

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE	7120.1	12/17/2002
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**SAFE AND SUITABLE INGREDIENTS USED IN THE PRODUCTION OF
MEAT AND POULTRY PRODUCTS**

I. PURPOSE

This directive provides inspection program personnel with an up-to-date list of approved substances for use in the production of meat and poultry products.

II. [RESERVED]

III. REFERENCES

9 CFR Chapter III

IV. RESERVED

V. BACKGROUND

A. On December 23, 1999, the Food Safety and Inspection Service (FSIS) published in the Federal Register a final rule on "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products." The final rule streamlined the process for approving the use of food ingredients and sources of radiation in meat and poultry products to provide for the simultaneous review, by FSIS and the Food and Drug Administration (FDA), of petitions for new uses of food and color additives and notifications for new uses of generally recognized as safe (GRAS) substances that are submitted to FDA. Subsequent to the publication of the final rule in January, 2000, FDA and FSIS entered into a Memorandum of Understanding (MOU) that outlines the procedures that are followed by FDA and FSIS regarding the joint review of requests for the use of food ingredients and sources of radiation in meat and poultry products. Except in certain circumstances, FDA will now list in its regulations (21 CFR) food additives and sources of radiation that are safe and suitable for use in the production of meat or poultry products.

B. FDA regulations permit ingredient and food manufacturers to make their own determination that a particular use of a substance in food is GRAS by qualified experts. The substances that are determined to be GRAS through self-determinations are not listed in the FDA regulations in Title 21 of the CFR. However, on April 17, 1997, FDA published in the Federal Register a Proposed Rule that would establish a notification

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procedure whereby any person may notify FDA of a determination that a particular use of a substance is GRAS. Although this proposed notification procedure is not yet final, FDA is operating in accordance with the proposal. FDA has received many GRAS notifications pertaining to meat and poultry products that are included in an Inventory of GRAS Notices that FDA has established on its Website. When a GRAS notification involves a use in a meat or poultry product, FDA's response to the notifier will include any restrictions or conditions of use of the substance in the production of meat or poultry products that FSIS recommends, provided such restrictions or conditions of use are consistent with Sections 201 and 409(s) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The Inventory of GRAS Notices, and FDA's responses, may be accessed on the Internet World-Wide Web at: <http://vm.cfsan.fda.gov/~rdb/opa-gras.html>.

C. FDA also maintains an inventory of premarket notifications for food contact substances. However, unlike the GRAS notices, a premarket notification only applies to the manufacturer or supplier identified in the notification. In the process of reviewing notifications, FDA will consult with FSIS if the intended use involves meat or poultry, per the MOU. The FDA inventory of premarket notifications may be accessed on the Internet World-Wide Web at: <http://www.cfsan.fda.gov/~dms/opa-fcn.html>.

D. Substances listed approved in FDA regulations for use in food generally (21 CFR, Parts 172-180) or listed as GRAS for use in food (21 CFR, Parts 182 and 184) are not automatically acceptable as safe and suitable for use in meat and poultry products. Unless the approval or listing specifically mentions meat and poultry products, FSIS' Labeling and Consumer Protection Staff would need from FDA an affirmative written statement that FDA's safety determination did, in fact, consider use in meat or poultry, or that FDA does not have any objections with regard to the safety of the use in meat or poultry products. FSIS would still need to determine the suitability of the use of the substance, and whether rulemaking is required to permit such use. Provided FDA confirms the safety of the new use of a substance, or when FDA regulations already state that the substance is safe for use in food generally, FDA will not amend its regulations to list the specific use in meat and poultry products. However, rulemaking by FSIS may be necessary where a standard of identity prohibits or limits the use of an ingredient, or the ingredient is not expected in the product, e.g., adding milk to hamburger. If FSIS determines that rulemaking is necessary, the appropriate labeling or standards of identity regulation in Title 9 of the CFR will be amended to include the substance. In the event that rulemaking is not required, FSIS would notify the requestor, in writing, concerning the acceptable use in meat and poultry products (referred to as an "acceptability determination," as described in the MOU).

E. In the December 23, 1999, final rule, FSIS acknowledged the need to provide direction to its inspection program personnel concerning the use of food ingredients and sources of radiation that have been accepted by the Agency for use in meat and poultry products, but not listed in Titles 9 or 21 of the CFR. Consequently, FSIS proposed to maintain in its directive system, a comprehensive listing of the substances that have been reviewed according to the MOU and that have been accepted as safe and suitable by FSIS.

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F. The attachment below identifies the substances that have been accepted since January 2000 by FSIS as safe and suitable for use in the production of meat and poultry products that are not listed in 9 CFR 424.21(c). In order to be comprehensive, substances that have been approved in 21 CFR for use in meat and poultry as food additives; in GRAS notices and pre-market notifications, as well as in letters conveying acceptability determinations, have been included. This table is current as of November 25, 2002. The information is also available on the United States Department of Agriculture (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 Labeling and Consumer Protection Staff by telephone at Area Code (202) 205-0279 or by electronic mail at: FSIS.Labeling@fsis.usda.gov. FSIS issues quarterly updates to the list, as needed.

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Attachment 1

SUBSTANCE	PURPOSE/PRODUCT	AMOUNT	REFERENCE
<i>Anticoagulants</i>			
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
<i>Antimicrobials</i>			
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 salad dressing	Acceptability determination
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
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
Lactoferrin	Beef carcasses and parts	At up to 2 percent of a water-based antimicrobial spray	GRAS Notice 000067
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
Nisin Preparation	Meat and poultry soups	Not to exceed 5 ppm of the product formulation	Acceptability determination
Ozone	All meat and poultry products	In accordance with current industry standards of good manufacturing practice	21 CFR 173.368
Peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)	Meat and poultry carcasses, parts, trim and organs	Maximum concentrations: Peroxyacetic acids 220 ppm, hydrogen peroxide 100 ppm	21 CFR 173.370
Potassium diacetate	Various meat and poultry products	Not to exceed 0.25 of the product formulation	Acceptability determination
Sodium citrate buffered with citric acid to a pH of 5.6	Non-standardized comminuted meat and poultry products	Not to exceed 1.3 percent of the product formulation in accordance with 21 CFR 184.1751	Acceptability determination

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)
<i>Antioxidants</i>			
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
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
<i>Binders</i>			
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
α-Cellulose from bamboo	Various non-standardized comminuted poultry products	Not to exceed 3.5 percent of the product formulation	Acceptability determination
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
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
Inulin	Various non-standardized meat and poultry products	2 to 5 percent of the product formulation	Acceptability determination
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
Methylcellulose	Various non-standardized comminuted meat and poultry products	Not to exceed 3.5 percent of the product formulation	Acceptability determination
Methylcellulose	Thickener in meat and poultry pot pie fillings, sauces, soups, and gravies; a binder in poultry patties, loaves, and nuggets; a binder in meat patties, loaves, and nuggets; texturizer in Policy Memo	Not to exceed 1 percent of the product formulation as a 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	Acceptability determination

	121B and 123 products	meat patties, loaves, and nuggets; 0.6 percent as a texturizer in Policy Memo 121B and 123 products	
Partially hydrolyzed proteins	Non-standardized meat and poultry products where binders are permitted. Standardized meat and poultry products with standards of identity that allow such use.	Not to exceed 3.5 percent of the product formulation	Acceptability determination
Pectin	Non-standardized meat and poultry products	Not to exceed 3 percent of the product formulation	Acceptability determination
Pork collagen	Non-standardized meat food products where binders are permitted and modified meat and poultry products addressed in Policy Memos 121B and 123	Not to exceed 3.5 percent of the product formulation	Acceptability determination
Sodium alginate	Various non-standardized meat products	Not to exceed 1 percent of the product formulation	Acceptability determination
Sodium alginate	Various non-standardized poultry products	Not to exceed 0.8 percent of the product formulation	Acceptability determination
Transglutaminase enzyme	Texturizing agent in non-standardized meat and poultry food products where texturizing agents and binders are permitted	Not to exceed 65 ppm of the product formulation	Acceptability determination
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
<i>Coloring agent</i>			
Carmine (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
<i>Curing Accelerators</i> (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 packaging (the use of such a solution shall not add a significant amount of moisture to the product)	Acceptability determination

<i>Film Forming Agents</i>			
A mixture of water, glycerin, carageenan, 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
A mixture of water, glycerin, carageenan, 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
A mixture of water, glycerin, carageenan, 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
Gelatin spice sheets	To ensure even distribution of seasonings on cooked pork products	Sufficient for purpose	Acceptability determination
Hydroxypropyl methylcellulose	Film-forming agent in glazes for meat and poultry products	Not to exceed 4 percent of the product formulation	Acceptability determination
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
<i>Flavoring Agents</i>			
Potassium acetate	Various meat and poultry products	No to exceed 1.2 percent of the product formulation	Acceptability determination
Sucralose	Non-nutritive sweetener in various non-standardized meat and poultry products	Not to exceed 500 ppm in the product formulation	Acceptability determination
<i>Miscellaneous</i>			
Cellulose (powdered)	To facilitate grinding and shredding in cheese	No to exceed 2 percent of the cheese	Acceptability determination
Erythorbic Acid	To delay discoloration in ground beef and ground beef patties	Not to exceed 0.04 percent of the product formulation (Must be descriptively labeled to distinguish from traditional standardized products)	Acceptability determination
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
Small planktivorous pelagic fish oil	For use as an alternative edible oil in the production of various meat, poultry, and egg products	Not to exceed 6.7 percent of the product formulation	GRAS Notice 000102
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

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
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
Xanthan gum	Suspending agent for carrageenan in a brine tank	Not to exceed 2 percent of the amount of carrageenan	Acceptability determination
Packaging Systems			
Carbon monoxide gas as part of the Pactiv modified atmosphere packaging system (ActiveTech 2001)	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 percent), carbon dioxide (30 percent) and nitrogen (69.6) as part of the Pactiv modified atmosphere packaging system (ActiveTech 2001)	GRAS Notice 000083
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
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
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