DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 310, 318, 319, and 381

[Docket No. 88–026P]

RIN 0583–AB02

Substances Approved for Use in the Preparation of Meat and Poultry Products

AGENCY: Food Safety and Inspection Service (FSIS), USDA.

ACTION: Proposed rule.

SUMMARY: FSIS is proposing to amend the Federal meat and poultry inspection regulations to harmonize and improve the efficiency of the procedures used by FSIS and the Food and Drug Administration (FDA) for reviewing and approving the use of substances in meat and poultry products. Under the proposed procedures, FSIS would no longer issue its own regulations listing substances it finds suitable for use in meat and poultry products. Instead, by agreement between USDA and the FDA, future FDA regulations would specify whether a substance approved for use in foods under the Federal Food, Drug, and Cosmetic Act (FFDCA) may be used in or on meat or poultry products. Current FDA regulations that approve the use of substances in foods generally and do not preclude meat and poultry uses will confer authority to use such substances in meat and poultry products unless expressly prohibited by USDA regulation.

Requests for meat and poultry uses of substances not permitted under title 9 or title 21 of the Code of Federal Regulations (CFR) would have to be made to FDA in the form of a petition for FDA approval. FDA is simultaneously publishing in this issue of the Federal Register a proposal that would amend the FDA regulations governing the review of petitions for the approval of food additives to provide for simultaneous review of such petitions by FSIS when meat or poultry product uses are indicated. This would permit FDA listings to specify whether, and if so under what conditions, such substances may be used in USDA-inspected meat and poultry products. Such listings would eliminate the need for separate FSIS rulemaking.

FSIS would limit any future, substance-specific rulemaking to prohibitions or limitations on meat or poultry uses of specific substances that may be necessary to protect the public under the Federal Meat Inspection Act (FMIA) or Poultry Products Inspection Act (PPIA). FSIS would continue to provide evaluations upon request as to whether substances permitted for general use under current regulations are suitable for specific uses in meat and poultry products.

FSIS proposes to adopt the position that substances that are listed in title 21, CFR, Parts 182 and 184, as generally recognized as safe (GRAS) for use in food generally, with no limitation other than good manufacturing practice, would be accepted by USDA as GRAS for use in meat, meat food products, and poultry products generally, unless otherwise restricted for such use by regulation in title 9, CFR. Other GRAS substances currently permitted for general food use would be evaluated by FSIS as to their suitability for specified uses in meat food products and poultry products on a case-by-case basis, in consultation with FDA as appropriate.

DATES: Comments must be received by February 27, 1996.

ADDRESSES: Written comments to: Diane Moore, Docket Clerk, Room 4352, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments, as provided under the Poultry Products Inspection Act (PPIA), should be directed to Mr. Ralph Stafko at (202) 720–8168. (See also ''Comments'' under **SUPPLEMENTARY INFORMATION**.)

FOR FURTHER INFORMATION CONTACT: Mr. Ralph Stafko, Deputy Director, Policy Evaluation and Planning Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; (202) 720–8168.

SUPPLEMENTARY INFORMATION:

Comments

Interested persons are invited to submit comments concerning this proposal. An original and two copies of written comments should be sent to the Docket Clerk's office at the address shown above and should refer to docket number 88–026P. Any person desiring opportunity for oral presentation of views, as provided under the PPIA, should make such request to Mr. Stafko at (202) 720–8168 so that arrangements may be made for such views to be presented. Copies of all comments submitted in response to this proposal will be available for public inspection in the office of the Docket Clerk between 8:30 and 1:00 a.m. and between 2:00 and 4:00 p.m., Monday through Friday.

Background

FDA and FSIS are both regulatory agencies mandated to protect consumers from adulterated or misbranded food products. FDA, under the FFDCA, is responsible for regulating foods generally. FSIS, under the FMIA and the PPIA, regulates products consisting wholly or in part of meat or poultry.

Products regulated by FSIS, for the most part, include those containing at least 2 percent cooked or 3 percent raw poultry or red meat. Products that contain meat or poultry only in condimental quantities or that historically have not been regarded as meat or poultry products are not regulated under the inspection Acts. Examples of such products are some cheese spreads with meat, close-faced sandwiches, bouillon cubes, and dried or dehydrated meat soups.

Even though FDA and FSIS have a common food safety mission, they have differing statutory mandates and carry out their individual statutory mandates in different ways. FDA relies primarily on the promulgation of and compliance with regulations to implement its mandate concerning substances intentionally added to food, such as food additives and color additives. FDA also relies on inspections of food manufacturing and storage facilities to enforce its statutory mandates relating to sanitation and conditions of manufacture and storage. Detection and seizure of violative products, and sanctions imposed on producers or manufacturers responsible for violations are based on evidence that violative product (or a component of the product) was introduced into interstate commerce.

The FMIA and PPIA (21 U.S.C. 601 et seq.; 21 U.S.C. 451 *et seq.*) require that meat and poultry products be inspected, and USDA inspection program personnel inspect such products before the products are placed in commerce. The USDA mark of inspection is placed only on those products found by USDA to be unadulterated and properly labeled. Thus, FSIS's primary enforcement activity is the conduct of inspection activities designed to prevent the production and distribution of adulterated or misbranded products. FSIS regulations on products under its jurisdiction are enforced primarily by inspectors and inspection program support staff on a plant-by-plant basis. Inplant FSIS personnel may retain suspect product and condemn adulterated product. In egregious cases, FSIS may withdraw inspection from plants.

This different approach to regulation, based on the statutes governing the activities of the respective agencies, has required FSIS and FDA, and their predecessor agencies, to work together closely to minimize the potential for