

- DIRECTIVE
 REVISION
 AMENDMENT
 OTHER

CHANGE TRANSMITTAL SHEET

Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products	7120.1, Amend 2	8/4/04
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I. PURPOSE

This transmittal issues the on-going updates to Attachment 1 for FSIS Directive 7120.1. Attachment 1 identifies the substances that have been approved in 21 CFR for use in meat and poultry products as food additives, approved in GRAS notices and pre-market notifications, and approved in letters conveying acceptability determinations. Substances added since the 11/3/2003 issuance of the directive are in **bold**.

This information is also available on the USDA website at:

www.fsis.usda.gov/OPPDE/larc/index.htm. For further policy information regarding any of the substances listed below please contact the New Technology Staff by telephone at Area Code (202) 205-0675. FSIS will continue to issue updates to the list, as needed.

NOTE: Attachment 1 does not include the use of substances in on-line reprocessing operations that operate under an experimental exemption listed in 9 CFR 381.3(c). Establishments operating under this exemption should follow the conditions of use that are specific to their FSIS approved on-line reprocessing protocol.

Because the number of pages increased in Attachment 1, Attachment 2 is reissued as well.

II. CANCELLATION

This transmittal is cancelled when contents have been incorporated into FSIS Directive 7120.1.

Philip S. Derfler /s/

Assistant Administrator
Office of Policy and Program Development

FILING INSTRUCTION

Remove Old Pages

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Insert New Pages

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DISTRIBUTION: Inspection Offices, T/A Inspectors, Plant Mgt., T/A Plant Mgt., TRA, ABB, TSC, Import Offices

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Table of Safe and Suitable Ingredients

SUBSTANCE	PRODUCT	AMOUNT	REFERENCE	LABELING REQUIREMENTS
Anticoagulants				
Sodium tripolyphosphate	Sequestrant/anti-coagulant for use in recovered livestock blood which is subsequently used in food products	Not to exceed 0.5 percent of recovered blood	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Antimicrobials				
A mixture of hops beta acids, egg white lysozyme, and cultured skim milk	In a salad dressing used in refrigerated meat and poultry deli salads	Not to exceed 1.5 percent of the finished salad	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
A mixture of maltodextrin (DE of 5 or greater), cultured dextrose, sodium diacetate, egg white lysozyme, and nisin preparation	In salads, sauces, and dressings to which fully cooked meat or poultry will be added	Not to exceed 1.5 percent by weight of the finished product	Acceptability determination	Listed by common or usual name in the ingredients statement (4)
Acidified sodium chlorite	Poultry carcasses and parts; meat carcasses, parts, and organs; processed, comminuted, or formed meat food products	500 to 1200 ppm in combination with any GRAS acid at a level sufficient to achieve a pH of 2.3 to 2.9 in accordance with 21 CFR 173.325 (<i>Note: The pH depends on the type of meat or poultry product.</i>)	21 CFR 173.325	None under the accepted conditions of use (3)
Acidified sodium chlorite	Processed, comminuted or formed poultry products	500 to 1200 ppm in combination with any GRAS acid at a level sufficient to achieve a pH of 2.3 to 2.9 in accordance with 21 CFR 173.325 (<i>Note: The pH depends on the type of meat or poultry product.</i>)	Acceptability determination	None under the accepted conditions of use (3)
Anhydrous ammonia	Lean finely textured beef which is subsequently quick chilled to 28 degrees Fahrenheit and mechanically "stressed"	In accordance with current industry standards of good manufacturing practice	Acceptability determination	None under the accepted conditions of use (1)
Cetylpyridinium chloride	To treat the surface of raw poultry carcasses prior to immersion in	Applied as a fine mist spray of an ambient temperature	21 CFR 173.375	None under the accepted conditions of use

	a chiller	aqueous solution. The aqueous solution shall also contain propylene glycol complying with 21 CFR 184.1666 at a concentration of 1.5 times that of the cetylpyridinium chloride		(3)
Citric acid	Bologna in an edible casing	Up to a 10 percent solution applied prior to slicing	Acceptability determination	Listed by common or usual name in the ingredients statement (4)
Citric acid	Bologna in an inedible casing	Up to a 10 percent solution applied prior to slicing	Acceptability determination	None under the accepted conditions of use (1)
Chlorine dioxide	In water used in poultry processing	Not to exceed 3 ppm residual chlorine dioxide as determined by Method 4500-ClO₂ E in the “Standard Methods for the Examination of Water and Wastewater,” 18th ed., 1992, or an equivalent method	21 CFR 173.300	None under the accepted conditions of use (3)
DBDMH (1,3dibromo-5,5-dimethylhydantoin)	For use in poultry chiller water and in water applied to poultry via an Inside-Outside Bird Washer (IOBW)	At a level not to exceed that needed to provide the equivalent of 100 ppm active bromine	Food Contact Substance Notification No. FCN 334	None under the accepted conditions of use (6)
Egg white lysozyme	In casings and on cooked (RTE) meat and poultry products	2.5 mg per pound in the finished product when used in casings; 2.0 mg per pound on cooked meat and poultry products	GRAS Notice No. 000064	Listed by common or usual name in the ingredients statement (2)
A blend of citric acid (1.87%), phosphoric acid (1.72%), and hydrochloric acid (0.8%)	Poultry carcasses	Dipped in solution, allowed to drip for 30 seconds, and rinsed with a spray application of water for 1-2 seconds	Acceptability determination	None under the accepted conditions of use (1)
A blend of citric acid, hydrochloric acid, and phosphoric acid	To adjust the acidity in various meat and poultry products	Sufficient for purpose	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Hops beta acids	In casings and on cooked (RTE) meat and	2.5 mg per pound in the finished product	GRAS Notice No. 000063	Listed by common or usual name in the

	poultry products	when used in casings; 2.0 mg per pound on cooked meat and poultry products		ingredients statement (2)
Lactic Acid	Beef carcasses prior to fabrication (i.e., pre- and post-chill)	Hot (≈55° C) 5 percent lactic acid solution	Acceptability determination	None under the accepted conditions of use (1)
Lactoferrin	Beef carcasses and parts	At up to 2 percent of a water-based antimicrobial spray	GRAS Notice No. 000067	Listed by common or usual name in ingredients statement (2)
Lactoferrin	Beef carcasses	As part of an antimicrobial spray that would deliver 1 gram of lactoferrin per dressed beef carcass, followed by a wash with tempered water and rinse with lactic acid	GRAS Notice No. 000130	None under the accepted conditions of use (1)
Nisin preparation	Components of sauces prepared under FDA jurisdiction and used with fully cooked meat or poultry	In sauces prepared under FDA jurisdiction that contain no more than 600 ppm nisin preparation may be used where the meat or poultry does not exceed 50 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Nisin	Meat and poultry soups	Not to exceed 5 ppm of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Nisin	In casings and on cooked (RTE) meat and poultry products	3.15 mg per pound in the finished product when used in casings; 2.5 mg per pound on cooked meat and poultry products	GRAS Notice No. 000065	Listed by common or usual name in the ingredients statement (2)
Organic Acids (i.e., lactic, acetic, and citric acid)	As part of carcass wash applied pre-chill	At up to 2.5 percent of a solution	FSIS Notice 49- 94	None under the accepted conditions of use (1)
Ozone	All meat and poultry products	In accordance with current industry standards of good manufacturing practice	21 CFR 173.368	None under the accepted conditions of use (3)
Peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1- hydroxyethylidene-1, 1- diphosphonic acid	Meat and poultry carcasses, parts, trim and organs	Maximum concentrations for meat carcasses, parts, and organs: Peroxyacetic acids 220 ppm, hydrogen peroxide 75 ppm; Maximum	21 CFR 173.370	None under the accepted conditions of use (3)

(HEDP)		concentrations for poultry carcasses, parts, and organs: Peroxyacetic acids 220 ppm, hydrogen peroxide 110 ppm, HEDP 13 ppm		
A mixture of Peroxyacetic acid, hydrogen peroxide, acetic acid, and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)	Process water for washing, rinsing, cooling, or otherwise for processing meat carcasses, parts, trim, and organs; and (2) process water applied to poultry carcasses as a spray, wash, rinse, dip, chiller water, or scald water	In either application, the level of Peroxyacetic acid will not exceed 230 ppm, hydrogen peroxide will not exceed 165 ppm, and HEDP will not exceed 14.0 ppm	Food Contact Substance Notification No. FCN 000323	None under the accepted conditions of use (6)
Potassium diacetate	Various meat and poultry products which permit the addition of antimicrobial agents, e.g., hot dogs	Not to exceed 0.25 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
A solution of water, lactic acid, propionic acid, and acidic calcium sulfate (solution with a pH range of 1.0-2.0)*	Various RTE meat products, e.g., hot dogs	Applied as a spray for 20-30 seconds of continual application just prior to packaging <i>*Propionic acid may be removed from the solution; sodium phosphate may be added to the solution as a buffering agent (the amount of sodium phosphate on the finished product must not exceed 5000ppm)</i>	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
A solution of water, acidic calcium sulfate and 85-95,000 ppm of lactic acid (solution with a pH range of 0.35 to 0.55)	Raw comminuted beef	To treat raw beef during grinding to lower the pH of the product	Acceptability determination	Product must be descriptively labeled (2)
A solution of water, acidic calcium sulfate, lactic acid, and sodium phosphate (solution with a pH range of 1.45 to 1.55)	Cooked roast beef and similar cooked beef products (e.g., corned beef, pastrami, etc.)	Spray applied for up to 30 seconds of continual application <i>*sodium phosphate on the finished product must not exceed 5000 ppm</i>	Acceptability determination	Listed by common or usual name in the ingredients statement of multi-ingredient products. Single ingredient roast beef products must be descriptively

				labeled (2)
A solution of water, acidic calcium sulfate, lactic acid, and sodium phosphate (solution with a pH of 1.45 to 1.6)	Cooked poultry carcasses and parts	Spray applied for 20 to 40 seconds of continual application * sodium phosphate on the finished product must not exceed 5000 ppm	Acceptability determination	Listed by common or usual name in the ingredients statement of multi-ingredient products. Single ingredient whole muscle cuts of poultry must be descriptively labeled (2)
Skim milk or dextrose cultured with <i>propionibacterium freudenreichii</i> subsp. <i>Shermanii</i>	Meat and poultry sausages including those with standards of identity which permit the use of antimicrobial agents	Not to exceed 2 percent by weight of the finished product	GRAS Notice No. 000128	Listed by common or usual name in the ingredients statement (2)
Sodium citrate buffered with citric acid to a pH of 5.6	Non-standardized and standardized comminuted meat and poultry products which permit ingredients of this type	Not to exceed 1.3 percent of the product formulation in accordance with 21 CFR 184.1751	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Sodium metasilicate	Raw beef carcasses, subprimals, and trimmings	For use at up to 4 percent (plus or minus 2 percent) of a solution	Acceptability determination	None under the accepted conditions of use (1)
Trisodium phosphate	Raw unchilled poultry carcasses and giblets	8-12 percent solution applied by spraying or dipping giblets for up to 30 seconds. 8-12 percent solution within a temperature range of 65° F to 85 ° F applied by spraying or dipping carcasses for up to 15 seconds	Acceptability determination (per 21 CFR 182.1778)	None under the accepted conditions of use (1)
Antioxidants				
BHA (butylated hydroxyanisole)	"Brown N Serve" sausages	0.02 percent in combination with other antioxidants for use in meat, based on fat content	Acceptability determination	Listed by common or usual name in the ingredients statement (4)
BHT (butylated hydroxytoluene)	"Brown N Serve" sausages	0.02 percent in combination with other antioxidants for use in meat, based on fat content	Acceptability determination	Listed by common or usual name in the ingredients statement (4)
Binders				
A mixture of carrageenan, whey protein concentrate, and xanthan gum	Sausages where binders are permitted; cooked poultry products; beef and	Not to exceed 3.5 percent by weight of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement

	poultry patties; modified breakfast sausage, cooked sausages, and fermented sausages covered by FSIS Policy Memo 123; and modified substitute versions of fresh sausage, ground beef, or hamburger covered by FSIS Policy Memo 121B			(4)
Binders listed in 9 CFR 424.21(c) for use in cured pork products and poultry products	"Turkey ham and water products"	In accordance with 9 CFR 319.104(d) and 424.21(c)	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Carrot Fiber	Various comminuted meat and poultry products where binders are permitted	Not to exceed 3.5 percent of the product formulation	GRAS Notice No. 000116	List as "isolated carrot product" (2)
Cellulose, powdered conforming to the specifications in the Food Chemicals Codex 5th Edition	Various comminuted poultry products where binders are permitted	Not to exceed 3.5 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Hydroxypropyl methylcellulose	Seasoning mixtures added to sauces and gravies produced under FDA jurisdiction that will be used in meat and poultry products	Sufficient for purpose	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Hydroxypropyl methylcellulose	Thickener in meat and poultry pot pie fillings, sauces, soups, and gravies	Not to exceed 1 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Inulin	Various meat and poultry products (e.g., frankfurters, sausage, patties, loaves, pates) where binders are permitted	2 to 5 percent of the product formulation	Acceptability determination and GRAS Notice No. 000118	Listed by common or usual name in the ingredients statement (2)
Konjac flour	Meat and poultry products in which starchy vegetable flours are permitted	No to exceed 3.5 percent of the product formulation individually or collectively with other binders	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Methylcellulose	Various comminuted meat and poultry products where binders are permitted	Not to exceed 3.5 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Methylcellulose	Thickener in meat and poultry pot pie fillings, sauces, soups, and	Not to exceed 1 percent of the product formulation as a	Acceptability determination	Listed by common or usual name in the ingredients

	gravies; a binder in poultry patties, loaves, and nuggets; a binder in meat patties, loaves, and nuggets; texturizer in Policy Memo 121B and 123 products	thickener in meat and poultry pot pie fillings, sauces, soups, and gravies; 1.6 percent as a binder in poultry patties, loaves, and nuggets; 0.25 percent as a binder in meat patties, loaves, and nuggets; 0.6 percent as a texturizer in Policy Memo 121B and 123 products		statement (2)
Partially hydrolyzed proteins	Various meat and poultry products where binders are permitted.	Not to exceed 3.5 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Pectin	Various meat and poultry products where binders are permitted	Not to exceed 3 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Pork collagen	Various meat and poultry food products where binders are permitted	Not to exceed 3.5 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Sodium alginate	Various meat products where binders are permitted	Not to exceed 1 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Sodium alginate	Various poultry products where binders are permitted	Not to exceed 0.8 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Transglutaminase enzyme	Texturizing agent in meat and poultry food products where texturizing agents and binders are permitted	Not to exceed 65 ppm of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Transglutaminase enzyme	Cross-linking agent in modified meat and poultry products addressed in Policy Memos 121B and 123.	Not to exceed 65 ppm of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Transglutaminase enzyme	Binding and cross-linking agent in uncooked restructured chicken breasts	Not to exceed 100 ppm of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Trehalose	Binding and purge control agent in various meat and poultry products where binders are permitted	Not to exceed 2 percent of the product formulation	GRAS Notice No. 000045	Listed by common or usual name in the ingredients statement (2)

Xanthan gum (purified by recovery with ethyl alcohol)	Various meat and poultry products where binders are permitted	Non-standardized meat and poultry products and products with a standard of identity which currently permit the use of xanthan gum listed in 9 CFR 424.21(c)	GRAS Notice No. 000121	Listed by common or usual name in the ingredients statement (4)
Coloring Agents				
Carmines (cochineal)	To color textured soy protein isolate for use in dry cured acidified sausages	0.2 to 0.4 percent of the hydrated protein gel. The protein gel must not exceed 30 percent of the meat food product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (5)
Curing Accelerators (must be used only in combination with curing agents)				
Potassium erythorbate	Cured pork and beef cuts; cured meat food products; cured comminuted poultry or poultry products	87.5 oz. to 100 gallons of pickle at 10 percent pump; 7/8 oz. to 100 lbs. Of meat, meat byproduct or poultry product; 10 percent to surfaces of cured meat cuts or poultry products prior to <i>packaging</i>	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Film Forming Agents				
A mixture of water, glycerin, carrageenan, and cornstarch	Used to aid in the release of elastic netting on cooked meat products that are cooked in elastic netting	Sufficient for purpose	Acceptability determination	None under the accepted conditions of use (1)
A mixture of water, glycerin, carrageenan, cornstarch, and caramel	Used to aid in the release of elastic netting on cooked meat products that are cooked in elastic netting	Sufficient for purpose	Acceptability determination	"Caramel Color" listed as an ingredient and as a product name qualifier (2)
A mixture of water, glycerin, carrageenan, cornstarch, and smoke flavoring	Used to aid in the release of elastic netting on cooked meat products that are cooked in elastic netting	Sufficient for purpose	Acceptability determination	"Smoke Flavor" listed as an ingredient and as a product name qualifier (2)
A solution of sodium alginate, dextrose, isolated pea protein, sugar, and maltodextrin (DE of 6) used with a solution	Used to form a calcium alginate-based casing on pork and poultry sausages.	Quantity of the casing on the sausage ranges from 8 to 15 percent of total product formulation and	Acceptability determination	Listed by common or usual name in the ingredients statement (4)

of calcium chloride, powdered sugar, oleoresin black pepper, and isolated pea protein.		calcium alginate not to exceed 0.219 percent of the finished product formulation		
Gelatin spice sheets	To ensure even distribution of seasonings on cooked pork products	Sufficient for purpose	Acceptability determination	None under the accepted conditions of use (1)
Hydroxypropyl methylcellulose	Film-forming agent in glazes for meat and poultry products	Not to exceed 4 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Methylcellulose	Film-forming agent in glazes for meat and poultry products	Not to exceed 3 percent of the product formulation for poultry products, 3.5 percent of the product formulation for meat products	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Flavoring Agents				
Laminaria japonica	As a flavor enhancer or flavoring agent in marinades for meat and poultry, meat and poultry soups, gravies, and seasonings	Not to exceed 0.08 percent of the product formulation	GRAS Notice No. 000123	Listed by common or usual name in the ingredients statement (2)
Potassium acetate	Various meat and poultry products	No to exceed 1.2 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (4)
Sucralose	Non-nutritive sweetener in various non-standardized meat and poultry products	Not to exceed 500 ppm in the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Trehalose	As a flavor enhancer in non-standardized RTE meat and poultry products	Not to exceed 2 percent by weight of product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Miscellaneous				
Algal oil derived from <i>Schizochytrium sp.</i>	For use as an alternative edible oil in the production of various meat products	Not to exceed 2.9 percent by weight of the product formulation	GRAS Notice No. 000137	Listed by common or usual name in the ingredients statement (2)
Cellulose (powdered)	To facilitate grinding and shredding in cheese	No to exceed 2 percent of the cheese	Acceptability determination	None under the accepted conditions of use (1)
Diacylglycerol oil	For use as an alternative edible oil in the production of various meat and poultry products	Not to exceed 11 percent of the meat or poultry product formula	GRAS Notice No. 000115	Listed by common or usual name in the ingredients statement (2)
Erythorbic Acid	To delay discoloration	Not to exceed 0.04	Acceptability	Product must be

	in ground beef and ground beef patties	percent of the product formulation	determination	descriptively labeled (2)
Fish oil concentrate	For use as an alternative edible oil in the production of various meat products	Not to exceed 5.7 percent of the product formulation	GRAS Notice No. 000105	Listed by common or usual name in the ingredients statement (2)
Hydrogen peroxide	To minimize biofilm buildup on reverse osmosis and ultrafiltration membranes for processing beef plasma	No to exceed 100 ppm added just prior to plasma entering membranes	Acceptability determination	None under the accepted conditions of use (1)
Small planktivorous pelagic fish oil	For use as an alternative edible oil in the production of various meat products	Not to exceed 6.7 percent of the product formulation	GRAS Notice No. 000102	Listed by common or usual name in the ingredients statement (2)
Sodium bicarbonate	Neutralize excess acidity (maintain pH) in fresh pork and beef cuts	In an injected solution, not to exceed 0.5 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Sodium bicarbonate	Maintain pH and reduce purge in fresh turkey products	In an injected solution, not to exceed 0.5 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Sodium bicarbonate	To soak natural casings to ease stuffing	1.06 percent of an aqueous solution. Casings must be rinsed with potable water prior to stuffing	Acceptability determination	None under the accepted conditions of use (1)
Sodium hydroxide and hydrochloric acid	To adjust the pH of (species) plasma during processing (in which it is exposed to heat) to prevent gelling	Sufficient for purpose to adjust pH	Acceptability determination	None under the accepted conditions of use (1)
Tuna oil	For use as an alternative edible oil in the production of various meat products	Not to exceed 6.2 percent of the product formulation	GRAS Notice No. 000109	Listed by common or usual name in the ingredients statement (2)
Xanthan gum	Suspending agent for carrageenan in a brine tank	Not to exceed 2 percent of the amount of carrageenan	Acceptability determination	None under the accepted conditions of use (1)
Packaging Systems				
Carbon monoxide gas as part of Cryovac's modified atmosphere packaging system (for use with 550P Tray/Lid and LID551P)	Packaging fresh cuts of case ready muscle meat and case ready ground meat to maintain wholesomeness, provide flexibility in distribution, and reduce shrinkage of the meat	The use of carbon monoxide (0.4 %), carbon dioxide (30 %) and nitrogen (69.6 %) as part of the Cryovac low oxygen modified atmosphere packaging system used with 550P Tray /Lid	Acceptability Determination	None under the accepted conditions of use (2)
Carbon monoxide gas as part of the Pactiv	Packaging fresh cuts of case ready muscle	The use of carbon monoxide (0.4 %),	GRAS Notice No. 000083	None under the accepted conditions

modified atmosphere packaging system (ActiveTech 2001)	meat and case ready ground meat to maintain wholesomeness	carbon dioxide (30 %) and nitrogen (69.6 %) as part of the Pactiv modified atmosphere packaging system		of use (2)
Carbon monoxide gas as part of a high oxygen modified atmosphere packaging system used in accordance with GRN 000083 (Cargill)	Packaging fresh cuts of case-ready muscle meat and ground meat to maintain wholesomeness	Not to exceed 0.4 percent of the modified atmosphere gas mixture	Acceptability determination	None under the accepted conditions of use (2)
Carbon monoxide gas a part of Cargill's modified atmosphere packaging system introduced directly into the bulk or master container used for bulk transportation of fresh meat products. Meat products are subsequently repackaged in packages not containing a carbon monoxide modified atmosphere prior to retail sale (In accordance with GRN 000083)	Packaging fresh cuts of muscle meat and ground meat to maintain wholesomeness	Not to exceed 0.4 percent of the modified atmosphere gas mixture	Acceptability determination	None under the accepted conditions of use (2)
Tenderizing Agents				
Calcium gluconate	Raw meat products	Solutions applied or injected into raw meat shall not result in a gain of 3 percent above green weight	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Protease preparation derived from <i>Bacillus subtilis</i>	Raw meat products	Solutions applied or injected into raw meat shall not result in a gain of 3 percent above green weight	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Protease produced from <i>Bacillus subtilis</i> var. <i>amyloliquefaciens</i>	Raw meat products	Solutions applied or injected into raw meat shall not result in a gain of 3 percent above green weight	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Protease produced from <i>Aspergillus niger</i>	Raw meat cuts and raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose,	Solutions applied or injected into raw meat or poultry tissue shall not result in a gain of 3	GRAS Notice No. 000089	Listed by common or usual name in the ingredients statement (2)

	and mature guinea	percent above green weight		
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- 1) The use of the substance(s) is consistent with FDA's labeling definition of a processing aid.
- 2) Generally Recognized as Safe (GRAS)
- 3) Secondary Direct Food Additive
- 4) Direct Food Additive
- 5) Color Additive
- 6) Food Contact Substance

* Substances identified in bold print in the table are substances that have been added to the directive since it was last issued on December 17, 2002.

Questions and Answers on the Use of Antimicrobial Agents in the Production of Meat and Poultry Products

The following set of questions and answers provide information regarding the requirements for the use of antimicrobial agents in meat and poultry production.

References

- Final Rule, "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products" (December 1999).
- MOU between FDA and FSIS for Ingredient Approval (January, 2000).
- FSIS Directive 7120.1, "Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products."
- Guidance document on "Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcass, Ground Beef and Beef Trimmings."
- Federal Register* Notice, "FSIS Procedures for Notification of New Technology" (68 FR 6873) (February, 2003)
- 9 CFR 416.4
- FSIS Directive 6355.1, "Use of Chlorine Dioxide in Poultry Chill Water."
- 9 CFR 424.21(c)
- FSIS Directive 6700.1, "Retained Water in Raw Meat and Poultry Products."
- 21 CFR Part 172,173, 182, 184
- 21 CFR 101.100(a)(3)(ii)

1. Question: What is the definition of a New Technology?

Answer: According to the FSIS *Federal Register* Notice (68 FR 6873) entitled, "FSIS Procedures for Notification of New Technology," FSIS defines a "new technology" as new, or new applications of, equipment, substances, methods, processes or procedures affecting the slaughter of livestock and poultry or processing of meat, poultry, or egg products which could affect product safety, inspection procedures, inspection program personnel safety, or require a waiver of a regulation.

2. Question: What is the definition of a processing aid?

Answer: According to the Food and Drug Administration's (FDA) regulations (21 CFR 101.100 (a) (3) (ii)), the definition of a processing aid is:

- a. Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.
- b. Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in food.
- c. Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

An example of a processing aid is the use of organic acid(s) (e.g., lactic, acetic, or citric acid) to treat livestock carcasses at up to 2.5% of a solution applied pre-chill.

3. Question: What are secondary direct food additives and direct food additives?

Answer: According to FDA's regulations (21 CFR Part 173), secondary direct food additives are substances whose functionality is required during the manufacture or processing of a food and are ordinarily removed from the final food. Although residuals might carry over to the final food, residuals must not exhibit any technical effects. Secondary direct food additives are consistent with FDA's definition of a processing aid so labeling is not required. Examples of secondary direct food additives are acidified sodium chlorite (21 CFR 173.325) and peroxyacids (21 CFR 173.370).

According to FDA's regulations (21 CFR Part 172), direct food additives are used to provide a technical effect in the final food. The antioxidants BHA and BHT are examples of substances that are approved as direct food additives.

4. Question: Do organic acid(s) (e.g., lactic, acetic, or citric acid) that are used as antimicrobial agents need to be declared on the label if they are applied to livestock carcasses after the chilling step?

Answer: Organic acid(s) are generally recognized as safe (GRAS) and are listed in FSIS regulations for use as an acidifier in various meat and poultry products at a level which is sufficient for purpose (9 CFR 424.21(c)). All ingredients, including organic acid(s), require labeling unless the use of a substance is consistent with FDA's definition of a processing aid or is a secondary direct food additive.

FSIS has recently stated no objection to the use of 5% hot lactic acid as an antimicrobial agent to treat beef carcasses prior to fabrication (i.e., pre and post-chill). Data was submitted to the Agency that demonstrated no lasting effect under the specified conditions of use. FSIS determined that the proposed use is consistent with the definition of a processing aid. Therefore, its use would not need to be reflected on the labeling for treated carcasses or products produced from treated carcasses. This new use is listed in the table of this directive.

If a company is interested in using one or more of these organic acid(s) as an antimicrobial agent on livestock carcasses or trim in a manner other than which is currently approved, they must provide data to the Agency that show that the use complies with FDA's definition of a processing aid. The data must show that the organic acid has only a momentary technical effect, not a lasting effect on the meat, e.g., fresh color is not preserved, normal spoilage indicators (e.g. discoloration) are not masked; and there is no extension of shelf life as compared to products made with untreated trimmings. The data must also show that the nutrient composition is not affected by the treatment and the sensory characteristics of the product are not affected. (Note: the reference to "Guidance on Ingredients and Sources of Radiation used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trim," can be accessed at <http://www.fsis.usda.gov/oppde/larc> at the "ingredients" link)

5. Question: What is the maximum amount of organic acid(s) permitted to be applied to livestock carcasses pre-chill without having to declare the organic acid(s) on the label?

Answer: Historically, the maximum amount of organic acid(s) that can be used to treat livestock carcasses without labeling is up to 2.5 % of a solution applied pre-chill. Labeling is not required for this specific use of organic acid(s) (which the Agency has permitted for many years) because it is based on data that showed that this application is consistent with FDA's definition of a processing aid.

Recently, FSIS has recently stated no objection to the use of 5 % hot lactic acid as an antimicrobial agent on beef carcasses prior to fabrication (see question number four). This use was determined to be consistent with the definition of a processing aid. Therefore, its use would not need to be reflected on the labeling for treated carcasses or products produced from treated carcasses.

6. Question: Do organic acid(s) (e.g., lactic, acetic, or citric acid) that are used as antimicrobial agents need to be declared on the label if they are applied to livestock carcasses at a concentration above 2.5%?

Answer: Unless the proposed use has been determined by FSIS to be consistent the definition of a processing aid (e.g., the application of organic acids at 2.5 % of a beef carcass wash solution applied pre-chill or the application of 5 percent hot lactic acid solution to pre or post chilled beef carcasses prior to fabrication) the organic acid(s) would require labeling.

7. Question: Is the maximum amount of organic acid(s) allowed, without labeling the product, based on the concentration of the organic acid(s) applied to the carcass or the concentration of the organic acid(s) draining from the carcass?

Answer: The amount of organic acid(s) is based on the percentage of organic acid(s) in the carcass wash (aqueous solution) prior to application. It is not based on the residual level of organic acid(s) draining from a treated carcass during application.

8. Question: Do organic acid(s) (e.g. lactic, acetic, or citric acid) have to be declared on the label if they are applied to cut-up and ground meat and poultry?

Answer: Yes, all ingredients, including organic acid(s), require labeling unless the use of a substance is consistent with FDA's definition of a processing aid or is a secondary direct food additive. If an establishment is interested in using organic acid(s) to treat meat and poultry cuts and/or ground meat and poultry to momentarily reduce microorganisms, data must be submitted to FSIS to show that the proposed use of organic acid(s) is consistent with FDA's definition of a processing aid.

9. Question: Do organic acid(s) (e.g. lactic, acetic, or citric acid) have to be declared on the label if they are applied to livestock or poultry byproducts and giblets (e.g. livers, hearts, and gizzards)?

Answer: No, labeling is not required when organic acid(s) are applied pre-chill at up to 2.5% of an aqueous solution to treat livestock and poultry byproducts and giblets

10. Question: Are organic acid(s) used as antimicrobial agents permitted to be used on poultry carcasses?

Answer: Yes, organic acid(s) are GRAS and are listed in FSIS regulations for use as an acidifier (which may have an antimicrobial effect) in various meat and poultry products at a level which is sufficient for purpose (9 CFR 424.21(c)). Organic acid(s) are permitted to be applied to poultry carcasses pre-chill at a concentration of up to 2.5 percent of a solution without labeling.

11. Question: If organic acid(s) (e.g., lactic, acetic, or citric acid) are used on ready-to-eat products as a spray or dip, must the application be followed by a potable water rinse?

Answer: No, the use of organic acid(s) on ready-to-eat products are not required to be followed by a potable water rinse. However, the organic acid(s) will be considered ingredients that require labeling unless data can be submitted to FSIS that show that their use is consistent with FDA's definition of a processing aid.

12. Question: Are organic acid(s) (e.g., lactic, acetic or citric acid) permitted to be used on a continuous basis on conveyor belts? What are the conditions for their use? When do the organic acids need to be declared on a product label?

Answer: FSIS has no objection to the use of organic acids on conveyor belts on a continuous basis. However, the process should not result in the organic acid(s) having a lasting technical effect on meat or poultry which comes into contact with the conveyor belts. Labeling is required if the organic acid(s) exhibit a lasting technical effect on meat or poultry which comes into contact with the treated conveyor belts.

13. Question: Are antimicrobial agents other than organic acid(s) permitted to be used on a continuous basis on conveyor belts if they are approved as an antimicrobial agent in the production of meat and poultry products? What are the conditions for their use? When do the antimicrobial agents have to be included on a product label?

Answer: Yes, antimicrobial agents approved for use in the production of meat and poultry products may be used on conveyor belts provided they are followed by a potable water rinse. Substances listed in 21 CFR 178.1010 may be used in sanitizing solutions on food contact surfaces with only adequate draining (no water rinse) before contact with food.

14. Question: Is trisodium phosphate (TSP) permitted to be used as an antimicrobial agent on livestock carcasses, viscera, and parts?

Answer: TSP may only be used on livestock carcasses according to interim Agency policy.

15. Question: Where is TSP allowed to be used as an antimicrobial agent on poultry?

Answer: FSIS regulations (9 CFR 424.21 (c)) permits the use of TSP on raw post-chill poultry carcasses. In addition, FSIS has permitted the application of TSP to raw poultry carcasses pre-chill by spraying or dipping the carcasses with an 8-12% solution maintained within a temperature range of 65° F to 85° F for up to 15 seconds. FSIS has permitted the use spraying or dipping of poultry giblets for up to 30 seconds with an 8-12% solution of TSP pre-chill.

TSP is also used in some on-line reprocessing operations. Establishments which use on-line reprocessing operate under an experimental exemption listed in 9 CFR 381.3(c). The conditions of use for TSP in on-line reprocessing are limited by the parameters listed in the FSIS approved on-line reprocessing protocol, not the conditions of use listed above.

16. Question: Is chlorine dioxide permitted to be used as an antimicrobial agent on livestock carcasses, viscera, and parts?

Answer: No.

17. Question: Is chlorine dioxide allowed to be used as an antimicrobial agent on poultry? What are the conditions for its use?

Answer: Chlorine dioxide may be used as an antimicrobial agent to treat water in poultry processing as prescribed in FDA's regulations (21 CFR 173.300). Residual chlorine dioxide must not exceed 3 ppm in the poultry processing water.

18. Question: Is hydrogen peroxide allowed to be used as an antimicrobial agent on meat and poultry products (e.g. carcasses, parts, processed products)?

Answer: No, hydrogen peroxide is listed as GRAS in FDA regulations (21 CFR 184.1366) for use as a bleaching agent to treat beef feet and in FSIS regulations (9 CFR 424.21 (c)) as a bleaching agent to treat tripe (followed by a water rinse). It is also a component of peroxyacids (21 CFR 173.370).

19. Question: Can any and all anti-microbial agents be used on poultry carcasses during on-line reprocessing?

Answer: No, on-line reprocessing operations function under an experimental exemption (9 CFR 381.3 (c)). The use of antimicrobial agents in on-line reprocessing are limited by the parameters of the FSIS approved on-line reprocessing protocol.

20. Question: Can antimicrobial agents be used (spray or dip) on the same carcasses or parts more

than once, without labeling?

Answer: Yes, antimicrobial agents may be used more than once. However, the antimicrobial agents must be used in accordance with the approved or accepted conditions of use. Labeling is required unless the use of the substance is consistent with FDA's definition of a processing aid or is a secondary direct food additive.

21. Question: Do all uses of antimicrobial agents need to comply with the requirements of 9 CFR 441.10 for retained water? What are the requirements?

Answer: Yes, any establishment that uses a post-evisceration process that results in water retention in raw livestock or poultry carcasses or parts must maintain on file a written data collection protocol in accordance with 9 CFR 441.10 (c) (1). Any treatment in the chilling process such as antimicrobial treatments should be described in the protocol. An establishment does not have to maintain a protocol on file if it has data or information that clearly demonstrates that its products do not retain water as a result of the process, e.g., spraying boneless meat with antimicrobial agents where the end product does not retain water from the antimicrobial application (FSIS Directive 6700.1).