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Guidance on Meaning of "Prohibited Substances" in FSIS Actions on the Use of Ingredients in Meat and Poultry Products

Purpose of the Compliance Guide

This document is intended to provide guidance on "prohibited substances" to interested parties who wish to use new food ingredients (hereafter referred to as "substances") in the manufacture of meat and poultry products.

Prohibited Substances

Title 9 of the Code of Federal Regulations (CFR), Section 424.23, specifically prohibits the use of any substance in or on any meat or poultry product if it conceals damage or inferiority, or makes the product appear to be better or of greater value than it is. One example of this would be the addition of paprika to ground beef or cuts of meat. While the use of paprika in some meat and poultry products is acceptable and expected (e.g., the use of paprika in chorizo, Italian sausage, or barbecued chicken), the addition of paprika to ground beef or cuts of meat is prohibited because it would impart a permanent color to the meat. The addition of paprika in this manner would misrepresent the leanness of the meat (e.g., making it appear to have less fat than a similar package of ground beef or cut of beef without paprika). For this reason, 9 CFR 424.23 specifically prohibits the use of paprika or oleoresin paprika in or on fresh meat, such as steaks; on comminuted fresh meat, such as chopped and formed steaks or patties; or in any other meat consisting of fresh meat (with or without seasoning).

The Food Safety and Inspection Service's (FSIS) regulation on "prohibited substances" covers any potential use of a substance that could be used to conceal damage or mislead consumers. FSIS considers 9 CFR 424.23 each time it evaluates the suitability of a new substance, or a new use of a previously approved substance, under the joint Food and Drug Administration (FDA) and FSIS ingredient approval process. Suitability relates to the effectiveness of the substance in performing the intended technical purpose of use, at the lowest level necessary, and the assurance that the conditions of use will not mislead consumers. For example, the use of preservatives (e.g., sorbic acid) are not permitted on fresh meat because their use could mask spoilage indicators (i.e., make spoiled meat appear fresh). Therefore, FSIS requires data to be submitted on the organoleptic properties (e.g., odor, taste, color and feel) of treated meat whenever the Agency is asked to evaluate a new use of a substance. While the new or expanded use of a substance may not require rulemaking under the joint FDA and FSIS approval process, rulemaking may be necessary where a standard of identity or other Federal regulation prohibits or limits the use of a substance. Currently, for example, potassium sorbate may be added only to dry sausages to retard mold growth. If the addition of potassium sorbate to ground beef is sought, rulemaking might be necessary to include that use.

Ingredient Approval Background

On December 23, 1999, FSIS published in the Federal Register (64 FR 72167) a final rule titled, "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products." This final rule explained how FDA and FSIS will work together regarding future requests for approvals of substances to be used in or on meat and poultry products. The final rule streamlined the process for approving the use of substances in meat and poultry products 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 and the MOU may be accessed through the FSIS Web Site at: http://www.fsis.usda.gov/Regulations_&_Policies/ingredients_guidance/index.asp

The Risk Management Division (RMD) and the Labeling and Program Delivery Division (LPDD) in the Office of Policy and Program Development (OPPD) serve as FSIS' key offices on the use and labeling of substances and on the implementation of the MOU with FDA on joint review and approval of substances. The Office of Food Additive Safety (OFAS) in the Center for Food Safety and Applied Nutrition (CFSAN) at FDA is responsible for leading that agency's regulation of food ingredients and additives, as well as for working collaboratively with FSIS in the implementation of the MOU.

Additional Guidance

Additional guidance on prohibited substances may be obtained from the Labeling and Program Delivery Division at (202) 205-0623.