, type of pest, action taken, and name of reporting employee. The log shall be reviewed by the technician at each visit and data shall be included in adjusting the pest management program as necessary. At the periodic training by the pest management company, the use of the log shall be discussed.

4.4 Licenses and Certificates

Credentials to be maintained at the plant with the pest management records must include:

- Copy of the certification or registration document, if issued in the plant jurisdiction, for each person who will perform pest management services in the plant
- Copy of the pest management company license to operate issued by the state or provincial lead pesticide enforcement agency if issued by the state or province in the jurisdiction.
- Copy of the insurance certificate
- Copy of proof of successful completion of verifiable training and exam for each technician servicing the plant.

4.5 Service Protocols and Standard Operating Procedures

Standard Operating Procedures shall be developed in partnership between the pest management company and the food plant. All scope of work information including methods of inspection and treatment must be documented and approved by the food plant. Protocols and procedures shall include at least the following:

- Procedures for all current or anticipated pest management activities including inspections and audits
- Pest sighting log
- Pest activity records
- Treatment Records (see 4.6 for minimum information required)
- Trend reports
- Plant layout with pest management activity information listed such as rodent stations, monitoring devices, etc.

4.6 Service and Treatment Records

All service records for service including applications and/or monitoring shall include:

- EPA or PMRA registration number
- Product brand name
- Target pest
- Rate of application or % concentration
- Time of application
- Location or site of application
- Amount of finished product used
- Date
- Lot number of product
- Signature of technician
- Signature of plant contact
- Certification or registration number of technician
- Emergency phone number
- Notes and observations and any other records required by the state pest management enforcement agency

Section 5
National Organic Program

5.1 Working in NOP Facilities

The USDA National Organic Program is governed by Rule 205.271 and requires the handler or management of the organic facility to use management practices to prevent pests. While many of the physical prevention methods are beyond the scope of the pest management company, the NOP records will work with the pest management program to ensure that there is compliance with Rule 205.271. The NOP does not prevent the use of pest management methods or products; however, the NOP does require that pest prevention is done through mechanical or physical management and/or natural or approved traps and repellents. If these measures fail to manage the pests, the facility may use a natural substance approved by the organic certifying body, and if that fails, then a synthetic substance may be used "provided that the handler and the certifying agent agree on the substance, method of application, and measures to be taken to prevent contact of the organically produced products or ingredients with the substance used." The NOP requires full attention to IPM. The plant will have specialized rules governing pest management activities in the plant.

In addition to the standards in sections one through four, the NOP facilities will require the Standard Operating Procedures (SOPs) to prioritize pest management methods based on the information above. The company shall work with the facility to make sure that the procedures and SOPs comply with the plant SOPs regarding pest management. See federal government publications for more information.

Note: some organic facilities are audited by a certification group which may have approved methods or products.The plant should be consulted as to special requirements.

Procedures to ensure that the food will not be contaminated by any pest management method must be in place prior to beginning any service.

Appendices

Inspector: _____ Date: _____

1. No evidence of pest activity
2. No pest harborage areas
3. Adequate trash handling
4. Proper trash containers
5. All trash contained
6. Proper storage of waste paper and cardboard
7. Pavement areas in good repair and properly drained
8. Adequate weed management adjacent to building
9. Adequate exterior rodent management program
10. Adequate exterior insect management program
11. No evidence of bird roosting
12. Sufficient cleaning capabilities to prevent buildup of food which may attract pests (e.g. flour spills at railroad offloading, corn syrup spills from trucks, etc.)
13. No evidence of plumbing or sewer leaks
14. Screens and vents clean
15. Open doors and windows screened
16. Visible condensate lines clear and clean

Interior Areas

1. Walls: Clean, proper materials, and in good repair
2. Floors: Clean, proper materials, and in good repair
3. Ceilings: Clean, proper materials, and in good repair
4. Elevator pits clean and dry
5. Floor drains clean with secured covers
6. Plumbing in good repair as related to pest potential
7. Visible condensate lines clear and no pooling of condensate
8. Other maintenance issues
9. No evidence of pest activity
10. Inspection aisles properly maintained
11. Other practices issues
12. Packaging material properly stored
13. Containers properly stored and clean
14. Damaged/returned good isolated
15. Equipment clean and pest free
16. Maintenance areas clean and no evidence of pests
17. Sanitation area clean and no evidence of pests; mops and tools stored off floor
18. Compliance with pest portion of GMPs
19. Pest management equipment clean and maintained (e.g. light traps, etc.)

Exterior Areas (including roof areas) ⬭ OK ⬭ Corrections Required ⬭ N/A

Technician: _____ Date: _____

Comments: _____

Signature of Technician: _____

Subpart D — Naturally Occurring Poisonous or Deleterious Substances [Reserved]

PART 110 — CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD — Table of Contents

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Subpart G — Defect Action Levels
110.110 Natural or unavoidable defects in food for human use that present no health hazard.
AUTHORITY: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264
SOURCE: 51 FR 24475, June 19, 1986, unless otherwise noted.

Subpart A — General Provisions
§ 110.3 Definitions.

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

(a) Acid foods or acidified foods means foods that have an equilibrium pH of 4.6 or below.

(b) Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(c) Batter means a semifluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.

(d) Blanching, except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.

(e) Critical control point means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.

(f) Food means food as defined in section 201(f) of the act and includes raw materials and ingredients.

(g) Food-contact surfaces are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ``Food-contact surfaces'' includes utensils and food-contact surfaces of equipment.

(h) Lot means the food produced during a period of time indicated by a specific code.

(i) Microorganisms means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term ``undesirable microorganisms'' includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA used the adjective ``microbial'' instead of using an adjectival phrase containing the word microorganism.

(j) Pest refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

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(k) Plant means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

(l) Quality control operation means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.

(m) Rework means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(n) Safe-moisture level is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (aw). An aw will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given aw will not support the growth of undesirable microorganisms.

(o) Sanitize means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(p) Shall is used to state mandatory requirements.

(q) Should is used to state recommended or advisory procedures or identify recommended equipment.

(r) Water activity (aw) is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 110.5 Current good manufacturing practice

(a) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

§ 110.10 Personnel

The plant management shall take all reasonable measures and precautions to ensure the following:

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

(b) Cleanliness. All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

(1) Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.

(2) Maintaining adequate personal cleanliness.

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work

station, and at any other time when the hands may have become soiled or contaminated.

(4) Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.

(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.

(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.

(9) Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(c) Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

(d) Supervision. Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§ 110.19 Exclusions.

(a) The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more ``raw agricultural commodities,'' as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.

(b) FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B — Buildings and Facilities

§ 110.20 Plant and grounds.

(a) Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(3) Adequately draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

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(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings.

(ii) Controlling areas over and around the vessels to eliminate harborages for pests.

(iii) Checking on a regular basis for pests and pest infestation.

(iv) Skimming the fermentation vessels, as necessary.

(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, adequate screening or other protection against pests.

§ 110.35 Sanitary operations.

(a) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(b) Substances used in cleaning and sanitizing; storage of toxic materials. (1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of

use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;

(ii) Those necessary for use in laboratory testing procedures;

(iii) Those necessary for plant and equipment maintenance and operation; and

(iv) Those necessary for use in the plant's operations.

Food and Drug Administration, HHS § 110.37

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

(c) Pest control. No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.

(4) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(5) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.

(e) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.
[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§ 110.37 Sanitary facilities and controls.

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(a) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

(b) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the plant.

(2) Properly convey sewage and liquid disposable waste from the plant.

(3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

21 CFR Ch. 1 (4—1—01 Edition) § 110.40

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(5) Provide that there is not backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(c) Sewage disposal. Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means.

(d) Toilet facilities. Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:

(1) Maintaining the facilities in a sanitary condition.

(2) Keeping the facilities in good repair at all times.

(3) Providing self-closing doors.

(4) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air-flow systems).

(e) Hand-washing facilities. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.

(2) Effective hand-cleaning and sanitizing preparations.

(3) Sanitary towel service or suitable drying devices.

(4) Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

(5) Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, of food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.

(6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

(f) Rubbish and offal disposal. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Subpart C — Equipment

§ 110.40 Equipment and utensils.

(a) All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained

to protect food from being contaminated by any source, including unlawful indirect food additives.

(b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(c) Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

Food and Drug Administration, HHS § 110.80

(d) Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

(g) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Subpart D [Reserved]

Subpart E — Production and Process Controls

§ 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(a) Raw materials and other ingredients. (1) Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.

(2) Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including

purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(3) Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or

21 CFR Ch. 1 (4—1—01 Edition) § 110.80

certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(4) Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(5) Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.

(6) Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.

(7) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(b) Manufacturing operations. (1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, aw, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.

(3) Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

(i) Maintaining refrigerated foods at 45 deg.F (7.2 deg.C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 deg. F (60 deg. C) or above.

(iv) Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

(4) Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

(5) Work-in-process shall be handled in a manner that protects against contamination.

(6) Effective measures shall be taken to protect finished food from contamination by

raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials, work-in-process, rework, or food shall be constructed, handled, and maintained during manufacturing or

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storage in a manner that protects against contamination.

(8) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

(9) Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

(10) Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

(11) Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

(12) Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.

(ii) Employing adequate heat processes where applicable.

(iii) Using adequate time and temperature controls.

(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.

(v) Cooling to an adequate temperature during manufacturing.

(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

(13) Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means, including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.

(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.

(iii) Using materials for food containers and food- packaging materials that are safe and suitable, as defined in Sec. 130.3(d) of this chapter.

(iv) Providing physical protection from contamination, particularly airborne contamination.

(v) Using sanitary handling procedures.

(14) Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and

dehydrated food, that relies on the control of aw for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the aw of food.

(ii) Controlling the soluble solids-water ratio in finished food.

(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the

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aw of the food does not increase to an unsafe level.

(15) Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.

(ii) Controlling the amount of acid or acidified food added to low-acid food.

(16) When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(17) Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food. [51 FR 24475, June 19, 1986, as amended at 65 FR 56479, Sept. 19, 2000]

§ 110.93 Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F [Reserved]

Subpart G — Defect Action Levels

§ 110.110 Natural or unavoidable defects in food for human use that present no health hazard.

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from

the Center for Food Safety and Applied Nutrition (HFS-565), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.
[51 FR 24475, June 19, 1986, as amended at 61 FR 14480, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

PART 111— CURRENT GOOD MANUFACTURING PRACTICE FOR DIETARY SUPPLEMENTS

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