

§ 94.17

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region in which the milk or milk product was processed. Further, the certificate must state that, except for movement under seal as described in § 94.16(c), the milk or milk product has never been in a region in which foot-and-mouth disease exists. Milk or milk products from a region listed under § 94.1(a) as free of foot-and-mouth disease and that were processed in whole or in part from milk or milk products from a region not listed under § 94.1(a) as free of foot-and-mouth disease may be imported into the United States only in accordance with paragraph (b)(3) of this section.

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EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 94.16, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 94.17 Dry-cured pork products from regions where foot-and-mouth disease, African swine fever, classical swine fever, or swine vesicular disease exists.

Notwithstanding any other provisions in this part, dry-cured ham, pork shoulder, or pork loin, whether whole or sliced and packaged, shall not be prohibited from being imported into the United States if it meets the following conditions:

(a) Except for Italian-type hams, Serrano hams, Iberian hams, Iberian pork shoulders, and Iberian pork loins that have been processed in accordance with paragraph (i) of this section, the dry-cured ham, pork shoulder, or pork loin came from a swine that was never out of the region in which the dry-cured ham, pork shoulder, or pork loin was processed;

(b) The ham, pork shoulder, or pork loin came from a region determined by the Administrator, to have and to enforce laws requiring the immediate reporting to the national veterinary services in that region any premises found to have any animal infected with foot-and-mouth disease, African Swine fever, classical swine fever, or swine vesicular disease;

(c) The ham, pork shoulder, or pork loin came from a swine that was not on

any premises where foot-and-mouth disease, African swine fever, classical swine fever, or swine vesicular disease exists or had existed within 60 days prior to slaughter;

(d) The whole ham, pork shoulder, or pork loin was accompanied from the slaughtering facility to the processing establishment by a numbered certificate issued by a person authorized by the government of the region of origin stating that the provisions of paragraphs (a) and (c) of this section have been met;

(e) The ham, pork shoulder, or pork loin was processed whole as set forth in paragraph (i) of this section in only one processing establishment;¹⁵

(f) The ham, pork shoulder, or pork loin was processed whole in a processing establishment that prior to the processing of any hams, pork shoulders, or pork loins in accordance with this section, was inspected by a veterinarian of APHIS and determined by the Administrator, to be capable of meeting the provisions of this section for processing hams, pork shoulders, or pork loins for importation into the United States;

(g) The ham, pork shoulder, or pork loin was processed whole in a processing establishment for which the operator of the establishment has signed an agreement with APHIS prior to receipt of the hams, pork shoulders, or pork loins for processing, stating that all hams, pork shoulders, or pork loins processed for importation into the United States will be processed only in accordance with the provisions of this part;

(h) Workers who handle fresh pork in the processing establishment where the dry-cured ham, pork shoulder, or pork loin was processed whole are required to shower and put on a full set of clean clothes, or to wait 24 hours after handling fresh pork, before handling hams, pork shoulders, or pork loins that have

¹⁵ As a condition of entry into the United States, pork and pork products must also meet all of the requirements of the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and regulations thereunder (9 CFR, chapter III), including requirements that the pork or pork products be prepared only in approved establishments.

progressed in the aging/curing process as follows:

(1) In the case of Italian-type hams processed in accordance with paragraph (i)(1) of this section, those that have progressed beyond the final wash stage;

(2) In the case of Serrano hams or Iberian hams or pork shoulders processed in accordance with paragraphs (i)(2), (i)(3), or (i)(4) of this section, those that have progressed beyond salting; and

(3) In the case of Iberian pork loins processed in accordance with paragraph (i)(5) of this section, those that have progressed beyond being placed in a casing.

(i) The dry-cured ham, pork shoulder, or pork loin was processed whole in accordance with this paragraph. Except for pork fat treated to at least 76 °C (168.8 °F), which may have been placed over the meat during curing, the dry-cured pork product must have had no contact with any other meat or animal product during processing.

(1) *Italian-type hams.* The ham was processed for a period of not less than 400 days in accordance with the following conditions: after slaughter the ham was held at a temperature of 0–3 °C. (32–34.7 °F) for a minimum of 72 hours during which time the “aitch” bone and the foot was removed and the blood vessels at the end of the femur were massaged to remove any remaining blood; thereafter the ham was covered with an amount of salt equal to 4–6 percent of the weight of the ham, with a sufficient amount of water added to ensure that the salt had adhered to the ham; thereafter the ham was placed for 5–7 days on racks in a chamber maintained at a temperature of 0–4 °C. (32–39.2 °F) and at a relative humidity of 70–85 percent; thereafter the ham was covered with an amount of salt equal to 4–6 percent of the weight of the ham, with a sufficient amount of water added to ensure that the salt had adhered to the ham; thereafter the ham was placed for 21 days in a chamber maintained at a temperature of 0–4 °C. (32–39.2 °F) and at a relative humidity of 70–85 percent; thereafter the salt was brushed off the ham; thereafter the ham was placed in a chamber maintained at a temperature

of 1–6 °C. (33.8–42.8 °F.) and at a relative humidity of 65–80 percent for between 52 and 72 days; thereafter the ham was brushed and rinsed with water; thereafter the ham was placed in a chamber for 5–7 days at a temperature of 15–23 °C. (59–73.4 °F.) and a relative humidity of 55–85 percent; thereafter the ham was placed for curing in a chamber maintained for a minimum of 314 days at a temperature of 15–20 °C. (59–68 °F.) and at a relative humidity of 65–80 percent at the beginning and increased by 5 percent every 2½ months until a relative humidity of 85 percent was reached.

(2) *Serrano hams.* Serrano hams were processed as follows (190-day minimum curing process):

(i) If the ham is received frozen, it was thawed in a chamber with relative humidity between 70 and 80 percent, with room temperature maintained at 12 °C to 13 °C (53.6 °F to 55.4 °F) for the first 24 hours, then at 13 °C to 14 °C (55.4 °F to 57.2 °F) until the internal temperature of the ham reached 3 °C to 4 °C (37.4 °F to 39.2 °F), at which point the blood vessels at the end of the femur were massaged to remove any remaining blood.

(ii) The ham was covered in salt and placed in a chamber maintained at a temperature from 0 °C to 4 °C (32 °F to 39.2 °F), with relative humidity between 75 and 95 percent, for a period no less than 0.65 days per kg and no more than 2 days per kg of the weight of the ham.

(iii) The ham was rinsed with water and/or brushed to remove any remaining surface salt.

(iv) The ham was placed in a chamber maintained at a temperature of 0 °C to 6 °C (32 °F to 42.8 °F), with a relative humidity of 70 to 95 percent, for no less than 40 and no more than 60 days;

(v) The ham was placed for curing in a chamber with a relative humidity of 60 to 80 percent and a temperature gradually raised in 3 phases, as follows:

(A) A temperature of 6 °C to 16 °C (42.8 °F to 60.8 °F), maintained for a minimum of 45 days;

(B) A temperature of 16 °C to 24 °C (60.8 °F to 75.2 °F), maintained for a minimum of 35 days;

(C) A temperature of 24 °C to 34 °C (75.2 °F to 93.2 °F), maintained for a minimum of 30 days;

(vi) Finally, with the relative humidity unchanged at 60 to 80 percent, the temperature was lowered to 12 °C to 20 °C (53.6 °F to 68 °F) and maintained at that level for a minimum of 35 days, until at least 190 days after the start of the curing process; *Except that:* In a region where swine vesicular disease exists, the ham must be maintained at that level an additional 370 days, until at least 560 days after the start of the curing process.

(3) *Iberian hams.* Iberian hams were processed as follows (365-day minimum curing process):

(i) If the ham is received frozen, it was thawed in a chamber with relative humidity between 70 and 80 percent, with room temperature maintained at 5.5 °C to 6.5 °C (41.9 °F to 43.7 °F) for the first 24 hours, then at 9.5 °C to 10.5 °C (49.1 °F to 50.9 °F) until the internal temperature of the ham reached 3 °C to 4 °C (37.4 °F to 39.2 °F), at which point the blood vessels at the end of the femur were massaged to remove any remaining blood.

(ii) The ham was covered in salt and placed in a chamber maintained at a temperature from 0 °C to 4 °C (32 °F to 39.2 °F), with relative humidity between 75 and 95 percent, and kept in the chamber for a period no less than 0.65 days per kg and no more than 2 days per kg of the weight of the ham;

(iii) The ham was rinsed with water and/or brushed to remove any remaining surface salt.

(iv) The ham was placed in a chamber maintained at a temperature of 0 °C to 6 °C (32 °F to 42.8 °F), with relative humidity of 70 to 95 percent, for no less than 40 and no more than 60 days.

(v) The ham was placed for curing in a chamber with a temperature of 6 °C to 16 °C (42.8 °F to 60.8 °F) and relative humidity of 60 to 80 percent for a minimum of 90 days.

(vi) The temperature was raised to 16 °C to 26 °C (60.8 °F to 78.8 °F) and the relative humidity reduced to 55 to 85 percent, for a minimum of 90 days.

(vii) Finally, with the relative humidity raised to 60 to 90 percent, the temperature was lowered to 12 °C to 22 °C (53.6 °F to 71.6 °F) and maintained at

that level for a minimum of 115 days, until at least 365 days after the start of the curing process; *Except that:* In a region where swine vesicular disease exists, the ham must be maintained at that level an additional 195 days, until at least 560 days after the start of the curing process.

(4) *Iberian pork shoulders.* Iberian pork shoulders were processed as follows (240-day minimum curing process):

(i) If the pork shoulder is received frozen, it was thawed at a room temperature of 12 °C to 13 °C (53.6 °F to 55.4 °F), with the relative humidity between 75 and 85 percent, for approximately 24 hours, until the internal temperature reached 3 °C to 4 °C (37.4 °F to 39.2 °F), at which point the blood vessels in the scapular region were massaged to remove any remaining blood.

(ii) The pork shoulder was covered in salt and placed in a chamber maintained at a temperature of 0 °C to 4 °C (32 °F to 39.2 °F) with the relative humidity between 75 and 95 percent, for a period of no less than 0.65 days per kg and no more than 2 days per kg of the weight of the pork shoulder.

(iii) The pork shoulder was rinsed with water and/or brushed to remove any remaining surface salt.

(iv) The pork shoulder was placed in a chamber maintained at a temperature of 0 °C to 6 °C (32 °F to 42.8 °F) and a relative humidity of 70 to 95 percent for not less than 40 days and not more than 60 days.

(v) The pork shoulder was placed for curing in a chamber at a temperature of 6 °C to 16 °C (42.8 °F to 60.8 °F) and a relative humidity of 60 to 80 percent for a minimum of 90 days.

(vi) The temperature was raised to 16 °C to 26 °C (60.8 °F to 78.8 °F) and the relative humidity was changed to 55 to 85 percent, and those levels were maintained for a minimum of 90 days.

(vii) Finally, the temperature was reduced to 12 °C to 22 °C (53.6 °F to 71.6 °F) and the relative humidity was raised to 60 to 90 percent for a minimum of 45 days, until at least 240 days after the start of the curing process.

(5) *Iberian pork loins.* Iberian pork loins were processed as follows (130-day minimum curing process):

(i) If the pork loin is received frozen, it was thawed at a room temperature maintained at 11 °C to 12 °C (51.8 °F to 53.6 °F), with the relative humidity between 70 and 80 per cent for the first 24 hours, then between 75 and 85 percent, until the loin's internal temperature reached 3 °C to 4 °C (37.4 °F to 39.2 °F), at which point the external fat, aponeurosis, and tendons were cleaned from the loin.

(ii) The pork loin was covered in a pickle preparation (25-30 grams of salt for each kilogram of pork loin) and placed in a chamber where it was maintained at a relative humidity of 75 to 95 percent and a temperature of 3 °C to 4 °C (37.4 °F to 39.2 °F) for 72 hours.

(iii) The pork loin was removed from the pickle preparation (25-30 grams of salt for each kilogram of pork loin), externally cleaned (brushed or rinsed), placed in an artificial casing, and fastened shut with a metal clip.

(iv) The pork loin was placed for curing in a chamber with a relative humidity of 60 to 90 percent and a temperature gradually raised in 3 phases, as follows:

(A) A temperature of 2 °C to 6 °C (35.6 °F to 42.8 °F), maintained for a minimum of 20 days;

(B) A temperature of 6 °C to 15 °C (42.8 °F to 59.0 °F), maintained for a minimum of 20 days;

(C) A temperature of 15 °C to 25 °C (59.0 °F to 77.0 °F), maintained for a minimum of 40 days;

(v) Finally, with the relative humidity unchanged at 60 to 80 percent and the temperature lowered to 0 °C to 5 °C (32.0 °F to 41.0 °F), the pork loin was vacuum-packed and maintained under those conditions for a minimum of 15 days, until at least 130 days after the start of the curing process.

(j)(1) The whole ham, if it is Italian-type ham processed in accordance with paragraph (i)(1) of this section, bears a hot iron brand or an ink seal (with the identifying number of the slaughtering establishment) which was placed thereon at the slaughtering establishment under the direct supervision of a person authorized to supervise such activity by the veterinary services of the national government of the region of origin, bears a button seal (approved by the Administrator, as being tamper-

proof) on the hock that states the month and year the ham entered the processing establishment and a hot iron brand (with the identifying number of the processing establishment and the date salting began) which were placed thereon at the processing establishment immediately prior to salting, under the supervision of a person authorized to supervise such activity by the veterinary services of the national government of the region of origin;

(2) The whole dry-cured ham, if it is processed in accordance with paragraphs (i)(2) or (i)(3) of this section, or the whole dry-cured pork shoulder, if it is processed in accordance with paragraph (i)(4) of this section, bears an ink seal (with the identifying number of the slaughtering establishment) which was placed thereon at the slaughtering establishment under the direct supervision of a person authorized to supervise such activity by the veterinary services of the national government of the region of origin, and an ink seal (with the identifying number of the processing establishment and the date the salting began) which was placed thereon at the processing establishment, immediately prior to salting, under the supervision of a person authorized to supervise such activity by the veterinary services of the national government of the region of origin; or

(3) The whole dry-cured pork loin, if it is processed in accordance with paragraph (i)(5) of this section, is packaged with material that bears a seal of the government of the region of origin which was placed thereon at the slaughtering establishment under the direct supervision of a person authorized to supervise such activity by the veterinary services of the national government of the region of origin, and bears a tamper-proof plastic tag, securely attached to the pork loin itself, that states the identifying number of the slaughtering establishment and the date the pork loin was placed in the pickle preparation under the supervision of a person authorized to supervise such activity by the veterinary service of the national government of the region of origin.

(k) The whole dry-cured ham, pork shoulder, or pork loin came from an establishment where a person authorized

by the veterinary services of the national government of the region of origin to conduct activities under this paragraph, maintained original records (which shall be kept for a minimum of two years) identifying the dry-cured ham, pork shoulder, or pork loin by the date it entered the processing establishment, by the slaughtering facility from which it came, and by the number of the certificate which accompanied the dry-cured ham, pork shoulder, or pork loin from the slaughtering facility to the processing establishment, and where such original records are maintained under lock and key by such person, with access to such original records restricted to officials of the government of the region of origin, officials of the United States Government, and such person maintaining the records;

(l) The whole dry-cured ham, pork shoulder, or pork loin came from a processing establishment which allows the unannounced entry into the establishment of APHIS personnel, or other persons authorized by the Administrator, for the purpose of inspecting the establishment and records of the establishment;

(m) The dry-cured ham, pork shoulder, or pork loin was processed in accordance with one of the following criteria:

(1) The ham, if it is an Italian-type ham processed in accordance with paragraph (i)(1) of this section, was processed in a region which has submitted, through its veterinary services, to the Administrator, a written statement stating that it conducts a program to authorize persons to supervise activities specified under this section;

(2) The Serrano ham, processed in accordance with paragraph (i)(2) of this section, and came from any breed of large, white swine, including but not limited to Landrace, Pietrain, Duroc, Jersey, Hampshire, and Yorkshire breeds, and crosses of such breeds;

(3) The Iberian ham, processed in accordance with paragraph (i)(3) of this section, and came from a swine of the Iberico breed of pigs;

(4) The Iberian pork shoulder, processed in accordance with paragraph (i)(4) of this section, and came from a swine of the Iberico breed of pigs;

(5) The Iberian pork loin, if processed in accordance with paragraph (i)(5) of this section, and came from a swine of the Iberico breed of pigs.

(n) The whole dry-cured ham, pork shoulder, or pork loin came from a processing establishment that has entered into a cooperative service agreement executed by the operator of the establishment or a representative of the establishment and APHIS, and that pursuant to the cooperative service agreement is current in paying all costs for a veterinarian of APHIS to inspect the establishment (it is anticipated that such inspections will occur up to four times per year), including travel, salary, subsistence, administrative overhead, and other incidental expenses (including an excess baggage provision up to 150 pounds). In accordance with the terms of the cooperative service agreement, the operator of the processing establishment shall deposit with the Administrator, an amount equal to the approximate costs for a veterinarian to inspect the establishment one time, including travel, salary, subsistence, administrative overhead and other incidental expenses (including an excess baggage provision up to 150 pounds), and as funds from that amount are obligated, bills for costs incurred based on official accounting records will be issued to restore the deposit to its original level. Amounts to restore the deposit to its original level shall be paid within 14 days of receipt of such bills.

(o) The dry-cured ham, pork shoulder, or pork loin is accompanied at the time of importation into the United States by a certificate issued by a person authorized to issue such certificates by the veterinary services of the national government of the region of origin, stating:

(1) That all the provisions of this section have been complied with, including paragraphs (i) and (m) of this section;

(2) The paragraph of this section under which the dry-cured ham, pork shoulder, or pork loin was processed; and stating further that, if the product covered by the certificate:

(i) Is an Italian-type ham processed under paragraph (i)(1) of this section, it

was processed for a minimum of 400 days;

(ii) Is a Serrano ham processed under paragraph (i)(2) of this section, it was:

(A) Processed for a minimum of 190 days in a region free of swine vesicular disease, in a facility authorized by the veterinary services of the national government of that region to process only meat from regions free of swine vesicular disease; or,

(B) Processed for a minimum of 560 days in any region, in a facility that may also process meat from regions where swine vesicular disease exists;

(iii) Is an Iberian ham processed under paragraph (i)(3) of this section, it was:

(A) Processed for a minimum of 365 days in a region free of swine vesicular disease, in a facility authorized by the veterinary services of the national government of that region to process only meat from regions free of swine vesicular disease; or,

(B) Processed for a minimum of 560 days in any region, in a facility that may also process meat from regions where swine vesicular disease exists;

(iv) Is a dry-cured pork shoulder, it was processed in accordance with paragraph (i)(4) of this section for a minimum of 240 days; or

(v) Is a dry-cured pork loin, it was processed in accordance with paragraph (i)(5) of this section for a minimum of 130 days.

(p) Whole hams, pork shoulders, and pork loins that have been dry-cured in accordance with paragraph (i) of this section may be transported to a facility in the same region for slicing and packaging in accordance with this paragraph.

(1) *The slicing/packaging facility.* (i) The slicing/packaging facility¹⁶ must be inspected, prior to slicing and packaging any hams, pork shoulders, or pork loins in accordance with this paragraph, by an APHIS representative and determined by the Administrator to be capable of meeting the provisions of this paragraph.

(ii) The slicing/packaging facility must be either in a separate, physically detached building, or in a separate room in the facility where the whole

ham, pork shoulder, or pork loin was dry-cured in accordance with paragraph (i) of this section. If the slicing/packaging facility is in a separate room, the room must have no direct access to areas in the facility where pork is cured and dried and it must be capable of being closed off from the rest of the facility so unauthorized individuals cannot enter.

(iii) The slicing/packaging facility, including all equipment used to handle pork and pork products, such as containers, work surfaces, slicing machines, and packaging equipment, must be cleaned and disinfected after sliced and packaged pork products that are not eligible for export to the United States leave the facility, and before whole dry-cured hams, pork shoulders, or pork intended for importation into the United States enter the facility for slicing and packaging. Cleaning and disinfecting must be adequate to ensure that disease agents of concern are killed or inactivated and that pork products intended for importation into the United States are not contaminated.

(iv) The slicing/packaging facility must maintain under lock and key for a minimum of 2 years, original records on each lot of whole dry-cured hams, pork shoulders, and pork loins entering the facility for slicing and packaging under this section, including:

(A) The approval number of the facility where the whole ham, shoulder, or loin was dry-cured in accordance with paragraph (i) of this section;

(B) The date the whole ham, shoulder, or loin started dry-curing;

(C) The date the whole ham, shoulder, or loin completed dry-curing;

(D) The date the whole ham, shoulder, or loin was sliced and packaged; and

(E) A copy of all certifications required under paragraph (p) of this section.

(v) Access to records required to be maintained under paragraph (p) of this section must be restricted to officials of the national government of the region of origin, representatives of the United States Government, and persons maintaining the records.

¹⁶ See footnote 15.

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(vi) The operator of the slicing/packaging facility must have signed a cooperative service agreement with APHIS prior to receipt of the whole dry-cured hams, pork shoulders, or pork loins for slicing and packaging, stating that all hams, pork shoulders, or pork loins sliced and packaged at the facility for importation into the United States will be sliced and packaged only in accordance with this section.

(vii) The operator of the slicing/packaging facility must be current, in accordance with the terms of the cooperative service agreement signed with APHIS, in paying all costs for an APHIS representative to inspect the establishment, including travel, salary, subsistence, administrative overhead, and other incidental expenses.

(viii) The slicing/packaging facility must allow the unannounced entry into the establishment of APHIS representatives, or other persons authorized by the Administrator, for the purpose of inspecting the establishment and records of the establishment.

(ix) Workers at the slicing/packaging facility who handle pork or pork products in the facility must shower and put on a full set of clean clothes, or wait 24 hours after handling pork or pork products that are not eligible for importation into the United States, before handling dry-cured hams, pork shoulders, or pork loins in the slicing/packaging facility that are intended for importation into the United States.

(x) Pork products intended for importation into the United States may not be in the slicing/packaging facility at the same time as pork products not intended for exportation to the United States.

(2) *Slicing and packaging and labeling procedures.* (i) A full-time salaried veterinarian employed by the national government of the region of origin must inspect each lot of whole dry-cured hams, pork shoulders, and pork loins at the slicing/packaging facility, before slicing is begun, and must certify in English that it is eligible for importation into the United States in accordance with this section; and

(ii) Either a full-time salaried veterinarian employed by the national government of the region of origin, or, if the national government of the region

of origin recognizes a local consortium as responsible for product quality, a representative of that local consortium, must certify in English that he or she personally supervised the entire process of slicing and packaging each lot of dry-cured hams, pork shoulders, and pork loins at the slicing/packaging facility; that each lot of dry-cured hams, pork shoulders, and pork loins was sliced and packaged in accordance with the requirements of this paragraph; and that the sliced and packaged pork ham, shoulder, or loin is the same dry-cured ham, pork shoulder, or pork loin certified under paragraph (p)(2)(i).

(iii) The sliced and packaged dry-cured pork ham, pork shoulder, or pork loin must be labeled with the date that processing of the meat under paragraph (i) of this section began, and with the date the meat was sliced and packaged.

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§94.18 Bovine spongiform encephalopathy; importation of edible products derived from bovines.

(a) The importation of meat, meat products, and other edible products derived from bovines is prohibited with regard to BSE, except as provided in this section and in §§94.19, 94.20, 94.21, 94.22, 94.23, and 94.27.

(b) The following commodities derived from bovines may be imported into the United States without restriction regarding BSE, provided that all other applicable requirements of this part are met:

- (1) Milk and milk products;
- (2) Boneless skeletal muscle meat (excluding mechanically separated meat) that:

(i) Is derived from bovines that were not, prior to slaughter, subjected to a pithing process or to stunning with a device injecting compressed air or gas into the cranial cavity, and that passed