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**TITLE 9--ANIMALS AND ANIMAL PRODUCTS**

**CHAPTER III--FOOD SAFETY AND INSPECTION SERVICE, MEAT AND POULTRY INSPECTION, DEPARTMENT OF AGRICULTURE**

**PART 318--ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS--Table of Contents**

Subpart A--General

Sec. 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.

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(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 chromotography 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 nitorosamines 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 if 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

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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 deg.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 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used; provided that the plant has an approved partial quality control program as provided in Sec. 318.4 (d), (e), and (g) such as to result 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 plant has an approved partial quality control program as provided in Sec. 318.4 (d), (e), and (g) such as to result 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

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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 <SUP>2..... | Sufficient for purpose.<SUP>3 |
| | Citric acid..... | .....do..... | .....do..... | Do. |
| | Glucono delta-lactone... | .....do..... | .....do..... | Do. |
| | Lactic acid..... | .....do..... | .....do..... | Do. |
| | Phosphoric acid..... | .....do..... | .....do..... | Do. |
| | Tartaric acid..... | .....do..... | .....do..... | 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 citrate..... | .....do..... | .....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.

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Antioxidants and oxygen interceptors. BHA (butylated hydroxyanisole). To retard rancidity..... Dry sausage..... 0.003 percent based on total weight. .006 percent in combination.

BHT (butylated hydroxytoluene). .....do..... .....do..... .....do.....

Propyl gallate..... .....do..... .....do..... .....do.....

TBHQ (tertiary butylhydroquinone). .....do..... .....do..... .....do..... 0.006 percent in combination only with BHA and/or BHT.

BHA (butylated hydroxyanisole). .....do..... Rendered animal fat or a combination of such fat and vegetable fat. 0.01 percent..... 0.02 percent in combination.

BHT (butylated hydroxytoluene). .....do..... .....do..... .....do.....

Glycine..... .....do..... .....do..... .....do.....

Propyl gallate..... .....do..... .....do..... .....do.....

Resin guaiac..... .....do..... .....do..... .....do.....

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TBHQ (tertiary butylhydroquinone). .....do..... .....do..... .....do..... 0.02 percent in combination only with BHA and/or BHT.

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| Tocopherols..... | .....do..... | .....do..... | 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. | 0.02 percent in combination based on fat content. |
| BHT (butylated hydroxytoluene). | .....do..... | .....do..... | .....do..... | |
| Propyl gallate..... | .....do..... | .....do..... | .....do..... | |
| TBHQ (tertiary | .....do..... | .....do..... | .....do..... | 0.02 |

percent in
butylhydroquinone).
combination only
with BHA and/or
BHT
based on fat
content.
BHA (butylated .....do..... Dried meats..... 0.01 percent based
0.01 percent in
hydroxyanisole). on total weight.
combination.
BHT (butylated .....do..... .....do..... .....do.....

hydroxytoluene).
Propyl gallate..... .....do..... .....do..... .....do.....
.....
TBHQ (tertiary .....do..... .....do..... .....do..... 0.01
percent in
butylhydroquinone).
combination only
with BHA and/or
BHT.

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BHA (butylated .....do..... Margarine or 0.02 percent (by
hydroxyanisole). oleomargarine. wt. of the
finished
product)
individually or
in combination
with other
antioxidants
approved for
use in
margarine.
BHT (butylated .....do..... .....do..... Do.
hydroxytol-)
uene). .....
Octyl gallate..... .....do..... .....do..... Do.
Propyl gallate..... .....do..... .....do..... Do.
Dodecyl gallate..... .....do..... .....do..... Do.
Ascorbyl palmitate..... .....do..... .....do..... Do.
Ascorbyl stearate..... .....do..... .....do..... Do.
TBHQ (tertiary .....do..... .....do..... 0.02 percent
butylhydroqui- alone or in
none). 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. |
| | Calcium reduced dried skim milk. | .....do..... | Sausages as provided in part 319. | Do. |
| | .....do..... | .....do..... | Chili con carne, chili con carne with beans. | 8 percent individually or collectively with other binders. |
| | .....do..... | .....do..... | Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products | 12 percent individually or collectively with other binders. |
| | 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. |

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| Cereal..... | To bind and extend product. | Sausages as provided in part 319, bockwurst | 3.5 percent individually or collectively with other binders. |
| .....do..... | .....do..... | Chili con carne, chili con carne with beans | 8 percent individually or collectively with other binders. |
| Dried milk..... | .....do..... | Sausage as provided in part 319. | 3.5 percent individually or collectively with other binders. |
| .....do..... | .....do..... | 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). |

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| .....do..... | .....do..... | 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 lactate | .....do..... | 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, vegetable..... | .....do..... | Egg roll..... | Sufficient for purpose in accordance with |

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| | | | 21 CFR 172.5. |
| 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. |
| .....do..... | .....do..... | Imitation sausages, nonspecific loaves, soups, stews | Sufficient for purpose in accordance with 21 CFR 172.5. |
| .....do..... | .....do..... | Chili con carne, chili con carne with beans | 8 percent individually or collectively with other binders. |
| .....do..... | .....do..... | Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products | 12 percent individually or collectively with other binders and extenders. |
| Sodium caseinate..... | .....do..... | Imitation sausages, nonspecific loaves, soups, stews | Sufficient for purpose in accordance with 21 CFR 182.1748 and 21 CFR 172.5. |
| .....do..... | .....do..... | Sausage as provided in Part 319.. | 2 percent in accordance with 21 CFR 182.1748. |
| .....do..... | .....do..... | 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. |
| .....do..... | .....do..... | 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 whey.... | .....do..... | .....do..... | Do. |

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| Reduced minerals whey... | .....do..... | .....do..... | Do. | |
| Whey protein concentrate | .....do..... | .....do..... | Do. In accordance with 21 CFR 184.1979c. | |
| Dry or dried whey..... | .....do..... | Imitation sausages, nonspecific loaves, soups, stews | Sufficient for purpose in accordance with 21 CFR 172.5. | |
| Reduced lactose whey.... | .....do..... | .....do..... | Do. | |
| Reduced minerals whey... | .....do..... | .....do..... | Do. | |
| Whey protein concentrate | .....do..... | .....do..... | Do. In accordance with 21 CFR 184.1979c. | |
| Dry or dried whey..... | .....do..... | 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 whey.... | .....do..... | .....do..... | Do. | |
| Reduced minerals whey... | .....do..... | .....do..... | Do. | |
| Whey protein concentrate | .....do..... | .....do..... | 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. | |

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| 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 concentrate. | .....do..... | .....do..... | Do. | |
| Starchy vegetable flour. | .....do..... | .....do..... | Do. | |
| Vegetable starch..... | .....do..... | .....do..... | Do. | |
| Wheat gluten..... | .....do..... | .....do..... | Do. In accordance with 21 CFR 184.1322. | |
| Tapioca dextrin..... | .....do..... | .....do..... | Do. In accordance with 21 CFR | |

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| | | | 184.1277. | |
| Soy flour..... | .....do..... | Chili con carne, chili con carne with beans | 8 percent individually or collectively with other binders and extenders. | |
| Soy protein concentrate. | .....do..... | .....do..... | Do. | |
| Starchy vegetable flour. | .....do..... | .....do..... | Do. | |
| Vegetable starch..... | .....do..... | .....do..... | Do. | |
| Wheat gluten..... | .....do..... | .....do..... | Do. In accordance with 21 CFR 184.1322. | |
| Tapioca dextrin..... | .....do..... | .....do..... | Do. In accordance with 21 CFR 184.1277. | |
| Soy flour..... | .....do..... | 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 concentrate. | .....do..... | .....do..... | Do. | |
| Wheat gluten..... | .....do..... | .....do..... | Do. In accordance with 21 CFR 184.1322. | |
| Tapioca dextrin..... | .....do..... | .....do..... | 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 | |

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| | | | | with 21 CFR 172.620, 172.623, and 172.626. |
| | Food starch modified.... | .....do..... | .....do..... | 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 caseinate..... | .....do..... | .....do..... | 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 protein.... | .....do..... | .....do..... | Not to exceed 2 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products. |

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| Bleaching agent..... | Hydrogen peroxide..... | To remove color..... | Tripe (substance must be removed from product by rinsing with clear water). | |
| 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 | .....do..... | Do. |

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| | | acid radicals. | | |
| | Sodium methoxide..... | .....do..... | .....do..... | Do. |
| Coloring agents (natural). | Alkanet, annatto, carotene cochineal, green chlorophyl, 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). | .....do..... | .....do..... | Sufficient for purpose (may be mixed with approved natural coloring matters or harmless inert material such as common salt or sugar). |
| | Titanium dioxide..... | .....do..... | 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; \3/4\ 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 acid..... | .....do..... | .....do..... | 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 |

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| | | | processing. |
| Glucone delta lactone... | To accelerate color fixing. | Cured, comminuted meat or meat food product. | 8 oz to each 100 lb of meat or meat byproduct. |
| | | Genoa salami..... | 16 oz to 100 lb of meat (1.0 percent). |
| Sodium acid pyrophosphate. | .....do..... | Frankfurters, wieners, vienna, bologna, garlic bologna, knockwurst, and similar products. | 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 ascorbate..... | To accelerate color fixing or preserve color during storage. | Cured pork and beef cuts, cured comminuted meat food product. | 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.) |
| Sodium erythorbate..... | .....do..... | .....do..... | Do. |

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| Citric acid or sodium citrate. | .....do..... | .....do..... | May be used in cured products or in 10 percent solution used to spray |

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| | | | 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. | |
| Curing agents..... | 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; 3\1/2\ oz to 100 lb meat (dry cure); 2\3/4\ 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); \1/4\ 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 | Lime (calcium oxide, calcium hydroxide) | To denude mucous membranes. | Tripe..... | Sufficient for purpose. |
| | Sodium carbonate. | .....do..... | .....do..... | |
| | Sodium Citrate..... | .....do..... | .....do..... | Do. |
| | Sodium gluconate..... | .....do..... | .....do..... | Do. |

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| with potable water.. | Sodium hydroxide..... | .....do..... | .....do..... | Do. |
| | Sodium persulfate..... | .....do..... | .....do..... | Do. |
| | Sodium silicates (ortho, meta, and sesqui). | .....do..... | .....do..... | Do. Do. |
| | Trisodium phosphate..... | .....do..... | .....do..... | Do. |
| Emulsifying agents.. | Acetylated monoglycerides. | To emulsify product... | Shortening..... | Do. |
| | Diacetyl 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. | .....do..... | .....do..... | 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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| | Polygylcerol esters of fatty acids (polygylcerol esters of fatty acids are restricted to those up to and including the decaglycerol esters and otherwise meeting the requirements of Sec. 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; oleomargaine. | 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 | .....do..... | Shortening for use in | 1 percent when |

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| | (polyoxyethylene (20) sorbitan monooleate). | | nonstandardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods. | 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 acid. | .....do..... | Shortening to be used for cake icings and fillings. | 3.0 percent. |
| | Stearyl monoglyceridyl citrate. | .....do..... | Shortening..... | Sufficient for purpose. |
| Film forming agents. | 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. |
| Flavoring agents; protectors and developers. | Artificial smoke flavoring. | To flavor product..... | Various\2\..... | Do. |
| | Smoke flavoring..... | .....do..... | .....do..... | Do. |
| | Autolyzed yeast extract. | .....do..... | .....do..... | Do. |
| | Harmless bacteria starters of the acidophilus type, lactic acid starter or culture of Pediococcus cerevisiae. | 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 Clostridium botulinum. | 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 |

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| | | | (expressed as the acids in the wt. of the finished foods). |

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| 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. |
| Diacetyl..... | .....do..... | Oleomargarine..... | Do. |
| Disodium guanylate..... | .....do..... | Various\2\..... | Do. |
| Disodium inosinate..... | .....do..... | .....do..... | Do. |
| Hydrolyzed plant protein | .....do..... | .....do..... | Do. |
| Isopropyl citrate..... | To protect flavor..... | Oleomargarine..... | 0.02 percent. |
| Malt syrup..... | To flavor product..... | Cured products..... | 2.5 percent. |
| Milk protein hydrolysate | .....do..... | Various\2\..... | Sufficient for purpose. |
| Monosodium glutamate.... | .....do..... | .....do..... | Do. |
| Monoammonium glutamate.. | .....do..... | .....do..... | Do. |
| Sodium sulfoacetate derivative of mono and diglycerides. | .....do..... | .....do..... | 0.5 percent. |
| Sodium tripoly-phosphate | 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. | .....do..... | .....do..... | Do. |
| Sorbitol..... | To flavor, to facilitate the removal of casings | Cooked sausage labeled frankfurter, frank, furter, wiener, and | Not to exceed 2 percent of the weight of the |

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| | | from product, and to reduce carmelization and charring. | knockwurst; cured pork and pork products, as provided in part 319 of this subchapter. | 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 flavor..... | .....do..... | 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 lactate..... | .....do..... | .....do..... | Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1768. |
| Gases..... | Carbon dioxide solid (dry ice). | To cool product..... | Chopping of meat, packaging of product. | Do. |
| | Nitrogen..... | To exclude oxygen..... | Sealed container..... | Do. |

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| Hog scald agents; must be removed by subsequent cleaning operations. | Caustic soda..... | To remove hair..... | Hog carcasses..... | Do. |
| | Dimethylpolysiloxane.... | .....do..... | .....do..... | Do. |
| | Dioctyl sodium sulfosuccinate. | .....do..... | .....do..... | Do. |
| | Disodium-calcium ethylenediamine-tetraacetate. | .....do..... | .....do..... | Do. |
| | Disodium phosphate..... | .....do..... | .....do..... | Do. |
| | Ethylenediamine-tetraacetic acid (sodium salts). | .....do..... | .....do..... | Do. |
| | Lime (calcium oxide, calcium hydroxide). | .....do..... | .....do..... | Do. |
| | Potassium hydroxide..... | .....do..... | .....do..... | Do. |
| | Propylene glycol..... | .....do..... | .....do..... | Do. |
| | Soap (prepared by the reaction of calcium, potassium, or sodium with rosin or fatty acids of natural fats and oils). | .....do..... | .....do..... | Do. |
| | Sodium acid pyrophosphate. | .....do..... | .....do..... | Do. |
| | Sodium carbonate..... | .....do..... | .....do..... | Do. |

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| | Sodium dodecylbenzene sulfonate. | .....do..... | .....do..... | Do. |
| | Sodium gluconate..... | .....do..... | .....do..... | Do. |
| | Sodium hexametaphosphate | .....do..... | .....do..... | Do. |
| | Sodium lauryl sulfate... | .....do..... | .....do..... | Do. |
| | Sodium mono and dimethylnaphthalene sulfonate (molecular weight 245-260). | .....do..... | .....do..... | Do. |
| | Sodium n-alkylbenzene sulfonate (alkyl group predominantly C<INF>12 and C<INF>13 and not less than 95 percent C<INF>10 and C<INF>16). | .....do..... | .....do..... | Do. |
| | Sodium pyrophosphate.... | .....do..... | .....do..... | Do. |
| | Sodium silicates (ortho, meta, and sesqui). | .....do..... | .....do..... | Do. |
| | Sodium sulfate..... | .....do..... | .....do..... | Do. |
| | Sodium tripolyphosphate. | .....do..... | .....do..... | Do. |
| | Sucrose..... | .....do..... | .....do..... | Do. |
| | Triethanolamine dodecylbenzene sulfonate. | .....do..... | .....do..... | Do. |
| | Trisodium phosphate..... | .....do..... | .....do..... | Do. |
| Miscellaneous..... | Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination, under an approved partial quality control (PQC) program (9 CFR 318.4 (d) & (e)). | 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 |

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| | | (in accordance with 21 CFR 182.6751). | |
| d- and dl-alphatocopherol. | To inhibit nitrosamine formation. | Pump-cured bacon..... | 500 ppm; by injection or surface application. |

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| 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/ dispersant. | Tocopherol-containing bacon curing premixes. | At level not to exceed 4.0 percent in the dry mix. |
| Sorbic acid (sodium, potassium, and calcium salts). | To preserve product and to retard mold growth. | Margarine or oleomargarine. | 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 disodium ethylene-diaminetetraacetate). | To preserve product and to protect flavor. | .....do..... | 75 parts per million by weight of the finished oleomargarine 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 curing pickle. | Rendered fats, soups, | Sufficient for purpose. |

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| | vegetables. | | |
| Calcium propionate..... | To retard mold growth. | Pizza crust..... | 0.32 percent alone or in combination based on weight of the flour brace used. |
| Sodium propionate..... | .....do..... | .....do..... | Do. |
| Sodium hydroxide..... | To decrease the amount of cooked out juices. | Meat food products containing phosphates. | 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 phosphate..... | .....do..... | Meat food products except where otherwise prohibited by the Federal meat inspection regulations. | 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in product (only clear solution may be injected into product). |
| Monosodium phosphate.... | .....do..... | .....do..... | Do. |
| Sodium metaphosphate, insoluble. | .....do..... | .....do..... | Do. |
| Sodium polyphosphate, glassy. | .....do..... | .....do..... | Do. |
| Sodium tripolyphosphate. | .....do..... | .....do..... | Do. |
| Sodium pyrophosphate.... | .....do..... | .....do..... | Do. |
| Sodium acid pyrophosphate. | .....do..... | .....do..... | Do. |
| Dipotassium phosphate... | .....do..... | .....do..... | Do. |
| Monopotassium phosphate. | .....do..... | .....do..... | Do. |
| Potassium tripolyphosphate. | .....do..... | .....do..... | Do. |
| Potassium pyrophosphate. | .....do..... | .....do..... | Do. |
| Citric acid (sodium and potassium salts). | To acidify..... | Margarine or oleomargarine. | Sufficient for purpose. |
| Lactic acid (sodium and potassium salts). | .....do..... | .....do..... | Do. |

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| L-Tartaric acid (sodium and sodium potassium salts). | .....do..... | .....do..... | | Do. |
| Adipic acid..... | .....do..... | .....do..... | | Do. |
| Phosphoric acid..... | .....do..... | .....do..... | | Do. |
| Hydrochloric acid..... | .....do..... | .....do..... | | Do. |
| Sodium bicarbonate..... | To alkalize..... | .....do..... | | Do. |

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| Sodium carbonate..... | .....do..... | .....do..... | | Do. |
| Sodium hydroxide..... | .....do..... | .....do..... | | Do. |
| Potassium carbonate..... | .....do..... | .....do..... | | Do. |
| Potassium bicarbonate... | .....do..... | .....do..... | | 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. | |
| 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 |

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| | | | | gain of more than 3 percent above the weight of the untreated product. |
| | Aspergillus flavusoryzae group. | .....do..... | .....do..... | Do. |
| | Bromelin..... | .....do..... | .....do..... | Do. |
| | Ficin..... | .....do..... | .....do..... | Do. |
| | Papain..... | .....do..... | .....do..... | 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 soda..... | .....do..... | .....do..... | Do. |
| | Carbon (purified charcoal). | To aid in refining of animal fats. | .....do..... | Do. |
| | Caustic soda (sodium hydroxide). | To refine fats..... | .....do..... | Do. |
| | Diatomaceous earth; Fuller's earth. | .....do..... | .....do..... | Do. |
| | Sodium carbonate..... | .....do..... | .....do..... | Do. |
| | Tannic acid..... | .....do..... | .....do..... | Do. |
| Rendering agents.... | Tricalcium phosphate.... | To aid rendering..... | Animal fats..... | Do. |
| | Trisodium phosphate..... | .....do..... | .....do..... | Do. |
| Sources of radiation | Ionizing radiation limited to gamma rays from cobalt-60 or cesium-137. | To control Trichinella spiralis. | 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 sweetners | 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 acid..... | .....do..... | Lard and shortening... | 0.01 percent based on total weight in combination with antioxidants. |
| | Monoisopropyl citrate... | .....do..... | Lard, shortening, oleomargarine, fresh pork sausage, dried meats. | 0.02 percent. |
| | Phosphoric acid..... | .....do..... | Lard and shortening... | 0.01 percent. |
| | Monoglyceride citrate... | .....do..... | Lard, shortening, fresh pork sausage, dried meats. | 0.02 percent. |

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| Tenderizing agents.. | 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. | .....do..... | .....do..... | Do. |
| | Bromelin..... | .....do..... | .....do..... | Do. |
| | Ficin..... | .....do..... | .....do..... | Do. |
| | Papain..... | .....do..... | .....do..... | Do. |
| | Potassium chloride..... | .....do..... | .....do..... | Not more than 3 percent of a 2.0 molar solution. |
| | Magnesium chloride..... | .....do..... | .....do..... | Not more than 3 percent of a 0.8 molar solution. |
| | Calcium chloride..... | .....do..... | .....do..... | Not more than 3 percent of a 0.8 molar solution. |
| | Potassium, magnesium or calcium chloride. | .....do..... | .....do..... | 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. |

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\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 Sec. 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 Sec. 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 Sec. 318.7, see the List of CFR Sections Affected in the Finding Aids section of this volume.

Effective Date Note: At 61 FR 58782, Nov. 19, 1996, Sec. 318.7(c)(4) was amended by revising in the chart of substances, under the Class of Substances, ``Flavoring agents; protectors and developers'', the entry for the substance ``Corn syrup solids, corn syrup, glucose syrup'', effective Jan. 21, 1997. For the convenience of the user, the superseded text is set forth as follows:

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

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| Class of substance | Substance | Purpose | Products | Amount |
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| Corn syrup solids, corn syrup, glucose syrup. | To flavor..... | Sausage, hamburger, meat loaf, luncheon meat, chopped or pressed ham. | 2.0 percent individually or collectively, calculated on a dry basis. |

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