2. USFDA, 21 Code of Federal Regulations, Part 120, subpart B, revised January 2001 https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/Juice/JuiceHACCPRegulations.pdf

Code of Federal Regulations

TITLE 21--FOOD AND DRUGS

PART 120 -- HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Subpart A--General Provisions

120.1 Applicability.
120.3 Definitions.
120.5 Current good manufacturing practice.
120.6 Sanitation standard operating procedures.
120.7 Hazard analysis.
120.8 Hazard Analysis and Critical Control Point (HACCP) plan.
120.9 Legal basis.
120.10 Corrective actions.
120.11 Verification and validation.
120.12 Records.
120.13 Training.
120.14 Application of requirements to imported products.

Subpart B--Pathogen Reduction

120.20 General.
120.24 Process controls.
120.25 Process verification for certain processors.

Authority: 21 U.S.C. 321, 342, 343, 346, 348, 371, 374, 379e, 381, 393; 42 U.S.C. 241, 242l, 264.

Subpart A--General Provisions

Sec. 120.1 Applicability.

(a) Any juice sold as such or used as an ingredient in beverages shall be processed in accordance with the requirements of this part. Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree. The requirements of this part shall apply to any juice regardless of whether the juice, or any of its ingredients, is or has been shipped in interstate commerce (as defined in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b)). Raw agricultural ingredients of juice are not subject to the requirements of this part. Processors should apply existing agency guidance to minimize microbial food safety hazards for fresh fruits and vegetables in handling raw agricultural products.

(b) The regulations in this part shall be effective January 22, 2002. However, by its terms, this part is not binding on small and very small businesses until the dates listed in paragraphs (b)(1) and (b)(2) of this section.
(1) For small businesses employing fewer than 500 persons the regulations in this part are binding on January 21, 2003.
(2) For very small businesses that have either total annual sales of less than $500,000, or if their total annual sales are greater than $500,000 but their total food sales are less than $50,000; or the person claiming this exemption employed fewer than an average of 100 full-time equivalent employees and fewer than 100,000 units of juice were sold in the United States, the regulations are binding on January 20, 2004.

Sec. 120.3 Definitions.

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act, 101.9(j)(18)(vi), and part 110 of this chapter are applicable to such terms when used in this part, except where redefined in this part. The following definitions shall also apply:

(a) *Cleaned* means washed with water of adequate sanitary quality.
(b) *Control* means to prevent, eliminate, or reduce.
(c) *Control measure* means any action or activity to prevent, reduce to acceptable levels, or eliminate a hazard.
(d) *Critical control point* means a point, step, or procedure in a food process at which a control measure can be applied and at which control is essential to reduce an identified food hazard to an acceptable level.
(e) *Critical limit* means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.
(f) *Culled* means separation of damaged fruit from undamaged fruit. For processors of citrus juices using treatments to fruit surfaces to comply with 120.24, *culled* means undamaged, tree-picked fruit that is U.S. Department of Agriculture choice or higher quality.
(g) *Food hazard* means any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
(h) *Importer* means either the U.S. owner or consignee at the time of entry of a food product into the United States, or the U.S. agent or representative of the foreign owner or consignee at the time of entry into the United States. The importer is responsible for ensuring that goods being offered for entry into the United States are in compliance with all applicable laws. For the purposes of this definition, the importer is ordinarily not the custom house broker, the freight forwarder, the carrier, or the steamship representative.
(i) *Monitor* means to conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.
(j) (1) *Processing* means activities that are directly related to the production of juice products.
(2) For purposes of this part, processing does not include:

(i) Harvesting, picking, or transporting raw agricultural ingredients of juice products, without otherwise engaging in processing; and
(ii) The operation of a retail establishment.

(k) *Processor* means any person engaged in commercial, custom, or institutional processing of juice products, either in the United States or in a foreign country, including any person engaged in the processing of juice products that are intended for use in market or consumer tests.

(l) *Retail establishment* is an operation that provides juice directly to the consumers and does not include an establishment that sells or distributes juice to other business entities as well as directly to consumers. "Provides" includes storing, preparing, packaging, serving, and vending.

(m) *Shall* is used to state mandatory requirements.

(n) *Shelf-stable product* means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.

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

(p) *Validation* means that element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the identified food hazards.

(q) *Verification* means those activities, other than monitoring, that establish the validity of the HACCP plan and that the system is operating according to the plan.

Sec. 120.5 Current good manufacturing practice.

Part 110 of this chapter applies in determining whether the facilities, methods, practices, and controls used to process juice are safe, and whether the food has been processed under sanitary conditions.

Sec. 120.6 Sanitation standard operating procedures.

(a) *Sanitation controls.* Each processor shall have and implement a sanitation standard operating procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing. The SSOP shall address:

(1) Safety of the water that comes into contact with food or food contact surfaces or that is used in the manufacture of ice;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;

(3) Prevention of cross contamination from insanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to processed product;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;

(6) Proper labeling, storage, and use of toxic compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
(8) Exclusion of pests from the food plant.

(b) *Monitoring.* The processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 of this chapter that are appropriate both to the plant and to the food being processed. Each processor shall correct, in a timely manner, those conditions and practices that are not met.

(c) *Records.* Each processor shall maintain SSOP records that, at a minimum, document the monitoring and corrections prescribed by paragraph (b) of this section. These records are subject to the recordkeeping requirements of 120.12.

(d) *Relationship to Hazard Analysis and Critical Control Point (HACCP) plan.* Sanitation standard operating procedure controls may be included in the HACCP plan required under 120.8(b). However, to the extent that they are implemented in accordance with this section, they need not be included in the HACCP plan.

Sec. 120.7 Hazard analysis.

(a) Each processor shall develop, or have developed for it, a written hazard analysis to determine whether there are food hazards that are reasonably likely to occur for each type of juice processed by that processor and to identify control measures that the processor can apply to control those hazards. The written hazard analysis shall consist of at least the following:
(1) Identification of food hazards;
(2) An evaluation of each food hazard identified to determine if the hazard is reasonably likely to occur and thus, constitutes a food hazard that must be addressed in the HACCP plan. A food hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of those controls, the food hazard will occur in the particular type of product being processed. This evaluation shall include an assessment of the severity of the illness or injury if the food hazard occurs;
(3) Identification of the control measures that the processor can apply to control the food hazards identified as reasonably likely to occur in paragraph (a)(2) of this section;
(4) Review of the current process to determine whether modifications are necessary; and
(5) Identification of critical control points.

(b) The hazard analysis shall include food hazards that can be introduced both within and outside the processing plant environment, including food hazards that can occur before, during, and after harvest. The hazard analysis shall be developed by an individual or individuals who have been trained in accordance with 120.13 and shall be subject to the recordkeeping requirements of 120.12.

(c) In evaluating what food hazards are reasonably likely to occur, consideration should be given, at a minimum, to the following:
(1) Microbiological contamination;
(2) Parasites;

(3) Chemical contamination;
(4) Unlawful pesticides residues;
(5) Decomposition in food where a food hazard has been associated with decomposition;
(6) Natural toxins;
(7) Unapproved use of food or color additives;
(8) Presence of undeclared ingredients that may be allergens; and
(9) Physical hazards.

(d) Processors should evaluate product ingredients, processing procedures, packaging, storage, and intended use; facility and equipment function and design; and plant sanitation, including employee hygiene, to determine the potential effect of each on the safety of the finished food for the intended consumer.

(e) HACCP plans for juice need not address the food hazards associated with microorganisms and microbial toxins that are controlled by the requirements of part 113 or part 114 of this chapter. A HACCP plan for such juice shall address any other food hazards that are reasonably likely to occur.

Sec. 120.8 Hazard Analysis and Critical Control Point (HACCP) plan.

(a) *HACCP plan.* Each processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food hazards that are reasonably likely to occur during processing, as described in 120.7. The HACCP plan shall be developed by an individual or individuals who have been trained in accordance with 120.13 and shall be subject to the recordkeeping requirements of 120.12. A HACCP plan shall be specific to:
(1) Each location where juice is processed by that processor; and
(2) Each type of juice processed by the processor. The plan may group types of juice products together, or group types of production methods together, if the food hazards, critical control points, critical limits, and procedures required to be identified and performed by paragraph (b) of this section are essentially identical, provided that any required features of the plan that are unique to a specific product or method are clearly delineated in the plan and are observed in practice.

(b) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:
(1) List all food hazards that are reasonably likely to occur as identified in accordance with 120.7, and that thus must be controlled for each type of product;
(2) List the critical control points for each of the identified food hazards that is reasonably likely to occur, including as appropriate:
(i) Critical control points designed to control food hazards that are reasonably likely to occur and could be introduced inside the processing plant environment; and
(ii) Critical control points designed to control food hazards introduced outside the processing plant environment, including food hazards that occur before, during, and after harvest;
(3) List the critical limits that shall be met at each of the critical control points;
(4) List the procedures, and the frequency with which they are to be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include any corrective action plans that have been developed in accordance with 120.10(a), and that are to be followed in response to deviations from critical limits at critical control points;
(6) List the validation and verification procedures, and the frequency with which they are to be performed, that the processor will use in accordance with 120.11; and
(7) Provide for a recordkeeping system that documents the monitoring of the critical control points in accordance with 120.12. The records shall contain the actual values and observations obtained during monitoring.

(c) *Sanitation.* Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with 120.6, they are not required to be included in the HACCP plan.

Sec. 120.9 Legal basis.

Failure of a processor to have and to implement a Hazard Analysis and Critical Control Point (HACCP) system that complies with 120.6, 120.7, and 120.8, or otherwise to operate in accordance with the requirements of this part, shall render the juice products of that processor adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Whether a processor's actions are consistent with ensuring the safety of juice will be determined through an evaluation of the processor's overall implementation of its HACCP system.

120.10 Corrective actions.

Whenever a deviation from a critical limit occurs, a processor shall take corrective action by following the procedures set forth in paragraph (a) or paragraph (b) of this section.

(a) Processors may develop written corrective action plans, which become part of their HACCP plans in accordance with 120.8(b)(5), by which processors predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:
(1) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and
(2) The cause of the deviation is corrected.

(b) When a deviation from a critical limit occurs, and the processor does not have a corrective action plan that is appropriate for that deviation, the processor shall:
(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;
(2) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such review;
(3) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;
(4) Take corrective action, when necessary, to correct the cause of the deviation; and
(5) Perform or obtain timely verification in accordance with 120.11, by an individual or individuals who have been trained in accordance with 120.13, to determine whether

modification of the HACCP plan is required to reduce the risk of recurrence of the deviation, and to modify the HACCP plan as necessary.

(c) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with 120.11(a)(1)(iv)(B) and the recordkeeping requirements of 120.12.

Sec. 120.11 Verification and validation.

(a) Verification. Each processor shall verify that the Hazard Analysis and Critical Control Point (HACCP) system is being implemented according to design.

(1) Verification activities shall include:

(i) A review of any consumer complaints that have been received by the processor to determine whether such complaints relate to the performance of the HACCP plan or reveal previously unidentified critical control points;

(ii) The calibration of process monitoring instruments;

(iii) At the option of the processor, the performance of periodic end-product or in-process testing; except that processors of citrus juice that rely in whole or in part on surface treatment of fruit shall perform end-product testing in accordance with 120.25.

(iv) A review, including signing and dating, by an individual who has been trained in accordance with 120.13, of the records that document:

(A) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that the records document values that are within the critical limits. This review shall occur within 1 week (7 days) of the day that the records are made;

(B) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with 120.10. This review shall occur within 1 week (7 days) of the day that the records are made; and

(C) The calibrating of any process monitoring instruments used at critical control points and the performance of any periodic end-product or in-process testing that is part of the processor's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made; and

(v) The following of procedures in 120.10 whenever any verification procedure, including the review of consumer complaints, establishes the need to take a corrective action; and

(vi) Additional process verification if required by 120.25.

(2) Records that document the calibration of process monitoring instruments, in accordance with paragraph (a)(1)(iv)(B) of this section, and the performance of any periodic end-product and in-process testing, in accordance with paragraph (a)(1)(iv)(C) of this section, are subject to the recordkeeping requirements of 120.12.

(b) Validation of the HACCP plan. Each processor shall validate that the HACCP plan is adequate to control food hazards that are reasonably likely to occur; this validation shall

occur at least once within 12 months after implementation and at least annually thereafter or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan in any way. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or consumers of the finished product. The validation shall be performed by an individual or individuals who have been trained in accordance with 120.13 and shall be subject to the recordkeeping requirements of 120.12. The HACCP plan shall be modified immediately whenever a validation reveals that the plan is no longer adequate to fully meet the requirements of this part.

(c) Validation of the hazard analysis. Whenever a juice processor has no HACCP plan because a hazard analysis has revealed no food hazards that are reasonably likely to occur, the processor shall reassess the adequacy of that hazard analysis whenever there are any changes in the process that could reasonably affect whether a food hazard exists. Such changes may include changes in the following: Raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product. The validation of the hazard analysis shall be performed by an individual or individuals who have been trained in accordance with 120.13, and, records documenting the validation shall be subject to the recordkeeping requirements of 120.12.

Sec. 120.12 Records.

(a) Required records. Each processor shall maintain the following records documenting the processor's Hazard Analysis and Critical Control Point (HACCP) system:
  (1) Records documenting the implementation of the sanitation standard operating procedures (SSOP's) (see 120.6);
  (2) The written hazard analysis required by 120.7;
  (3) The written HACCP plan required by 120.8;
  (4) Records documenting the ongoing application of the HACCP plan that include:
    (i) Monitoring of critical control points and their critical limits, including the recording of actual times, temperatures, or other measurements, as prescribed in the HACCP plan; and
    (ii) Corrective actions, including all actions taken in response to a deviation; and
  (5) Records documenting verification of the HACCP system and validation of the HACCP plan or hazard analysis, as appropriate.

(b) General requirements. All records required by this part shall include:
  (1) The name of the processor or importer and the location of the processor or importer, if the processor or importer has more than one location;
  (2) The date and time of the activity that the record reflects, except that records required by paragraphs (a)(2), (a)(3), and (a)(5) of this section need not include the time;
  (3) The signature or initials of the person performing the operation or creating the record; and
  (4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is

observed. The records shall contain the actual values and observations obtained during monitoring.

(c) Documentation.

(1) The records in paragraphs (a)(2) and (a)(3) of this section shall be signed and dated by the most responsible individual onsite at the processing facility or by a higher level official of the processor. These signatures shall signify that these records have been accepted by the firm.

(2) The records in paragraphs (a)(2) and (a)(3) of this section shall be signed and dated:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) Upon verification and validation in accordance with 120.11.

(d) Record retention.

(1) All records required by this part shall be retained at the processing facility or at the importer's place of business in the United States for, in the case of perishable or refrigerated juices, at least 1 year after the date that such products were prepared, and for, in the case of frozen, preserved, or shelf stable products, 2 years or the shelf life of the product, whichever is greater, after the date that the products were prepared.

(2) Offsite storage of processing records required by paragraphs (a)(1) and (a)(4) of this section is permitted after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location and comply with paragraph (g) of this section.

(3) If the processing facility is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned to the processing facility for official review upon request.

(e) Official review. All records required by this part shall be available for review and copying at reasonable times.

(f) Public disclosure.

(1) All records required by this part are not available for public disclosure unless they have been previously disclosed to the public, as defined in 20.81 of this chapter, or unless they relate to a product or ingredient that has been abandoned and no longer represent a trade secret or confidential commercial or financial information as defined in 20.61 of this chapter.

(2) Records required to be maintained by this part are subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic type HACCP plans that reflect standard industry practices.

(g) Records maintained on computers. The maintenance of computerized records, in accordance with part 11 of this chapter, is acceptable.

Sec. 120.13 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section shall be responsible for the following functions:

(1) Developing the hazard analysis, including delineating control measures, as required by 120.7.
(2) Developing a Hazard Analysis and Critical Control Point (HACCP) plan that is appropriate for a specific processor, in order to meet the requirements of 120.8;
(3) Verifying and modifying the HACCP plan in accordance with the corrective action procedures specified in 120.10(b)(5) and the validation activities specified in 120.11(b) and (c); and 120.7;
(4) Performing the record review required by 120.11(a)(1)(iv).

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration, or shall be otherwise qualified through job experience to perform these functions. Job experience may qualify an individual to perform these functions if such experience has provided knowledge at least equivalent to that provided through the standardized curriculum. The trained individual need not be an employee of the processor.

Sec. 120.14 Application of requirements to imported products.

This section sets forth specific requirements for imported juice.

(a) Importer requirements. Every importer of juice shall either:
(1) Obtain the juice from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the food and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the relationship between the signing parties, and is functioning and enforceable in its entirety; or
(2) Have and implement written procedures for ensuring that the juice that such importer receives for import into the United States was processed in accordance with the requirements of this part. The procedures shall provide, at a minimum:
(i) Product specifications that are designed to ensure that the juice is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or because it may have been processed under insanitary conditions; and
(ii) Affirmative steps to ensure that the products being offered for entry were processed under controls that meet the requirements of this part. These steps may include any of the following:
(A) Obtaining from the foreign processor the Hazard Analysis and Critical Control Point (HACCP) plan and prerequisite program of the standard operating procedure records required by this part that relate to the specific lot of food being offered for import;
(B) Obtaining either a continuing or lot specific certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported food has been processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported food is being processed in accordance with the requirements of this part;
(D) Maintaining on file a copy, in English, of the foreign processor's hazard analysis and HACCP plan, and a written guarantee from the foreign processor that the imported food is processed in accordance with the requirements of this part;
(E) Periodically testing the imported food, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported food is processed in accordance with the requirements of this part; or
(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) Competent third party. An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) Records. The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of 120.12.

(d) Determination of compliance. The importer shall provide evidence that all juice offered for entry into the United States has been processed under conditions that comply with this part. If assurances do not exist that an imported juice has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B--Pathogen Reduction

Sec. 120.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for process controls.

Sec. 120.24 Process controls.

(a) In order to meet the requirements of subpart A of this part, processors of juice products shall include in their Hazard Analysis and Critical Control Point (HACCP) plans control measures that will consistently produce, at a minimum, a 5 log (i.e., 10 5) reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism. For the purposes of this regulation, the "pertinent microorganism" is the most resistant microorganism of public health significance that is likely to occur in the juice. The following juice processors are exempt from this paragraph:
(1) A juice processor that is subject to the requirements of part 113 or part 114 of this chapter; and
(2) A juice processor using a single thermal processing step sufficient to achieve shelf-stability of the juice or a thermal concentration process that includes thermal

treatment of all ingredients, provided that the processor includes a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis required by 120.7.

(b) All juice processors shall meet the requirements of paragraph (a) of this section through treatments that are applied directly to the juice, except that citrus juice processors may use treatments to fruit surfaces, provided that the 5-log reduction process begins after culling and cleaning as defined in 120.3(a) and (f) and the reduction is accomplished within a single production facility.

(c) All juice processors shall meet the requirements of paragraphs (a) and (b) of this section and perform final product packaging within a single production facility operating under current good manufacturing practices. Processors claiming an exemption under paragraph (a)(1) or (a)(2) of this section shall also process and perform final product packaging of all juice subject to the claimed exemption within a single production facility operating under current good manufacturing practices.

Sec. 120.25 Process verification for certain processors.

Each juice processor that relies on treatments that do not come into direct contact with all parts of the juice to achieve the requirements of 120.24 shall analyze the finished product for biotype I Escherichia coli as follows:

(a) One 20 milliliter (mL) sample (consisting of two 10 mL subsamples) for each 1,000 gallons of juice produced shall be sampled each production day. If less than 1,000 gallons of juice is produced per day, the sample must be taken for each 1,000 gallons produced but not less than once every 5 working days that the facility is producing that juice. Each subsample shall be taken by randomly selecting a package of juice ready for distribution to consumers.

(b) If the facility is producing more than one type of juice covered by this section, processors shall take subsamples according to paragraph (a) of this section for each of the covered juice products produced.

(c) Processors shall analyze each subsample for the presence of E. coli by the method entitled "Analysis for Escherichia coli in Citrus Juices--Modification of AOAC Official Method 992.30" or another method that is at least equivalent to this method in terms of accuracy, precision, and sensitivity in detecting E. coli. This method is designed to detect the presence or absence of E. coli in a 20 mL sample of juice (consisting of two 10 mL subsamples). The method is as follows:

(1) Sample size. Total-20 mL of juice; perform analysis using two 10 mL aliquots.

(2) Media. Universal Preenrichment Broth (Difco, Detroit, MI), EC Broth (various manufacturers).

(3) Method. ColiComplete (AOAC Official Method 992.30--modified).

(4) Procedure. Perform the following procedure two times:

(i) Aseptically inoculate 10 mL of juice into 90 mL of Universal Preenrichment Broth (Difco) and incubate at 35 deg. C for 18 to 24 hours.

(ii) Next day, transfer 1 mL of preenriched sample into 10 mL of EC Broth, without durham gas vials. After inoculation, aseptically add a ColiComplete SSD disc into each tube.

(iii) Incubate at 44.5 deg. C for 18 to 24 hours.

(iv) Examine the tubes under longwave ultra violet light (366 nm). Fluorescent tubes indicate presence of E. coli.

(v) MUG positive and negative controls should be used as reference in interpreting fluorescence reactions. Use an E. coli for positive control and 2 negative controls--a MUG negative strain and an uninoculated tube media.

(d) If either 10 mL subsample is positive for E. coli, the 20 mL sample is recorded as positive and the processor shall:

(1) Review monitoring records for the control measures to attain the 5-log reduction standard and correct those conditions and practices that are not met. In addition, the processor may choose to test the sample for the presence of pathogens of concern.

(2) If the review of monitoring records or the additional testing indicates that the 5-log reduction standard was not achieved (e.g., a sample is found to be positive for the presence of a pathogen or a deviation in the process or its delivery is identified), the processor shall take corrective action as set forth in 120.10.

(e) If two samples in a series of seven tests are positive for E. coli, the control measures to attain the 5-log reduction standard shall be deemed to be inadequate and the processor shall immediately:

(1) Until corrective actions are completed, use an alternative process or processes that achieve the 5-log reduction after the juice has been expressed;

(2) Perform a review of the monitoring records for control measures to attain the 5-log reduction standard. The review shall be sufficiently extensive to determine that there are no trends towards loss of control;

(i) If the conditions and practices are not being met, correct those that do not conform to the HACCP plan; or

(ii) If the conditions and practices are being met, the processor shall validate the HACCP plan in relation to the 5-log reduction standard; and

(3) Take corrective action as set forth in 120.10. Corrective actions shall include ensuring no product enters commerce that is injurious to health as set forth in 120.10(a)(1).

Source: 66 FR 6197, Jan. 19, 2001, unless otherwise noted.

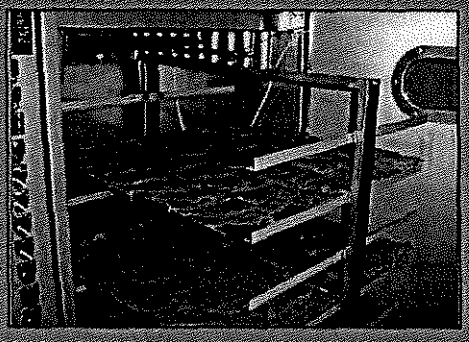
3. United States Department of Agriculture (USDA), FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments: 2014 Compliance Guideline
https://www.fsis.usda.gov/wps/wcm/connect/5fd4a01d-a381-4134-8b91-99617e56a90a/Compliance-Guideline-Jerky-2014.pdf?MOD=AJPERES

FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments

2014 Compliance Guideline

This guidance document is designed to help very small meat and poultry establishments that manufacture jerky identify:

- The key steps in the jerky process needed to ensure safety; and
- The scientific support available to help develop a safe process and product.



This Compliance Guideline provides **guidance** to assist establishments in meeting FSIS regulations related to jerky processing. The guideline also contains recommendations to help industry produce a safe product based on the scientific information available in the literature. Guidance represents **best practice** recommendations by FSIS, based on the best scientific and practical considerations, and does not represent **requirements** that must be met. Establishments may choose to adopt different procedures than those outlined in the guideline, but they would need to support why those procedures are effective. It is important to note that this guideline represents FSIS's current thinking on this topic and should be considered usable as of the issuance date.

This version of the guidance document, dated August 2014, replaces previous versions of the document which was last updated in July 2012. FSIS updated the guideline based on four comments from three trade associations and one individual. The following are changes made in response to comments:

- Broken link on page 4 (see footnote) has been changed to a link to a report from the New Mexico Department of Health;
- Surface preparation step was added to the step-by-step guide on page 7;
- Definition of shelf-stability and recommended shelf-stability parameters were clarified on page 15;
- Continuously introducing steam option was clarified on page 22;
- Attachment 4, which provides guidance on supporting the continuously introducing steam option, was added.

A more detailed summary of the comments and FSIS' responses can be found in Attachment 1.

In addition to making changes in response to public comments, FSIS also made the following changes in response to questions submitted through askFSIS:

- Clarified on page 8 that the lethality treatment of poultry jerky should achieve at least a 5.0-$\log_{10}$ reduction of *Salmonella* spp.;
- Provided guidance on pages 13 – 14 on how to calibrate a humidity recorder;
- Clarified on page 19 that reference to the cooking time in the humidity options in *Appendix A* refers to the entire cooking time (including come up time), not just the time during which the temperature in *Appendix A* is achieved and maintained (e.g., 145°F for 4 minutes);
- Clarified in the text on page 19 that if an establishment using *Appendix A* as support for the lethality treatment introduces steam or seals the oven, cooking time should never be less than one hour; and
- Clarified the documentation that should be collected to support that humidity is being implemented consistent with *Appendix A* when the sealed oven or continuously introducing steam methods are used on pages 21 and 22.

Although comments will no longer be accepted through regulations.gov on this guidance document, FSIS will update this document as necessary should new information become available.

Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments

Table of Contents

Purpose 4

Background 4

Step-by-Step Guide for Jerky Processing 5

Critical Operational Parameters during the Lethality Treatment 9

Scientific Support Available for Jerky Processing 18

References 29

Helpful Websites 31

Attachment 1: FSIS Response to Comments 32

Attachment 2: Time, temperature, and humidity combinations reported in the literature for beef jerky that achieve at least a 5–$\log_{10}$ reduction in *Salmonella* and *E. coli* O157:H7 40

Attachment 3: Making Your Own Wet bulb (Reprinted with Permission from the University of Wisconsin) 49

Attachment 4: Example Time-Temperature Recorder Chart to Support Option to Continuously Inject Steam 53

Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments

Purpose

This guideline is designed to help small and very small meat and poultry establishments that manufacture jerky to identify:

- The key steps in the jerky process needed to ensure safety; and
- The scientific support available to help develop a safe process and product.

This guideline is not intended to set any regulatory requirements. This document replaces previous versions of the guideline last updated in July 2012.

Background

Meat or poultry jerky is a ready-to-eat (RTE), dried product that is considered shelf-stable (i.e., it does not require refrigeration after proper processing). Following a 2003 salmonellosis outbreak from *Salmonella* Kiambu in jerky produced in New Mexico[1], FSIS published the first version of the *Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments*. The Compliance Guideline provided guidance for small and very small meat and poultry establishments on the critical steps for jerky processing and the controls needed at each of these steps to ensure a safe product is produced.

One potential cause of the 2003 *Salmonella* Kiambu outbreak in jerky was the very slow drying process under low humidity conditions (1% Relative Humidity - 82°C dry bulb, 30°C wet bulb), which allowed *Salmonella* organisms to dehydrate during drying and become resistant to heat. Therefore, the first version of the jerky compliance guidelines emphasized the need for high levels of humidity during jerky processing. Since 2003, a number of journal articles have been published that has increased scientific understanding of the critical factors during jerky processing including the role of humidity.

One potential cause of the 2003 *Salmonella* Kiambu in jerky outbreak was the very slow drying process under low humidity conditions

This document updates and replaces the 2007 and 2012 versions of the guideline to reflect the most up-to-date science and understanding of jerky processing. This guideline also addresses concerns identified through Food Safety Assessments (FSAs) and askFSIS questions and responds to public comments received on the 2012 version.

[1] http://aces.nmsu.edu/ces/nmhs/documents/albanese.pdf

Step-by-Step Guide for Jerky Processing

Below is a summary of the eight (8) general processing steps used in jerky production. Although an establishment's process may not include these same steps, **the lethality treatment followed by drying should be used to produce a safe product**. Other steps such as the intervention and post-drying steps may be used by establishments when the lethality and drying steps do not achieve adequate lethality. Further descriptions of the key steps in the jerky process, including the microbial interventions that can be applied to ensure safety, are included in the pages that follow.

- **Step 1 - Strip preparation**: Whole muscle is sliced or ground; ground product is formed into strips (some jerky is formed).

- **Step 2 – Marination**: The strips are marinated in a solution that often contains salt, sugar, and flavoring ingredients.

- **Step 3 – Interventions**: Antimicrobial interventions before, during, and after marinating the strips of raw product may be added to increase the level of pathogen reduction beyond that achieved by heating alone.

- **Step 4 - Surface preparation:** Strips are heated using a low temperature heat step, which makes the surface tacky to aid in smoke adherence and improve product texture.

- **Step 5 – Lethality**: The lethality treatment is defined as the process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption. The lethality treatment is considered to include the time when the product is placed in the heated oven (including surface preparation and color setting) until the product reaches the desired lethality time-temperature combination (also referred to as "the cooking time").

  In order to achieve adequate lethality, it is important that an establishment's actual process adheres to the following critical operational parameters (see Key Definitions on page 8) in the scientific support:
  - Product time-temperature combination
  - Relative humidity

- **Step 6 – Drying:** Drying is the process during which water (moisture) is removed from the product. After the lethality treatment, jerky is dried to meet a water activity level sufficient to prevent the growth of microorganisms, especially toxigenic microorganisms, such as *Staphylococcus aureus.*

- **Step 7 – Post-drying heat step**: A post-drying heat step may be added to increase the level of pathogen reduction beyond that achieved by heating alone.

- **Step 8 – Handling**: Product is often handled after the lethality and drying steps and prior to packaging.

Jerky producers (and all producers of RTE product) are required to control the food safety hazards in their products (9 CFR 417.4(a)) and to document that their Hazard Analysis and Critical Control Point (HACCP) systems work according to 9 CFR 417.5(a). Establishments producing RTE products need to achieve lethality of pathogens (e.g., *Salmonella*) in the product, and stabilize the product to inhibit the growth of spore-forming bacteria (e.g., *C. botulinum* and *C. perfringens*). In addition, jerky producers need to ensure the growth of toxigenic microorganisms, such as *Staphylococcus aureus*, is controlled during the process and prevented during the distribution and storage of the finished product. This guideline provides steps jerky processors can take to ensure that the jerky processes they employ effectively control these hazards. The guideline discusses each step in the jerky process in more detail below with key considerations related to pathogen reduction or control highlighted for each step. Each process is unique, so some processors may not use all 8 steps. Some may perform the steps below in different order, or some may use additional steps.

- **Step 1 - Strip preparation**: Whole muscle is sliced or ground; ground product is formed into strips (some jerky is formed).

It is critical for establishments to use source materials prepared under good manufacturing practices (GMPs) designed to minimize contamination and the presence and growth of pathogens of public health concern, so the initial pathogen load is not higher than what the process is designed to reduce. Establishments that choose to purchase source materials known to be contaminated with pathogens of public health concern, such as *Salmonella* or shiga toxin-producing *Escherichia coli* (*E. coli)* (STEC) organisms such as *E. coli* O157:H7 or *E. coli* O45, should pay special attention to the controls they put in place to ensure cross-contamination between raw and RTE product does not occur.

- **Step 2 – Marination**: The strips are marinated in a solution that often contains salt, sugar, and flavoring ingredients.

Establishments should use non-meat ingredients for marinades and spice mixes that are prepared under GMPs designed to minimize contamination and the presence and growth of pathogens of public health concern, so the initial pathogen load is not higher than what the process is designed to reduce. FSIS recommends that establishments use a new liquid marinade solution or dry spice mix with each production batch to reduce chances of cross-contamination from one batch of production to another. If an establishment does reuse a marinade or spice mix, it should consider and address the potential hazards associated with cross-contamination from one batch of production to another.

- **Step 3 - Interventions**: Antimicrobial interventions before, during, and, after marinating the strips of raw product have been shown to increase the level of pathogen reduction beyond that achieved by heating alone.

Some heating processes may not deliver an adequate lethality and, thus, may require an additional intervention step to ensure product safety. Examples of interventions that may increase the lethality of the process are:

- Preheating the meat or poultry jerky strips in the marinade to a minimum internal temperature of 160°F will provide an immediate reduction of *Salmonella* (Harrison and Harrison, 1996). Heating in marinade may produce unacceptable flavors for some products; however, other liquids such as water could be used. The times and temperatures in *FSIS Appendix A: Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat and Poultry Products* (referred to throughout this document as Appendix A) could be used for preheating in the liquid, although the product internal temperature should be monitored to ensure adequate lethality is achieved).

- Dipping the product in 5% acetic acid for 10 minutes before placing it in the marinade can augment the log reduction effects of drying but not enough to eliminate pathogens (Calicioglu, 2002 & 2003). This intervention may also result in an undesirable flavor.

- Dipping the product in 1:2 or 1:3 mixtures of calcium sulfate (Mionix $Safe_2O$™) and water for 30 seconds or dipping in acidified sodium chlorite (Keeper®) at concentrations between 500 and 1,200 ppm can reduce the level of *Salmonella*, *Listeria monocytogenes (Lm)*, and *E. coli* O157:H7 compared with no pretreatment. These pretreatments were effective in both dehydrators and smokehouse processing (Harrison et al., 2006).

➢ **Step 4 - Surface preparation:** Strips are heated using a low temperature heat step which makes the surface tacky to aid in smoke adherence and improve product texture.

Humidity is often not introduced until the next step, the lethality treatment. The lack of humidity during the initial surface preparation step is generally not a food safety concern because the step is usually too short (30 minutes or less) to dry out the product to such a degree that the heat resistance of *Salmonella* would be increased. This step may include or be followed by a color setting step during which humidity is also not introduced. This color setting step plus the surface preparation step should be 30 minutes or less in total. If an establishment uses a preparation or color setting step that is longer than 30 minutes, it should provide support for why the lack of humidity does not result in the product drying out before the lethality treatment.

➢ **Step 5 - Lethality treatment**: The lethality treatment is defined as the process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption. The lethality treatment is considered to include the time when the product is placed in the heated oven (including surface preparation and color setting) until the point at which the product reaches the desired lethality time-temperature combination (also referred to as the "cooking time").

In order to achieve adequate lethality, the establishment's actual process needs to adhere to the following critical operational parameters (see Key Definitions on page 8) in the scientific support:

- Product time-temperature combination
- Relative humidity

In recent years, several jerky products have been found to be adulterated with *Salmonella* or *E. coli* O157:H7. Often the contamination has been linked to inadequate lethality treatment. The lethality treatment of meat jerky should achieve at least a 5.0-$\log_{10}$ reduction of *Salmonella* spp. and at least a 5.0-$\log_{10}$ reduction for shiga toxin-producing *Escherichia coli* (*E. coli)* (STEC) for products containing beef as recommended in the *Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products*. The lethality treatment of poultry jerky should achieve at least a 5.0-$\log_{10}$ reduction of *Salmonella* spp. Although poultry jerky is considered to fall under the performance standard in 9 CFR 381.150 (i.e., a 7.0-$\log_{10}$ reduction of *Salmonella* spp.), the regulation allows for the use of an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product. Research has supported that a 5.0-$\log_{10}$ reduction in *Salmonella* is sufficient for such shelf-stable products. Indeed, the *FSIS Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products* found that there would not be a significant increase in the cases of salmonellosis if jerky and other shelf-stable products achieved a 5.0-$\log_{10}$ vs. 7.0-$\log_{10}$ lethality. In addition to *Salmonella spp.*, the lethality treatment of meat and poultry jerky should achieve at least a 3.0-$\log_{10}$ reduction in *Lm*, although a 5.0-$\log_{10}$ reduction or greater is desirable for providing an even greater safety margin for ensuring that *Lm* does not grow to detectable levels during storage. However, establishments are not required to validate that their process achieves reduction in *Lm* (or STEC for products containing beef) if it achieves sufficient reductions in *Salmonella* because *Salmonella* is more heat resistant than other pathogens and is, therefore, considered an indicator of lethality.

Establishments should make sound decisions in the hazard analysis that support that source materials were prepared using GMPs and other process controls as discussed in the previous steps of strip preparation and marination such that a 5.0-$\log_{10}$ reduction in *Salmonella* results in the production of a safe product.

Official establishments choosing to use cooking to achieve lethality before drying may consider a number of different

KEY DEFINITIONS

The **lethality treatment** is defined as the process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption. The lethality treatment is considered to include the time when the thermal processing begins (e.g., the product is placed in the heated oven) until the point at which the product reaches the desired lethality time-temperature combination (also referred to as the "cooking time").

Critical operational parameters are those parameters of an intervention that must be met in order for the intervention to operate effectively and as intended. Such parameters include but are not limited to time, temperature, water activity, concentration, relative humidity, and type of equipment (to the extent that the use of different equipment would result in an inability to achieve the critical parameters of the study).

types of scientific documents to support the time-temperature-humidity combination used in the actual process.

Such types of scientific support documents include:

- Compliance Guidelines (e.g., *Appendix A*)
- Journal articles
- Challenge studies
- In-plant data

Finished product testing would not be considered adequate scientific support for the process used on its own, however, because such testing does not support that at least an adequate reduction of *Salmonella* spp. is achieved by the process.

An in-depth discussion of considerations for each of these types of scientific support documents, along with examples, is discussed in the section titled: **Scientific Support Documents for Jerky Processing**.

Critical Operational Parameters during the Lethality Treatment

Regardless of the scientific support document used, it is important that an establishment's actual process and procedures relate and adhere to the critical operational parameters in the scientific support in order to achieve adequate lethality. There are several critical operational parameters that are important for jerky processing that will be reviewed.

Product time-temperature combination

FSIS has found through FSAs that many establishments use temperatures from support documents to set critical limits for the oven temperature; however, setting the oven temperature to the temperature in the support does not ensure that the product will reach the same internal temperature which is critical to ensure adequate lethality is achieved. The FSAs show that some establishments do not measure or verify that the product has achieved the desired internal lethality temperature until after drying. FSIS does not recommended verifying product temperatures only after drying because the product may have dried out before the lethality temperature was reached, resulting in lower than expected pathogen reduction.

One of the critical operational parameters during the jerky process is the time-temperature combination the product achieves. Most often the temperatures used during the lethality treatment that are reported in scientific support documents, such as the *Appendix A* guidelines, are the temperatures that the product should reach. FSIS has found that establishments will use these same temperatures to set critical limits for the oven temperature. However, setting the oven temperature to the temperature in the support is not appropriate because it does not ensure that the product will reach the same internal temperature, which is critical to ensure adequate lethality is achieved.

For this reason, FSIS recommends that

establishments monitor the internal product temperature. Product internal temperature can be measured by inserting a thermocouple probe into the center of a beef strip. Proper insertion may be difficult because the product is so thin; therefore, FSIS recommends that establishments slice one piece of jerky twice as thick as normal so that the probe can be inserted. If this thicker piece reaches the lethality temperature, the thinner pieces should as well. In addition, to accurately measure the product temperature, the establishment should understand factors that could affect the temperature of the product. These factors include cold spots in the oven, as well as variation in oven temperature during different seasons. Although monitoring product temperature is strongly encouraged, establishments can use the oven or smokehouse temperature in place of the product temperature, provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the product temperature in the scientific support.

In addition to the product temperature, the amount of time the product is held at this temperature is also critical to ensuring that adequate lethality is achieved. It is important for the establishment to understand how the actual temperature of the product was taken, the time it takes the product to reach the target temperature (known as the come-up time or CUT), and the amount of time the product is held at the target temperature compared to the scientific support documentation. If the product is held at the target lethality treatment for less time than what was used in the scientific support, then adequate lethality may not be achieved.

KEY DEFINITIONS

Relative Humidity is defined as the degree of saturation of the air by water (vapor), expressed as a percentage. Relative humidity describes the relation of the existing vapor pressure at a given temperature to the maximum vapor pressure at that temperature. Air at a given temperature can absorb vapor until its saturation (100%). The difference between the dry and wet bulb temperature is the relative humidity at that temperature. The following website http://www.ringbell.co.uk/info/humid.htm contains a function for calculating the relative humidity given the wet and dry bulb temperatures.

Relative Humidity

In addition to the product time-temperature combination, the relative humidity (e.g., steam) in the oven is also critical to achieve adequate lethality in jerky. It is important that the establishment maintains humidity according to its scientific support. If relative humidity is not added or maintained by the process, the establishment should maintain scientific support demonstrating that humidity is not a critical operational parameter. Some jerky processors may be concerned that adding humidity will affect the ability to dry the meat or poultry and result in unacceptable product texture; however, the lethality treatment during which relative humidity is applied takes very little time. Adding humidity during the lethality treatment should accelerate subsequent drying and prevent case-hardening, which may actually improve product texture.

Relative humidity around a product during the lethality treatment promotes lethality in two ways:

- First, the humidity reduces surface evaporation and the energy or heat that evaporation removes from the product during heating. If sufficient relative humidity surrounding the product is not maintained during the lethality treatment, undesirable evaporative cooling at the surface will occur, and the product will not reach the desired temperature. Producing products under conditions of high humidity early in the cooking process reduces evaporative cooling allowing products to reach higher product surface temperatures which results in a greater reduction in microorganisms.

- Second, the humidity keeps the product surface (and any pathogens) more moist and prevents unwanted concentration of solutes (e.g., sugar and salt) as a result of drying. Research has demonstrated that bacteria can become more heat resistant as their moisture levels decrease, and increased concentrations of solutes, especially sugars, increase the heat resistance of bacteria. Therefore, the drying of the product surface before the pathogens are destroyed will increase pathogen heat resistance and allow them to survive the heating process. By incorporating humidity to minimize evaporation, the D values (time at a constant temperature necessary to destroy 90% or 1-$\log_{10}$ of the target organism) that are the basis for Appendix A and other scientific support documents remain valid (Goepfert, 1970; Goodfellow and Brown, 1978; Faith, N.G. et al. 1998).

Without sufficient humidity the product surface may dry too quickly, and the bacteria may become more heat resistant.

For these reasons, it is crucial that the processor prevent drying of the product until a lethal time-temperature combination is attained. In order to be most effective, the humidity should be applied during the lethality treatment and before the drying step occurs. Although the lethality treatment includes the time when the product is placed in the heated oven until the product reaches the desired lethality time and temperature combination (the "cooking time"), establishments may not introduce relative humidity into the process until 15 to 30 minutes after the product is placed in the heated oven. The establishment would do so because of the previous step of surface preparation that is needed to set the surface to aid in the adherence of smoke. As discussed earlier, the lack of humidity during this initial step is not a food safety concern because of its short duration.

In addition to applying humidity early in the lethality treatment, FSIS also recommends that establishments treat the lethality and drying steps as separate stages to ensure that lethality is achieved before the product dries out. Therefore, the establishment should measure and verify the desired product temperature has been met before the drying stage. One way for an establishment to know that the product has not dried out before a lethal time-temperature combination is attained is to measure the water activity of the

product after the lethality treatment but before drying and again after drying. Some published articles (for example, Buege et al., 2006a) report the water activity at these points in the process for comparison. Another approach is for the establishment to monitor the wet bulb temperature early in the process because it provides a good indication of product surface temperature, which strongly influences lethality (Buege, 2006a). Further explanation and directions for making a wet bulb thermometer are in Attachment 3. Although this information may be useful, establishments do not need such data to validate the process if they are able to demonstrate that their process can achieve the level of relative humidity in their scientific support.

Some simple and practical measures that can be used to aid in meeting the humidity level utilized in the scientific support documents include:

- Seal the oven: Close the smokehouse doors and oven dampers to provide a closed system and prevent moisture loss.

- Add humidity:
  - Place one or more shallow, wide pans of hot water in the oven to increase the humidity in the system. Conduct a test run to determine whether the water evaporates.
  - Injecting steam or a fine water mist into the oven can also add humidity.

The use of a humidity sensor or the use of wet bulb and dry bulb thermometers (to measure relative humidity) would enable the operator to determine whether adequate humidity is being applied for either measure.

In order to ensure that adequate humidity is attained, the establishment should monitor the humidity throughout the lethality treatment. The process should be monitored using wet and dry bulb thermometers (used to determine relative humidity) or a humidity sensor.

The following website http://home.fuse.net/clymer/water/wet.html contains a function for calculating the relative humidity given the wet and dry bulb temperatures. A basic wet bulb thermometer can be prepared by fitting a wet, moisture-wicking cloth around a dry bulb thermometer. To maintain a wet cloth during the process, submerse an end of the cloth in a water supply. The cloth must remain wet during the entire lethality treatment especially if smoke is applied. The establishment

KEY DEFINITIONS

The **dry bulb** temperature refers to the ambient air temperature. It is called "dry bulb" because the air temperature is indicated by a thermometer not affected by the moisture in the air or evaporative cooling that removes heat and moisture from the surface of the product. The dry bulb temperature is most commonly measured by jerky-makers. Jerky makers commonly measure the dry bulb temperature.

The **wet bulb** temperature is the temperature indicated by a moistened thermometer bulb exposed to the air flow. A wet bulb thermometer measures the extent of cooling that happens as moisture dries from a surface, a process also known as evaporative cooling. The wet bulb temperature is always lower than the dry bulb temperature except when there is 100% relative humidity, when they will be identical. Because evaporative cooling occurs on the surface of thin jerky strips, the wet bulb temperature is a more accurate measure of product surface temperature.

A **sealed oven** is generally defined as one in which the smokehouse doors and smokehouse oven dampers are closed to prevent moisture loss.

should inspect the wet bulb sock prior to thermal processing, and the sock should be changed as necessary depending on its condition. Attachment 3 contains more details for creating a wet bulb thermometer.

The use of a wet bulb thermometer is especially important for production at altitudes between 3,000 to 7,000 feet or areas of low humidity. Processing failures in the manufacture of jerky have occurred in establishments in New Mexico located between these altitudes (Eidson et al, 2000). Establishments located at higher altitudes will generally have a lower atmospheric pressure. This lower pressure leads to lower boiling points and faster evaporation from the product surface, which can lead to undesirable evaporative cooling and drying of the product surface. Furthermore, the relative humidity can be less at the higher altitude because of the lower air pressure (if the temperature at sea level and the high altitude is the same). As a result, at higher altitudes, the amount of moisture added to the smokehouse chamber necessary to achieve a given log reduction of bacteria may need to be increased to account for lower levels of humidity in the ambient (or room) air. Relative humidity in the ambient air will have an effect on the relative humidity in the smokehouse chamber, particularly when humidity is maintained by sealing the oven, because heat in the smokehouses is typically provided by heating ambient air that is passed over electrically-heated or steam-heated coils. For this reason, all establishments should also take into account variability in relative humidity in the ambient air throughout different times of year.

Establishments will need to make adjustments to the amount of humidity added to the smokehouse chamber to account for changes in humidity in the ambient air at high altitudes or during dry months. These adjustments should be made on a case-by-case basis as part of the initial design of the system to ensure that the humidity in the actual process matches the level in the scientific support.

FSIS recommends that establishments monitor relative humidity using wet and dry bulb thermometers or a humidity sensor with every lot or batch of product although FSIS does not require this monitoring frequency. Establishments have flexibility in how they address humidity in their HACCP systems. If relative humidity is addressed as part of a critical control point (CCP), the establishment is required to list the critical limits per 9 CFR 417.2(c)(3) and list and support the monitoring procedures and frequencies chosen for each CCP to ensure compliance with the critical limits per 9 CFR 417.2(c)(4) and 9 CFR 417.5(a)(2). Furthermore, per 9 CFR 417.4(a)(2), establishments are required to calibrate process-monitoring instruments as part of ongoing verification activities and, per 417.5(a)(2), are required to support their verification procedures and frequencies of those procedures. If relative humidity is addressed in a prerequisite program, and the establishment determines that the implementation of that program results in potential hazards being not reasonably likely to occur, then it must have supporting documentation for the decisions made in the hazard analysis per 9 CFR 417.5(a)(1).

NOTE: Accurate recordkeeping documenting the implementation of the critical operational parameters is critical to support the fact that safe products are produced. Inadequate or inaccurate recordkeeping (e.g., data entry error or unclear monitoring records) has contributed to jerky product recalls in the past, particularly when such records were associated with a lack of information regarding the implementation of all of the critical operational parameters for each batch or lot produced.

Often the owner's manual for humidity recorders recommends calibration on an annual basis. Establishments should follow the manual's instructions for calibration. Establishments may calibrate by comparing the temperature readouts from the microprocessor to the temperature and time plotted on the recorder charts to check for accuracy. For this procedure, FSIS recommends that the establishment calibrate the microprocessor controls before use and show that the calibration is accurate. This procedure can be performed "in-house" in a few simple steps:

1. The wet bulb and dry bulb probes can be placed in a bucket of hot water along with a National Institute of Standards and Technology (NIST) reference thermometer. Some establishments use a small propane burner to maintain the water at a constant temperature.
2. The NIST thermometer represents the known temperature standard, and the establishment can compare the wet and dry bulb probe readings on the microprocessor to the NIST device to verify accuracy of the probes.
3. Once the probe readings are verified on the microprocessor as being accurate, the temperature reading on the microprocessor can be compared to the chart recorder temperature. The chart recorder is then adjusted (if needed) to the microprocessor reading.

These procedures for calibrating humidity recorders are provided as guidance to establishments; other procedures may be used, provided the establishment maintains support for the method chosen.

- **Step 6 – Drying**: Drying is the process during which water (moisture) is removed from the product. After the lethality treatment, jerky is dried to meet a water activity level sufficient to prevent the growth of microorganisms, especially toxigenic microorganisms such as *Staphylococcus aureus*.

Jerky is a shelf-stable product. After drying is complete, the establishment should monitor or verify the water activity to demonstrate that the product has attained shelf-stability in accordance with the scientific support. FSIS does not have a standard of identity for jerky in its regulations. However, jerky has historically been dried to an MPR of 0.75:1 or below as described in the *FSIS Food Standards and Labeling Policy Book*. FSIS is aware that some manufacturers rely upon the MPR, rather than water activity, for determining whether their process adequately dries the jerky to produce a shelf-stable product. MPR is an inappropriate indicator of shelf-stability. Water activity (also referred to as a_w), measured by an instrument such as a water activity meter, is the more appropriate indicator to verify jerky is properly dried for food safety. This is because water activity is a better measure of available water (or water that is not bound by other components) for microbial growth than is MPR. Minimizing available water (e.g., achieving a sufficiently low water activity) is necessary to achieve shelf stability, provided measures are taken to address mold growth. Such measures to prevent mold growth may include using short inventory pull dates, low pH, antimycotics, coatings, packaging, or any combination of these measures.

KEY QUESTION

Question: Can a product be labeled as "jerky" if it meets the MPR of 0.75:1 but is not shelf-stable?

Answer: No. In order to label a product "jerky" it must be shelf-stable. Although FSIS does not define jerky as shelf-stable in the regulatory standards of identity (9 CFR part 319), consumers consider and expect jerky to be shelf-stable.

In order to achieve a shelf-stable product, a water activity critical limit of 0.85 or lower should be targeted for products stored in an aerobic or oxygen containing environment such as in ambient air, provided the establishment takes steps to prevent mold growth on the finished product. If the product is vacuum packaged in an oxygen impervious packaging (creating an anaerobic environment where no oxygen is present), then the water activity critical limit can be 0.91 or lower. These limits are based on the growth limits for *Staphylococcus aureus* with and without oxygen present (ICMSF, 1996) and FSIS' definition of shelf-stability (see the Key Definition in the right panel).

According to the International Commission on Microbiological Specifications for Foods (ICMSF), the water activity limit for *Staphylococcus aureus* growth is 0.83 under aerobic conditions and 0.90 under anaerobic conditions. However, as noted in a footnote of that book, this criterion is based on optimal conditions. FSIS recognizes that most jerky type products have other intrinsic factors, such as sodium nitrite, indigenous microflora, and salt concentration, that would also act as barriers to *Staphylococcus aureus* growth. By considering these factors, FSIS recommends an upper limit of 0.85 under aerobic conditions or 0.91 under anaerobic conditions.

Establishments that choose to use these limits as support for the shelf-stability of their product may cite this guideline as scientific support for these limits and are not required to provide additional scientific support. Establishments may be able to support other water activity critical limits, provided scientific support is available to support the decision-making. The establishment needs to achieve the water activity of the finished product identified in its scientific support.

KEY DEFINITIONS

Shelf-stable is the condition achieved when meat and poultry products can be stored under ambient temperature and humidity conditions; if the package integrity is maintained during storage, shipping, and display at retail and in the home; and the product will not spoil or become unsafe throughout the manufacturer's specified shelf-life.

Water activity, also referred to as a_w, is a measure of the concentration of moisture (i.e., water) **and** its availability in a food. The amount of water available in a food depends on the total concentration of all dissolved substances in the product because they bind water. Thus, if ingredients such as salt or sugar are added to food, they compete with the bacteria for available water.

Moisture-protein-ratio (MPR) expresses the percent moisture divided by the percent protein. MPR is commonly used in the U.S. to classify dried sausages and other meat products. Although MPR values indicate the degree of product drying, they are not necessarily indicative of microbial safety or product shelf-stability because they do not take into account availability of the water.

NOTE: Vacuum packaged products with a water activity level > 0.85 and ≤ 0.91 should be kept refrigerated once the package is opened because the product would no longer be considered shelf-stable once it is exposed to oxygen. Lack of shelf-stability once the product is exposed to oxygen is mainly a concern for products that would not be consumed within a single serving as these products are not likely to be vacuum packaged by the consumer between servings. Therefore, unless the establishment has support that the product is likely to be consumed in a single serving, vacuum packaged products with a water activity in the range of > 0.85 and ≤ 0.91 should be labeled with a statement such as "Refrigerate After Opening" (as described in 9 CFR 317.2(k)).

Finally, it should be noted that although the establishment may control the water activity level of a product to achieve shelf-stability, controlling water activity alone would not be sufficient to assure the safety of the product. Drying the product does not necessarily result in an adequate reduction of *Salmonella* organisms because the pathogen can be resistant to drying. For this reason, the establishment should use a validated lethality treatment, as described in Step 5 – Lethality treatment.

KEY QUESTION

Question: Should an establishment use the MPR to determine whether its process produces a shelf-stable product?

Answer: No. Establishments should use water activity to demonstrate that the product has attained the critical limit for shelf-stability.

- **Step 7 – Post-drying heat step**: A post-drying heat step may be added to increase the level of pathogen reduction beyond that achieved by heating alone.

This step may be needed for processes that do not result in an adequate reduction of *Salmonella* through the initial heating process. Adding a post-drying heat step has the potential to reduce *Salmonella* levels by approximately 2-$\log_{10}$'s from the level of reduction achieved during the initial heat step. One example of a post-drying heat step that has been found to reduce *Salmonella* levels by approximately 2-$\log_{10}$'s is to heat the dried product in a 275°F oven for 10 minutes (Harrison et al., 2001).

- **Step 8 – Handling**: Product is often handled after the lethality and drying steps and prior to/during packaging.

Establishments should control their processes to prevent contamination of product with pathogens from handling after the lethality and drying steps. Such controls should

include ensuring that cross-contamination of product is minimized before packaging, and ensuring that the product is packaged in such a way that cross-contamination of product post-packaging is also minimized (e.g., with a good seal to maintain package integrity throughout storage, shipment, and display). Preventing cross-contamination is important even if the product is dried to a water activity such that the product is considered shelf-stable. Pathogens may still be able to survive on the product if it becomes contaminated during handling.

Cross-contamination of product can occur from situations such as the following:

- Using the same equipment (e.g., preparation tables, scales, or packaging equipment) for both raw and cooked products without completely cleaning and sanitizing the equipment between production lots.
- Placing cooked product on the same surface (e.g., cutting table) as raw product without completely cleaning and sanitizing the surface before reuse.
- Using the same utensils or containers (e.g., scoops or buckets) for both raw and cooked product without completely cleaning and sanitizing the surface before reuse.
- Condensation, aerosolization, or dusting of dry ingredients into the processing environment.
- Employee movement between raw and ready-to-eat areas without hand-washing or garment changing.

The establishment is required to maintain sanitation in the RTE area to ensure that food contact surfaces are free of contamination from *Lm* and other pathogens, such as *Salmonella*, in accordance with 9 CFR part 430. The establishment is required to develop and implement Sanitation SOPs (9 CFR 416) to ensure that contamination and adulteration of the product is prevented after the lethality treatment.

Further guidance on post-processing handling and sanitation for ready-to-eat products including jerky is in the *Salmonella* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and the Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products.

Scientific Support Available for Jerky Processing

Establishments have numerous options for the types of scientific documents that can be used to support that the process achieves adequate lethality. Examples of the scientific support available to help develop a safe jerky process and product are discussed below, along with considerations for each type of support. Product sampling results, based on historical data alone, should not be used as scientific support for a jerky process because they do not provide information on the level of pathogen reduction that is achieved for the process.

Compliance Guidelines

FSIS has issued a number of different compliance guidelines that have application to jerky processing. It is important to note that, while FSIS considers these documents to be guidelines, if followed precisely, they are considered as validated process schedules because the guidelines contain processing methods already accepted by the Agency as effective in safely producing meat and poultry products.

Some considerations for each of these compliance guidelines are outlined on the following pages.

- ***FSIS Appendix A: Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat and Poultry Products***

For meat jerky, use of the **product time-temperature combinations** provided in *Appendix A*, including those temperatures above 158°F in which the time for the desired lethality is instantaneous, should help to ensure the safety of the product. These time-temperature combinations are based on experiments that were done with products without added salt or sugar. Added salt, sugar, or other substances that reduce water activity will increase the heat resistance of bacteria in a product. However, time and experience have shown that the time-temperature combinations in the lethality compliance guidelines have been sufficient to produce safe products even with both salt and sugar added, but the **humidity during heating is a critical factor**.
FSIS has found through FSAs and askFSIS questions that there is confusion regarding the humidity options in *Appendix A* that apply to jerky, when establishments can introduce humidity by continuously introducing steam or sealing the oven, and for how long humidity should be introduced.

The humidity options in *Appendix A* that are applicable to jerky processing are:

- Heating jerky to a minimum internal temperature of 145 °F (62.8 °C) in an oven maintained at any temperature if the relative humidity of the oven is maintained either by continuously introducing steam for 50 percent of the cooking time or by use of a sealed oven for over 50 percent of the cooking time, or if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time but in no case less than 1 hour; or

- Heating jerky in an oven maintained at any temperature that will satisfy the internal temperature and time combinations from the chart provided in

Appendix A if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time but in no case less than 1 hour. The relative humidity may be achieved by use of steam injection or sealed ovens capable of producing and maintaining the required relative humidity.

In order to introduce humidity by continuously introducing steam or sealing the oven, establishments should:

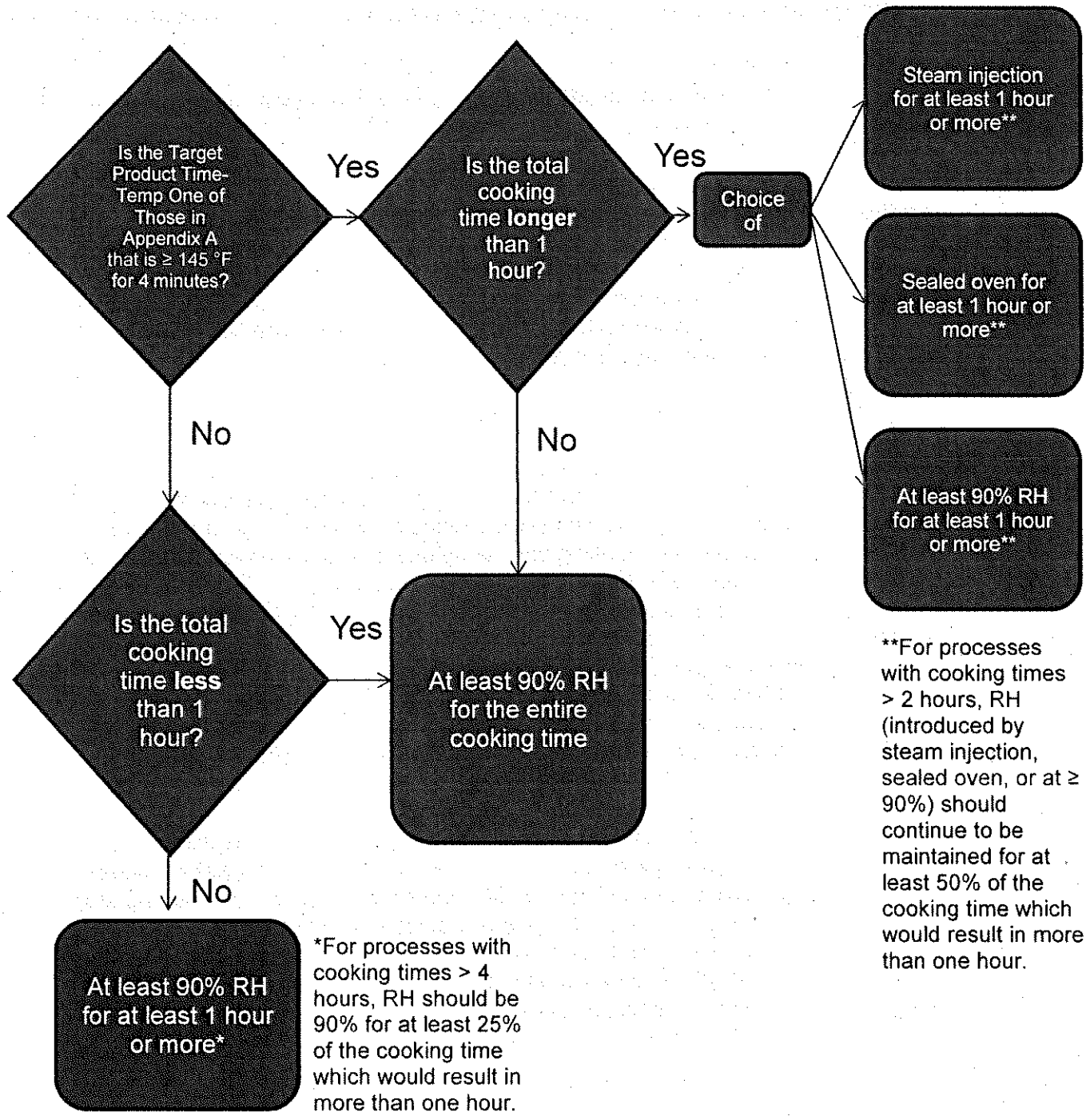
☑ Cook the jerky product to an internal temperature-time combination of equal to or greater than 145°F for 4 minutes. It is important to note again that the temperature values in *Appendix A* correspond to product temperatures, not oven temperatures. If an establishment cooks its jerky product to an internal temperature-time combination of less than 145°F for 4 minutes, then the relative humidity should be maintained at 90% or above for at least one hour or 25% of the cooking time (whichever is longer).

AND

☑ Cook the jerky product for at least one hour and in some cases longer. Cooking time should never be less than one hour. *Appendix A* states that the relative humidity of the oven should be maintained either by continuously introducing steam for 50 percent of the cooking time or by use of a sealed oven for over 50 percent of the cooking time, but in no case less than one hour. This means that these options should be applied for at least one hour or 50% of the cooking time - whichever is longer. If an establishment can not apply these humidity options for equal to or more than one hour (for example because the lethality treatment takes less than one hour), then the humidity of the oven should be maintained at 90% or above throughout the lethality treatment (not just during the time and temperature combination in *Appendix A)* with the exception of a surface preparation step

Establishments can use the flow chart on the following page to determine the humidity options when using the *Appendix A* guidelines as scientific support for a jerky process. The times listed in the chart do not include any surface preparation or color setting step where humidity is not introduced. So, if a process includes a 30 minute surface preparation or color setting step, the total cooking time would need to be ≥ 90 minutes in order to continuously introduce steam or seal the oven for at least 1 hour (or 50% of the cooking time, whichever is longer) as specified in *Appendix A*.

Flow Chart to Identify Humidity Options when Using the *Appendix A* Guidelines as Scientific Support For a Jerky Process



**For processes with cooking times > 2 hours, RH (introduced by steam injection, sealed oven, or at ≥ 90%) should continue to be maintained for at least 50% of the cooking time which would result in more than one hour.

*For processes with cooking times > 4 hours, RH should be 90% for at least 25% of the cooking time which would result in more than one hour.

Specific guidance for using the sealed oven option to introduce humidity

In order to support that the sealed oven option for introducing humidity is being implemented consistent with the ***Appendix A*** guidelines, establishments should:

1) **Maintain documentation that supports that the jerky product achieves an internal product time-temperature combination from *Appendix A* of equal to or greater than 145°F for 4 minutes.** Such documentation could include:
   a. Records of internal product temperature and time held at that temperature (if applicable); or
   b. Records of the oven or smokehouse temperature in place of product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the product temperature in the scientific support;

2) **Maintain documentation that supports that the oven dampers are closed for at least one hour or 50% of the cooking time - whichever is longer.** Such documentation could include:
   a. Records from a computerized system that contains the time at which the oven dampers were open and were closed; or
   b. Records of the times at which the oven dampers were open and closed made manually; or
   c. Records demonstrating the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time - whichever is longer (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement) with correlation data supporting a relationship between the relative humidity level in the oven and the time at which the oven dampers were open and closed (see page 23 for guidance on minimum levels of relative humidity/wet and dry bulb temperatures to achieve);

3) **Maintain documentation that supports that when the oven dampers are closed, humidity is maintained in the ovens.** Such documentation could include:
   a. Records demonstrating the relative humidity level in the ovens is maintained (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or
   b. Data gathered during the initial validation period along with ongoing verification which demonstrates that the relative humidity in the oven is maintained while the dampers are closed; and

4) **Have an ongoing procedure for checking that the dampers are properly working along with a maintenance program to periodically monitor that the seals are intact and functional, and that when the oven dampers are closed, a tight seal is obtained.** A tight seal is one in which a significant loss of humidity is prevented. FSIS acknowledges that a small amount of smoke or vapors might be seen escaping the smokehouse even when a tight seal is obtained. Establishments should also consider whether there are other openings, particularly in older smokehouses, such as drain valves or air intake valves, that need to be closed in order to ensure that a seal is obtained. Finally, some older ovens may have a stack or other opening that cannot be closed. For those establishments with older ovens that cannot be completely closed, the sealed oven method should not be used. However, the establishment may choose to close what they are able to and add moisture in the system either by continuously introducing steam or another validated method.

Specific guidance for using the continuously injecting steam option to introduce humidity

In order to support that the continuously introducing steam option for introducing humidity is being implemented consistent with the *Appendix A* guidelines, establishments should:

1) **Maintain documentation that supports that the jerky product achieves an internal product time-temperature combination from *Appendix A* of equal to or greater than 145°F for 4 minutes.** Such documentation could include:
   a. Records of internal product temperature and time held at that temperature (if applicable); or
   b. Records of the oven or smokehouse temperature in place of product temperature provided that the establishment has a consistent product and process and has sufficient data correlating the oven temperature selected with the product temperature in the scientific support;

2) **Maintain documentation that supports that steam is continuously introduced for at least one hour or 50% of the cooking time - whichever is longer.** Such documentation could include:
   a. Records from a computerized system that contains the time at which the steam is turned on and off; or
   b. Records of the times at which the steam is turned on and off made manually; or
   c. Records demonstrating the relative humidity level in the oven is maintained for at least one hour or 50% of the cooking time - whichever is longer (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement) along with correlation data supporting a relationship between the relative humidity level in the oven and the time steam is turned on or a letter from the manufacturer stating that when the relative humidity is rising it is because of live steam injection (see page 23 for guidance on minimum levels of relative humidity/wet and dry bulb temperatures to achieve);

3) **Maintain documentation that supports that when steam is injected, humidity is maintained in the ovens.** Such documentation could include:
   a. Records demonstrating the relative humidity level in the ovens is maintained (e.g., by use of dry and wet bulb thermometers to calculate the relative humidity or use of a humidity sensor that provides a direct measurement), or
   b. Data gathered during the initial validation period along with ongoing verification which demonstrates that the relative humidity in the oven is maintained while steam is being injected.

NOTE: The "continuously introducing steam" option refers to the use of live steam, although it may also apply to establishments that spray water onto hot heating elements, which creates steam that in turn produces humidity in the smokehouse. "Continuous" does not mean that the steam is injected for at least one hour during one stage; rather, steam could be injected during stages or time intervals during the lethality (cooking) treatment as long as the total amount of time the steam is introduced adds up to at least one hour or 50% of the cooking time - whichever is longer. Furthermore, the establishment may turn the steam on and off throughout the cooking time when the target humidity is reached.

Attachment 4 has an example of a temperature chart, with wet and dry bulb temperatures, that an establishment could use to demonstrate it is meeting the option to continuously inject steam on an ongoing basis using monitoring records.

It is important that establishments maintain and monitor the humidity levels in the oven. Establishments using either the sealed oven or continuously introducing steam options for introducing humidity can support that humidity is being introduced consistent with *Appendix A* following the guidance on the previous two pages. Establishments do not need to achieve a specific humidity level in the oven if *Appendix A* is used as the scientific support. However, FSIS recommends that establishments that monitor relative humidity try to achieve a wet bulb temperature of **at least 125-130°F for 1 hour or more** along with a corresponding dry bulb temperature needed to achieve **at least 27-32% relative humidity or more.** FSIS is making this recommendation based on expert opinion and a review of the literature that suggests that the wet bulb temperature should reach at least 125-130°F for an hour or more during the lethality process, and that **at least 27-32% relative humidity** should be present to ensure that adequate lethality is attained. Wet bulb temperature is generally a strong indicator of product surface temperature early in the process. Therefore, maintaining the wet bulb temperature at a high enough level to cause lethality (125-130°F) is recommended (Buege, 2006a; Harper, 2009).

Although establishments using either the sealed oven or continuously introducing steam option for introducing humidity are not required to achieve a specific humidity level, the values provided in this document are listed so that establishments have further guidance concerning minimum levels to achieve as recommended by experts at FSIS. Establishments should be aware that achieving a low wet bulb temperature for a short time (i.e., below 125-130°F for less than one hour) or low relative humidity for a short time (below 27-32% for less than one hour) may indicate that the jerky process may not be achieving sufficient lethality at the product surface which could represent a vulnerability in the establishment's process to control food safety hazards of concern.

NOTE: Achieving a wet bulb temperature of at least 125-130°F and at least 27-32% relative humidity for 1 hour or more is not adequate on its own to support that the process is being implemented consistently with *Appendix A*. Rather, establishments should ensure that all critical operational parameters from *Appendix A* are met (i.e., product time-temperature combination and humidity). Guidance for introducing humidity for the options that require less than 90% relative humidity (continuously introducing steam or sealing the oven) is provided on the previous two pages.

Processes for which Appendix A is not appropriate as scientific support

Finally, although *Appendix A* is commonly used as scientific support for jerky processes, the time-temperature-humidity combinations can not be applied in every scenario. For example, establishments should not use *Appendix A*:

- ☑ **To support a process in which the drying step comes before the cooking step. *Appendix A* was not developed for such processes.**
- ☑ **To support a process that uses a home-style dehydrator. The humidity parameters in *Appendix A* cannot be maintained in a home-style dehydrator. Processes that can achieve an adequate reduction of *Salmonella* and *E. coli* O157:H7 using home-style dehydrators are described in studies by Borowski et al. (2009b), and Harrison et al. (2006).**

- ***FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks***

To support the safe production of meat jerky, establishments can use the time-temperature combinations provided in the *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks*. Humidity should be considered when using this time-temperature table; therefore, the same options for humidity in *Appendix A* should be used with this guidance. In addition, the same recommendations regarding maintaining and monitoring humidity for *Appendix A* apply for establishments that use the *FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks* for time-temperature combinations.

- ***Time-Temperature Tables For Cooking Ready-To-Eat Poultry Products***

To support the safe production of poultry jerky, establishments can use the minimum internal temperatures listed in *Appendix A* of 160°F for uncured poultry or 155°F for cured and smoked poultry. Establishments should not use the time and temperature combinations provided in *Appendix A* for cooked beef, roast beef, and corned beef for poultry jerky.

NOTE: If highly pathogenic avian influenza (HPAI) virus H5N1 is identified as a hazard reasonably likely to occur, cured and smoked poultry should be cooked to at least 158°F or a time and temperature combination that achieves a 7-$\log_{10}$ reduction of *Salmonella*.

The required reduction of *Salmonella* can also be achieved by using one of the time-temperature combinations listed in the *Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products*. As stated in the *Time-Temperature Tables* guidance document, the tables reflect newer data on the temperatures needed to control *Salmonella* in poultry than the data used in developing *Appendix A*. The Agency has not rescinded the guidance for poultry in Appendix A, but an establishment needs to take into account the data in the *Time-Temperature Tables* regarding increased time at a specific temperature to achieve a given level of reduction of *Salmonella*. An establishment that utilizes *Appendix A* within its process should conduct on-going verification to confirm that the process is being effectively controlled. If an establishment is using *Appendix A*, and the Agency collects an RTE sample that is positive for *Salmonella*, the establishment would be required under 9 CFR 417.3(b), among other things, to support its decision within its hazard analysis.

Regardless of which time-temperature combinations an establishment uses, **humidity during heating is a critical factor**. As with meat jerky, the time-temperature combinations would be sufficient to produce safe products with both salt and sugar additives if the processor uses the humidity parameters applicable to beef as described in *Appendix A*. The same recommendations regarding maintaining and monitoring humidity for *Appendix A* apply for establishments that use the *Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products*.

Journal articles

Journal articles are a primary type of support used for jerky processes. A number of studies have been conducted to determine time-temperature-humidity combinations that result in adequate lethality for jerky. Attachment 2 contains a summary of time-temperature-humidity combinations, along with other critical operational parameters from published studies that have been found to result in adequate lethality.

If an establishment chooses to use a journal article as scientific support, it should ensure that all of the critical operational parameters (i.e., product time-temperature combination and relative humidity) used in the study match those used in the actual process. If one or more of the parameters are not addressed or do not match the level used in the support, then the establishment's process may not achieve the same level of lethality as cited in the journal article. In that case, the establishment should document a justification as to why that parameter does not need to be met or measured, or why it differs from the support. When identifying a journal article, the establishment should consider whether it is using the same:

- Product (e.g., species, type-whole muscle or ground);
- Product formulation;
- Product time-temperature combination;
- Relative humidity at each stage (including, if reported, using the same humidity levels at the beginning and end of each stage);
- Type or pH of marination (if applicable); and
- Smoke (if applicable) as used in the article.

The establishment should also ensure that the composition of the product (% salt, % fat) used in the study is the same as the composition of the actual product being produced. A prudent establishment should have knowledge of the products it produces. Because meeting the critical operational parameters is essential to achieve lethality in the product, the parameters used or measured in the article should be addressed in the process.

Key Considerations for Journal Articles in Attachment 2

Attachment 2 contains a summary of processes, and the critical operational parameters of those processes, that have been found to achieve adequate lethality for jerky in the published literature. The Attachment is provided to help establishments identify alternatives to the *Appendix A* guidelines.

This Attachment is not considered adequate support on its own because it does not provide the details of each study that an establishment needs to determine if the study is representative of the actual process.

For this reason, if an establishment chooses to use one of the articles provided in Attachment 2 for scientific support, the establishment will need to have a full copy of the original article on file.

KEY QUESTION

Question: Can an establishment's process use a different level of a critical operational parameter (for example, a higher concentration of an antimicrobial or a higher processing temperature) than what was used in the scientific support?

Answer: Generally, establishments should use the same critical operational parameters as those in the scientific support. In some circumstances, establishments may be able to support using critical operational parameters (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures) that are different from those in the scientific support. In these cases, establishments should provide justification supporting that the levels chosen are at least as effective as those in the scientific support. This justification is needed because higher levels of a critical operational parameter may not always be equally effective. For example, antimicrobial agents may only be effective within a range of concentration after which point efficacy may decrease. Similarly, higher processing temperatures may result in the surface of the product drying out before adequate lethality is achieved. In addition to ensuring that the levels chosen are at least equally as effective, establishments should ensure the levels are also safe and suitable (*FSIS Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products* and 9 CFR 424.21(c)).

Challenge Studies

In cases where an establishment's process does not match available scientific support documents, such as a Compliance Guideline or published journal article, an establishment may decide to conduct an inoculation challenge study to support that its process achieves adequate lethality (e.g., for meat and poultry jerky at least a 5.0-$\log_{10}$ reduction of *Salmonella* spp.). A challenge study is a study that documents the adequacy of control measures in a process. Obtaining this documentation involves inoculating the target organism (e.g., *Salmonella spp.* or an appropriate surrogate organism such as certain *Pediococcus* strains) into a product to determine the effect of control measures such as cooking and drying to reduce the organism. Challenge studies should be conducted by a microbiologist trained in performing challenge studies in a laboratory to avoid the possible spread of contamination in an establishment. In a challenge study, the number of organisms before and after the application of the control measure is counted to determine the effect of the control measure. The challenge study should be designed to closely match the critical operational parameters (e.g., time, temperature, and relative humidity) in the establishment's actual process.

Challenge studies should be based on a sound statistical design and should also employ positive and negative controls. As recommended by the National Advisory Committee on Microbiological Criteria of Foods (NACMCF), the number of samples to be analyzed initially and at each time interval during processing or storage should be at a minimum two; however, analysis of three or more samples is preferred. Replicates should also be conducted. Replicates should be independent trials using different batches of product and inoculum to account for variations in product, inoculum, and other factors. Generally, the number of samples and replicates should be increased in situations of higher variability or uncertainty. When the number of samples analyzed at each time interval is only two, it is better for the study to be repeated (replicated) more than two times. In studies with three or more samples tested at each time interval, two replicates are usually adequate.

At a minimum, a study for a microbiological food safety hazard should identify:

- The hazard (including the specific strains studied),
- The expected level of hazard reduction or prevention to be achieved,
- The processing steps that will achieve the specified reduction or prevention,
- All critical operational parameters or conditions (e.g., time, temperature, and humidity) necessary to achieve the reduction,
- How these processing steps/parameters can be monitored,
- The critical ingredients (e.g., salt, sugar, and cure), and
- The critical product characteristics (e.g., pH, water activity, and fat content).

In addition, the inoculum level should be at least two logs greater than the log reduction to be demonstrated. FSIS recommends that establishments use *Salmonella* (or an appropriate surrogate of *Salmonella*) as an indicator of lethality because it tends to be more heat resistant than other pathogens (Goodfellow & Brown, 1978; Line et al, 1991). FSIS considers all *Salmonella* serotypes to be pathogens of public health concern.

FSIS does not require establishments to validate that their process achieves reduction in *E. coli* O157:H7 or *Lm* if they achieve sufficient reductions in *Salmonella* because *Salmonella* is an indicator of lethality. Without further scientific support, establishments should not use pathogens other than *Salmonella* as indicators of lethality. For example, establishments should not use reductions in *Lm* to support similar reductions in *Salmonella* without support that *Lm* is at least equally as heat resistant as *Salmonella* under the conditions being studied.

If an establishment chooses to conduct a challenge study in a testing laboratory, the study should use at least five strains of *Salmonella*, including strains associated with human illness and strains isolated from meat and poultry products. Ideally, some of the strains selected should be those with known heat-resistance properties. One good choice, for example, might be *Salmonella enterica* serovar Senftenberg strain 775W, which displays heat resistance properties (Ng et al., 1969). *Salmonella enterica* serovar Senftenberg occurs in the top 10 serotypes seen in FSIS testing for both cow/bull carcass testing and ground beef, as well as in turkeys (carcass and ground) (FSIS testing data, 2012), so it would also be an appropriate choice for what might be seen in these products being tested.

If an establishment chooses to conduct a challenge study in a plant environment, to best represent actual processing conditions for example, then the establishment should choose surrogate organisms that have been found to respond similarly to the pathogens of interest (e.g., *Salmonella*, and if applicable, *E. coli* O157:H7). For example, the University of Wisconsin has conducted research with ground-and-formed jerky and found that two *Pediococcus* strains (*Saga 200* and *Biosource*) have similar heat-resistance to *Salmonella* and can be used in in-plant validation studies (Borowski et al., 2009a). FSIS has identified four surrogate organisms that have been shown to respond similarly to *E. coli* O157:H7 during cooking (the following askFSIS Q&A has more information) for use in in-plant validation studies. For the reasons explained above, establishments also should not use surrogate organisms that have been shown to respond similarly to *E. coli* O157:H7 to support similar reductions in *Salmonella* without support that the organisms are at least as heat resistant as *Salmonella*.

Challenge studies should be equivalent to peer-reviewed scientific literature. All of the critical elements listed above for a study above need to be included to permit evaluation or confirmation of the results. More information on conducting challenge studies is found in the article published by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) in the Journal of Food Protection in 2010.

References

Borowski, A.G., Ingham, S.C., Ingham, B.H. 2009a. Validation of ground-and-formed beef jerky processes using commercial lactic acid bacteria starter cultures as pathogen surrogates. J. Food Prot. 72(6): 1234-1247.

Borowski, A.G., Ingham, S.C., Ingham, B.H. 2009b. Lethality of home-style dehydrator processes against *Escherichia coli* O157:H7 and *Salmonella* serovars in the manufacture of ground-and-formed beef jerky and the potential for using a pathogen surrogate in process validation. J. Food Prot. 72(10): 2056-2064.

Buege, D. R., Searls, G. Ingham, S.C. 2006a. Lethality of commercial whole-muscle beef jerky manufacturing processes against *Salmonella* serovars and *Escherichia coli* O157:H7. J. Food Prot. 69(9): 2091-2099.

Buege, D.R., Searls, G., Mohanan, S., Buege, D.R. 2006b. Survival of *Staphylococcus aureus* and *Listeria monocytogenes* on vacuum-packaged beef jerky and related products stored at 21°C. J. Food Prot. 69(9) 2263-2267.

Calicioglu, M., Sofos, J.N., Samelis, J., Kendall, P.A., Smith, G.C. 2002. Destruction of acid-adapted and non-adapted *Salmonella* during drying and storage of beef jerky treated with marinade. Animal Sciences Research Report. Colorado State University.

Calicioglu, M., Sofos, J.N., Samelis, J., Kendall, P.A., Smith, G.C. 2003. Effects of acid adaptation and modified marinades on survival of post drying *Salmonella* contamination on beef jerky during storage. J. Food Prot. 66(3):396-402.

Centers for Disease Control (CDC). 1995. Outbreak of Salmonellosis Associated with Beef Jerky – New Mexico, 1995. MMWR 1995; 44(42); 785-788.

Eidson, M., Sewell, C. M., Graves, G, Olson, R. 2000. Beef jerky gastroenteritis outbreaks. Environ. Health. 62:9-13.

Faith, N.G., Le-Coutour, N.S., Alvarenga, M.B., Calicioglu, M., Buege, D.R., Luchansky, and J. B. 1998. Viability of *Escherichia coli* O157:H7 in ground and formed beef jerky prepared at levels of 5 and 20% fat and dried at 52, 57, 63, or 68 degrees C in a home-style dehydrator. Int. J. Food Microbiol. 41(3):213-221.

FSIS. 2005. Risk Assessment of the Impact of Lethality Standards on Salmonellosis from Ready-to-Eat Meat and Poultry Products. Final Report. Available at: http://www.fsis.usda.gov/wps/wcm/connect/210d3d19-96bc-4b1e-8829-325e25e63e0b/Salm_RTE_Risk_Assess_Sep2005.pdf?MOD=AJPERES. Accessed 22 November 2013.

FSIS. 2011. Annual Report: Serotypes profile of *Salmonella* isolates from meat and poultry products, January 1998 through December 2011. Available at: http://www.fsis.usda.gov/wps/wcm/connect/26c0911b-b61e-4877-a630-23f314300ef8/salmonella-serotype-annual-2011.pdf?MOD=AJPERES. Accessed 22 November 2013.

Getty, K.J.K., Boyle, E.A.E., Roberts, M.N., Lonneker, S.M. 2006. Jerky Validation for Small and Very Small meat and Poultry Businesses: Final Report. Available at: http://www.fsis.usda.gov/wps/wcm/connect/35151cb4-1603-4164-b71f-bfea44e487e8/C-12_New_Technology_FY2004_Final_Report.pdf?MOD=AJPERES. Accessed 17 August 2013. **Note**: the full study for this report can be found in the Harper et al. (2009) reference below.

Goepfert, J.M., Iskander, I.K., Amundson, C.H. 1970. Relation of the heat resistance of *Salmonellae* to the water activity of the environment. Appl. Microbiol. 19(3):429-33.

Goodfellow, S.J., Brown, W.L.. 1978. Fate of *Salmonella* inoculated into beef for cooking. J. Food Prot. 41(8):598-605.

Harper, N.M., Roberts, M.N., Getty, K.J.K., Boyle, E.A.E., Fung, D.Y.C., Higgins, J.J. 2009. Evaluation of two thermal processing schedules at low relative humidity for elimination of *Escherichia coli* O157:H7 and *Salmonella* Serovars in chopped and formed beef jerky. J. Food Prot. 72: 2476-2482.

Harrison, J.A. Harrison, M.A. 1996. Fate of *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* Typhimurium during preparation and storage of beef jerky. J. Food Prot. 59(12):1336-8.

Harrison, J.A. Harrison, M.A., Rose-Morrow, R.A., Shewfelt, R.L. 2001. Home-style beef jerky: effect of four preparation methods on consumer acceptability and pathogen inactivation. J. Food Prot. 64(8):1194-98.

Harrison, M. A., Singh, R.K., Harrison, J.A., Singh, N. 2006. Antimicrobial intervention and process validation in beef jerky processing. Final Report. Available at: http://www.fsis.usda.gov/wps/wcm/connect/8dd0f238-08d7-4ca0-a31a-77fa3ca8acf6/C-17_New_Technology_FY2004_Final_Report.pdf?MOD=AJPERES. Accessed 17 August 2013.

International Commission on Microbiological Specifications for Foods (ICMSF). 1996. Microorganisms in Foods 5: Characteristics of Microbial Pathogens. London: Blackie Academic & Professional. p. 304, Table B.

Line, J.E. Fain, A.R. Moran, A.B, Martin, L.M., Lechowch, R.V., Carosella, J.M., and Brown, W.L. 1991. Lethality of heat to *Escherichia coli* O157:H7: D-value and Z-value determinations in ground beef. J Food Prot. 54: 762-766.

National Advisory Committee on Microbiological Criteria for Foods. 2010. Parameters for determining inoculated pack/challenge study protocols. J. Food Prot. 73(1): 140-202.

Ng, H., Bayne, H.G., Garibaldi, J.A. 1969. Heat resistance of *Salmonella*: the uniqueness of *Salmonella senftenberg* 775W., Appl. Micro. 17(1):78-82.

Porto-Fett, A.C.S., Call, J.E., Luchansky, J.B. 2008. Validation of a commercial process for inactivation of *Escherichia coli* O157:H7, *Salmonella* Typhimurium, and

Listeria monocytogenes on the surface of whole muscle beef jerky. J. Food Prot. 71(5): 918-926.

Swayne, D. E. and Beck, J.R. 2005. Experimental study to determine if low-pathogenicity and high-pathogenicity avian influenza viruses can be present in chicken breast and thigh meat following intranasal virus inoculation. Avian. Dis. 49:81-85.

Thomas, C. and Swayne, D.E. 2007. Thermal inactivation of H5N1 high pathogenicity avian influenza virus in naturally infected chicken meat. J. Food Prot. 70(3):674-680.

Helpful Websites

Dry Bulb, Wet Bulb, and Dew Point Temperature

Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products

Food Safety Regulatory Essentials (FSRE) Processing Procedures: Dried Meats

FSIS Appendix A: Compliance Guidelines For Meeting Lethality Performance Standards For Certain Meat and Poultry Products

FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks

Making Your Own Wet Bulb Thermometer

Relative Humidity Calculation Using Dry and Wet Bulb Temperature Measurements

Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products

Time-Temperature Tables For Cooking Ready-To-Eat Poultry Products

Attachment 1: FSIS Response to Comments

The following is a summary of FSIS' response to the comments received during the comment period.

1. Need for guidance

Comment: One commenter questioned the need for the guidance given the limited information publicly available on the causes of past outbreaks in jerky and the importance of humidity in the production of jerky. The commenter also identified a broken link to a reference to one of the past outbreaks in the 2012 version of the guidance.

Response: FSIS initially issued this guidance in 2007 to clarify the importance of introducing humidity to jerky processors given the lack of humidity control identified in past outbreaks. One potential cause of the 2003 *Salmonella* Kiambu outbreak in jerky was the very slow drying process under low humidity conditions (1% RH - 82°C dry bulb, 30°C wet bulb), which allowed *Salmonella* organisms to dehydrate during drying and become resistant to heat. This information was gathered by FSIS during the course of the investigation. Research has demonstrated that bacteria can become more heat resistant as their moisture level decreases, and increased concentrations of solutes, especially sugars, increase the heat resistance of bacteria. Therefore, drying of the product surface before the pathogens are destroyed will increase pathogen heat resistance and allow them to survive the heating process. By incorporating humidity to minimize evaporation, the D values (time at a constant temperature necessary to destroy 90% or 1-$\log_{10}$ of the target organism) that are the basis for *Appendix A* and other scientific support documents remain valid (Goepfert, 1970; Goodfellow and Brown, 1978; Faith, N.G. et al. 1998). For this reason, the low humidity conditions were considered to be a plausible cause of the outbreak. The low humidity conditions were likely related to the location of the processing establishment in Albuquerque, New Mexico, which is at an elevation of greater than 4,000 feet[2]. As described on page 13 of the guidance, the relative humidity in the ambient (or room) air is lower at higher altitudes, which affects the relative humidity in the smokehouse chamber. Prior to the 2003 outbreak, at least six other salmonellosis outbreaks occurred in New Mexico between 1966 and 1995 suggesting the high altitude/low ambient humidity conditions in the state played a role, among other factors (CDC, 1995; Eiden, 2000). Since the 2003 outbreak, FSIS has continued to refine the guidance document based on the most up-to-date science and lessons learned from FSAs.

Finally, the broken link provided in the previous version of the guideline has been replaced with a functioning link to an Epidemiology Presentation from the New Mexico Department of Health (http://aces.nmsu.edu/ces/nmhs/documents/albanese.pdf).

Comment: One commenter questioned why the Jerky Compliance Guidelines focused on small and very small establishments. According to one commenter, small and very small meat processors in the U.S. represent 5 percent of the total meat production volume, but 95 percent of the total meat processing businesses in the U.S.

[2] http://egsc.usgs.gov/isb/pubs/booklets/elvadist/elvadist.html

This commenter suggested that the guidelines not be limited to small and very small establishments but rather should be addressed to the whole industry.

Response: FSIS focused the Jerky Compliance Guidelines on small and very small establishments in support of the Small Business Administration's initiative to provide small and very small establishments with compliance assistance under the Small Business Regulatory Flexibility Act (SBRFA). However, all FSIS regulated meat and poultry establishments may be able to apply the recommendations in this guidance. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to establish safe and effective HACCP systems. Although large establishments can benefit from the guidance that FSIS provides, focusing the guidance on the needs of small and very small establishments provides them with information that may be otherwise unavailable to them because of cost. For example, FSIS included growth limits for *Staphylococcus aureus* published in an ICMSF book chapter. Establishments can reference this guideline for support for the development of critical limits based on these values instead of having to purchase the costly textbook. FSIS also included an inexpensive way for establishment's to make their own wet bulb in Attachment 3 courtesy of University of Wisconsin-Madison Center for Meat Process Validation.

2. Validation

Comment: One commenter recommended FSIS postpone the release of the finalized guidance document until the finalized HACCP systems validation guidance document is released to ensure the documents are cohesive and complete.

Response: This Compliance Guideline articulates how industry can meet FSIS requirements regarding jerky processing as well as FSIS recommendations to help produce a safe product based on the scientific information available in the literature. The primary focus of this guidance document is on the first element of validation: scientific support. This element includes the process of identifying scientific support documents that closely match the establishment's actual process along with identification of the critical operational parameters from the scientific support relevant to the establishment's process. FSIS is currently enforcing this element of the initial validation requirement (9 CFR 417.4(a)(1)). In addition, FSIS does not wish to delay finalizing this document because it reflects the most up-to-date science and understanding of jerky processing and addresses key issues FSIS has identified through FSAs and response to outbreak investigations. FSIS is sharing this information in a timely manner in order to help establishments produce a safe product.

Comment: One commenter expressed concern with the following "Key Question" in the guidance document: "Can an establishment's process use a different level of a critical operational parameter (for example, a higher concentration of an antimicrobial or a higher processing temperature) than what was used in the support document?". The commenter provided an example of shelf-stable jerky that has a water activity of 0.85 or less. In the example, some processors may reduce the water activity lower than 0.85 for quality issues or an extended shelf life. The commenter expressed concern that establishments would have to provide a justification for the lower water activity level chosen.

Response: FSIS has found through FSAs that establishments use levels of critical operational parameters that are different from those in their scientific support without any consideration as to whether this will result in the same efficacy demonstrated in the scientific support. The Agency is recommending that establishments provide a scientific justification as to why the same efficacy would be achieved with a different level of a critical operational parameter. In the example provided by the commenter, an establishment could provide the justification, with reference to applicable scientific support, that pathogen growth decreases as water activity decreases, supporting that if 0.85 is adequate to preclude growth, then a lower water activity would also preclude growth of pathogenic microorganisms. Such a justification would be adequate and could be maintained in the establishment's decision-making documents as scientific support for the process used.

Comment: One commenter indicated that the guidance document is not specific enough in explaining how closely scientific support must match an establishment's process, species, or products. In addition, the commenter stated that inspection program personnel would find noncompliance with the validation regulations simply because the supporting document does not match the establishment's production precisely.

Response: FSIS is not prescriptive in terms of how closely the scientific support should match the actual process. Rather, FSIS recommends that the critical operational parameters used in the scientific support be consistent with those used in the establishment's process and is providing establishments the flexibility to use different levels as long as a scientific justification is provided. FSIS inspection program personnel (IPP) verify establishment validation when performing the Hazard Analysis Verification (HAV) task. Instructions for performing the HAV task are provided in *FSIS Directive 5000.6 Performance of the Hazard Analysis Verification (HAV) Task* and in the HAV section of the Inspection Methods training. FSIS will issue additional instructions to its field personnel for them to verify that establishments meet all validation requirements once the *FSIS HACCP Systems Validation Guidance* is finalized.

Comment: One commenter stated that the type of equipment used in the process should not be considered a critical operational parameter.

Response: FSIS has found through FSAs that establishments use different types of equipment than that used in the scientific support without any consideration as to whether this change will result in the same efficacy demonstrated in the scientific support. The type of equipment, such as a smokehouse, could influence the ability to implement other critical operational parameters such as humidity. FSIS is recommending that establishments consider the type of equipment as a critical operational parameter so that establishments take into account whether changes in equipment affect the implementation of other critical operational parameters. This consideration should be a part of the initial set-up of the system and would not need to be done on an on-going basis unless changes to the equipment are made.

3. Step-by-step guide for jerky processing

Comment: Two commenters stated that Steps 2 (Marination) and 3 (Interventions) in the 2007 and 2012 versions of the guidance are not commonly used steps in the industry.

Response: FSIS recognizes that not all processes may include the same steps listed in the step-by-step guide. FSIS included steps such as intervention in the guidance because some heating processes may not deliver an adequate lethality and, thus, may require an additional intervention step to ensure product safety. To more accurately reflect commonly used processing steps, FSIS has included the surface preparation step (now Step 4) in the guidance, which is a commonly used step in which strips are heated using a low temperature heat step to make the surface tacky, thus aiding in smoke adherence and improving product texture.

Comment: Two commenters stated that steps 5 (drying) and 6 (post-drying heat step) in the 2007 and 2012 versions of the guidance should be combined because they are often performed as single step by processors.

Response: Although the steps may be combined, in a processing schedule, for example, these steps are listed separately for purposes of the guidance document to provide information to establishments on the use of a post-drying heat step for processes that do not result in an adequate reduction of *Salmonella* through the initial heating process. Adding a post-drying heat step has the potential to reduce *Salmonella* levels by approximately 2-$\log_{10}$'s from the level of reduction achieved during initial heat step.

4. Lethality treatment

Comment: One commenter questioned the recommendation that the lethality treatment of meat jerky should achieve at least a 5.0-$\log_{10}$ reduction of *Salmonella* spp. when there is no USDA/FSIS performance standard specifically for this product.

Response: Jerky producers (and all producers of RTE product) are required to control the food safety hazards in their products (9 CFR 417.4(a)) and document that their HACCP systems work according to 9 CFR 417.5(a). For RTE products, this requirement means that, among other controls, the establishment needs to achieve lethality of pathogens (e.g., *Salmonella*) in the product. In the FSIS *Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products*, FSIS recommends that processors achieve a 5-$\log_{10}$ reduction of *Salmonella* in such meat products as jerky to produce a product safe for consumption. This recommendation is based on expected levels of *Salmonella* in raw products. The compliance guideline also provides alternative forms of lethality that establishments may use. Establishments producing a RTE product must provide adequate scientific support that the process for the RTE product will not result in an adulterated product. In addition, FSIS tests ready-to-eat product for *Salmonella* (as well as *Listeria monocytogenes*) to verify that establishments are addressing the pathogen.

5. Highly pathogenic avian influenza

Comment: Two commenters disagreed with the following statement: "If highly pathogenic avian influenza (HPAI) virus H5N1 is identified as a hazard reasonably likely

to occur, cured and smoked poultry should be cooked to at least 158°F or a time and temperature combination that achieves a 7-log reduction of *Salmonella*." The commenters stated that if this statement is included in this guidance document, establishments will now have to reassess all their HACCP plans if inspection personnel interpret it as a requirement.

Response: This statement has appeared in previous versions of the jerky compliance guidance document. The Agency has not required establishments to reassess their HACCP plans for highly pathogenic avian influenza and does not intend to do so at this time. This information has been included as guidance in the event that an establishment identifies HPAI virus H5N1 as a hazard reasonably likely to occur.

6. Humidity

Comment: One commenter disagreed with the following statement: "One way for an establishment to know that the product has not dried out before a lethal time-temperature combination is attained is to measure the water activity of the product after the lethality treatment but before drying." The commenter stated that this is not necessary if the humidity requirements are achieved. The commenter also said the guideline should clearly state that lethality should be achieved prior to drying the product to achieve desired quality and water activity for shelf stability.

Response: FSIS has added the following clarifying information: "Although this information may provide useful information to an establishment, such data are not needed if an establishment is following procedures to achieve the relative humidity in the scientific support."

Comment: One commenter disagreed with statements in the guidance document that establishments should monitor humidity throughout the entire lethality treatment. The commenter stated that establishments could conduct some sort of 90-day validation of their thermal processing schedules to achieve confidence that humidity was properly addressed.

Response: As stated on page 13, FSIS recommends that establishments monitor relative humidity using wet and dry bulb thermometers or a humidity sensor with every lot or batch of product although FSIS does not require this monitoring frequency. It is the responsibility of the establishment to support its monitoring procedures and frequencies. However, inadequate or inaccurate recordkeeping (e.g., data entry error or unclear monitoring records) has contributed to jerky product recalls, particularly when such records were associated with a lack of information regarding the implementation of all of the critical operational parameters for each batch or lot produced.

Comment: One commenter recommended that FSIS remove the following statement related to *Appendix A*: "If an establishment cannot apply these humidity options for equal to or more than one hour, then the humidity of the oven should be maintained at 90% or above throughout the lethality treatment."

Response: The option in *Appendix A* that allows for humidity levels less than 90% is as follows: "Heating roasts of any size to a minimum internal temperature of 145 °F (62.8 °C) in an oven maintained at any temperature if the relative humidity of the

oven is maintained either by continuously introducing steam for 50 percent of the cooking time or by use of a sealed oven for over 50 percent of the cooking time, or if the relative humidity of the oven is maintained at 90 percent or above for at least 25 percent of the total cooking time, but in no case less than 1 hour." The final clause "but in no case less than 1 hour" means that the humidity options of continuously introducing steam or sealing the oven should be applied for at least 1 hour. FSIS recognizes that jerky is a small mass product that often has total cooking times of less than 1 hour. *Appendix A*, and that the additional humidity options were originally designed for large mass products with longer cooking times. In cases where these humidity options can not be applied for at least 1 hour, the establishment should apply at least 90% humidity throughout the cooking time (even if the cooking time is less than 1 hour) in order to use *Appendix A* as scientific support and to ensure product reaches a lethal temperature and does not dry out before lethality is achieved. Establishments have flexibility to use other scientific support if they are unable to meet the critical operational parameters. FSIS clarified this issue in the guidance.

Comment: FSIS received one question through askFSIS inquiring whether reference to the cooking time in the humidity options in *Appendix A* refers to the entire cooking time (including come up time) or just the time during which the temperature in *Appendix A* is achieved and maintained (e.g., 145°F for 4 minutes).

Response: As stated on page 7, the cooking time (also referred to as the lethality treatment) includes the time when the thermal processing begins (e.g., the product is placed in the heated oven) until the time the product reaches the desired lethality time-temperature combination from *Appendix A*. Therefore, if an establishment is applying humidity by continuously introducing steam for 50% of the cooking time, but in no case less than 1 hour, 50% of the cooking time should be calculated based on the total cooking time, not just the time during which the temperature in *Appendix A* is achieved and maintained. If humidity is not applied early in the process, evaporating water will absorb the heat and a lethal temperature will not be achieved.

Comment: One commenter disagreed with the statement: "Establishments using the option to continuously inject steam should also have a procedure or mechanism in place to ensure that steam is being continuously injected...." The commenter indicated that smokehouses do not operate this way, and that if a program is set for 40% relative humidity, the smokehouse may spray water on the heating element to achieve this 40% relative humidity. If the smokehouse reads that the house has, for example, 50% relative humidity, it will stop spraying water on the heating elements and the dampers will fluctuate to achieve the desired 40% relative humidity in the smokehouse.

Response: FSIS recognizes that steam may be turned on and off throughout the cooking time when the target humidity is reached and has included this approach in the guideline. Some of the supporting documentation that can be used to demonstrate that steam is being "continuously introduced" is illustrated in Attachment 4.

7. Ambient vs. smokehouse temperatures

Comment: One commenter requested further explanation of the effects of ambient temperature on the smokehouse or oven temperatures. The commenter also

requested that FSIS acknowledge that smokehouses/ovens cannot be completely sealed.

Response: FSIS has provided additional information on page 12 regarding the role relative humidity in the ambient air plays on the relative humidity in the smokehouse or oven. FSIS has also provided clarification on page 21 that, even when a tight seal is obtained, some loss of humidity is the form of minor smoke or vapors may be seen.

8. Reference to International Commission on Microbiological Specifications in Foods (ICMSF) (1996) Microorganisms in Foods 5

Comment: Two commenters expressed concern that establishments will use the ICMSF book chapter in place of *Appendix A*.

Response: The only reference to the ICMSF book made in this guidance document is provided as support for finished water activity limits in order to support product shelf-stability. It would not be acceptable for an establishment to cite the water activity critical limits or the ICSMF book chapter as support for a lethality or drying process because meeting a specific water activity level does not support that a 5-$\log_{10}$ reduction is achieved. In general, establishments should not use finished product water activity levels alone as support that a product is RTE. The reason is that low water activity alone, without a further heat treatment, would not necessarily result in adequate reduction of *Salmonella* because the pathogen is known to be resistant to drying. This issue has been clarified and addressed in this guidance on page 15.

Comment: One commenter stated that FSIS should not provide specific guidance on water activity values that can be used to support shelf-stability by an establishment within the guidance. The commenter indicated if FSIS provides one specific number in any guidance document, industry or FSIS may consider the guidance a requirement.

Response: FSIS has found through *ask*FSIS questions and FSAs that establishments are not maintaining adequate scientific support that products are shelf-stable. Therefore, water activity values are provided as guidance to provide small and very small establishments with compliance assistance under SBRFA. However, establishments have flexibility in terms of selecting and supporting the critical limits of their process and are not required to use the limits provided. FSIS has made clear that this document is guidance and is not establishing new requirements (see page 2)

Comment: One commenter requested a rationale for the guidance provided on water activity limits to support shelf-stability for products packaged under aerobic and anaerobic conditions because the limits are different than those in the ICMSF book chapter. The commenter also pointed out that the citation for the ICMSF book chapter referenced the wrong page.

Response: The water activity limits of 0.85 under aerobic conditions and 0.91 under anaerobic conditions provided in this document are based on the definition of shelf-stability in the guidance on page 15 and the growth limit of *Staphylococcus aureus* in the ICMSF Book chapter (Page 304 Table B). The definition of shelf-stability in the guidance is stated as the "condition achieved when meat and poultry products can be

stored under ambient temperature and humidity conditions; if the package integrity is maintained during storage, shipping, and display at retail and in the home; and the product will not spoil or become unsafe throughout the manufacturer's specified shelf-life. " Under this definition, no growth of pathogenic organisms occurs. According to the ICMSF book chapter, the limit of growth for *Staphylococcus aureus* is 0.83 under aerobic conditions and 0.90 under anaerobic conditions. However, as noted in the footnote of the book, this criterion is based on optimal conditions. FSIS recognizes that most jerky type products have other intrinsic factors such as sodium nitrite, indigenous microflora, and salt concentration that would also act as barriers to *Staphylococcus aureus* growth. By considering these factors, FSIS has recommended an upper limit of 0.85 under aerobic conditions or 0.91 under anaerobic conditions. This rationale is now provided in the guidance document. The guidance document also now clarifies that these factors may be used to consider a product stable provided the establishment takes steps to prevent mold growth on the finished product. Finally, FSIS revised the reference to include the page number of the specific table containing these values.

Comment: One commenter expressed concern that the ICMSF book chapter used as the reference for the limits of growth of *Staphylococcus aureus* under aerobic and anaerobic conditions does not contain microbiological data supporting the limits.

Response: FSIS considers information found in textbooks and other scientific texts as acceptable scientific support because this type of scientific data goes through a process of evaluation involving qualified individuals within the relevant field. Often textbooks and other scientific texts contain a summary of information based on other peer-reviewed published research, as is the case with the ICMSF book. In the case of the water activity values provided in this guidance, establishments can refer to the guidance and are not required to provide a copy of the ICMSF book chapter or the original research referred to in the book because this guidance document contains the critical operational parameter (water activity).

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Attachment 2: Time, temperature, and humidity combinations reported in the literature for beef jerky that achieve at least a 5-$\log_{10}$ reduction in *Salmonella* and *E. coli* O157:H7. Unless noted, finished product water levels were ≤ 0.85.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (min)	Humidity (%)	$\log_{10}$ Reduction *Salmonella*	$\log_{10}$ Reduction *E. coli* O157:H7
Buege et al. (2006a)[3]	Whole muscle beef jerky	Yes – pH 5.3	No	Type 1-A* Stage 1 – 145 170	 15 15			
				Stage 2 – Choose either: dry bulb at 170 and wet bulb at 125	at least 60	27	6.5	6.9
				OR dry bulb at 170 and wet bulb at 130†	at least 60	32	6.9	7.1
				OR dry bulb at 170 and wet bulb at 135†	at least 30	37	7.0	7.1
				OR dry bulb at 170 and wet bulb at 140†	at least 10	43	6.9	7.1
				Stage 3- Dry at 170 dry bulb	to targeted doneness			

[3] Buege, D.R., Searls, G., and Ingham, S.C. 2006. Lethality of commercial whole-muscle beef jerky manufacturing processes against *Salmonella* Serovars and *Escherichia coli* O157:H7. Also see the following website for a more detailed, user-friendly critical limit summary document: http://www.meathaccp.wisc.edu/validation/assets/CLSummary_WMJerkyJune2013.pdf.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (min)	Humidity (%)	Log_{10} Reduction *Salmonella*	Log_{10} Reduction *E. coli* O157:H7
Buege et al. (2006a)	Whole muscle beef jerky	Yes – pH 5.3	No	Type 1-B*†				
				Stage 1 – 145	15			
				Then choose either:				
				Stage 2 – dry bulb at 150 THEN dry bulb at 150 and wet bulb at 130; THEN dry bulb at 150	15 60 to targeted doneness	56	6.8	7.0
				OR				
				Stage 2- dry bulb at 190 THEN dry bulb at 190 and wet bulb at 130; THEN dry bulb at 190	15 60 to targeted doneness	19	7.1	7.3
		Yes – pH 5.3	No	Type 2**† 145 170	15 to targeted doneness	27-31(start)*** 17-21(end)	6.3	6.0

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (min)	Humidity (%)	Log_{10} Reduction	
							Salmonella	*E. coli* O157:H7
Buege et al. (2006a)	Whole muscle beef jerky	Yes – pH 5.3	No	Type 3**[†] 145 170	90 to targeted doneness	41(start)*** 21(end)	5.5	5.6
		Yes – pH 5.3	No	Type 5** 180	to targeted doneness	29(start)**** 15(end)	5.1	5.6

*Type 1-A and Type 1-B processes with a higher dry bulb temperature in Stage 1, a higher wet bulb temperature or longer time in Stage 2, or a higher dry bulb temperature in Stage 3, as long as other parts of the process are not changed, can also be considered validated because they should have greater lethality.
**Processes reaching higher dry bulb temperatures in either stage can also be considered validated because they would have greater lethality.
***Humidity values are from Table 3 in Buege et al. (2006a).
****Humidity values are from Table 5 in Buege et al. (2006a).
[†]Finished product water activity level was > 0.85 (if an establishment wants to support the product is shelf-stable using 0.85 as a criteria, it should consider further drying the product).

Oven: Pans of water were placed on the lowest rack in the smokehouse, and a low fan speed was used. Humidity (steam or water) was introduced in Type 1-A and 1-B processes. Study did not indicate whether dampers were open or closed.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (min)	Humidity (%)	Log_{10} Reduction *Salmonella*	Log_{10} Reduction *E. coli* O157:H7
Buege et al. (2006a)	Whole muscle beef jerky	Yes – pH 5.3	No	Type 7**†				
				120	60	43***	6.0	5.6
				130	60			
				140	60			
				170	60	15		

**Processes reaching higher dry bulb temperatures in either stage can also be considered validated because they would have greater lethality.

***Humidity values are from Table 3 in Buege et al. (2006a).

†Finished product water activity level was > 0.85 (if an establishment wants to support the product is shelf-stable using 0.85 as a criteria, it should consider further drying the product).

Oven: Pans of water were placed on the lowest rack in the smokehouse, and a low fan speed was used. Humidity (steam or water) was introduced in Type 1-A and 1-B processes. Study did not indicate whether dampers were open or closed.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven/Product Temperature (°F)*	Time (hours)	Humidity (%) (Start/End)	Log_{10} Reduction (cfu/strip)	
							Salmonella	*E. coli* O157:H7
Porto-Fett et al. (2008)[4]	Whole muscle beef jerky	Yes – ~pH 5.5	Yes	178	1.5	63.4 21.9	≥7	≥7[†]
	Whole muscle beef jerky	No	Yes	178	1.5	63.4 21.9	≥7	≥7[†]
	Whole muscle beef jerky	Yes – ~pH 5.5	Yes	178.3	2.5	63.8 21.5	≥7	≥7
	Whole muscle beef jerky	No	Yes	178.3	2.5	63.8 21.5	≥7	≥7[†]
	Whole muscle beef jerky	Yes – ~pH 5.5	Yes	178.5	3.5	62.3 19.2	≥7	≥7
		No	Yes	178.5	3.5	62.3 19.2	≥7	≥7

*Oven temperatures are average of continuous readings taken every 30s after CUT.
[†]Finished product water activity level was > 0.85 (if an establishment wants to support the product is shelf-stable using 0.85 as a criteria, it should consider further drying the product).

Oven: Dampers were completely open.

[4] Porto-Fett, A.C.S., Call, J.E., and Luchansky, J.B. 2008. Validation of a commercial process for inactivation of *Escherichia coli* O157:H7, *Salmonella* Typhimurium, and *Listeria monocytogenes* on the surface of whole muscle beef jerky. Journal of Food Protection. 71(5): 918-926.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (min)	Humidity (%)*	Log_{10} Reduction	
							Salmonella	*E. coli* O157:H7
Harper et al. (2009),[5] Getty et al. (2006)[6]	Chopped and formed beef jerky	No	No (smoke flavor was added)	Stage 0 –			7.1	7.1
				Stage 1 – 132	14	32.6		
				Stage 2 – 132	16	52		
				Stage 3 – 132	14	14.5		
				Stage 4 – 172	16	22		
				Stage 5 – 172	14	22		
				Stage 6 – 172	16	22		
				Stage 7 – 172	14	22		
				Stage 8 – 172	16	22		
				Stage 9 – 172	14	22		
				Stage 10 – 172	16	22		
				Stage 11 – 172	14	22		
				Stage 12 – 172	5 h	22		

*Humidity levels were calculated from actual dry and wet bulb temperatures reported in Getty et al. (2006): http://www.fsis.usda.gov/wps/wcm/connect/35151cb4-1603-4164-b71f-bfea44e487e8/C-12_New_Technology_FY2004_Final_Report.pdf?MOD=AJPERES. Although the report states that humidity remained at less than 10% throughout the entire smokehouse cycle, humidity levels calculated from dry and wet bulb temperatures in the report were higher, as indicated in the table. This was verified through personal communication with the author [April 2011].

Oven: Automated dampers and steam injection.

[5] Harper, N.M., Roberts, M.N., Getty, K.J.K., Boyle, E.A.E., Fung, D.Y.C., Higgins, J.J. 2009. Evaluation of two thermal processing schedules at low relative humidity for elimination of *Escherichia coli* O157:H7 and *Salmonella* Serovars in chopped and formed beef jerky. Journal of Food Protection. 72: 2476-2482.

[6] Getty, K.J.K., Boyle, E.A.E., Roberts, M.N., Lonneker, S.M. 2006. Jerky Validation for Small and Very Small meat and Poultry Businesses: Final Report. Available at: http://www.fsis.usda.gov/wps/wcm/connect/35151cb4-1603-4164-b71f-bfea44e487e8/C-12_New_Technology_FY2004_Final_Report.pdf?MOD=AJPERES. Accessed 17 August 2013.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (min)	Humidity (%)**	Log_{10} Reduction *Salmonella*	Log_{10} Reduction *E. coli* O157:H7
Borowski et al. (2009a)[7]	Ground-and-formed beef jerky	No*		Type 2-A				
			No	170	30	57	7.4	7.4
			No	130	120	22		
			No	170	90	28		
	Ground-and-formed beef jerky	No*		Type 3-A				
			No	170	30	7	6.1	6.8
			No	170	15	23		
			No	170	130	ND		
	Ground-and-formed beef jerky	No*		Type 4-A				
			No	135	90	67	7.8	8.1
			No	185	150	9		

*A spice rub mix was used. Two types of spice mixes (Colorado and BBQ) were used in the study. Results for one type of spice mix (Colorado) are reported here. Variability in lethality was found due to spice mix type. See Borowski et al. (2009a) for details on the spice mixes used including pH and a_w values and results for products prepared with the BBQ spice mix.
**%RH values are approximate based on an average of the range of actual dry and wet bulb temperatures provided in the article. RH values reported as ND were not determined.

NOTE: All processes reported here used a commercial oven-smokehouse.
Oven: Dampers were open for processes without smoke added.

[7] Borowski, A.G., Ingham, S.C., Ingham, B.H. 2009. Validation of ground-and-formed beef jerky processes using commercial lactic acid bacteria starter cultures as pathogen surrogates. Journal of Food Protection. 72(6): 1234-1247.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Temperature (°F)	Time (min)	Humidity (%)**	Log_{10} Reduction *Salmonella*	Log_{10} Reduction *E. coli* O157:H7
Borowski et al. (2009a)	Ground-and-formed beef jerky	No*		Type 2-B				
			Yes	170	30	32	7.2	7.4
			Yes	130	120	ND		
			Yes	170	90	ND		
	Ground-and-formed beef jerky	No*		Type 3-B				
			No	170	30	7	7.3	7.4
			No	170	15	39		
			Yes	170	130	ND		
	Ground-and-formed beef jerky	No*		Type 4-B				
			Yes[8]	135	90	68	7.5	7.5
			Yes[9]	185	150	ND		

**A spice rub mix was used. Two types of spice mixes (Colorado and BBQ) were used in the study. Results for one type of spice mix (Colorado) are reported here. Variability in lethality was found due to spice mix type. See Borowski et al. (2009a) for details on the spice mixes used including pH and a_w values and results for products prepared with the BBQ spice mix.
**%RH values are approximate based on an average of the range of actual dry and wet bulb temperatures provided in the article. RH values reported as ND were not determined.

NOTE: All processes reported here used a commercial oven-smokehouse.
Oven: Dampers were open until smoke was added at which point dampers were closed.

[8] Smoke added after 30 min.
[9] Smoke discontinued after 90 min.

This Attachment is not considered adequate support on its own because it does not provide the details of each study an establishment needs to determine if the study is representative of the actual process.

Reference	Product	Marinated (Yes/No)	Smoke Added (Yes/No)	Oven Temperature (°F)	Time (hours)	Humidity (%)	Log_{10} Reduction	
							Salmonella	*E. coli* O157:H7
Harrison et al. (2006)[10]	Beef jerky strips	Yes	No	143.6	8-9	33	>6	>6

NOTE: The process reported here used a commercial oven-smokehouse.
Oven: No humidity control. Study did not indicate whether dampers were open or not.

[10] Harrison, M. A., R. K. Singh, J. A. Harrison and N. Singh. 2006. Antimicrobial intervention and process validation in beef jerky processing. Final Report. Available at: http://www.fsis.usda.gov/wps/wcm/connect/8dd0f238-08d7-4ca0-a31a-77fa3ca8acf6/C-17_New_Technology_FY2004_Final_Report.pdf?MOD=AJPERES. Accessed 17 August 2013.

Attachment 3: Making Your Own Wet Bulb Thermometer (Reprinted with permission)

By G. Burnham, S.C. Ingham and B.H. Ingham
University of Wisconsin-Madison Center for Meat Process Validation

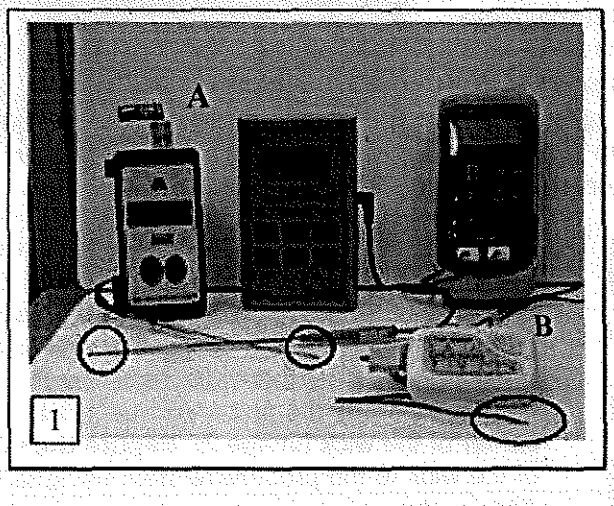
If you are smoking or drying meat, there are several parameters to monitor which will help you control your process: **dry bulb temperature**, **wet bulb temperature**, and **relative humidity**. Research at the University of Wisconsin Center for Meat Process Validation has shown that **monitoring wet bulb temperature is even more important (and much easier!) than monitoring product temperature** during your process. Since wet bulb temperature is critical to process monitoring, this document describes how to easily, and perhaps inexpensively, construct a wet bulb thermometer.

Dry bulb temperature, usually referred to as air temperature, is the smokehouse/oven property that is most commonly measured by jerky-makers. When people refer to the temperature (heat content) of the air, they are normally referring to the dry bulb temperature. It is called "dry bulb" because the air temperature is indicated by a thermometer that is not moistened and will not be affected by evaporative cooling.

Wet bulb temperature is the temperature indicated by a moistened thermometer bulb exposed to air. A wet bulb thermometer measures the extent of cooling that happens as moisture dries from a surface (evaporative cooling). The wet bulb temperature is always lower than the dry bulb temperature except when there is 100% relative humidity. **Because evaporative cooling occurs on the surface of thin jerky strips, the wet bulb temperature is more accurate measurement of product temperature**.

We developed a **wet bulb thermometer (WBT)** which is easy to assemble and economical for a meat processor to use.

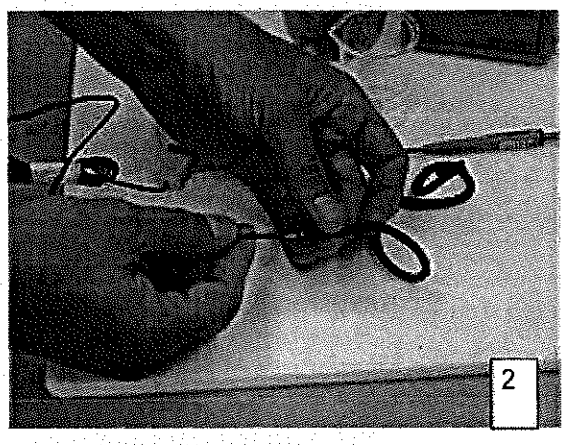
To begin assembling a wet bulb thermometer, you will need to determine what type of **temperature measuring device** you will use. You will need to use a temperature recorder with a "tip reading" probe/wire/stem. Either an **instant read** or a **data-logging temperature measuring device** will work; both are pictured in image 1.



A - 3 styles of 'instant read' temperature measuring device
B - a data logger-style of temperature measuring device
In each case, the 'tip reading' probe/wire is circled.

Instant read temperature recorders. **(A)** An instant read temperature Recorder will offer immediate feedback, with the temperature displayed on the front of the unit. However, data may not be recorded with this type of unit; the processor must record the data periodically. See page 51 for more information on ordering instant-read temperature recorders.

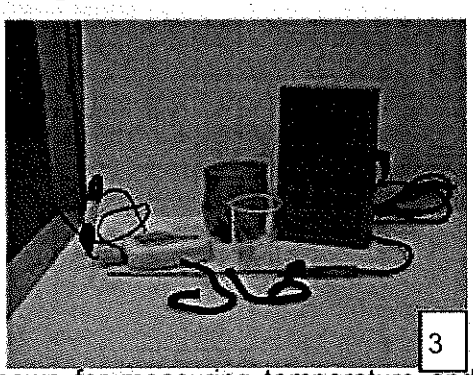
A data logger-style temperature recorder. (B) This type of device keeps track of, or 'logs' temperature over a period of time. An inexpensive data logger usually does not offer immediate readout of data. A processor must connect the data logger to a computer to view the temperature data. A data logger does, however, offer a continuous record of temperature history which can be important for HACCP documentation. See page 51 for information on ordering a standard data logger.

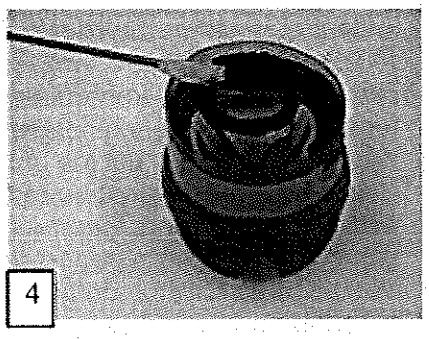

2

Once you have your temperature recorder, you will need to choose material to serve as the **"wick"** to cover the tip probe. Water evaporating from the wick will reduce the temperature recorded, giving an indication of evaporative cooling. The wick should be made from an absorbent material, preferably cotton. It should also be constructed of **two phases**: a loose, absorbent interior, and an exterior that is of an absorbent tighter meshing material. The exterior keeps the inner absorbent material around the sensing portion of the temperature probe and prevents the sensing portion of the recorder from being exposed to direct ambient conditions. You may wish to purchase wicks commercially, such as from an online supplier (http://www.wickstore.com/wetbulbwick.html), or a good substitute is a round cotton bootlace (image 2). See page 51 for more information on supplies for a wet bulb thermometer.

There are several simple steps to setting up a **wet bulb thermometer**.

1. **Gather materials.** You will need a **vessel for holding water** which must either be refilled during processing, or must be sufficiently large to hold enough water (allowing for evaporation) to keep the water level close to the temperature probe. Choosing a vessel with a small diameter opening will reduce evaporation. Once a water vessel has been chosen, simply fill it with water. You will also need a **temperature measuring device** and material to serve as a **wick**. In image 3, the bottom of a soda bottle and a glass beaker are pictured as vessels. Both an instant read and a data logger are shown for measuring temperature and pieces of brown cotton shoelace serve as the wick.


3

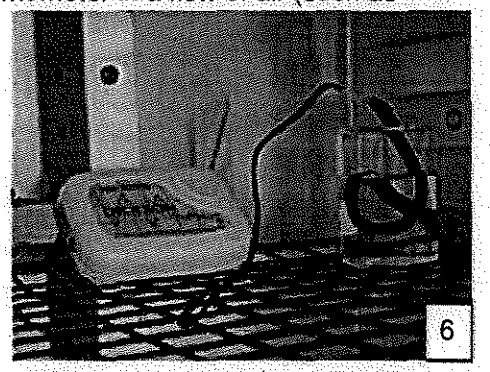

4

2. **Assemble the wet bulb thermometer. Cut** a portion of the wicking material (it should be long enough to reach the bottom of the water vessel and than some). **Connect** the sensing portion of your temperature recorder to the wick by inserting the probe/wire/stem into the center of the wick (image 2). **Secure the end** of the wick to the probe/wire/stem using tape. **Place the wick** in the water-containing vessel. **Make sure** the wick is completely

saturated with water, then position the wick-covered sensing portion of your temperature recorder so that it is completely exposed to ambient conditions, yet as close as possible to the water source (image 4). This will ensure adequate wicking of the water to the sensing portion of the temperature recorder. If exposure to ambient conditions is too great, such as when the wick is too long or the recorder too far from the water surface, the wick may dry out, and evaporative cooling will not be recorded.

3. **Place the wet bulb thermometer inside the chamber.** If you are using an instant reading temperature measuring device to make process adjustments, place the wet bulb thermometer for easy access and readability, such as near a door or window (image 5). If immediate feedback is not a consideration (image 6), place the device where the ambient conditions of your process are least likely to give you optimum conditions - hence a "worst case" reading. Position the wet bulb thermometer in a flow of air (such as in a stream of incoming air), but away from fans which will cause excessive evaporation and drying of the wick.


5


6

4. **Record wet bulb temperature.** Establish a regular schedule of recording or down-loading wet bulb temperature. Check water level in the vessel periodically, and also check the position of the wick. The portion of the wick above the water must remain moist for accurate temperature measurement. The wet bulb temperature can be used to adjust your process conditions, as needed.

Supplies for Making a Wet Bulb Thermometer*

Instant Read Temperature Recorders
Fisher Scientific (800-766-7000)
- Part 15-078-38; price $131.49 plus shipping
- Part 15-077-14; price $111.15 plus shipping

Data Logger-Type Temperature Recorders
Dickson Company (800-323-2448)
- Part SM325 (LCD Display Temperature Data Logger w/ 2 K-thermocouple probes); price $399 plus shipping
- Also order software to download information to computer ($79)

Wick Material
- Round cotton bootlace (pictured in this document) - available at many general stores
- Wet-bulb wick ($50-$60 per spool http://www.wickstore.com/wetbulbwick.html)

- Wet-bulb sock: Alkar, part #50040; price $127.00 for bundle of 100 (608-592-4865)

**The items and suppliers listed here are suggestions only, based on price and availability. The mention of particular suppliers is not meant to exclude others from consideration.*

For more information contact:
Steve Ingham, Extension Food Safety Specialist (608) 265-4801, scingham@wisc.edu
May, 2006

The University of Wisconsin-Madison Center for Meat Process Validation provides science-based HACCP support to small meat processors in meeting state and federal mandates for safe food processing and handling. For more information on the Center contact Dr. Steve Ingham, 1605 Linden Drive, UW-Madison, Madison, WI 53706 (608) 265-4801 Email: scingham@wisc.edu

Cooking Program and Recorder Chart Courtesy of: Dr. Jeff J. Sindelar; Meat Science & Muscle Biology Lab, University of Wisconsin-Madison & Robert Hanson; HansonTech, LLC

Attachment 4: Example Time-Temperature Recorder Chart to Support Option to Continuously Inject Steam

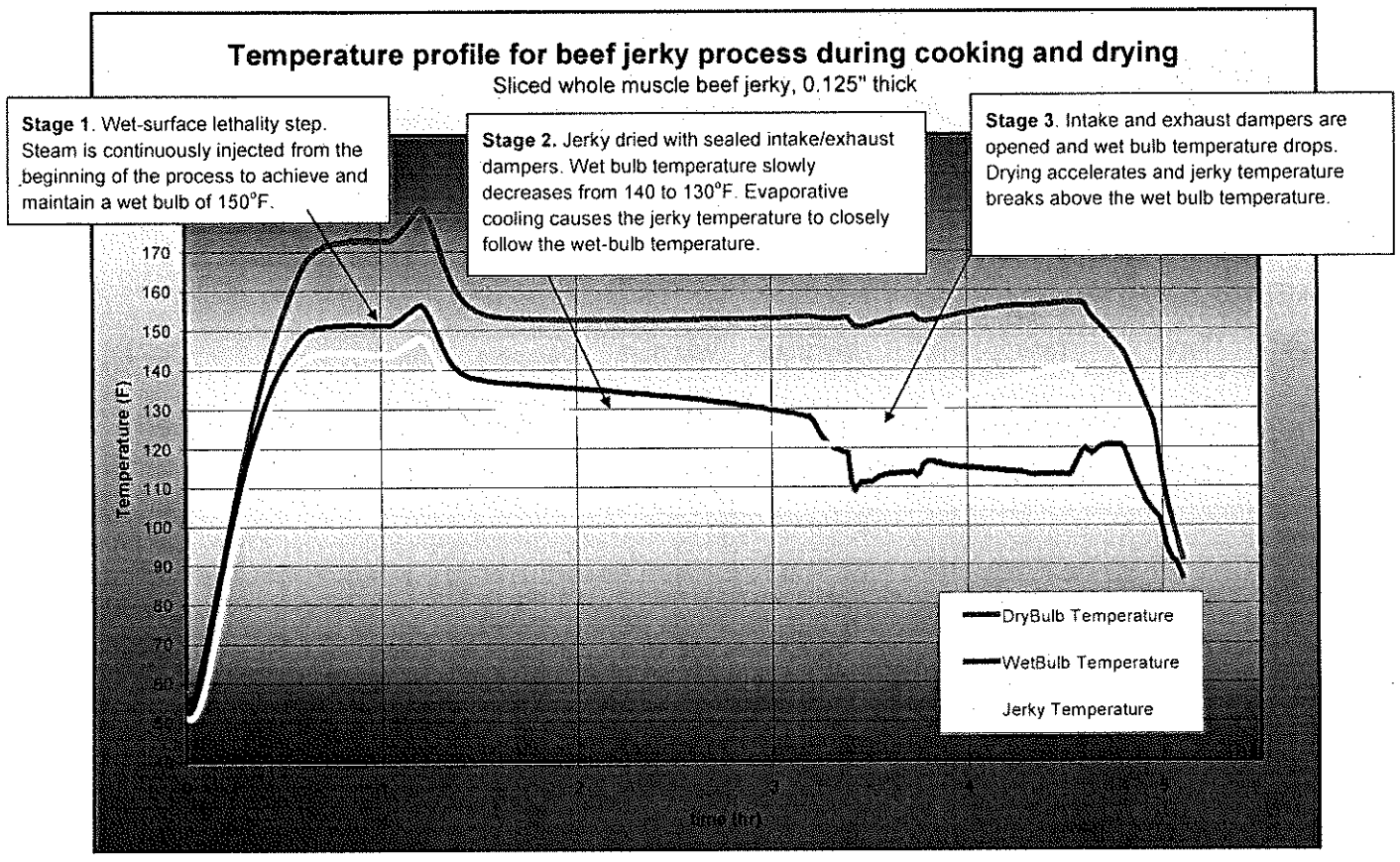
The chart on the next page illustrates and supports that steam is being continuously introduced into the smokehouse for at least 50% of the cooking time but in no case for less than one hour per *Appendix A*. The smokehouse schedule is provided for reference below. As can be seen on the recorder chart, during the cooking time (that is the first hour of the process), the wet bulb rises while humidity (in the form of steam) is continuously injected. The process eventually achieves and maintains a wet bulb of 150°F, which at a dry bulb temperature of 170°F equates to a relative humidity of 59%. The process targets an internal product temperature of 145°F for 4 minutes per *Appendix A*.

Cooking program for beef jerky

Stage	Type	Time	Dry Bulb	Wet Bulb	Dampers	Notes
1	Cook	60 min	170°F	150°F	Closed	Humidity continuously injected
2	Dry	120 min	150	---	Closed	
3	Dry	80 min (to a_w)	150	---	Open	

In addition to supporting that steam is being continuously introduced, the chart provides a good illustration of why wet bulb temperature is a better indicator of product internal temperature than dry bulb temperature. As can be seen on the chart, the product internal temperature (shown by the yellow line), follows the wet bulb temperature (shown by the blue line) more closely than the dry bulb temperature (shown by the dark red line) during the lethality treatment. Towards the end of the process, the product internal temperature breaks above the wet bulb temperature and rises towards the dry bulb temperature as a result of diminishing evaporative cooling of the jerky that occurs because the product is drying out (i.e., moisture has been lost) (Buege et al., 2006a).

Cooking Program and Recorder Chart Courtesy of: Dr. Jeff J. Sindelar; Meat Science & Muscle Biology Lab, University of Wisconsin-Madison & Robert Hanson; HansonTech, LLC



4. USFDA, 21 Code of Federal Regulations, Part 700, subpart B, revised March 2016. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=700&showFR=1&subpartNode=21:7.0.1.2.10.2

FDA

CFR - Code of Federal Regulations Title 21

The information on this page is current as of April 1 2017.

For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).[6]

[Code of Federal Regulations]
[Title 21, Volume 7]
[Revised as of April 1, 2017]
[CITE: 21CFR700]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER G--COSMETICS
PART 700GENERAL

Subpart B--Requirements for Specific Cosmetic Products

Sec. 700.11 Cosmetics containing bithionol.

(a) Bithionol has been used to some extent as an antibacterial agent in cosmetic preparations such as detergent bars, shampoos, creams, lotions, and bases used to hide blemishes. New evidence of clinical experience and photopatch tests indicate that bithionol is capable of causing photosensitivity in man when used topically and that in some instances the photosensitization may persist for prolonged periods as severe reactions without further contact with sensitizing articles. Also, there is evidence to indicate that bithionol may produce cross-sensitization with other commonly used chemicals such as certain halogenated salicylanilides and hexachlorophene. It is, therefore, the view of the Food and Drug Administration that bithionol is a deleterious substance which may render any cosmetic product that contains it injurious to users. Accordingly, any cosmetic containing bithionol is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(b) Regulatory proceedings may be initiated with respect to any cosmetic preparation containing bithionol shipped within the jurisdiction of the act after March 15, 1968.

Sec. 700.13 Use of mercury compounds in cosmetics including use as skinbleaching agents in cosmetic preparations also regarded as drugs.

(a) Mercury-containing cosmetic preparations have been represented for many years as skin-bleaching agents or as preparations to remove or prevent freckles and/or brown spots (so-called age spots). Preparations intended for such use are regarded as drugs as well as cosmetics. In addition to such use as skin-bleaching agents, mercury compounds have also been widely used as preservatives in cosmetics such as hand and body creams and lotions; hair shampoos, hair sets and rinses, hair straighteners, hair coloring, and other preparations; bath oils, bubble bath, and other bath preparations; makeup; antiperspirants and deodorants; and eye-area cosmetics.

(b) The toxicity of mercury compounds is extensively documented in scientific literature. It is well known that mercury compounds are readily absorbed through the unbroken skin as well as through the lungs by inhalation and by intestinal absorption after ingestion. Mercury is absorbed from topical application and is accumulated in the body, giving rise to numerous adverse effects. Mercury is a potent allergen and sensitizer, and skin irritation is common after topical application. Cosmetic preparations containing mercury compounds are often applied with regularity and frequency for prolonged periods. Such chronic use of mercury-containing skin-bleaching preparations has resulted in the accumulation of mercury in the body and the occurrence of severe reactions. Recently it has also been determined that microorganisms in the environment can convert various forms of mercury into highly toxic methyl mercury which has been found in the food supply and is now considered to be a serious environmental problem.

(c) The effectiveness of mercury-containing preparations as skin-bleaching agents is questionable. The Food and Drug Administration has not been provided with well controlled studies to document the effectiveness of these preparations. Although mercurial preservatives are recognized as highly effective, less toxic and satisfactory substitutes are available except in the case of certain eye-area cosmetics.

(d) Because of the known hazards of mercury, its questionable efficacy as a skin-bleaching agent, and the availability of effective and less toxic nonmercurial preservatives, there is no justification for the use of mercury in skin-bleaching preparations or its use as a preservative in cosmetics, with the exception of eye-area cosmetics for which no other effective and safe nonmercurial preservative is available. The continued use of mercurial preservatives in such eye-area cosmetics is warranted because mercury compounds are exceptionally effective in preventing *Pseudomonas* contamination of cosmetics and *Pseudomonas* infection of the eye can cause serious injury, including blindness. Therefore:

(1) The Food and Drug Administration withdraws the opinion expressed in trade correspondence TC-9 (issued May 13, 1939) and concludes that any product containing mercury as a skin-bleaching agent and offered for sale as skin-bleaching, beauty, or facial preparation is misbranded within the meaning of sections 502(a), 502(f)(1) and (2), and 502(j), and may be a new drug without approval in violation of section 505 of the Federal Food, Drug, and Cosmetic Act. Any such preparation shipped within the jurisdiction of the Act after January 5, 1973 will be the subject of regulatory action.

(2) The Food and Drug Administration withdraws the opinion expressed in trade correspondence TC-412 (issued Feb. 11, 1944) and will regard as adulterated within the meaning of section 601(a) of the Act any cosmetic containing mercury unless the cosmetic meets the conditions of paragraph (d)(2) (i) or (ii) of this section.

(i) It is a cosmetic containing no more than a trace amount of mercury and such trace amount is unavoidable under conditions of good manufacturing practice and is less than 1 part per million (0.0001 percent), calculated as the metal; or

(ii) It is a cosmetic intended for use only in the area of the eye, it contains no more than 65 parts per million (0.0065 percent) of mercury, calculated as the metal, as a preservative, and there is no effective and safe nonmercurial substitute preservative available for use in such cosmetic.

Sec. 700.14 Use of vinyl chloride as an ingredient, including propellant of cosmetic aerosol products.

(a) Vinyl chloride has been used as an ingredient in cosmetic aerosol products including hair sprays. Where such aerosol products are used in the confines of a small room, as is often the case, the level of vinyl chloride to which the individual may be exposed could be significantly in excess of the safe level established in connection with occupational exposure. Evidence indicates that vinyl chloride inhalation can result in acute toxicity, manifested by dizziness, headache, disorientation, and unconsciousness where inhaled at high concentrations. Studies also demonstrate carcinogenic effects in animals as a result of inhalation exposure to vinyl chloride. Furthermore, vinyl chloride has recently been linked to liver disease, including liver cancer, in workers engaged in the polymerization of vinyl chloride. It is the view of the Commissioner that vinyl chloride is a deleterious substance which may render any cosmetic aerosol product that contains it as an ingredient injurious to users. Accordingly, any cosmetic aerosol product containing vinyl chloride as an ingredient is deemed to be adulterated under section 601 (a) of the Federal Food, Drug, and Cosmetic Act.

(b) Any cosmetic aerosol product containing vinyl chloride as an ingredient shipped within the jurisdiction of the Act is subject to regulatory action.

[39 FR 30830, Aug. 26, 1974]

Sec. 700.15 Use of certain halogenated salicylanilides as ingredients in cosmetic products.

(a) Halogenated salicylanilides (tribromsalan (TBS,3,4',5-tribromosalicylanilide), dibromsalan (DBS,4'5-dibromosalicylanilide), metabromsalan (MBS, 3,5-dibromosalicylanilide) and 3,3',4,5'-tetrachlorosalicylanilide (TCSA)) have been used as antimicrobial agents for a variety of purposes in cosmetic products. These halogenated salicylanilides are potent photosensitizers and cross-sensitizers and can cause disabling skin disorders. In some instances, the photosensitization may persist for prolonged periods as a severe reaction without further exposure to these chemicals. Safer alternative antimicrobial agents are available.

(b) These halogenated salicylanilides are deleterious substances which render any cosmetic that contains them injurious to users. Therefore, any cosmetic product that contains such a halogenated salicylanilide as an ingredient at any level for any purpose is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(c) Any cosmetic product containing these halogenated salicylanilides as an ingredient that is initially introduced into interstate commerce after December 1, 1975, that is not in compliance with this section is subject to regulatory action.

[40 FR 50531, Oct. 30, 1975]

Sec. 700.16 Use of aerosol cosmetic products containing zirconium.

(a) Zirconium-containing complexes have been used as an ingredient in cosmetics and/or cosmetics that are also drugs, as, for example, aerosol antiperspirants. Evidence indicates that certain zirconium compounds have caused human skin granulomas and toxic effects in the lungs and other organs of experimental animals. When used in aerosol form, some zirconium will reach the deep portions of the lungs of users. The lung is an organ, like skin, subject to the development of granulomas. Unlike the skin, the lung will not reveal the presence of granulomatous changes until they have become advanced and, in some cases, permanent. It is the view of the Commissioner that zirconium is a deleterious substance that may render any cosmetic aerosol product that contains it injurious to users.

(b) Any aerosol cosmetic product containing zirconium is deemed to be adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(c) Any such cosmetic product introduced in interstate commerce after September 15, 1977 is subject to regulatory action.

[42 FR 41376, Aug. 16, 1977]

Sec. 700.18 Use of chloroform as an ingredient in cosmetic products.

(a) Chloroform has been used as an ingredient in cosmetic products. Recent information has become available associating chloroform with carcinogenic effects in animals. Studies conducted by the National Cancer Institute have demonstrated that the oral administration of chloroform to mice and rats induced hepatocellular carcinomas (liver cancer) in mice and renal tumors in male rats. Scientific literature indicates that chloroform is absorbed from the gastrointestinal tract, through the respiratory system, and through the skin. The Commissioner concludes that, on the basis of these findings, chloroform is a deleterious substance which may render injurious to users any cosmetic product that contains chloroform as an ingredient.

(b) Any cosmetic product containing chloroform as an ingredient is adulterated and is subject to regulatory action under sections 301 and 601(a) of the Federal Food, Drug, and Cosmetic Act. Any cosmetic product containing chloroform in residual amounts from its use as a processing solvent during manufacture, or as a byproduct from the synthesis of an ingredient, is not, for the purpose of this section, considered to contain chloroform as an ingredient.

[41 FR 26845, June 29, 1976]

Sec. 700.19 Use of methylene chloride as an ingredient of cosmetic products.

(a) Methylene chloride has been used as an ingredient of aerosol cosmetic products, principally hair sprays, at concentrations generally ranging from 10 to 25 percent. In a 2-year animal inhalation study sponsored by the National Toxicology Program, methylene chloride produced a significant increase in benign and malignant tumors of the lung and liver of male and female mice. Based on these findings and on estimates of human exposure from the customary use of hair sprays, the Food and Drug Administration concludes that the use of methylene chloride in cosmetic products poses a significant cancer risk to consumers, and that the use of this ingredient in cosmetic products may render these products injurious to health.

(b) Any cosmetic product that contains methylene chloride as an ingredient is deemed adulterated and is subject to regulatory action under sections 301 and 601(a) of the Federal Food, Drug, and Cosmetic Act.

[54 FR 27342, June 29, 1989]

Sec. 700.23 Chlorofluorocarbon propellants.

The use of chlorofluorocarbons in cosmetics as propellants in self-pressurized containers is prohibited as provided in 2.125 of this chapter.

[43 FR 11317, Mar. 17, 1978]

Sec. 700.25 Tamper-resistant packaging requirements for cosmetic products.

(a) *General.* Because most cosmetic liquid oral hygiene products and vaginal products are not now packaged in tamper-resistant retail packages, there is the opportunity for the malicious adulteration of those cosmetic products with health risks to individuals who unknowingly purchase adulterated products and with loss of consumer confidence in the security of cosmetic product packages. The Food and Drug Administration has the authority and responsibility under the Federal Food, Drug, and Cosmetic Act (the act) to establish a uniform national requirement for tamper-resistant packaging of cosmetic liquid oral hygiene products or products used vaginally that will improve the packaging security and help assure the safety of those products. Such a cosmetic product for retail sale that is not packaged in a tamper-resistant package or that is not properly labeled under this section is adulterated under section 601 of the act or misbranded under section 602 of the act, or both.

(b) *Requirement for tamper-resistant package.* Each manufacturer and packer who packages a cosmetic liquid oral hygiene product or vaginal product for retail sale shall package the product in a tamper-resistant package, if this product is accessible to the public while held for sale. A tamper-resistant package is one having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred. To reduce the likelihood of substitution of a tamper-resistant feature after tampering, the indicator or barrier to entry is required to be distinctive by design (e.g., an aerosol product container) or by the use of an identifying characteristic (e.g., a pattern, name, registered trademark, logo, or picture). For purposes of this section, the term "distinctive by design" means the packaging cannot be duplicated with commonly available materials or through commonly available processes. For purposes of this section, the term "aerosol product" means a product which depends upon the power of a liquified or compressed gas to expel the contents from the container. A tamper-resistant package may involve an immediate-container and closure system or secondary-container or carton system or any combination of systems intended to provide a visual indication of package integrity. The tamper-resistant feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display.

(c) *Labeling.* Each retail package of a cosmetic product covered by this section, except aerosol products as defined in paragraph (b) of this section, is required to bear a statement that is prominently placed so that consumers are alerted to the specific tamper-resistant feature of the package. The labeling statement is also required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing. If the tamper-resistant feature chosen to meet the requirement in paragraph (b) of this section is one that uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement. For example, the labeling statement on a bottle with a shrink band could say "For your protection, this bottle has an imprinted seal around the neck."

(d) *Requests for exemptions from packaging and labeling requirements.* A manufacturer or packer may request an exemption from the packaging and labeling requirements of this section. A request for an exemption is required to be submitted in the form of a citizen petition under 10.30 of this chapter and should be clearly identified on the envelope as a "Request for Exemption from Tamper-resistant Rule." The petition is required to contain the following:

(1) The name of the product.

(2) The reasons that the product's compliance with the tamper-resistant packaging or labeling requirements of this section is unnecessary or cannot be achieved.

(3) A description of alternative steps that are available, or that the petitioner has already taken, to reduce the likelihood that the product will be the subject of malicious adulteration.

(4) Other information justifying an exemption.

This information collection requirement has been approved by the Office of Management and Budget under number 0910-0149.

(e) *Effective date.* Cosmetic products covered by this section are required to comply with the requirements of this section on the dates listed below except to the extent that a product's manufacturer or packer has obtained an exemption from a packaging or

labeling requirement.

(1) *Initial effective date for packaging requirements.* (i) The packaging requirement in paragraph (b) of this section is effective on Feburary 7, 1983 for each affected cosmetic product (except vaginal tablets) packaged for retail sale on or after that date, except for the requirement in paragraph (b) of this section for a distinctive indicator or barrier to entry.

(ii) The packaging requirement in paragraph (b) of this section is effective on May 5, 1983 for each cosmetic product that is a vaginal tablet packaged for retail sale on or after that date.

(2) *Initial effective date for labeling requirements.* The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in paragraph (c) of this section for a labeling statement are effective on May 5, 1983 for each affected cosmetic product packaged for retail sale on or after that date, except that the requirement for a specific label reference to any identifying characteristic is effective on February 6, 1984 for each affected cosmetic product packaged for retail sale on or after that date.

(3) *Retail level effective date.* The tamper-resistant packaging requirement of paragraph (b) of this section is effective February 6, 1984 for each affected cosmetic product held for sale on or after that date that was packaged for retail sale before May 5, 1983. This does not include the requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design. Products packaged for retail sale after May 5, 1983, as required to be in compliance with all aspects of the regulations without regard to the retail level effective date.

[47 FR 50451, Nov. 5, 1982; 48 FR 1707, Jan. 14, 1983; 48 FR 11427, Mar. 18, 1983, as amended at 48 FR 16664, Apr. 19, 1983; 48 FR 37624, Aug. 19, 1983]

Effective Date Note:

See 48 FR 41579, Sept. 16, 1983, for a document announcing an interim stay of the effective date of certain provisions in paragraph (e)(3) of 700.25.

Sec. 700.27 Use of prohibited cattle materials in cosmetic products.

(a) *Definitions.* The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) apply to such terms when used in this part. The following definitions also apply:

(1) *Prohibited cattle materials* mean specified risk materials, small intestine of all cattle except as provided in paragraph (b)(2) of this section, material from nonambulatory disabled cattle, material from cattle not inspected and passed, or mechanically separated (MS) (Beef). Prohibited cattle materials do not include the following:

(i) Tallow that contains no more than 0.15 percent insoluble impurities, tallow derivatives, gelatin, hides and hide-derived products, and milk and milk products, and

(ii) Cattle materials inspected and passed from a country designated under paragraph (e) of this section.

(2) *Inspected and passed* means that the product has been inspected and passed for human consumption by the appropriate regulatory authority, and at the time it was inspected and passed, it was found to be not adulterated.

(3) *Mechanically separated (MS) (Beef)* means a meat food product that is finely comminuted, resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of cattle carcasses and parts of carcasses that meets the specifications contained in 9 CFR 319.5, the U.S. Department of Agriculture regulation that prescribes the standard of identity for MS (Species).

(4) *Nonambulatory disabled cattle* means cattle that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

(5) *Specified risk material* means the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older and the tonsils and distal ileum of the small intestine of all cattle.

(6) *Tallow* means the rendered fat of cattle obtained by pressing or by applying any other extraction process to tissues derived directly from discrete adipose tissue masses

or to other carcass parts and tissues. Tallow must be produced from tissues that are not prohibited cattle materials or must contain no more than 0.15 percent insoluble impurities as determined by the method entitled "Insoluble Impurities" (AOCS Official Method Ca 3a-46), American Oil Chemists' Society (AOCS), 5th Edition, 1997, incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, or another method equivalent in accuracy, precision, and sensitivity to AOCS Official Method Ca 3a-46. You may obtain copies of the method from AOCS (*http://www.aocs.org*) 2211 W. Bradley Ave. Champaign, IL 61821. Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(7) *Tallow derivative* means any chemical obtained through initial hydrolysis, saponification, or trans-esterification of tallow; chemical conversion of material obtained by hydrolysis, saponification, or trans-esterification may be applied to obtain the desired product.

(8) *Gelatin* means a product that has been obtained by the partial hydrolysis of collagen derived from hides, connective tissue, and/or bone bones of cattle and swine. Gelatin may be either Type A (derived from an acid-treated precursor) or Type B (derived from an alkali-treated precursor) that has gone through processing steps that include filtration and sterilization or an equivalent process in terms of infectivity reduction.

(b) *Requirements*. (1) No cosmetic shall be manufactured from, processed with, or otherwise contain, prohibited cattle materials.

(2) The small intestine is not considered prohibited cattle material if the distal ileum is removed by a procedure that removes at least 80 inches of the uncoiled and trimmed small intestine, as measured from the caeco-colic junction and progressing proximally towards the jejunum, or by a procedure that the establishment can demonstrate is equally effective in ensuring complete removal of the distal ileum.

(c) *Records*. (1) Manufacturers and processors of a cosmetic that is manufactured from, processed with, or otherwise contains, material from cattle must establish and maintain records sufficient to demonstrate that the cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials.

(2) Records must be retained for 2 years after the date they were created.

(3) Records must be retained at the manufacturing or processing establishment or at a reasonably accessible location.

(4) The maintenance of electronic records is acceptable. Electronic records are considered to be reasonably accessible if they are accessible from an onsite location.

(5) Records required by this section and existing records relevant to compliance with this section must be available to FDA for inspection and copying.

(6) When filing entry with U.S. Customs and Border Protection, the importer of record of a cosmetic manufactured from, processed with, or otherwise containing, cattle material must affirm that the cosmetic was manufactured from, processed with, or otherwise contains, cattle material and must affirm that the cosmetic was manufactured in accordance with this section. If a cosmetic is manufactured from, processed with, or otherwise contains, cattle material, then the importer of record must, if requested, provide within 5 days records sufficient to demonstrate that the cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle material.

(7) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

(d) *Adulteration*. Failure of a manufacturer or processor to operate in compliance with the requirements of paragraph (b) or (c) of this section renders a cosmetic adulterated under section 601(c) of the act.

(e) *Process for designating countries*. A country seeking designation must send a written request to the Director, Office of the Center Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration, at the address designated in 21 CFR 5.1100. The request shall include information about a country's bovine spongiform encephalopathy (BSE) case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether specified risk materials, the small intestine of cattle except as provided in paragraph

(b)(2) of this section, material from nonambulatory disabled cattle, or MS (Beef) from cattle from the country should be considered prohibited cattle materials. FDA shall respond in writing to any such request and may impose conditions in granting any such request. A country designation granted by FDA under this paragraph will be subject to future review by FDA, and may be revoked if FDA determines that it is no longer appropriate.

[70 FR 53068, Sept. 7, 2005, as amended at 71 FR 59668, Oct. 11, 2006; 73 FR 20794, Apr. 17, 2008; 81 FR 5596, Feb. 3, 2016; 81 FR 14732, Mar. 18, 2016]

Sec. 700.35 Cosmetics containing sunscreen ingredients.

(a) A product that includes the term "sunscreen" in its labeling or in any other way represents or suggests that it is intended to prevent, cure, treat, or mitigate disease or to affect a structure or function of the body comes within the definition of a drug in section 201(g)(1) of the act. Sunscreen active ingredients affect the structure or function of the body by absorbing, reflecting, or scattering the harmful, burning rays of the sun, thereby altering the normal physiological response to solar radiation. These ingredients also help to prevent diseases such as sunburn and may reduce the chance of premature skin aging, skin cancer, and other harmful effects due to the sun when used in conjunction with limiting sun exposure and wearing protective clothing. When consumers see the term "sunscreen" or similar sun protection terminology in the labeling of a product, they expect the product to protect them in some way from the harmful effects of the sun, irrespective of other labeling statements. Consequently, the use of the term "sunscreen" or similar sun protection terminology in a product's labeling generally causes the product to be subject to regulation as a drug. However, sunscreen ingredients may also be used in some products for nontherapeutic, nonphysiologic uses (e.g., as a color additive or to protect the color of the product). To avoid consumer misunderstanding, if a cosmetic product contains a sunscreen ingredient and uses the term "sunscreen" or similar sun protection terminology anywhere in its labeling, the term must be qualified by describing the cosmetic benefit provided by the sunscreen ingredient.

(b) The qualifying information required under paragraph (a) of this section shall appear prominently and conspicuously at least once in the labeling in conjunction with the term "sunscreen" or other similar sun protection terminology used in the labeling. For example: "Contains a sunscreen--to protect product color."

[64 FR 27693, May 21, 1999]

Authority: 21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374.
Source: 39 FR 10054, Mar. 15, 1974, unless otherwise noted.

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. https://www.fda.gov/MedicalDevices/default.htm
5. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. http://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl
7. /scripts/cdrh/cfdocs/search/default.cfm?FAQ=true
8. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm135680.htm

10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

(c) *Applicability.* Special packaging standards for drugs listed under paragraph (a) of this section shall be in addition to any packaging requirements of the Federal Food, Drug, and Cosmetic Act or regulations promulgated thereunder or of any official compendia recognized by that act.

(Pub. L. 91–601, secs. 2(4), 3, 5, 85 Stat. 1670–72; 15 U.S.C. 1471(4), 1472, 1474; Pub. L. 92–573, 86 Stat. 1231; 15 U.S.C. 2079(a))

[38 FR 21247, Aug. 7, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §1700.14, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov*.

§1700.15 Poison prevention packaging standards.

To protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances, the Commission has determined that packaging designed and constructed to meet the following standards shall be regarded as "special packaging" within the meaning of section 2(4) of the act. Specific application of these standards to substances requiring special packaging is in accordance with §1700.14.

(a) *General requirements.* The special packaging must continue to function with the effectiveness specifications set forth in paragraph (b) of this section when in actual contact with the substance contained therein. This requirement may be satisfied by appropriate scientific evaluation of the compatibility of the substance with the special packaging to determine that the chemical and physical characteristics of the substance will not compromise or interfere with the proper functioning of the special packaging. The special packaging must also continue to function with the effectiveness specifications set forth in paragraph (b) of this section for the number of openings and closings customary for its size and contents. This requirement may be satisfied by appropriate technical evaluation based on physical wear and stress factors, force required for activation, and other such relevant factors which establish that, for the duration of normal use, the effectiveness specifications of the packaging would not be expected to lessen.

(b) *Effectiveness specifications.* Special packaging, tested by the method described in §1700.20, shall meet the following specifications:

(1) Child-resistant effectiveness of not less than 85 percent without a demonstration and not less than 80 percent after a demonstration of the proper means of opening such special packaging. In the case of unit packaging, child-resistant effectiveness of not less than 80 percent.

(2) *Ease of adult opening*—(i) *Senior-adult test.* Except for products specified in paragraph (b)(2)(ii) of this section, special packaging shall have a senior adult use effectiveness (SAUE) of not less than 90% for the senior-adult panel test of §1700.20(a)(3).

(ii) *Younger-adult test*—(A) *When applicable.* Products that must be in aerosol form and products that require metal containers, under the criteria specified below, shall have an effectiveness of not less than 90% for the younger-adult test of §1700.20(a)(4). The senior-adult panel test of §1700.20(a)(3) does not apply to these products. For the purposes of this paragraph, metal containers are those that have both a metal package and a recloseable metal closure, and aerosol products are self-contained pressurized products.

(B) *Determination of need for metal or aerosol container—(1) Criteria.* A product will be deemed to require metal containers or aerosol form only if:

(*i*) No other packaging type would comply with other state or Federal regulations,

(*ii*) No other packaging can reasonably be used for the product's intended application,

(*iii*) No other packaging or closure material would be compatible with the substance,

(*iv*) No other suitable packaging type would provide adequate shelf-life for the product's intended use, or

(*v*) Any other reason clearly demonstrates that such packaging is required.

(2) Presumption. In the absence of convincing evidence to the contrary, a product shall be presumed not to require a metal container if the product,

or another product of identical composition, has previously been marketed in packaging using either a nonmetal package or a nonmetal closure.

(*3*) *Justification.* A manufacturer or packager of a product that is in a metal container or aerosol form that the manufacturer or packager contends is not required to comply with the SAUE requirements of §1700.20(a)(3) shall provide, if requested by the Commission's staff, a written explanation of why the product must have a metal container or be an aerosol. Manufacturers and packagers who wish to do so voluntarily may submit to the Commission's Office of Compliance a rationale for why their product must be in metal containers or be an aerosol. In such cases, the staff will reply to the manufacturer or packager, if requested, stating the staff's views on the adequacy of the rationale.

(c) *Reuse of special packaging.* Special packaging for substances subject to the provisions of this paragraph shall not be reused.

(d) *Restricted flow.* Special packaging subject to the provisions of this paragraph shall be special packaging from which the flow of liquid is so restricted that not more than 2 milliliters of the contents can be obtained when the inverted, opened container is taken or squeezed once or when the container is otherwise activated once.

(Secs. 2(4), 3, 5, 84 Stat. 1670–72; 15 U.S.C. 1471(4), 1472, 1474)

[38 FR 21247, Aug. 7, 1973, as amended at 60 FR 37734, July 21, 1995]

§ 1700.20 Testing procedure for special packaging.

(a) *Test protocols*—(1) *General requirements*—(i) *Requirements for packaging.* As specified in §1700.15(b), special packaging is required to meet the child test requirements and the applicable adult test requirements of this §1700.20.

(ii) *Condition of packages to be tested*—(A) *Tamper-resistant feature.* Any tamper-resistant feature of the package to be tested shall be removed prior to testing unless it is part of the package's child-resistant design. Where a package is supplied to the consumer in an outer package that is not part of the package's child-resistant design, one of the following situations applies:

(*1*) In the child test, the package is removed from the outer package, and the outer package is not given to the child.

(*2*) In both the adult tests, if the outer package bears instructions for how to open or properly resecure the package, the package shall be given to the test subject in the outer package. The time required to remove the package from the outer package is not counted in the times allowed for attempting to open and, if appropriate, reclose the package.

(*3*) In both the adult tests, if the outer package does not bear any instructions relevant to the test, the package will be removed from the outer package, and the outer package will not be given to the test subject.

(B) *Reclosable packages—adult tests.* In both the adult tests, reclosable packages, if assembled by the testing agency, shall be properly secured at least 72 hours prior to beginning the test to allow the materials (e.g., the closure liner) to "take a set." If assembled by the testing agency, torque-dependent closures shall be secured at the same on-torque as applied on the packaging line. Application torques must be recorded in the test report. All packages shall be handled so that no damage or jarring will occur during storage or transportation. The packages shall not be exposed to extreme conditions of heat or cold. The packages shall be tested at room temperature.

(2) *Child test*—(i) *Test subjects*—(A) *Selection criteria.* Use from 1 to 4 groups of 50 children, as required under the sequential testing criteria in table 1. No more than 20% of the children in each group shall be tested at or obtained from any given site. Each group of children shall be randomly selected as to age, subject to the limitations set forth below. Thirty percent of the children in each group shall be of age 42–44 months, 40% of the children in each group shall be of age 45–48 months, and 30% of the children in each group shall be of age 49–51 months. The children's ages in months shall be calculated as follows:

(*1*) Arrange the birth date and test date by the numerical designations for month, day, and year (e.g., test date: 8/3/1990; birth date: 6/23/1986).

California Department of Public Health
Manufactured Cannabis Safety Branch

Temporary License Application: Cannabis Manufacturing

Application Instructions:

Complete one form for each premises in which you will be conducting commercial cannabis manufacturing.

Please type or write legibly.

Submit the completed application and attachments via mail or email to:

MCLS@cdph.ca.gov

California Department of Public Health
Manufactured Cannabis Safety Branch
PO Box 997377, MS-7377
Sacramento, CA 95899-7377

If you have any questions, please visit our website, www.cdph.ca.gov/mcsb, or contact us at MCLS@cdph.ca.gov.

State of California - Health and Human Services Agency

California Department of Public Health
Manufactured Cannabis Safety Branch

Temporary License Application: Cannabis Manufacturing

SECTION A – LICENSE TYPE (Check all that apply)

☐ Medicinal (M) ☐ Adult-Use (A)

SECTION B – APPLICANT INFORMATION

First Name | MI | Last Name

Title | Phone Number | Email Address

SECTION C – BUSINESS INFORMATION

Legal Business Name (as registered with the CA Secretary of State) | Trade Name (DBA) | Federal EIN

Mailing Address | City | State | Zip | County

SECTION D – PREMISES INFORMATION

Physical Address of Manufacturing Premises | City | State | Zip | County

SECTION E – OPERATIONAL ACTIVITIES (Check all that apply for the premises listed in Section D)

Product Types	M	A
Edibles		
Concentrates		
Topicals		
Capsules		
Vape Cartridges		
Tinctures		
Other:		

Activities	M	A
Extraction		
Infusion		
Packaging/Labeling		

Extraction Methods	M	A
Butane/Hexane/Propane		
Ethanol		
Carbon Dioxide (CO_2)		
Water/Food-grade Dry Ice		
Food-grade Butter/Oil		
Mechanical		
Other:		

SECTION F – LOCAL AUTHORIZATION

Local Issuing Authority | Local Office Phone Number | Local Office Email Address

SECTION G – LOCAL AUTHORIZATION ATTACHMENT

☐ A copy of a valid license, permit or other authorization issued by the local jurisdiction that enables the applicant to conduct commercial cannabis activity at the premises listed in Section D.

SECTION H – DECLARATIONS AND SIGNATURE

I declare under penalty that:

- The information contained within and attached to this application is complete, true and accurate. I understand a misrepresentation of fact is cause for rejection of this application, denial of license or revocation of an issued license.
- I understand that the temporary license is a conditional license that authorizes my business to engage in the commercial cannabis activity described in the application.
- I understand that refusal by the licensing authority to issue or extend a temporary license shall not entitle the business to a hearing or appeal of the decision.
- I understand that the issuance of a temporary license does not obligate the Department to issue a non-temporary license, nor does it create a vested right to either an extension of the temporary license or to the granting of a non-temporary license.
- I understand that I am responsible for knowing and complying with all state laws and regulations governing medicinal and adult-use cannabis manufacturing pursuant to Medicinal and Adult-Use Cannabis Regulation and Safety Act and all other applicable laws and regulations, upon issuance of my temporary license. I understand that I am responsible for compliance with subsequent updates to cannabis manufacturing laws and regulations.

Signature | Print Name | Date