FSHN 05-01

Guidance for Processing FERMENTED AND DRIED SAUSAGE *in Retail Operations*

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Credits

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Background

This guidance has been prepared in response to a notable increase in on-site retail processing (manufacturing) of foods traditionally processed in controlled plant environments. Such retail processing can involve, but is not limited to acidifying, smoking, drying, fermenting, curing, reduced oxygen packaging, and other operations that are traditionally done at a food manufacturing plant level. The key distinction for processing as related to this guidance is that the processing occurs on-site in the retail setting.

This guidance is intended for retailers and regulatory personnel to help understand the controls to implement in a retail operation in order to process and sell safe food products. It can be referenced in developing considerations for **variances** for any exception or special provision to state or local food safety or sanitary codes. It addresses those special variances required by the FDA Food Code which may require HACCP plans for those jurisdictions that have adopted those portions of the FDA Food Code. In addition, it also applies to regulatory oversight and/or approval for regulatory overlap that may occur between the states' processing requirements and the state or local retail food safety and sanitary codes. This guidance assumes retail compliance with applicable retail food codes, prerequisite standard sanitary operations procedures, and labeling requirements specified in 21 CFR 101. This guidance is not intended to replace or duplicate existing regulations, but it does offer a reference for more uniform practices.

Disclaimer

This guidance is not a binding set of requirements. The information provided in the guidance are recommendations based on current science, commercial experience and practical considerations as assembled by the assigned committees and reviewed by a variety of selected experts and the Project Steering Committee. Use of these recommendations would likely result in retail processing practices that are acceptable to the pertinent authorities for food safety. Retail compliance and enforcement will remain within the interpretations and decisions of the pertinent state and local regulatory authorities.

Product Description

This recommended guidance is for specialty meat products processed at retail, for display and distribution at retail.

Related Terminology:

Approved source - is defined as a source that has been determined to conform to principles, practices, and standards that protect public health.

Casings - natural animal stomachs, intestines or bladders or manufactured casings of cellulose or collagen, which are used to contain comminuted meat, or poultry mixtures for sausages.

Dry Fermented Sausage - a product made of chopped or ground meat products that, as a result of bacterial action, reaches a pH of 5.3 or less and is then dried to remove 25 to 50 percent of the moisture to yield a moisture/protein ratio in compliance with USDA FSIS requirements. Dry fermented sausages include salamis and pepperonis.

Fermentation Culture - an active culture of one or more bacteria which affects the rapid development of a lower pH in dry and semi-dry fermented sausages.

Identifiable source - can include the name and address of the immediate supplier and the actual source or location of the supplies.

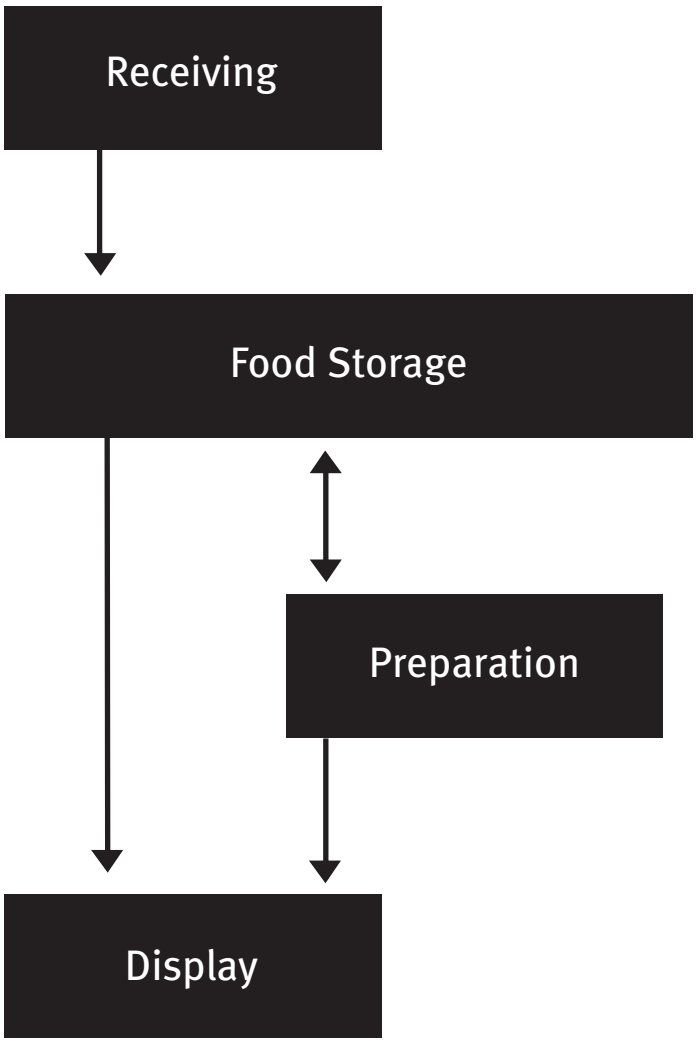
Moisture / Protein Ratio - the ratio of moisture content to protein content in the sausage. Required MPR can be found in USDA FSIS labeling policies website (http://www.fsis.usda.gov/OPPDE/larc/policies/policybook.pdf).

Potentially hazardous food (PHF) - means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms; the growth and toxin production of *Clostridium botulinum*. Potentially hazardous food includes a food of plant origin that is heat-treated or consists of raw seed spouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified in this definition.

Semi-dry Fermented Sausage - a product made of chopped or ground meat products that, as a result of bacterial action, reaches a pH of 5.3 or less and undergoes up to 15 percent removal of moisture during the fermentation/heating process. Semi-dry fermented sausages include summer sausage, thuringer, cervelat and Lebanon bologna.

Trichina treatment - one of the prescribed methods in 9 CFR 318.10 to render food products, i.e., pork and game meat products, free of the *Trichinella spiralis* parasite.

Flow Diagram of Operations



Check List for Operations

Receiving

All meats come from an identifiable, approved, licensed and inspected source. All food is properly packaged and labeled, and complies with all specifications to minimize contamination with potential food safety hazards (Appendix 1 - Food Safety Hazards).

All PHF are delivered at or below 41ºF (5ºC) or solidly frozen. A calibrated thermometer is used to monitor the internal and/or surface temperature of the incoming foods before acceptance (Appendix 2 - Calibrations).

Retail establishment actively manages a program for routine inspection of incoming products for approved sources, product condition and temperature as necessary, integrity of packaging and proper label information, and documents product acceptance or rejection with dates, times and the person in decision, plus any necessary comments.

Food Storage

Food storage should be in appropriate temperature control units (walk-in coolers, refrigerators or freezers) capable of maintaining proper product temperatures. All potentially hazardous foods (PHF) should be maintained at 41°F (5°C) or less and it is recommended that frozen items be stored at 0°F (-18°C) or less. The foods may include raw ingredients or finished products. These types of foods may be stored in separate units or segregated with adequate protection to prevent cross-contamination within the same unit. Display counters are not considered storage units and should not be used to store raw ingredients or finished products prior to actual display. The storage temperatures should be monitored as part of the daily SOP's (Appendix 4 - Daily SOP Check List).

The storage unit(s) are clean and orderly.

Products are contained and/or covered for protection.

Containers of products or ingredients that are removed from the original (identified) packages are relabeled, marked for identification and dated.

Ready-to-eat items and items ready-for-display are segregated from products that require further handling or processing.

Products are not stacked without adequate support and means to prevent any leakage between products.

Drippage is prevented in or on packaged products due to condensation, cooler pan leaks or other wet sources.

Products are stored above the floor (approx. 6 inches) and away from walls and the ceiling.

The schedule for product rotation should use a 'First-in First-out' rule (FIFO).

Display units are not considered storage units and should not be used to store raw ingredients. Display units must be maintained at or below 41ºF (5ºC).

Frozen storage unit(s) have the capacity and are operating correctly to assure the frozen foods are maintained solidly frozen, preferably at /or below ooF (-18ºC).

Routine monitoring for proper refrigerated storage unit temperatures involves use of a continuous time-temperature recording device or by periodic checks with a thermometer. All recorders and thermometers are calibrated periodically or as needed (Appendix 2 - Calibrations). When storage conditions above 41°F (5°C) are detected, an evaluation is conducted of all products stored in the unit. The evaluations will document considerations for the actual temperature of the products and duration of exposure. All temperature abused, off-color, off-odor, off-condition, out-of-date or otherwise suspect product is discarded.

Frozen products are thawed in refrigeration (below 41ºF / 5ºC) in a manner to prevent cross-contamination with other refrigerated foods. If more rapid thawing is necessary, the products are placed in clean flowing water no warmer than 70°F (21°C) only until thawing is complete. Product does not have to reach 70°F to be thawed. Do not allow products to thaw beyond 41°F (5°C) continuing processing or return to proper refrigeration. Packaging is recommended to protect the product from direct contact with the thaw water. If thawing requires direct water contact with the food, the procedure should be conducted in a sanitized sink or container that is designated or dedicated to this operation. Thawing is not conducted in water warmer than 70°F or at room temperature.

Preparation

Standard Operating Procedures (SOP's) for basic sanitation and food safety are used and documented daily (Appendix 4 - Daily SOP Check List). The daily check list should focus attention to assure:

Work area is maintained in an orderly manner, consisting of clean and sanitized countertops and sinks, clean floor and drains, and convenient and properly supplied handwash sinks.

All chemicals are properly stored and labeled.

All utensils, equipment, cutting boards, cooking or heating equipment are properly cleaned and sanitized.

Thermometers and recorders are calibrated and operating properly.

Processing Steps

There are numerous processing steps required to produce specialty meats and the variety and details for these steps can vary depending on the particular products. Explanation for the various processing steps in terms of necessary HACCP considerations have been compiled in an AFDO training manual, "Meat and Poultry Processing at Retail" and an accompanying guide, "Retail Meat and Poultry Processing Guidelines" (http://www.afdo.org). Additional references can be obtained through the USDA website (http://www.fsis.usda.gov) or the FDA Food Code and Annexes (http://www.cfsan.fda.gov/~dms/foodcode.html).

This guide features the primary processing step for the following products:

Fermented & Dried Sausage (Shelf-stable)

Grinding, blending and slicing

Fermentation, heating and drying

Preparation – Grinding, Blending and Stuffing

The initial step of the sausage production is the grinding of the meat to reduce the particle size and aid in the blending between the meat and non-meat ingredients. All meat used in the formulation of sausage should be clean and wholesome. The final particle size will vary depending on the type of sausage produced. Non-meat ingredients are extensively used to impart flavor, color, texture and other sensory characteristics or to help preserve the finished product. The allowable amount of these non-meat ingredients could be restricted by regulations, i.e., amount of water in the finished product or the amount of extenders or nitrites in the sausage.

After the initial grinding, all ingredients must be blended to create a homogeneous product. During this step, all ground meat and non-meat ingredients are combined in a mixer under close monitoring to prevent excessive blending of the ingredients. Excessive blending could be detrimental for the quality and appearance of the final product.

Preparation – Fermentation, Heating and Drying

The **fermentation, heating and drying steps** are necessary to produce a ready-to-eat stable product. The fermentation step quickly lowers the pH and stabilizes the product to prevent the growth of *Staphylococcus aureus* during this elevated temperature process. The low pH also aids in drying and destruction of potential bacterial pathogens (Appendix 1 - Food Safety Hazards) present in the raw ingredients. During the heating step, all potential bacterial pathogens are inactivated and in some cases it acts as the trichina treatment for the more labile nematodes, *Trichinella spiralis*. The drying step is primarily to help yield a stable finished product and in some cases help complete the inactivation of potential human pathogens.

Dry fermented sausages must have a pH lower than 5.3 and they should be dried to remove 25 to 50 percent of the moisture such that the product moisture to protein ratio is 1.9:1.0 or less. Genoa salami and Milano are exceptions with a moisture to protein ratio (MPR) of 2.3:1.0.

Semi-dry fermented sausages must have a pH lower than 5.3 and they have been dried to remove up to 15% of the moisture such that the product moisture to protein ratio is greater than 1.9:1.0, but less than 3.3:1.0. Refrigerated semi-dry sausages do not have standards for MPR.

The processes to produce the proper product pH level and moisture to protein ratios must be validated through actual trial productions and analysis before conducting commercial production.

The fermentation process should be monitored to assure the products reach the desired pH (Appendix 5 - Fermentation Log).

During fermentation of the sausages, it is necessary to limit the time during which the sausage meat is exposed to temperatures exceeding 60ºF or higher which is the critical temperature at which *Staphylococcal* growth effectively begins. Temperature measures should be taken at the surface of the product. Where surface temperature monitoring is not possible, fermentation room temperatures should be controlled. Guidelines for exposure time prior to reaching the product pH of 5.3 have been developed based on the actual surface temperature of the products. These guidelines are expressed as "degree-hours" which can be calculated by multiplying the number of hours the product is exposed times the exposure in degrees of temperature above 60°F. Example for a constant temperature process:

Process A: Constant 80°F temperature for 55 hours with a pH decline to 5.3

Degrees: 80° – 60°= 20°

Hours: 55 hrs.

Degree-Hours: (20°) x (55 hr) = 1100 degree/hours

Process A passes the guideline (Limit: 1200 degree/hours)

Degree/Hours	Temperature (ºF)	Allowed Hours
1200	75	80
1200	80	60
1200	85	48
1000	90	33
1000	95	28
1000	100	25
900	105	20
900	110	18

Source: Retail Meat and Poultry Processing Guidelines, 1998 AFDO

In some cases, a **heating/cooking step** could be used after fermentation and prior to the drying step. This moist heating can be accomplished by using a sealed oven or steam injection to raise the relative humidity above 90 percent throughout the cooking process and meet one of the following time-temperature requirements designed to kill Trichinae parasites, Salmonella and/or E. coli. The heating process should be monitored to assure proper time and temperature treatments (Appendix 6 - Smokehouse / Product Temperature Log).

Min. oF internal temperature	Min. Holding Time for that Temp.
130	121
131	97
132	77
133	62
134	47
135	37
136	32
137	24
138	19
139	15
140	12
141	10
142	8
143	6
144	5
145	4
158	0

Source: FSIS (www.fsis.usda.gov/OA/fr/95033F-a.htm), January 1999. Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat and Poultry Products.

Optional drying steps that yield a 5D bacterial kill or more reduction of E. coli O157:H7 are:

a. Ferment at 90°F to pH 5.3 and apply cook, then dry for ≥ 7 days (large casing).

b. Ferment at 90°F to pH 4.6 and hold at 90°F ≥ 6 days (small casing).

c. Ferment at 90°F to pH 4.6 and apply cook (small and large casings).

d. Ferment at 110°F to pH 4.6 and hold at 110°F for ≥ 4 days (small and large casings).

Display

Display involves holding the finished products in temperature control units for a specified duration and condition for public sale.

The specialty meats that require refrigerated storage (not shelf-stable) should be displayed in units maintained below 41°F (5°C).

Display units are maintained in a clean, sanitized and orderly manner.

Food is properly labeled with "Appropriate Handling Instructions" (Appendix 3 - Product Labels).

Appendices

1. Food Safety Hazards
2. Calibrations
3. Product Labels
4. Daily SOP Check List
5. Fermentation Log
6. Smokehouse/Product Temperature Log

Appendix 1 Food Safety Hazards

Biological

Hazard: Bacterial growth

Problem: Certain bacteria, i.e., *Salmonella*, *Listeria, Staphylacoccus and E. coli O157:H7*, can contaminate and grow on ready-to-eat meat products due to poor handling of the ingredients or finished products.

Controls: Practice time-temperature controls in storage and product handling
Clean and sanitize equipment and utensils.
Record daily SOP's.
Maintain process temperatures.
Maintain heating controls for proper time and temperatures exposure.
Prevent contamination of finished product from the environment or food handlers.

Hazard: Parasites

Problems: Consumption of certain undercooked, cured and fermented products that may contain 'live" parasites, *Trichinella spiralis* in pork.

Controls: Detection and elimination, Cook to greater than 155°F (68°C) internal temperature for 15 seconds.

Chemical

Hazard: Chemical contamination

Problems: Product may arrive with chemical contamination.

Controls: Purchase from reliable and identifiable source, with a HACCP plan to control antibiotic residues, pesticides, and growth promotants. These plans and records can be obtained on request. Verify appropriate amounts of curing chemicals are added by using calibrated and certified scales or pre-weighed packets.

Physical

Hazard: Metal fragments

Problems: Physical hazards (i.e., metal fragments) can be introduced or received in product.

Controls: Purchase from reliable and identifiable source that maintain HACCP plans and records that can be accessed on request. Maintain equipment and protect product to prevent physical contaminants and /or install calibrated metal detector.

Temperature Monitoring Devices – Thermometers

Many types of thermometers and temperature recording devices are readily available for use in food handling operations. We recommend thermistors, thermocouples and infrared thermometers with either a digital or analog readout. All of these instruments are acceptable for use in the food processing operations as long as the operator understands how they are used and if they are calibrated for proper readings.

The method and frequency of calibration for thermometers will depend on the use and temperature range where the equipment is used. In the absence of manufacture's recommendations, thermometers should be calibrated at least once a month with more frequent calibrations when the instrument is physically abused or if the readings are questionable.

Temperature Monitoring Devices (TMD) - Calibration Procedures (options):

a. TMD's can be calibrated against a thermometer certified by the National Institute of Standards and Technology (NIST) by simply comparing both units at two preset temperatures (hot and cold).

b. TMD's can be calibrated using an ice-water slush. Insert the temperature probe into a mixture of ice and water slush and stir (2-3 min) until the thermometer stabilizes. The probe should be at the center of the container. The thermometer should read 32±1°F (0±1°C). Adjust accordingly or discard and replace the faulty thermometer.

c. Hot point calibration is used when monitoring temperatures higher than room temperature (e.g., cooking temperatures). Heating blocks or boiling water can be used for this calibration. When using the boiling water procedure, the probe is placed inside a container with boiling water until the thermometer stabilizes (2-3 min). The probe should be at the center of the container. The thermometer should read 212±1°F (100±1°C) or appropriate temperature according to elevation (Table 1 - Altitude to Boiling Point of Pure Water Relationship). Adjust accordingly or discard and replace the faulty thermometer.

d. A combination of the procedures b and c is recommended for a more accurate calibration of thermometer used to monitor a wide range of temperatures.

Altitude to Boiling Point of Pure Water Relationship

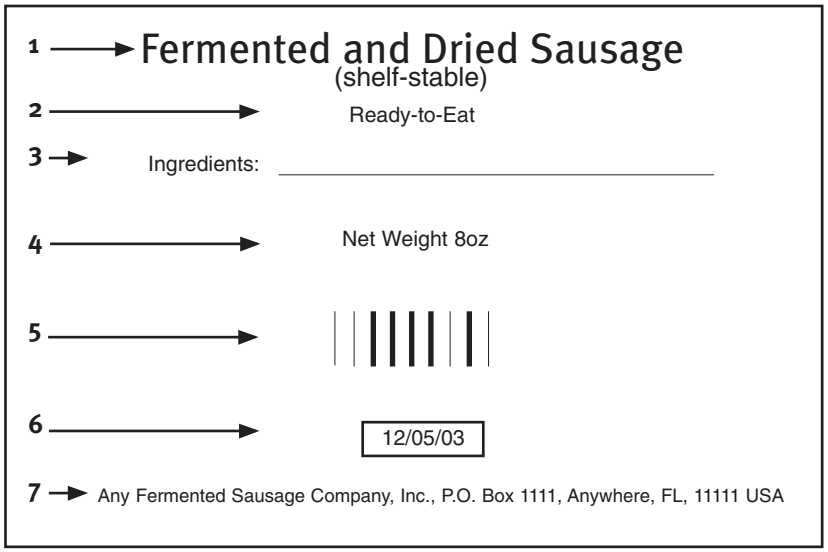
Feet Above Sea Level	Boiling Point (ºF)
0	212
500	211
1,000	210
1,500	209
2,000	208
2,500	207
3,000	206
3,500	205
4,000	204
4,500	203
5,000	203
6,000	201
7,000	199
8,000	197
10,000	194
12,000	190
14,000	187

Source: Thermometer Calibration, food safety webpage, University of Nebraska Cooperative Extension (http://foodsafety.unl.edu/html/thermometer.html)

Appendix 3 Product Labels

All specialty product sold through display in a retail setting must contain certain details on the product label that informs the consumer and could prevent potential food safety problems. The detail provided on this example includes both required and recommended information. The actual placement and size of the labeled information can vary. The example is enlarged for illustration.

1. Product name used to describe the product. The descriptive name should be in common terms associated with the product and recognized by the consumer.
2. *Ready-to-Eat* statement and instructions for safe handling and consuming the product.
3. Product ingredients listed in descending order by weight.
4. Net weight and pricing information.
5. Bar code for product inventory and identity.
6. Lot or date code.
7. Company name and address.



Note: This would not apply for bulk displayed items.

Disclaimer: This label is simply provided as a guide. Retailers should consult with their local authorities to assure compliance with more immediate requirements in their region

Appendix 4 Daily SOP Check list

Store Name/Number: _____ **DATE:** _____

Storage	**Time/Temp**	**Time/Temp**	**Time/Temp**	**Time/Temp**
Refrigerators (°F / Time)	°F	°F	°F	°F
Freezers (°F / Time)	°F	°F	°F	°F
Display	**Time/Temp**	**Time/Temp**	**Time/Temp**	**Time/Temp**
Display temperature (°F / Time)	°F	°F	°F	°F
Clean and Orderly. Food in good condition and properly labeled.				
	SOP CHECK LIST			
Work Area	**Comments**			
Orderly; Clean and Sanitized tables, countertops and sinks. Orderly, all work surfaces cleared. Clean floor and drains				
Proper storage and labeling of chemicals and cleaning items				
Wet and dry trash separate and removed from work area.				
All utensils, pots, pans, bowls, cutting boards, cooking or heating equipment properly cleaned and sanitized.				
Thermometer and recorder available and calibrated				
Personnel				
Personnel Health, hand-washing practices, glove use, clean and well maintained outer garments, proper hair covering and no jewelry.				
Food Storage				
All food protected, dated and labeled properly				
Refrigerators and freezers clean, orderly and operating correctly.				
	Pre-Op	**Time**	**Post-Op**	**Time**
Employee Initials				
Manager Review				

This particular form is not mandated but it does indicate information that should be recorded to demonstrate an appropriate process for food safety. Different and additional forms can be used to record the same information.

Appendix 5 Fermented Log

Fermented Sausage-Shelf Stable

Processing Date: _____

Lot # Batch	Temperature	Time In	Time Out	Final Product pH	Operator initials

Comments:

Note: Continuous smokehouse temperature charts can be used in place of the temperature logos.

Reviewer's Signature:_____ **Date:** _____

This particular form is not mandated but it does indicate information that should be recorded to evidence an appropriate process for food safety. Different and additional forms can be used to record the same information.

Appendix 6 Smokehouse / Product Temperature Log

Fermented Sausage-Shelf Stable

Processing Date: _____

Product Temperature / Times

Lot # Batch	Start				Finish	Operator initials

Comments:

Note: Continuous smokehouse temperature charts can be used in place of the temperature logos.

Reviewer Signature:_____ **Date:** _____

This particular form is not mandated but it does indicate information that should be recorded to evidence an appropriate process for food safety. Different and additional forms can be used to record the same information.

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