

(3) Hog and sheep casings intended for use as containers of product may be treated by soaking in or applying thereto sound, fresh pineapple juice or papain or bromelin or pancreatic extract to permit the enzymes contained in these substances to act on the casings to make them less resistant. The casings shall be handled in a clean and sanitary manner throughout and the treatment shall be followed by washing and flushing the casings with water sufficiently to effectively remove the substance used and terminate the enzymatic action.

(4) On account of the invariable presence of bone splinters, detached spinal cords shall not be used in the preparation of edible product other than for rendering where they constitute a suitable raw material.

(5) Testicles if handled as an edible product may be shipped from the official establishment as such, but they shall not be used as an ingredient of a meat food product.

(6) Tonsils shall be removed and shall not be used as ingredients of meat food products.

(7) Blood from livestock prepared in accordance with §310.20 of this subchapter may be used as an ingredient of a meat food product for which a standard is prescribed in part 319 of this subchapter, if permitted by such standard, and may be used in any meat food product for which no such standard is prescribed in part 319 of this subchapter if it is a common and usual ingredient of such product.

(8) Intestines shall not be used as ingredients in any meat food product for which a standard is prescribed in part 319 of this subchapter and shall not be used in other products unless the products are labeled in accordance with §317.8(b)(3) of this subchapter.

(9) Poultry products and egg products (other than shell eggs) which are intended for use as ingredients of meat food products shall be considered acceptable for such use only when identified as having been inspected and passed for wholesomeness by the Department under the regulations in 7 CFR part 59 or 9 CFR part 362 or 381 and when found to be sound and otherwise acceptable when presented for use. Poultry products and egg products

(other than shell eggs) which have not been so inspected and passed for wholesomeness shall not be used in the preparation of such meat food products.

(10) Dry milk products which are intended for use as ingredients of meat food products shall be considered acceptable for such use only when produced in a plant approved by the Department under the regulations in 7 CFR part 58, and when found to be sound and otherwise acceptable when presented for use. Dry milk products prepared in a plant not so approved shall not be used in the preparation of such meat food products.

(11) [Reserved]

(12) Ingredients for use in any product may not bear or contain any pesticide chemical or other residues in excess of level permitted in §318.16.

(13) Use of "Mechanically Separated (Kind of Poultry)," as defined in §381.173 of this chapter, in the preparation of meat food products shall accord with §381.174 and all other applicable provisions of this subchapter.

[35 FR 15586, Oct. 3, 1970, as amended at 38 FR 14368, June 1, 1973; 38 FR 29214, Oct. 23, 1973; 39 FR 1973, Jan. 16, 1974; 41 FR 23702, June 11, 1976; 49 FR 19623, May 9, 1984; 50 FR 6, Jan. 2, 1985; 60 FR 55982, Nov. 3, 1995]

§318.7 Approval of substances for use in the preparation of products.

(a)(1) No substance may be used in the preparation of any product unless it is approved in paragraph (c)(4) of this section or elsewhere in part 318 or in part 319 of this subchapter, or by the Administrator in specific cases.

(2) Approval of new substances or new uses or new levels of use of approved substances may be granted by the Administrator if:

(i) The substance has been previously approved by the Food and Drug Administration (FDA) for use in meat or meat food products as a food additive, color additive, or as a substance generally recognized as safe and is listed in title 21 of the Code of Federal Regulations, parts 73, 74, 81, 172, 173, 179, 182 or 184.

(ii) Its use is in compliance with applicable FDA requirements; and

(iii) The Administrator has determined that:

(A) The use of the substance will not render the product in which it is used adulterated or misbranded or otherwise not in compliance with the requirements of the Act; and

(B) Its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the stated technical effect as determined in specific cases.

(3) Whenever the Administrator determines that approval of a new substance or new use or new level of use of an approved substance should be granted in accordance with paragraph (a)(2) of this section, the Administrator shall issue a final rule amending the chart of substances in paragraph (c)(4) of this section to include the additional substance or new use of the substance, and any technical effect or change in level of use of the substance.

(4) No product shall bear or contain any substance which would render it adulterated or misbranded, or which is not approved in part 318 or part 319 of this subchapter, or by the Administrator in specific cases.

(b) Requirements for the use of nitrite and sodium ascorbate or sodium erythorbate (isoascorbate) in bacon. Nitrates shall not be used in curing bacon.

(1) *Pumped bacon.* With respect to bacon injected with curing ingredients and massaged bacon: sodium nitrite shall be used at 120 parts per million (PPM) ingoing or an equivalent amount of potassium nitrite shall be used (148 PPM ingoing); and 550 PPM of sodium ascorbate or sodium erythorbate (isoascorbate) shall be used. Sodium ascorbate or sodium erythorbate have a molecular weight of approximately 198. Hydrated forms of these substances shall be adjusted to attain the equivalent of 550 PPM of sodium ascorbate or sodium erythorbate.

(2) The Department shall collect samples of pumped bacon from producing plants and analyze them for the level of nitrosamines by the Thermal Energy Analyzer (TEA). In the event that a TEA analysis indicates that a confirmable level of nitrosamines might be present, additional samples shall be collected and analyzed by gas chromatography. Presumptive positive results must be confirmed by mass

spectrometry before being considered positive. If, during the interval required for the Department to analyze the confirmatory samples by gas chromatography and mass spectrometry, changes are made in processing procedures which are expected to result in no confirmable levels of nitrosamines in pumped bacon produced by these new procedures, an establishment may submit samples to USDA for analysis upon prior notification and arrangements with USDA. If, however, an establishment furnishes USDA with laboratory results from testing five consecutive lots of pumped bacon produced under the new procedures and the testing is performed by the USDA methodology and procedures, those results will be utilized in making the determination concerning the product produced under the new procedures. Should the results of these tests reveal that confirmable levels of nitrosamines are not indicated in any of the five consecutive lots, the confirmation analysis by USDA shall be terminated and the establishment shall revert to normal monitoring status. In the event the test results continue to indicate nitrosamines, however, USDA shall proceed in its confirmation analysis on the original samples taken for confirmation. If any one of the original samples collected by USDA for confirmation is found to contain confirmable levels of nitrosamines, all pumped bacon in the producing establishment and all future production will be retained. The Department shall sample and analyze such retained pumped bacon for nitrosamines on a lot by lot basis. A production lot shall be that pumped bacon produced by the establishment in any single shift. Samples from any lot of pumped bacon under retention found to contain nitrosamines at a confirmable level shall cause the lot of pumped bacon to be disposed of in a manner to assure it will not form nitrosamines when cooked. Such disposal may include incorporation of the uncooked pumped bacon as an ingredient of another meat food product provided it is processed for eating without further preparation in a manner to preclude the formation of nitrosamines. Bacon subsequently produced shall not be retained because of nitrosamines if

the operator of the establishment makes adjustments in the processing of the product and laboratory results obtained by TEA analysis of samples from five consecutive normal sized lots of pumped bacon indicates that the product being produced contains no confirmable levels of nitrosamines. These tests from five consecutive normal sized lots of pumped bacon shall be conducted by the Department: *Provided, however,* That if the establishment furnishes the Department with the results of tests conducted under the methodology and procedures used by the Department, such test results will be utilized in making the determination concerning the nitrosamine content of the product. All tests of pumped bacon for nitrosamines under this subparagraph shall be made on pumped bacon cooked 340 °F. for 3 minutes on each side. In order to determine that no confirmable levels of nitrosamines are present in a sample tested, the testing must be performed by methodology and procedures that would detect the presence of any nitrosamines at 10 PPB.

(3) Notwithstanding the provisions of paragraph (b)(1) of this section, sodium nitrite may be used at:

(i) 100 ppm ingoing (potassium nitrite at 123 ppm ingoing); and 500 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used; provided that the establishment has a partial quality control program as provided in §318.4(d) that results in compliance with this provision, or

(ii) A predetermined level between 40 and 80 ppm (potassium nitrite at a level between 49 and 99 ppm); 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate); and additional sucrose or other similar fermentable carbohydrate at a minimum of 0.7 percent and an inoculum of lactic acid producing bacteria such as *Pediococcus acetolactii* or other bacteria demonstrated to be equally effective in preventing the growth of botulinum toxin at a level sufficient for the purpose of preventing the growth of botulinum toxin; provided that the establishment has a partial quality control program as provided in §318.4(d) that results in compliance with this provision.

(4) The Department shall collect samples of bacon from plants producing under paragraph (b)(3) of this section and analyze them for the level of nitrosamines. Samples shall be randomly selected throughout the production of a lot. The actual sampling plans and methods of analysis that are used will result in approximately the same likelihood as under paragraph (b)(2) of this section of having a presumptive positive result when the true mean level of nitrosamines in a production lot is 10 ppb. In the event of a presumptive positive result, the plant shall become subject to the provisions of paragraph (b)(2) of this section.

(5) *Immersion cured bacon.* Immersion cured bacon may be placed in a brine solution containing salt, nitrite and flavoring material or in a container with salt, nitrite and flavoring material. Sodium nitrite shall not exceed 120 ppm ingoing or an equivalent amount of potassium nitrite (148 ppm ingoing) based on the actual or estimated skin-free green weight of the bacon bellies.

(6) *Bacon made with dry curing materials.* With respect to bacon made with dry curing materials, the product shall be cured by applying a premeasured amount of cure mixture to the bacon belly surfaces, completely covering the surfaces. Sodium nitrite shall not exceed 200 ppm ingoing or an equivalent amount of potassium nitrite (246 ppm ingoing) in dry cured bacon based on the actual or estimated skin-free green weight of the bacon belly.

(c) Under appropriate declaration as required in parts 316 and 317 of this subchapter, the following substances may be added to products:

(1) Common salt, approved sugars (sucrose, cane or beet sugar), maple sugar, dextrose, invert sugar, honey, corn syrup solids, (corn syrup, glucose syrup and fructose), wood smoke, vinegar, flavorings, spices, sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite, and other substances specified in the chart in paragraph (c)(4) of this section may be added to products under conditions, if any, specified in this part or in part 317 of this subchapter.

(2) Other harmless artificial flavorings may be added to products

with the approval of the Administrator in specific cases.

(3) Coloring matter and dyes other than those specified in the chart in paragraph (c)(4) of this section may be applied to products, mixed with rendered fat, applied to natural and artificial casings, and applied to such casings enclosing products, if approved by the Administrator in specific cases. When any coloring matter or dye is applied to casings, there shall be no penetration of coloring into the product.

(4) The substances specified in the following chart are acceptable for use in the preparation of products, provided they are used for the purposes indicated, within the limits of the amounts stated and under other conditions specified in this part and part 317 of this subchapter. In addition to the substances listed in the following chart, part 319 of this subchapter specifies other substances that are acceptable in preparing specified products.

Class of substance	Substance	Purpose	Products	Amount	
Acidifiers	Acetic acid	To adjust acidity	Various ²	Sufficient for purpose. ³	
	Citric aciddodo	Do.	
	Glucono delta-lactonedodo	Do.	
	Lactic aciddodo	Do.	
	Phosphoric aciddodo	Do.	
	Tartaric aciddodo	Do.	
Anti-coagulants	Citric acid	To prevent clotting	Fresh blood of livestock.	0.2 percent with or without water. When Water is used to make a solution of citric acid added to blood of livestock, not more than 2 parts of water to 1 part of citric acid shall be used.	
	Sodium citratedo.....do.....	Not to exceed 0.5 percent based on the ingoing weight of the product. When water is used to make a solution of sodium citrate added to blood of livestock, not more than 2 parts of water to 1 part of sodium citrate shall be used.	
Antifoaming agent ..	Methyl polysilicone	To retard foaming	Soups	10 parts per million.	
			Rendered fats	Do.	
			Curing pickle	50 parts per million.	
Antioxidants and oxygen interceptors.	BHA (butylated hydroxy-anisole).	To retard rancidity	Dry sausage	0.003 percent based on total weight.	.006 percent in combination.
	BHT (butylated hydroxy-toluene).dododo	
	Propyl gallatedododo	
	TBHQ (tertiary butylhydroquinone).dododo	0.006 percent in combination only with BHA and/or BHT.
	BHA (butylated hydroxy-anisole).do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination.
	BHT (butylated hydroxy-toluene).dododo	
	Glycinedododo	
	Propyl gallatedododo	
	Resin guaiaicdododo	
	TBHQ (tertiary butylhydroquinone).dododo	0.02 percent in combination only with BHA and/or BHT.

Tocopherolsdodo	0.03 percent. A 30 percent concentration of tocopherols in vegetable oils shall be used when added as an antioxidant to products designated as "lard" or "rendered pork fat."
do	Dry sausage, semidry sausage, dried meats, uncooked or cooked fresh sausage made with beef and/or pork, uncooked or cooked Italian sausage products, uncooked or cooked meatballs, uncooked or cooked meat pizza toppings, brown and serve sausage, pregrilled beef patties, and restructured meats.	Not to exceed 0.03 percent based on fat content. Not used in combination with other antioxidants.
BHA (butylated hydroxyanisole).do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.
BHT (butylated hydroxytoluene).dododo
Propyl gallatedododo
TBHQ (tertiary butylhydroquinone).dododo
			0.02 percent in combination only with BHA and/or BHT based on fat content.
BHA (butylated hydroxyanisole).do	Dried meats	0.01 percent based on total weight.
BHT (butylated hydroxytoluene).dododo
Propyl gallatedododo
TBHQ (tertiary butylhydroquinone).dododo
			0.01 percent in combination only with BHA and/or BHT.
BHA (butylated hydroxyanisole).do	Margarine or oleomargarine.	0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine.
BHT (butylated hydroxytoluene).dodo	Do.
Octyl gallatedodo	Do.
Propyl gallatedodo	Do.
Dodecyl gallatedodo	Do.
Ascorbyl palmitatedodo	Do.

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Ascorbyl stearatedodo	Do.
TBHQ (tertiary butylhydroquinone).dodo	0.02 percent alone or in combination only with BHA and/or BHT based on fat or oil content.

Class of substance	Substance	Purpose	Products	Amount
Binders and extenders.	Agar-agar	To stabilize and thicken.	Thermally processed canned jellied meat food products	0.25 percent of finished product.
	Algin	To extend and stabilize product	Breading mix; sauces	Sufficient for purpose in accordance with 21 CFR 172.5.
	A mixture of sodium alginate, calcium carbonate and calcium lactate/lactic acid (or glucono delta-lactone)	To bind meat pieces	Restructured meat food products.	Sodium alginate not to exceed 1.0 percent; calcium carbonate not to exceed 0.2 percent; and lactic acid/calcium lactate (or glucono delta-lactone) not to exceed 0.3 percent of product formulation. Added mixture may not exceed 1.5 percent of product at formulation. Ingredients of mixture must be added dry.
	Bread	To bind and extend product.	Bockwurst	3.5 percent individually or collectively with other binders. Do.
	Calcium reduced dried skim milk.do	Sausages as provided in part 319.	8 percent individually or collectively with other binders.
dodo	Chili con carne, chili con carne with beans.	12 percent individually or collectively with other binders.
dodo	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products	
	Carrageenan	To extend and stabilize product	Breading mix; sauces	Sufficient for purpose in accordance with 21 CFR 172.5.
	Carboxymethyl cellulose (cellulose gum)do	Baked pies	Do.
	Cereal	To bind and extend product.	Sausages as provided in part 319, bockwurst	3.5 percent individually or collectively with other binders.
dodo	Chili con carne, chili con carne with beans	8 percent individually or collectively with other binders.
	Dried milkdo	Sausage as provided in part 319.	3.5 percent individually or collectively with other binders.
dodo	Chili con carne, chili con carne with beans	8 percent individually or collectively with other binders.
	Enzyme (rennet) treated calcium reduced dried skim milk and calcium lactate	To bind and extend product.	Sausages as provided in part 319.	3.5 percent total finished product. (Calcium lactate required at rate of 10 percent of binder).
dodo	Imitation sausages, nonspecific loaves, soups, stews	Sufficient for purpose in accordance with 21 CFR 172.5 (Calcium lactate required at rate of 10 percent of binder).
Enzyme (rennet) treated sodium caseinate and calcium lactatedo	Imitation sausages, nonspecific loaves, soups, stews	Sufficient for purpose in accordance with 21 CFR 172.5. (Calcium lactate required at rate of 25 percent of binder).	
Gums, vegetabledo	Egg roll	Sufficient for purpose in accordance with 21 CFR 172.5.	

Class of substance	Substance	Purpose	Products	Amount
	Methyl cellulose	To extend and to stabilize product (also carrier)	Meat and vegetable patties.	0.15 percent.
	Isolated soy protein	To bind and extend product.	Sausage as provided in Part 319, bockwurst	2 percent.
dodo	Imitation sausages, nonspecific loaves, soups, stews	Sufficient for purpose in accordance with 21 CFR 172.5.
dodo	Chili con carne, chili con carne with beans	8 percent individually or collectively with other binders.
dodo	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products	12 percent individually or collectively with other binders and extenders.
	Sodium caseinatedo	Imitation sausages, nonspecific loaves, soups, stews	Sufficient for purpose in accordance with 21 CFR 182.1748 and 21 CFR 172.5.
dodo	Sausage as provided in Part 319..	2 percent in accordance with 21 CFR 182.1748.
dodo	Chili con carne, chili con carne with beans	8 percent individually or collectively with other binders and extenders in accordance with 21 CFR 182.1748.
dodo	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products	12 percent individually or collectively with other binders and extenders in accordance with 21 CFR 182.1748.
	Dry or dried whey	To bind or thicken	Sausage as provided in Part 319, bockwurst	3.5 percent individually or collectively with other binders and extenders.
	Reduced lactose wheydodo	Do.
	Reduced minerals wheydodo	Do.
	Whey protein concentrate.dodo	Do. In accordance with 21 CFR 184.1979c.
	Dry or dried wheydo	Imitation sausages, nonspecific loaves, soups, stews	Sufficient for purpose in accordance with 21 CFR 172.5.
	Reduced lactose wheydodo	Do.
	Reduced minerals wheydodo	Do.
	Whey protein concentrate.dodo	Do. In accordance with 21 CFR 184.1979c.
	Dry or dried wheydo	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce	8 percent individually or collectively with other binders and extenders.
	Reduced lactose wheydodo	Do.
	Reduced minerals wheydodo	Do.
	Whey protein concentrate.dodo	Do. In accordance with 21 CFR 184.1979c.
do	To bind meat pieces	Restructured meat food products, whole muscle meat cuts	3.5 percent individually or collectively with other binders and extenders. In accordance with 21 CFR 184.1979c.
	Soy flour	To bind and extend product.	Sausage as provided in Part 319, bockwurst	3.5 percent individually or collectively with other binders and extenders.
	Soy protein concentratedodo	Do.
	Starchy vegetable flourdodo	Do.
	Vegetable starchdodo	Do.
	Wheat glutendodo	Do. In accordance with 21 CFR 184.1322.
	Tapioca dextrindodo	Do. In accordance with 21 CFR 184.1277.
	Soy flourdo	Chili con carne, chili con carne with beans	8 percent individually or collectively with other binders and extenders.

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Class of substance	Substance	Purpose	Products	Amount
	Soy protein concentratedodo	Do.
	Starchy vegetable flourdodo	Do.
	Vegetable starchdodo	Do.
	Wheat glutendodo	Do. In accordance with 21 CFR 184.1322.
	Tapioca dextrindodo	Do. In accordance with 21 CFR 184.1277.
	Soy flourdo	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products	12 percent individually or collectively with other binders and extenders.
	Soy protein concentratedodo	Do.
	Wheat glutendodo	Do. In accordance with 21 CFR 184.1322.
	Tapioca dextrindodo	Do. In accordance with 21 CFR 184.1277.
	Xanthan gum	To maintain uniform viscosity; suspension of particulate matter, emulsion stability; freeze-thaw stability.	Meat sauces, gravies or sauces and meats, canned or frozen and/or refrigerated meat salads, canned or frozen meat stews, canned chili or chili with beans, pizza topping mixes and batter or breading mixes.	Sufficient for purpose in accordance with 21 CFR 172.5.
	Carrageenan	To prevent purging of brine solution.	Cured pork products as provided in 9 CFR 319.104.	Not to exceed 1.5 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 172.620, 172.623, and 172.626.
	Food starch modifieddodo	Not to exceed 2 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 172.892.
	Sodium caseinatedodo	Not to exceed 2 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 182.1748.
	Isolated soy proteindodo	Not to exceed 2 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products.
	Carrageenan, Locust bean gum, and Xanthan gum blend.	To prevent purging of solution..	Cured pork products as provided in 9 CFR 319.104(d)..	In combination, not to exceed 0.5 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 172.620, 172.623, 172.626, 184.1343, and 172.695.
Bleaching agent	Hydrogen peroxide	To remove color	Tripe (substance must be removed from product by rinsing with clear water).	

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Class of substance	Substance	Purpose	Products	Amount
Catalysts (substances must be eliminated during process).	Nickel	To accelerate chemical reaction.	Rendered animal fats or a combination of such fats and vegetable fats.	Do.
	Sodium amide	Rearrangement of fatty acid radicals.do	Do.
Coloring agents (natural).	Sodium methoxidedodo	Do.
	Alkanet, annatto, carotene cochineal, green chlorophyll, saffron and tumeric.	To color casings or rendered fats; marking and branding product.	Sausage casings, oleomargarine, shortening, marking or branding ink on product.	Sufficient for purpose (may be mixed with approved artificial dyes or harmless inert material such as common salt and sugar).
Coloring agents (artificial).	Color additives listed in 21 CFR Part 74, Subpart A of Part 82, Subpart B (operator must furnish evidence to inspector in charge that color additive has been certified for use in connection with foods by the Food and Drug Administration).dodo	Sufficient for purpose (may be mixed with approved natural coloring matters or harmless inert material such as common salt or sugar).
	Titanium dioxidedo	Canned ham salad spread and creamed type canned products.	0.5 percent.
Curing accelerators' must be used only in combination with curing agents.	Ascorbic acid	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food product.	75 oz to 100 gal pickle at 10 percent pump level; ¾ oz to 100 lb meat or meat byproduct; 10 percent solution to surfaces of cured cuts prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)
	Erythorbic aciddodo	Do.
	Fumaric acid	To accelerate color fixing.	Cured, comminuted meat or meat food products.	0.065 percent (or 1 oz to 100 lb) of the weight of the meat or meat byproducts, before processing.
	Glucose delta lactone ...	To accelerate color fixing.	Cured, comminuted meat or meat food product.	8 oz to each 100 lb of meat or meat byproduct.
	Sodium acid pyrophosphate.do	Frankfurters, wieners, vienna, bologna, garlic bologna, knockwurst, and similar products.	16 oz to 100 lb of meat (1.0 percent).
	Sodium ascorbate	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food product.	Not to exceed, alone or in combination with other curing accelerators, the following: 8 oz in 100 lb of the meat, or meat and meat byproducts, content of the formula; nor 0.5 percent in the finished product.
	Sodium erythorbatedodo	87.5 oz to 100 gal pickle at 10 percent pump level; 7/8 oz to 100 lb meat or meat byproduct; 10 percent solution to surfaces of cured cuts prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)

Class of substance	Substance	Purpose	Products	Amount
Curing agents	Citric acid or sodium citrate.dodo	May be used in cured products or in 10 percent solution used to spray surfaces of cured cuts prior to packaging to replace up to 50 percent of the ascorbic acid, erythorbic acid, sodium ascorbate, or sodium erythorbate that is used.
	Sodium or potassium nitrate.	Source of nitrite	Cured products other than bacon. Nitrates may not be used in baby, junior, and toddler foods.	7 lb to 100 gal pickle; 3½ oz to 100 lb meat (dry cure); 2¾ oz to 100 lb chopped meat.
	Sodium or potassium nitrite. (Supplies of sodium nitrite and potassium nitrite and mixtures containing them must be kept securely under the care of a responsible employee of the establishment. The specific nitrite content of such supplies must be known and clearly marked accordingly).	To fix color	Cured products. Nitrites may not be used in baby, junior, or toddler foods.	2 lb to 100 gal pickle at 10 percent pump level; 1 oz to 100 lb meat (dry cure); ¼ oz to 100 lb chopped meat and/or meat byproduct. The use of nitrites, nitrates, or combination shall not result in more than 200 parts per million of nitrite, calculated as sodium nitrite, in finished product. Except that nitrites may be used in bacon only in accordance with paragraph (b) of this section.
Denuding agents; may be used in combination. Must be removed from tripe by rinsing with potable water..	Lime (calcium oxide, calcium hydroxide)	To denude mucous membranes.	Tripe	Sufficient for purpose.
	Sodium carbonate.dodo.	Do.
	Sodium Citratedodo	Do.
	Sodium gluconatedodo	Do.
	Sodium hydroxidedodo	Do.
	Sodium persulfatedodo	Do.
Emulsifying agents	Sodium silicates (ortho, meta, and sesqui).dodo	Do.
	Trisodium phosphatedo.do.	Do.
	Acetylated monoglycerides.	To emulsify product ...	Shortening	Do.
	Diacyl tartaric acid esters of mono- and diglycerides.do	Rendered animal fat or a combination of such fat with vegetable fat.	Do.
	Glycerol-lacto stearate, oleate, or palmitate.dodo	Do.
	Lecithin	To emulsify product (also as an Antioxidant).	Oleomargarine, shortening, various meat food products.	0.5 percent in oleomargarine; use in other products—sufficient amount for emulsification.
	Mono and diglycerides (glycerol palmitate, etc.).	To emulsify product ...	Rendered animal fat or a combination of such fat with vegetable fat; oleomargarine.	Sufficient for purpose in lard and shortening; 0.5 percent in oleomargarine.
Mono and diglycerides of fatty acids esterified with any of the following acids: acetic, acetyltartaric, citric, lactic, tartaric, and their sodium and calcium salts; the sodium sulfoacetate derivatives of these mono and diglycerides.do	Margarine or oleomargarine.	0.5 percent.	

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Class of substance	Substance	Purpose	Products	Amount
Film forming agents	Polyglycerol esters of fatty acids (polyglycerol esters of fatty acids are restricted to those up to and including the decaglycerol esters and otherwise meeting the requirements of §172.854(a) of the Food Additive Regulations).do	Rendered animal fat or a combination of such fat with vegetable fat when use is not precluded by standards of identity or composition; oleomargarine.	Sufficient for purpose for rendered animal fat or combination with vegetable fat; 0.5 percent for oleomargarine.
	1,2-propylene glycol esters of fatty acids.do	Margarine or oleomargarine.	2.0 percent.
	Polysorbate 80 (polyoxyethylene (20) sorbitan monooleate).do	Shortening for use in nonstandardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods.	1 percent when used alone. If used with polysorbate 60 the combined total shall not exceed 1 percent.
	Propylene glycol mono and diesters of fats and fatty acids.do	Rendered animal fat or a combination of such fat with vegetable fat.	Sufficient for purpose.
	Polysorbate 60 (polyoxyethylene (20) sorbitan monostearate).do	Shortening for use in nonstandardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods.	1 percent when used alone. If used with polysorbate 80 the combined total shall not exceed 1 percent.
	Stearyl-2-lactylic aciddo	Shortening to be used for cake icings and fillings.	3.0 percent.
	Stearyl monoglyceridyl citrate.do	Shortening	Sufficient for purpose.
Flavoring agents; protectors and developers.	A mixture consisting of water, sodium alginate, calcium chloride, sodium carboxymethyl-cellulose, and corn syrup solids.	To reduce cooler shrinkage and help protect surface.	Freshly dressed meat carcasses. Such carcasses must bear a statement "Protected with a film of water, corn syrup solids, sodium alginate, calcium chloride and sodium carboxymethyl-cellulose.	Formulation may not exceed 1.5% of hot carcass weight when applied. Chilled weight may not exceed hot weight.
	Artificial smoke flavoring	To flavor product	Various ²	Do.
Flavoring agents; protectors and developers.	Smoke flavoringdodo	Do.
	Autolyzed yeast extractdodo	Do.
	Harmless bacteria starters of the acidophilus type, lactic acid starter or culture of <i>Pediococcus cerevisiae</i> .	To develop flavor	Dry sausage, pork roll, thuringer, lebanon bologna, cervelat, and salami.	0.5 percent.
	Harmless lactic acid producing bacteria.	To prevent growth of <i>Clostridium botulinum</i> .	Bacon	Sufficient for purpose.
	Benzoic acid (sodium, potassium and calcium salts).	To retard flavor reversion.	Margarine or oleomargarine.	0.1 percent individually, or if used in combination or with sorbic acid and its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods).

Class of substance	Substance	Purpose	Products	Amount
	Calcium lactate	To protect flavor	Cooked semi-dry and dry products including sausage, imitation sausage, and non-specific meat food sticks.	0.6 percent in product formulation.
	Citric acid	Flavoring	Chili con carne	Sufficient for purpose.
	Corn syrup solids, corn syrup, glucose syrup.	To flavor	Sausage, hamburger, meat loaf, luncheon meat, chopped or pressed ham.	Sufficient for purpose.
	Dextrose	To flavor product	Sausage, ham and cured products.	Sufficient for purpose.
	Diacetyldo	Oleomargarine	Do.
	Disodium guanylatedo	Various ²	Do.
	Disodium inosinatedodo	Do.
	Hydrolyzed plant proteindodo	Do.
	Isopropyl citrate	To protect flavor	Oleomargarine	0.02 percent.
	Malt syrup	To flavor product	Cured products	2.5 percent.
	Milk protein hydrolysatedo	Various ²	Sufficient for purpose.
	Monosodium glutamatedodo	Do.
	Monoammonium glutamate.dodo	Do.
	Sodium sulfoacetate derivative of mono and diglycerides.dodo	0.5 percent.
	Sodium tripolyphosphate.	To help protect flavor	"Fresh Beef," ² "Beef for Further Cooking," "Cooked Beef," Beef Patties, Meat Loaves, Meat Toppings, and similar products derived from pork, lamb, veal, mutton, and goat meat which are cooked or frozen after processing.	0.5 percent of total product.
	Mixtures of sodium tripolyphosphate and sodium metaphosphate, insoluble; and sodium polyphosphates, glassy.dodo	Do.
	Sorbitol	To flavor, to facilitate the removal of casings from product, and to reduce carmelization and charring.	Cooked sausage labeled frankfurter, frank, furter, wiener, and knockwurst; cured pork and pork products, as provided in part 319 of this subchapter.	Not to exceed 2 percent of the weight of the formula, excluding the formula weight of water or ice, when used in accordance with 21 CFR 184.1835.
	Starter distillate	To help protect flavor	Oleomargarine	Sufficient for purpose.
	Stearyl citrate	To protect flavordo	0.15 percent.
	Sugars (sucrose and dextrose).	To flavor product	Various ²	Sufficient for purpose.
	Potassium lactate	To flavor product	Various meat and meat food products, except infant formula and infant food. ²	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1639.
	Sodium lactatedodo	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1768.
	Sodium acetate	To flavor products	Various	Not to exceed 0.12 percent of formulate in accordance
	Sodium diacetatedodo	Not to exceed 0.1 percent of formulate in accordance with 21 CFR 184.1754
Gases	Carbon dioxide solid (dry ice).	To cool product	Chopping of meat, packaging of product.	Do.

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Class of substance	Substance	Purpose	Products	Amount
Hog scald agents; must be removed by subsequent cleaning operations.	Liquid nitrogen	Contact freeze	Various	Sufficient for purpose
	Nitrogen	To exclude oxygen ...	Sealed container	Do.
	Caustic soda	To remove hair	Hog carcasses	Do.
	Dimethylpolysiloxanedodo	Do.
	Diocetyl sodium sulfo-succinate.dodo	Do.
	Disodium-calcium ethylenediamine-tetraacetate.dodo	Do.
	Disodium phosphatedodo	Do.
	Ethylenediamine-tetraacetic acid (sodium salts).dodo	Do.
	Lime (calcium oxide, calcium hydroxide).dodo	Do.
	Potassium hydroxidedodo	Do.
	Propylene glycoldodo	Do.
	Soap (prepared by the reaction of calcium, potassium, or sodium with rosin or fatty acids of natural fats and oils).dodo	Do.
	Sodium acid pyrophosphate.dodo	Do.
	Sodium carbonatedodo	Do.
	Sodium dodecylbenzene sulfonate.dodo	Do.
	Sodium gluconatedodo	Do.
	Sodium hexametaphosphate.dodo	Do.
	Sodium lauryl sulfatedodo	Do.
	Sodium mono and dimethylnaphthalene sulfonate (molecular weight 245–260).dodo	Do.
	Sodium n-alkylbenzene sulfonate (alkyl group predominantly C ₁₂ and C ₁₃ and not less than 95 percent C ₁₀ and C ₁₆).dodo	Do.
	Sodium pyrophosphatedodo	Do.
	Sodium silicates (ortho, meta, and sesqui).dodo	Do.
	Sodium sulfatedodo	Do.
Sodium tripolyphosphate.dodo	Do.	
Sucrosedodo	Do.	
Triethanolamine dodecylbenzene sulfonate.dodo	Do.	
Trisodium phosphatedodo	Do.	
Miscellaneous	Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination under quality control.	To delay discoloration	Fresh beef cuts, fresh lamb cuts, and fresh pork cuts.	Not to exceed, singly or in combination, 500 ppm or 1.8 mg/sq inch of product surface of ascorbic acid (in accordance with 21 CFR 182.3013), erythorbic acid (in accordance with 21 CFR 182.3041), or sodium ascorbate (in accordance with 21 CFR 182.3731); and/or not to exceed, singly or in combination, 250 ppm or 0.9 mg/sq inch of product surface of citric acid (in accordance with 21 CFR 182.6033), or sodium citrate (in accordance with 21 CFR 182.6751).
	d- and dl-alpha-tocopherol.	To inhibit nitrosamine formation.	Pump-cured bacon	500 ppm; by injection or surface application.

Class of substance	Substance	Purpose	Products	Amount
	Potassium sorbate	To retard mold growth	Dry sausage	10 percent in water solution may be applied to casings after stuffing or casings may be dipped in a 10 percent water solution prior to stuffing.
	Silicon dioxide	Processing aid/dis-persant.	Tocopherol-containing bacon curing pre-mixes.	At level not to exceed 4.0 percent in the dry mix.
	Sorbic acid (sodium, po-tassium, and calcium salts).	To preserve product and to retard mold growth.	Margarine or oleo-margarine.	0.1 percent individually, or if used in combination or with benzoic acid or its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods).
	Calcium disodium, EDTA (calcium diso-dium ethylene-diaminetetraacetate).	To preserve product and to protect flavor.do	75 parts per million by weight of the finished oleo-margarine or margarine.
	Propyl paraben (propyl p-hydroxybenzoate).	To retard mold growth	Dry sausage	3.5 percent in water solution may be applied to casings after stuffing, or casings may be dipped in solution prior to stuffing.
	Sodium bicarbonate	To neutralize excess acidity, cleaning vegetables.	Rendered fats, soups, curing pickle.	Sufficient for purpose.
	Calcium propionate	To retard mold growth	Pizza crust	0.32 percent alone or in combination based on weight of the flour brace used.
	Sodium propionatedodo	Do.
	Sodium hydroxide	To decrease the amount of cooked out juices.	Meat food products containing phos-phates.	May be used only in combination with phosphates in a ratio not to exceed one part sodium hydroxide to four parts phosphate; the combination shall not exceed 5 percent in pickle at 10 percent pump level; 0.5 percent in product.
	Disodium phosphatedo	Meat food products except where other-wise prohibited by the Federal meat inspection regula-tions.	5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phos-phate in product (only clear solution may be injected into product).
	Monosodium phosphatedodo	Do.
	Sodium metaphosphate, insoluble.dodo	Do.
	Sodium polyphosphate, glassy.dodo	Do.
	Sodium tripolyphosphate.dodo	Do.
	Sodium pyrophosphatedodo	Do.
	Sodium acid pyrophosphate.dodo	Do.
	Dipotassium phosphatedodo	Do.
	Monopotassium phos-phate.dodo	Do.
	Potassium tripolyphosphate.dodo	Do.
	Potassium pyrophosphate.dodo	Do.
	Citric acid (sodium and potassium salts).	To acidify	Margarine or oleo-margarine.	Sufficient for purpose.
	Lactic acid (sodium and potassium salts).dodo	Do.
	L-Tartaric acid (sodium and sodium potas-sium salts).dodo	Do.
	Adipic aciddodo	Do.
	Phosphoric aciddodo	Do.
	Hydrochloric aciddodo	Do.
	Sodium bicarbonate	To alkalizedo	Do.

Class of substance	Substance	Purpose	Products	Amount
	Sodium carbonatedodo	Do.
	Sodium hydroxidedodo	Do.
	Potassium carbonatedodo	Do.
	Potassium bicarbonatedodo	Do.
	Citric acid	To preserve cured color during storage.	Cured pork cuts	Not to exceed 30 percent in water solution used to spray surfaces of cured cuts, prior to packaging, in accordance with 21 CFR 182.1033. (The use of such solution shall not result in the addition of a significant amount of moisture to the product and shall be applied only once to the product.)
	Sodium citrate buffered with citric acid to a pH of 5.6.	To inhibit the growth of micro-organisms and retain product flavor during storage.	Cured and uncured, processed whole-muscle meat food products, e.g., ham.	Not to exceed 1.3 percent of the formulation weight of the product in accordance with 21 CFR 184.1751.
	Glycerine	Humecant	Shelf stable (Can Be stored at room temperature) meat snacks.	Not to exceed 2 percent of the formulation weight of the product in accordance with 21 CFR 182.1320
Proteolytic enzymes	Aspergillus oryzae	To soften tissues	Raw meat cuts	Solutions consisting of water and approved proteolytic enzymes applied or injected into raw meat cuts shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus flavusoryzae group.dodo	Do.
	Bromelindodo	Do.
	Ficindodo	Do.
	Papaindodo	Do.
Refining agents (must be eliminated during process of manufacturing).	Acetic acid	To separate fatty acids and glycerol.	Rendered fats	Sufficient for purpose.
	Bicarbonate of sodadodo	Do.
	Carbon (purified charcoal).	To aid in refining of animal fats.do	Do.
	Caustic soda (sodium hydroxide).	To refine fatsdo	Do.
	Diatomaceous earth; Fuller's earth.dodo	Do.
	Sodium carbonatedodo	Do.
	Tannic aciddodo	Do.
Rendering agents ..	Tricalcium phosphate	To aid rendering	Animal fats	Do.
	Trisodium phosphatedodo	Do.
Sources of radiation	Ionizing radiation limited to gamma rays from cobalt-60 or cesium-137.	To control <i>Trichinella spiralis</i> .	Pork carcasses, or fresh or previously frozen cuts of pork carcasses that have not been cured or heat-processed.	Minimum absorbed dose of 0.3 kiloGray (30 kilorads) to a maximum absorbed dose of 1 kiloGray (100 kilorads).
Artificial sweeteners	Saccharin	To sweeten product ..	Bacon	0.01 percent.
Synergists (used in combination with antioxidants).	Citric acid	To increase effectiveness of antioxidants.	Any product permitted to contain antioxidants as provided in this part.	Not to exceed 0.01 percent based on fat content.
	Malic aciddo	Lard and shortening ..	0.01 percent based on total weight in combination with antioxidants.
	Monoisopropyl citratedo	Lard, shortening, oleomargarine, fresh pork sausage, dried meats.	0.02 percent.
	Phosphoric aciddo	Lard and shortening ..	0.01 percent.

Class of substance	Substance	Purpose	Products	Amount
Tenderizing agents	Monoglyceride citratedo	Lard, shortening, fresh pork sausage, dried meats.	0.02 percent.
	Aspergillus oryzae	To soften tissue	Raw meat cuts	Solutions consisting of water and approved proteolytic enzymes applied or injected into raw meat cuts shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus flavus oryzae group.dodo	Do.
	Bromelindodo	Do.
	Ficindodo	Do.
	Papaindodo	Do.
	Potassium chloridedodo	Not more than 3 percent of a 2.0 molar solution.
	Magnesium chloridedodo	Not more than 3 percent of a 0.8 molar solution.
Calcium chloridedodo	Not more than 3 percent of a 0.8 molar solution.	
Potassium, magnesium or calcium chloride.dodo	A solution of approved inorganic chlorides injected into or applied to raw meat cuts shall not result in a gain of more than 3 percent above the weight of the untreated product.	

¹ [Reserved]
² Information as to the specific products for which use of this substance is approved may be obtained upon inquiry addressed to the Standards and Labeling Division, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.
³ Provided, that its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the desired technical effect as determined in specific cases prior to label approval under § 317.4.

(d) No substance may be used in or on any product if it conceals damage or inferiority or makes the product appear to be better or of greater value than it is. Therefore:

(1) Paprika or oleoresin paprika may not be used in or on fresh meat, such as steaks, or comminuted fresh meat food products, such as chopped and formed steaks or patties; or in any other meat food products consisting of fresh meat (with or without seasoning), except chorizo sausage, and except other meat food products in which paprika or oleoresin paprika is permitted as an ingredient in a standard of identity or composition in part 319 of this subchapter.

(2) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid may not be used in cooked sausage or any other product; sulfurous acid and salts of sulfurous acid may not be used in or on any product and niacin or nicotinamide may not be used in or on fresh product; except that potassium sorbate, propylparaben (propyl p-hydroxybenzoate), calcium propionate, sodium propionate, benzoic acid, and

sodium benzoate may be used in or on any product only as provided in the chart in § 318.7(c)(4) or as approved by the Administrator in specific cases.

(Approved by the Office of Management and Budget under control number 0583-008)

[35 FR 15586, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 318.7, see the List of CFR Sections Affected in the Finding Aids section of this volume.

EFFECTIVE DATE NOTE: At 62 FR 61620, Nov. 19, 1997, § 318.7(c)(4) was amended by adding the entry for "Carrageenan, Locust bean gum, and Xanthan gum blend" under the class "Binders and extenders", effective January 20, 1998.

§ 318.8 Preservatives and other substances permitted in product for export only; handling; such product not to be used for domestic food purposes.

(a) Preservatives and other substances not permitted in domestic product under the regulations in this subchapter may be used in the preparation and packing of product intended