

**Guidelines for Developing  
Good Manufacturing Practices (GMPs)  
and  
Standard Operating Procedures (SOPs)  
for  
Raw Ground Products**

**coordinated by**

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**for**

**National Meat Association  
Oakland, California**

**March 1998**



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March 1998

Ground beef is a very important product in the meat industry. In its various forms, it represents nearly half of all the beef consumed in the United States. National Meat Association's members who make ground beef met during its Convention in San Francisco in February 1998 and recommended that the Association develop Good Manufacturing Practices (GMPs) and Standard Operating Procedures (SOPs) for Grinding to support processors as they move into HACCP. Invitations to participate in the working sessions were accepted by a core group of members who represent a broad cross section of the grinding industry. They met in March 1998, and completed their review of the materials in two telephone conference calls.

NMA is pleased to have facilitated the development of these Guidelines. However, it is important to recognize that these guidelines are just that: Guidelines. We have identified certain procedures which may be followed to improve process control. Obviously, there may be other procedures that are available and in use. Each plant should employ the good manufacturing practices and standard operating procedures that work best for it.

Rosemary Mucklow  
Executive Director

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**INTRODUCTION**

Producers of raw ground beef and other raw ground products recognize that these products have an inherent food safety risk due to the nature of the process and the lack of a sufficient “kill” step for biological hazards in the process. Therefore, it is extremely important that grinders develop and implement effective Good Manufacturing Practices (GMPs) and Standard Operating Procedures (SOPs) as the foundations of successful HACCP programs. All of these activities combined will help grinders continue to produce the safest products possible by increasing total process control.

This document provides general recommendations for GMPs and SOPs for grinding operations, and it can be used as a guideline for developing plant specific GMPs and SOPs. It also addresses the issues of designing an effective lotting system and reprocessing ground product. These recommendations focus solely on the grinding operation. However, it should be noted that the following items are not addressed in this document, but they should be covered by existing Sanitation Standard Operating Procedures (SSOPs) and/or other plant-specific processing programs:

- Personnel — disease control, hygiene, clothing, training, etc.
- Plant and grounds — construction and design, product flow, drainage, etc.
- Sanitary operations — general maintenance, cleaning and sanitizing, pest control, etc.
- Sanitary facilities and controls — water supply, plumbing, sewage disposal, rubbish and offal disposal, etc.
- Freezers and coolers — monitored and maintained to ensure temperature control, recording devices, alarms, etc.
- Equipment maintenance and calibration — adequate frequency for thermometers, recording devices, compressed air equipment, etc.
- Recall program — It is recommended that all grinding operations develop a recall program and that mock recalls should be conducted periodically to ensure that the program works as planned.

Many of the items listed above are also addressed in 21 CFR Part 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (Attachment 1) - which was developed by the Food and Drug Administration and can be used as a resource if more information on any of these areas is needed.

**The Grinding Process**

For the purpose of developing this document, a very general flow diagram (Attachment 2) was developed to cover the major steps of the grinding process. The flow diagram was used only as a tool to stimulate discussion and make sure that common areas of the grinding process were covered. It is being provided to demonstrate common process steps that are addressed in this document. However, every establishment should accurately document its individual flow according to specific plant operation.

## LOTTING

All grinding operations should have a lotting mechanism for coding or recording finished products to allow for tracing the product back through the system and for tracing the product forward through the chain. Some establishments may develop computerized bar codes or tracking systems that are very elaborate and detailed, and others may have simple handwritten documentation and box/package codes. Lotting is driven by some time factor (i.e., hour, shift, day, etc.) and is given a specific code. Creating smaller lots or utilizing a sub-lotting system for tracking information may help demonstrate/document process control and could possibly help to minimize the economic impact of recalls. This is an area for further investigation by researchers.

Regardless of the mechanism each operation should have a record keeping system, and it is recommended that the following items be documented for each identified lot/sub-lot.

- Raw material source(s) by vendor and including vendor lot identification
- Data collected during process (temperatures, microbial data, etc.)
- Metal detector records
- Equipment evaluation records (i.e., grinder checks)
- Other items as specified by individual customer

If any abnormal indicator is found during the process then it is recommended that the product be segregated, that cleaning and sanitizing of the processing line is completed prior to reinitiating production, and that a new lot/sub-lot is started when production starts back up.

The concept of lotting systems in ground beef operations is a complex and detailed issue. The existing USDA definition for a lot, when a positive result for microbial contaminants is encountered such as *E. coli* O157:H7, is “from full sanitation to full sanitation.” In most commercial grinding operations this definition affects a full day’s production. However, proper documentation and controls allow for products to be sub-lotted under this definition to minimize the amount of affected products.

Sub-lotting under the context of the definition described above, as a result of microbial contamination, requires the following types of documentation:

- Batching records — These records should identify the types of raw material used by its tracking codes; the amount used in each batch of formulated product, the time it was used and the locations of equipment it was used on.
- Packaged product tracking systems — The finished products should be coded with the actual times they are packed and sealed and pallets of products should contain consecutive products off the line. Packaging systems with multiple lines should have a consistent flow of raw materials to each packaging line and the ability to code and identify products from a specific line is necessary. Downtime tracking sheets can be used to identify lines that were not packaging products at the time of suspect incidents and therefore created a break in the flow of products through the system.
- Microbiological testing and tracking — If a company is sampling and testing finished formulated raw materials from each batch for potential microbial adulterants, then it should include the batch number samples, the time of the sample and a protocol tracking form for submission to the laboratory for analysis.

- Finished Product “On-Hold” Programs — If a company is testing finished ground products for potential microbial adulterants, then it should require all of the product to be held until laboratory testing is completed and the results are available. Records for operations should include the total amount of products produced as well as their location.

Utilizing the information suggested above will allow companies to better identify and document the amount of suspect or affected product. Assume that if one composite sample for formulated products tested positive for E. coli O157:H7 during a day’s production where many more batch composites tested negative. Utilizing the information above and providing information on raw material control programs, batching records, microbiological sampling/testing records and in-process records for products, companies may be able to provide added assurance to USDA Inspectors that sufficient controls were in place to minimize the risk of carryover of the suspect microbial contamination throughout the entire production day.

Sub-lotting can also be used for other potential contamination such as a physical contamination. Sub-lotting for something such as a physical contaminant will require the following:

- Batching records — These records should identify the types of raw materials used by its tracking codes, the amount used in each batch of formulated product, grinder head cleaning and inspections by authorized representatives.
- In-Process Control Records — These records should identify the types of control checks performed on metal detectors and other control instruments, the times checks were performed and the line and or product code information.

An example of a lotting system that could be used for ground products is provided in Attachment 3.

## **REPROCESSED PRODUCT**

In developing the flow diagram, the issue of reintroducing broken patties, over-run at the end of the day, rework, etc. back into the processing flow was identified as an area that should be fully addressed by grinders. For the purpose of this document, a lot was defined as the finished product and a batch was defined as material that is in-process. The following categories are recommended to help distinguish between the types of raw materials being reintroduced and the points of entry into the grinding operation.

1. Intrabatch materials — These are raw materials that are maintained within the same batch. It should be covered in the actual flow diagram and a specific SOP should be written to document the establishments procedure(s) for these activities. For example, the formulation of ground beef requires that raw materials be analyzed for chemical composition (%fat-lean). This is part of the actual process flow of making the ground beef; therefore, the raw materials used for the analysis should remain within the same batch. It is recommended that the equipment used for testing chemical composition should be cleaned and sanitized between samples from different batches.
2. Product over-run — These are excess raw materials at the end of a production period that are not in final product form. The optimal situation is to eliminate product over-run by controlling the amount of raw materials needed to meet the desired production levels. Unfortunately, this is not always a realistic option. Therefore, the following recommendations are being provided to address product over-run:
  - Direct the product to further processing — cooking process, identified/specified product only.
  - Utilize the product to produce a designated batch/lot — Combine the raw materials for a specified time-period and process at the end of a shift or on a specified day as a designated batch/lot. (It should be noted that if this option is utilized, then one must accept the risk that if a problem is found in the designated batch/lot then all of the batches/lots that contributed to the designated batch/lot are subject to review. It will be imperative that a very detailed and accurate record keeping systems is developed to document amounts and identify all of the batches/lots that were used in the designated batch/lot.)
  - Identify a customer and sell the product to them for further processing.
  - Donate the product to charity.
  - Sell/give the products to plant employees.
  - Destroy the product.

It should be noted that products remaining at the end of a day or due to line failure during the day that cannot be processed on the same day should be treated as above.

6. Returned and reinspected product — The optimal situation is to eliminate the need for products being returned after they leave the establishment. Unfortunately, this is not always a realistic option. For example, a shipment of frozen patties may be returned because the patties have stuck together. The product is still safe for consumption but it does not meet the customer specifications and is returned. Therefore, the following recommendations are being provided to address returned and reinspected products:
  - Direct the product to further processing — cooking process, identified/specified product only.
  - Identify a customer and sell the product to them for further processing.
  - Donate the product to charity.
  - Sell/give the products to plant employees.
  - Destroy the product
  - Utilize the product to produce a designated batch/lot — Combine the raw materials for a specified time-period and process at the end of a shift or on a specified day as a designated batch/lot. (It should be noted that if this option is utilized, then one must accept the risk that if a problem is found in the designated batch/lot then all of the batches/lots that contributed to the designated batch/lot are subject to review. It will be imperative that a very detailed and accurate record keeping systems is developed to document amounts and identify all of the batches/lots that were used in the designated batch/lot.)
  
4. Interlot reprocessing. This allows the establishment to reprocess a batch over a designated time period (i.e. - shift) to allow an out-of-spec batch to be used on the same day's production. It should be noted that if product is added from an out-of-spec batch into other batches/lots during the day, then all products produced that contain out-of-spec batch are subject to review if a problem is found with any of the final batches because it may be impossible to distinguish if the problem was from the out-of-spec batch or from the batch that it was added to. Therefore, it will be imperative that detailed and accurate records documenting the amount of the out-of-spec batch used, the batches/lots that it is used in, and clear breaks in the process (i.e., clean-ups) are maintained.

The recommendations provided above should help an establishment make decisions relating to the reprocessing of products. Each establishment will need to carefully consider the options and determine which one works best within their operation based on amount of production, opportunities for further processing, etc. Each establishment is encouraged to develop written procedures for how it will handle these issues.

## **GOOD MANUFACTURING PRACTICES**

Good Manufacturing Practices (GMPs) as defined by the Food and Drug Administration in 21 CFR part 110 are the minimum sanitary and processing requirements for food companies. GMPs are fairly broad and general and can be used to help guide the development of Standard Operating Procedures (SOPs) which are very specific.

The following guidelines for developing Good Manufacturing Practices for grinding operations are recommended for voluntary consideration and use in developing plant-specific procedures. These GMPs are not designed to control specific hazards, but are intended to provide guidelines to help grinders produce safe and wholesome products.

### *Receiving Meat*

Incoming meat should be evaluated to ensure that it meets the plant-established purchase specifications.

Trucks, containers and carriers of raw materials should be evaluated upon receipt to ensure that the conditions meet plant requirements for transporting meat. All incoming meat should be coded/identified for plant use and for the in-plant tracking system.

### *Non-Meat Items*

Grinding operators will need to make sure that all non-meat items, such as packaging materials, seasonings/spices, etc. meet the plant-established specifications. USDA currently requires companies to have a Letter of Guarantee (LOG) from suppliers of non-meat ingredients relating to the use of food grade substances, foreign materials, pest control programs, etc. After the company accepts the non-meat items, then these items should be stored, handled and used in a manner that will maintain the integrity of the items.

### *Storage of Raw Materials*

It is recommended that raw materials be used on a First-In/First-Out (FIFO) basis or according to a plant specified product rotation/inventory control schedule. Raw materials should be stored at temperatures that maintain proper product condition. Frozen materials should be kept frozen, unless tempering or thawing is required prior to use. The package/pallet integrity must be maintained throughout the storage period to maintain the condition of the raw material. Product identity in storage should allow for the in-plant tracking system.

### *Tempering/Thawing of Frozen Materials*

If tempering or thawing is required prior to use, then it should be done in a time/temperature controlled manner which is adequately monitored and documented. The product package integrity is important during this process. The product's traceability should be maintained throughout the tempering/thawing process.



### Grinding/Processing

This includes weighing, mixing, blending, coarse and final grinds, forming, packaging, and labeling.

Throughout these steps the temperature of the product should be maintained and documented. Steps should be taken to prevent species cross-contamination and proper labeling to maintain endproduct identity. An organoleptic evaluation of the raw material ingredients should be completed prior to adding the meat to the batch. The ingredients should be evaluated for chemical composition (%fat and lean) to formulate product to desired endpoint. Procedures for ensuring proper endproduct characteristics (i.e., weights, physical characteristics, quantity, etc.) should be in place. The in-plant tracking mechanism should allow for batch identification and time of batch production.

It is recommended that all grinding operations have a mechanism for detecting and controlling metal and other foreign materials. For the purpose of checking products for metal, companies may have a mechanism for evaluating the equipment, visually checking the raw materials and products and other steps for controlling metal or they may utilize a metal detector. If companies are using metal detectors, then the sensitivity level should be sufficient for this process.

Establishments may conduct microbiological testing to monitor the process for trend analysis or because specific tests are required by individual customers. Final product packaging should include a code relating to the in-plant tracking system.

### Storage of Finished Product

Finished products should be stored at plant-designated time/temperatures to maintain product shelf-life. Frozen products should be kept frozen. A FIFO or a plant specified product rotation/inventory control schedule should be maintained for finished products. The package/pallet integrity should be maintained throughout the storage period to maintain the condition of the finished product. Product identity in storage should allow for the in-plant tracking system to be used for recall and/or market withdrawal purposes.

### Loading and Shipping

Finished products should be handled properly on the loading docks and during transport to prevent product deterioration by temperature abuse or improper handling practices. Trucks, containers and carriers of finished products should be evaluated prior to loading and shipping to ensure that their condition meets plant requirements for transporting raw ground meat. All trucks and carriers should be suitable for transporting food products; therefore, it may be important to consider what items were hauled in prior loads by the truck. All of the finished product should be coded/identified for intended use and for recall or market withdrawal purposes.

## **STANDARD OPERATING PROCEDURES**

Standard Operating Procedures (SOPs) can be defined as established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations. They are very concise and specific step-by-step instructions. Establishments are encouraged to have SOPs for every task or activity in the facility. GMPs can help guide the development of SOPs. SOPs are also very useful in training employees and in establishing a consistent method for conducting daily operations. Therefore, all grinders should develop SOPs for their operations.

The following guidelines relate to the areas identified in the GMPs listed above. However, it should be noted that these do not cover all of the areas discussed above and are only examples for which an establishment can develop plant-specific SOPs. Several of the items listed below would require more than one SOP for each specific operation. For example, it is recommended that product temperatures should be checked; therefore, a specific SOP for checking product temperatures should be developed that gives specific instructions on which combos of a load to check; the location(s) in the combo to check, how to check them, etc., and a SOP should be developed for calibrating thermometers. Both of these SOPs would be useful for checking product temperatures. Therefore, this list is basically an outline of general issues and will require additional plant-specific information to develop operational SOPs.

### Receiving Meat

1. Designated employee should verify that the raw material is from a company approved supplier. (Each plant should set supplier requirements and maintain a list of approved suppliers. It is recommended that review of records related to the specific product and an on-site audit of the supplier be conducted to make sure they are operating as the company desires. For example, a company may require that suppliers have an intervention step or that they are operating under HACCP systems.)
2. Designated employee should evaluate and document on a product receiving log the condition of truck, container and carriers of raw material upon arrival.  
Items for evaluation may include:
  - Cleanliness of truck — no foreign materials, dirt, free of debris, free of off odors
  - Temperature of truck — Temperature of the truck must be acceptable to maintain product temperature. Plant may set specific temperature.
  - Condition of door seals
  - General truck condition — void of cracks, insulation in good condition, paper on floors for carcass carriers
3. If truck condition is acceptable, then designated employee should verify that incoming material meets plant purchase specifications and/or that required documentation is provided.  
The following items may be included in purchase specifications:
  - Species identity and/or origin (bull, cow, etc.)
  - Domestic vs. foreign supply source
  - IMPs or product identity
  - Boning date/slaughter date
  - No foreign objects

- Supplier microbiological testing results, if required. If the supplier is required to test for *E. coli* O157:H7, then the material should not be used until the test results are received. If the supplier is testing for generic *E. coli*, coliforms, TPC or other microorganisms that can be used to establish supplier trend data, then the product does not have to be held until the results are received. However, if specific accept/reject levels are set for any specific microorganism then the product should not be accepted or it can be placed on hold until the test results are received.
  - Packaging/pallet requirements — i.e. - no metal fasteners or bands, pallets in good usable condition, slip sheets, covers on combos, plastic pallets, etc.
  - Age of raw material — recommend fresh products  $\leq 5$  days from fabrication; and frozen meat no more than 6 months from fabrication.
4. If the product meets the purchase specifications, then the designated employee should evaluate the actual condition of the raw materials.  
The following items are recommended for evaluation:
- Temperature of raw material (i.e., frozen  $\leq 0^{\circ}\text{F}$ ; fresh  $\leq 40^{\circ}\text{F}$ ). (Each operation should have a separate SOP for taking the temperature of incoming products and calibrating thermometers.)
  - Organoleptic evaluation of raw material for off odor, discoloration, improper appearance.
  - Material must have supplier code information and proper lot/load identification on materials
5. If incoming raw materials pass receiving inspection, then all raw materials should receive plant-specific tracking/coding information prior to entering the storage facility.

#### Storing Meat

1. Place fresh product into cold storage (recommend  $35^{\circ}\text{F}$ ) and frozen product into freezers (recommend less than  $10^{\circ}\text{F}$ ).
2. Complete plant specific storage records or product identification, so product will be used on a FIFO basis or according to plant product rotation/inventory control schedule.
3. Utilize all fresh product within 7 days of fabrication. Utilize all frozen product within 6 months of fabrication.
4. Store products to maintain package/pallet integrity. It is recommended that combo bins have a protective covering (second cover) if they are being stored in racks and that the protective covering should be removed prior to entering the processing area where the primary covering is removed.

#### Tempering/Thawing of Frozen Materials

1. Place frozen product in a tempering room that is  $\leq 40^{\circ}\text{F}$  and allow product to reach desired level of tempering or thawed state; actual time will vary depending on amount of product and type of packaging. (If the room temperature is higher than  $40^{\circ}\text{F}$  then one must evaluate the time/temperature relationship to reduce the risk of potential microbial growth on the surface of the product.)

2. The product should be monitored on a scheduled basis to prevent loss of package integrity and product drip.
3. The product temperature should be monitored on a scheduled basis to ensure that the desired end temperature is not exceeded.
4. All of the products should maintain the plant-specific tracking/coding information to ensure proper traceability of product from receiving through to final end products.

#### Grinding/Processing

1. It is recommended that the temperature of the room(s) be controlled throughout this process and that the actual time of processing should be as fast as possible to control product integrity. It is recommended that the temperature for the processing rooms be less than 50°F. Logs of room temperatures should be maintained.
2. The end product temperatures are recommended to be  $\leq 35^{\circ}\text{F}$  for forming fresh products;  $\leq 35^{\circ}$  for spiral/tunnel freezing chubs, and  $\leq 5-10^{\circ}\text{F}$  for IQF patties. During processing, these temperatures may be exceeded for brief time periods, but companies should carefully evaluate and control the time and temperature.
3. Production employees should evaluate the chemical composition of the raw materials to ensure that proper formulation is obtained.
4. Production employees should evaluate the organoleptic properties for off odor, discoloration, improper appearance prior to allowing product to enter the batch.
5. Production employees should record batch identification information and times of batch production to maintain plant-specific tracking information.
6. Production employees should complete an evaluation of the equipment (grinders, defect eliminators, metal detectors, etc.) on a scheduled basis and the time of each evaluation should be recorded.
7. The product identification/tracking mechanism should identify specific processing lines.
8. Packaging and labeling employees are responsible for properly labeling end-products with product identity and code dates which include an expiration date, sell-by date, use-by date, production date, etc. using a dating system according to company procedures.
9. Packaging and labeling employees are responsible for including all handling and storage information according to each product's requirements.
10. Microbiological testing can be conducted during this process, if desired or required by customers. If the customer requires testing for *E. coli* O157:H7, then it is recommended that control of the product should not be released until the test results are obtained. If testing for generic *E. coli*, coliforms, TPC or other microorganisms that can be used to establish processing trend data, then the product does not have to be held until the test results are received. However, if customers have specific accept/reject levels on any specific microorganism then control of the product should not be released until the test results are received.

### Storing Finished Product(s)

1. Place fresh products into cold storage (recommend 35°F) and frozen product into freezers (recommend less than 10°F).
2. Utilize products in a plant specified time-period to maintain shelf-life requirements. Shelf-life of the product is dependent upon type of product, type of package, temperature of storage, condition of incoming materials, etc. Therefore, each establishment should have specific guidelines for storing and utilizing finished products.
3. Store products to maintain package/pallet integrity.
4. Product identification should be maintained during storage.

### Loading/Shipping of Finished Product(s)

1. Designated employee should evaluate and document the condition of truck, container and carriers of finished product prior to loading products.  
The following items should be evaluated:
  - Cleanliness of truck — no foreign materials, dirt, free of debris, free of off odors
  - Temperature of truck — Temperature of the truck should be acceptable to maintain product temperature. Plant may set specific temperature.
  - Condition of door seals
  - General truck condition — void of cracks, insulation in good condition, paper on floors for carcass carriers
2. All finished products should be handled properly to maintain the condition of the products. Therefore, it is recommended that the time the products remain on the loading and receiving docks should be controlled based on the temperature of the docks.
3. The loading/shipping employees should be aware of the products being transported and the proper handling techniques for those products.
4. It is recommended that all trucks should be pre-chilled prior to loading product and that the trucks should at least reach the same temperature as the temperature of the product being shipped and lower if possible.
5. Package integrity should be maintained during loading/shipping.
6. Product identification should be maintained through loading and shipping to ensure that the products can be traced if needed for recall and/or market withdrawal purpose.

**FOOD AND DRUG  
ADMINISTRATION,  
DEPARTMENT OF HEALTH  
AND HUMAN SERVICES**

**21 CFR PART 110 - CURRENT  
GOOD MANUFACTURING  
PRACTICE IN  
MANUFACTURING,  
PACKING, OR HOLDING  
HUMAN FOOD**

**Subpart A - General Provisions**

Sec. 110.3 Definitions.  
Sec. 110.5 Current good  
manufacturing practice.  
Sec. 110.10 Personnel.  
Sec. 110.19 Exclusions.

**Subpart B - Buildings and Facilities**

Sec. 110.20 Plant and grounds.  
Sec. 110.35 Sanitary operations.  
Sec. 110.37 Sanitary facilities and  
controls.

**Subpart C - Equipment**

Sec. 110.40 Equipment and utensils.

**Subpart D - [Reserved]**

**Subpart E - Production and  
Process Controls**

Sec. 110.80 Processes and controls.  
Sec. 110.93 Warehousing and  
distribution.

**Subpart F - [Reserved]**

**Subpart G - Defect Action Levels**

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

**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.

(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 (a (INFERIOR w)). An a (INFERIOR w) will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a (INFERIOR w) 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" (a (INFERIOR w)) 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.

### **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 - BUILDING 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.

(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.

(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.

### **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.

(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.

(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, guidelines, 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 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, guidelines, 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, a (INFERIOR w), 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 (degree)F (7.2 (degree)C) or below as appropriate for the particular food involved.

(ii) Maintaining frozen foods in a frozen state.

(iii) Maintaining hot foods at 140 (degree)F (60 (degree)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 a (INFERIOR w) 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 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, breadings, 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 a (INFERIOR w) 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 a (INFERIOR w) 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 a (INFERIOR w) 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.

### **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.

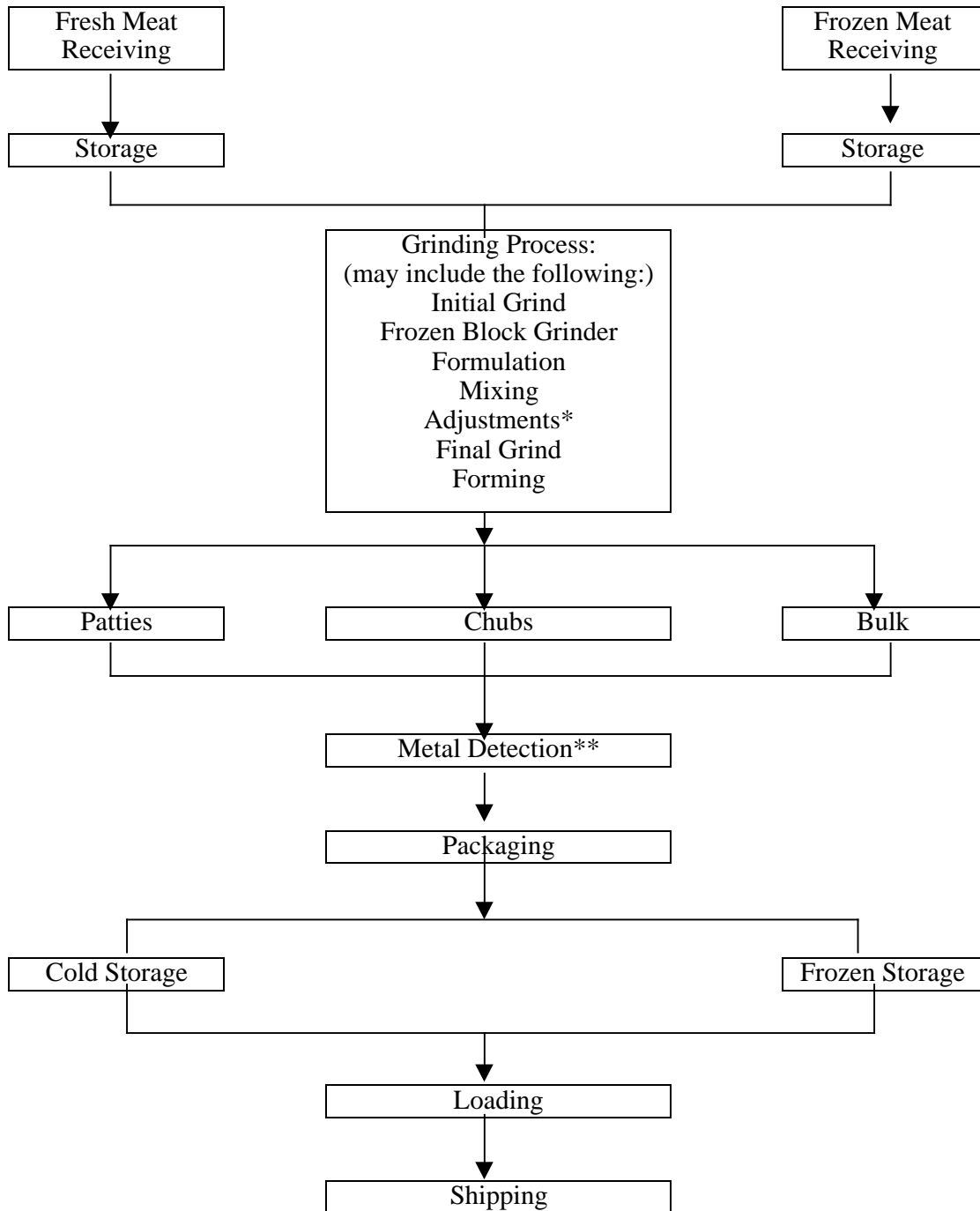
(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing

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 Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

## Ground Product Flow



\*Adjustments may be for temperature, fat/lean %, etc.

\*\*Metal detection may occur at various points throughout the flow, and it may be detected by plant-established procedures or by using metal detectors.

## GROUND PRODUCT LOTTING SYSTEM

