

requesting approval of the use of substances in meat or poultry products.

5. When petitioned, conduct rulemaking that would permit under the FFDCA use of a substance in meat or poultry, including those restrictions or conditions of use in meat or poultry products that are recommended in writing by FSIS, and for which there are data or other information establishing that the use of the substance is safe and not deceptive. FDA will also consult with FSIS on any comments received on petitions regarding meat or poultry uses.

C. FSIS and FDA jointly agree:

1. That the officials of the two Agencies responsible for implementing the Agreement are:

At FSIS: the Administrator and Deputy Administrators (as may be designated); Director, Product Assessment Division; Branch Chief, Food Standards and Ingredients Branch.

At FDA: Director, Center for Food Safety and Applied Nutrition; Director, Office of Pre-Market Approval.

2. That the responsible officials will concur on rulemaking documents that, when published by FDA, will list or amend listings of substances permitted for use in meat and poultry products.

3. That the Administrator of FSIS and the Director, CFSAN, FDA, shall resolve problems and make decisions by consensus in areas of disagreement.

VI. Conflict Resolution

Each Agency reserves the authority to review, independently of the other, matters of concern to their respective authorities. However, written notice will be provided to the Commissioner of Food and Drugs and to the Under Secretary for Food Safety, USDA, of any rulemaking initiative not in keeping with the provisions of this MOU or about which there is an interagency disagreement, prior to public announcement of the rulemaking.

VII. Other Agreements

A. The provisions of this MOU are not intended to add to or detract from any of the authorities provided to either FDA or FSIS by the FFDCA, FMIA, or the PPIA, or the regulations by which these laws are implemented.

B. FSIS and FDA may enter into additional, separate agreements with each other as they deem appropriate to achieve the objectives of this MOU.

VIII. Duration of MOU

This Agreement becomes effective upon acceptance by both Agencies and will continue indefinitely. It may be modified by mutual written consent or terminated by either agency with a 30-day written notice to the other agency.

Signed:

Director, CFSAN, FDA

Date

Administrator, FSIS

Guidelines for Acceptability Determinations for New Substances and New Uses of Substances in Meat and Poultry Products

The evaluation by FSIS of the acceptable use of a new substance or new use of a substance in meat and poultry products subject to this MOU will be based on the following conditions that must be addressed by the requester. The conditions set forth are in accordance with the provisions for use of substances in 9 CFR and 21 CFR.

1. The substance has a documented history of use in foods.

2. The substance is derived from food or a food ingredient and is not considered to be a chemical or synthesized additive.

3. The process for manufacturing the substance does not result in a severe alteration of the molecular structure resulting in the formation of a chemical residue whose safety has not been shown.

4. The safety of the substance has been evaluated by an independent authority and adequate safety data have been presented.

5. The suitability and efficacy of the substance have been shown through adequate data submission. The lowest level of the substance necessary to achieve the intended functional effect must be shown and the use cannot render the products to which the substance is intended for use adulterated or misbranded.

6. The FDA has determined the common or usual name of the substance(s).

7. FDA must concur with FSIS's determination of acceptability in order to allow use.

[FR Doc. 95-31390 Filed 12-26-95; 3:36 pm]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 301, 304, 305, 306, 307, 318, 325, and 381

[Docket No. 95-008A]

RIN 0583-AB89

FSIS Agenda for Change: Regulatory Review

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Advance Notice of Proposed Rulemaking; Request for Comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) has begun a comprehensive review of its regulatory procedures and requirements to determine which are still needed and which ought to be modified, streamlined, or eliminated. This review is an integral part of the FSIS initiative to improve the safety of meat and poultry products by modernizing the Agency's system of food safety regulation. It also moves beyond the page-by-page review of FSIS regulations carried out earlier this year under the

President's Reinvention of Government Initiative. A thorough review of FSIS's regulations is needed to prepare for implementation of the Agency's proposed Hazard Analysis and Critical Control Points (HACCP) regulations and a new food safety strategy that will reduce reliance on command-and-control regulations and increase reliance on science-based preventive measures and performance standards to improve food safety. This review and any changes in FSIS regulations that are necessary to make them compatible with HACCP will be completed prior to implementation of HACCP. FSIS invites comment from the public and all interested parties on the Agency's preliminary review of its regulations and specific suggestions on which regulations need to be eliminated or changed to be compatible with HACCP, and how they should be changed, or to achieve Reinvention of Government goals of having fewer, clearer, and more user-friendly regulations.

Some of the rulemakings needed to streamline existing requirements and carry out the FSIS food safety strategy are being initiated or effectuated in documents that appear elsewhere in this issue of the Federal Register: A proposed rule that would eliminate the FSIS prior approval system for substances added to meat and poultry products; a proposed rule that would facilitate marketing of nutritionally improved alternatives to standardized meat and poultry food products; and a final rule streamlining the prior approval system for meat and poultry labels.

As FSIS progresses in its comprehensive regulatory review, FSIS will publish further proposals to eliminate unnecessary regulations and modify remaining regulations, replacing, to the extent possible, command-and-control regulations with performance standards, clarifying the role of inspectors in enforcing those standards, and reorganizing and simplifying the regulations to make them easier to understand and use.

DATES: Comments must be received on or before February 27, 1996.

ADDRESSES: Please send an original and two copies of written comments to Policy, Evaluation, and Planning Staff, Attn: FSIS Docket Clerk, DOCKET No. 95-008A, Room 4352 South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments, as permitted under the Poultry Products Inspection Act, should be directed to the person listed under **FOR FURTHER INFORMATION CONTACT**.