

Guidance on
Ingredients and Sources of Radiation Used to Reduce Microorganisms on
Carcasses, Ground Beef, and Beef Trimmings

Purpose

This document is intended to provide guidance to interested parties who wish to use new antimicrobial agents, e.g. organic acids and acidified sodium chlorite or to make new use of antimicrobial agents that are already employed in the production of beef carcasses, ground beef, and beef trimmings, to reduce the presence of pathogenic microorganisms on meat products. This document will provide some background information on the ingredient approval process and the different classes of approved antimicrobial agents, and then provide guidance on the labeling of these substances.

Background

All ingredients and sources of radiation must be determined to be safe and suitable before they can be used in the production of meat and poultry products. On December 23, 1999, the Food Safety and Inspection Service (FSIS) published, in the Federal Register, a final rule entitled "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products." This final rule explained how the Food and Drug Administration (FDA) and FSIS will work together regarding requests for approvals of ingredients and sources of radiation to be used in or on meat and poultry products. The final rule streamlined the approval process by providing for the simultaneous review by FDA and FSIS of requests and petitions. A Memorandum of Understanding (MOU) was implemented in January 2000 that outlines the procedures for such reviews. The final rule, the MOU, and a document entitled "Guidance on the Procedures for Joint Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) Approval of Ingredients Used in the Production of Meat and Poultry Products," which describes the process for approving the use of ingredients in detail, may be accessed through the FSIS Labeling and Additives Policy website at: www.fsis.usda.gov/oppde/larc.

Antimicrobial Agents

Some studies show that certain ingredients provide an antimicrobial effect of reducing the levels of pathogenic microorganisms, such as *E. coli* O157:H7, *Salmonella*, and *Listeria*. Since December 1999, FSIS and FDA have worked together to evaluate and approve or list as safe and suitable food ingredients for use in the production of meat and poultry that have an antimicrobial effect.

Classification of Antimicrobial Agents

Antimicrobial agents can have a momentary or a lasting effect in or on the treated product and, thus, are classified by the technical effect. The technical effect will determine the approval process and the labeling.

Direct Additives

FSIS and FDA regulations allow various meat and poultry products, including ground beef and trimmings, to be treated with direct food additives, e.g., Lactoferrin, a Generally Recognized as Safe (GRAS) substance. Direct food additives are considered ingredients of a product and must be included in the ingredients statement on the product’s labeling. Substances are considered to be ingredient if they remain in the food product and have a lasting effect on the product. Furthermore, because, at present, the standards of identity for ground beef and trimmings are such that these are considered to be single-ingredient raw products, they are not expected by consumers to include other substances, the use of direct additives in these products must be reflected in the product’s name, e.g., “Ground Beef, treated with milk-derived Lactoferrin.” Comminuted beef products that do not have established regulatory food standards of identity may include these ingredients in their formulations without implications for product names.

Secondary Direct Food Additives

Acidified sodium chlorite, peroxyacids, and ozone are examples of substances that have been approved as secondary direct food additives. Secondary direct food additives provide a momentary technical effect and not a lasting effect in the treated food. These substances are ordinarily removed from the final food, and any residuals that may carry over to the final product are not expected to exhibit any technical effect. Thus, they would be considered processing aids under FDA’s definition of that term in 21 CFR, 101.100(a)(3), i.e., there is no lasting functional effect, and there is an insignificant amount present in the finished product under the proposed conditions of use. Even though FSIS has no definition of "processing aid" in its labeling regulations, the Agency, through the Labeling and Consumer Protection Staff (LCPS), which serves as FSIS’ focal point on the use and labeling of food ingredients, makes judgments on a case-by-case basis using FDA’s definition of a processing aid to decide whether the use of a substance is as a processing aid or as an ingredient of a food. If a substance is a processing aid, it need not be declared in the ingredients statement, nor need there be provision for its use in any standard of identity that is applicable to the finished food.

The Table below reflects the currently approved substances for use in the production of meat carcasses, parts, and comminuted products for the purpose of microbial reduction.

Ingredient Name	CFR Reference/Other Reference	Products for Which Application Approved	Classification
Sodium and Potassium Lactate	9 CFR 424.21 (c)	Various meat and poultry products.	Direct food additive
Sodium Citrate buffered with citric acid to a pH Of 5.6	Acceptability determination	Non-standardized comminuted meat and poultry	Direct food additive

		products.	
Sodium Diacetate	9 CFR 424.21 (c)	Various meat and poultry products.	Direct food additive
Lactoferrin	GRAS Notice (FDA Website)	Beef carcasses and parts	Direct food additive
Peroxyacids (a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid)	21 CFR 173.370	Beef carcasses	Secondary direct food additive/Processing Aid
Acidified sodium chlorite	21 CFR 173.325	Carcasses, parts, and trimmings, as well as all processed, comminuted or formed meat food products.	Secondary direct food additive/Processing Aid
Ozone	21 CFR 173.368	All meat and poultry products	Secondary direct food additive/Processing Aid
Sources of ionizing radiation	21 CFR 179.26	Pork, poultry, and beef products as listed.	Food additive

The Use of Organic Acids

One example of how FSIS' approach works is presented by the use of organic acids. Lactic acid, acetic acid, citric acid, ascorbic acid, and other organic acids are approved or listed in FDA regulations for various technical purposes, e.g., as acidulants, antioxidants, flavoring agents, pH adjusters, nutrients, and preservatives. There may also be other uses of these organic acids by non-meat and poultry food processors for which FDA has accepted a determination by the proponent of use of the substance that the use is GRAS. For these uses, FSIS must have from FDA, at the very least, a written statement of no objection with regard to the safety of the use of the substance. The USDA mark of inspection for meat and poultry products reflects a determination by FSIS that the food product is not adulterated, and thus that all ingredients used to make the product must be safe and suitable for the product to receive the mark.

FSIS has specifically approved lactic acid, acetic acid, and citric acid as antimicrobial agents in the final wash that is applied to livestock carcasses after trimming and inspection but before chilling. The Agency's decision about this use of organic acids was based on industry requests that were supported by data that showed that this application of organic acids meets FDA's definition a processing aid (21 CFR 101.100 (a) (3)). Therefore, products made from the organic acid-treated carcasses do not have to declare the organic acids in the ingredients statement on the product label.

Organic acids have also been approved for use in various meat food products for certain technical effects (e.g., as acidulants to adjust pH, flavoring agents, and color preservatives). These uses are listed in the table of approved substances in 9 CFR 424.21 (c). When organic acids are used for the purposes indicated in the table, they are considered to be ingredients of the product since they are in the finished meat food product at a detectable level, and they exhibit a continuing technical effect in or on the meat food product. Therefore, the organic acids must be declared on the label of the meat food product.

If a company is interested in using one or more of these organic acids as an antimicrobial agent on beef trim (i.e., a post-chill application) and does not want to declare the acid in the ingredients statement on the label of the meat food product, they must provide data to LCPS that show that the use complies with FDA's definition of a processing aid. The data must show that the acid is not having a continuing effect on the meat food product. Specifically, the supporting data must show that the fresh color of the meat is not preserved. The product will exhibit normal spoilage indicators (e.g., discoloration); and that there is no extension of shelf life as compared to products made from untreated trimmings. The data must also show that the nutrient composition is not affected by the treatment, e.g., protein is not denatured, and vitamins are not enhanced. The data must address the sensory characteristics (i.e., color and odor) of the product and show that the characteristics are not altered as compared to untreated trim. Finally, there must not be any detectable residues of the organic acid in the meat food product derived from the treated trim.

Occasionally, processors request consideration of the use of ingredients without the need for labeling them on products, e.g., the treatment of meat cuts and ground beef with organic acids. To date, no data have been submitted to LCPS to show that post-chiller applications of these organic acids to carcasses, parts or trimmings are situations that are consistent with FDA's labeling definition of a processing aid. Therefore, these substances would be considered ingredients that are direct food additives when used in this way, and their use in ground beef and trimmings derived from trimmings treated post-chiller would need to be identified on product labeling.

Additional Information

Additional guidance on the use and labeling of ingredients and sources of radiation for use in meat and poultry may be obtained from LCPS at www.fsis.usda.gov/oppde/larc or at (202) 205-0279.