All products in which the substance would be used would be required to be properly labeled and subject to other applicable requirements of the meat and poultry products inspection regulations.

This ''fast-track'' listing procedure did result in time and resource savings by both FSIS and the industry. In August 1988, however, FSIS discontinued its fast-track procedures because of concerns that the procedures might not satisfy the requirements of the Administrative Procedure Act.

While reverting to notice-and-comment procedures for these rulemaking proceedings, FSIS also decided to investigate other means of reducing the rulemaking burden. FSIS concluded that duplicative rulemaking could be avoided if all relevant FMIA and PPIA issues could be resolved in the context of the rulemaking proceeding already required under the FFDCA and conducted by FDA. This proposed rule was conceived at that time, was agreed upon in principle by FDA, and is now being published for public comment.

Comments submitted in response to USDA's February 25, 1992, notice (57 FR 6483) requesting public comments on how Departmental regulations can be improved, updated, or streamlined, support the Agency's decision to initiate this proposed rulemaking. In a March 13, 1992, letter, the American Meat Institute (AMI), an organization representing meat packers and processors of meat and meat food products, noted that the ''industry's current inability to use a wide variety of safe food ingredients'' because of the Agency's regulatory procedures prevents the use of least-cost formulations and impedes product development. The organization estimated that ''direct costs associated with pursuing unnecessary regulatory changes may exceed $100,000, and such proceedings generally delay introductions of new products for several years.''

Proposed New Policy

FDA and FSIS have agreed on a proposed new procedure for regulating substances intended for use in meat and poultry products. Under this new procedure, FSIS inspection program personnel will permit meat and poultry use of substances if such uses are permitted under FDA regulations, unless otherwise restricted or prohibited by other FDA regulations or FSIS regulations.

FSIS will no longer issue regulations to list substances found by the Agency to be acceptable for certain uses in meat and poultry product. Instead, the Agency will refer to FDA regulations in order to determine whether a substance may legally be used in or on a meat or poultry product.

A key point of this new procedure, reflecting provisions of the FMIA and PPIA and the intent of previous rulemakings, is that substances added to meat and poultry products, including GRAS or prior-sanctioned substances, must be permitted under the FFDCA and be used consistently with any applicable regulations.

Under the proposed procedure, FSIS will be exercising the same authority and continuing the same reviews that it has been conducting all along.

FSIS, in carrying out the mandates of the FMIA and PPIA, has published regulatory requirements and guidelines in the areas of facilities, equipment, sanitation, and production and process controls that apply to establishments where meat, meat food, and poultry products are prepared for distribution in interstate or foreign commerce. As it has in the past, when FSIS must decide on the acceptability of a substance approved by FDA for general food use, it will seek FDA concurrence.

In its future regulatory listings of substances and after consultation with FSIS, FDA will include, as appropriate, the amounts and uses of substances permitted for use in meat and poultry products.

This is consistent with current FDA listing format. FDA's determination of the acceptability of any food additive or GRAS substance use is conditioned on the substance being used in accordance with GMP. The general regulations for determining GMP criteria are set forth in 21 CFR part 110. These regulations set minimum general requirements for buildings, facilities, equipment, sanitation, and production and process controls to be observed in food plants where products are prepared for distribution in interstate or foreign commerce. Further GMP criteria are set forth in 21 CFR part 172 for food additives, 21 CFR part 182 for GRAS substances, and 21 CFR part 184 for substances affirmed as GRAS.

FSIS's title 9 listing of authorized substances is incomplete, inconsistent with, and duplicative of FDA's listings. The Agency plans to eliminate its current listings over time by rulemaking, as listings are determined to be duplicative of FDA regulations. However, FSIS will retain its own regulations on specific substance use prohibitions and will add new prohibitions as necessary.

To provide guidance to its inspectors, inspected establishments, and other interested persons, FSIS will maintain a comprehensive listing, in its directive system, of substances authorized for meat and poultry uses under title 9 or title 21, CFR. FSIS's listing will include:

a. Substances currently listed in title 9;

b. Substances currently listed for meat or poultry uses in FDA food additive, GRAS, or prior-sanction listings;

c. Approved color additives currently listed in 21 CFR Parts 73, 74, and 82, food additives listed in 21 CFR Parts 172–173 and 180, prior sanctioned substances listed under part 181, GRAS substances listed in 21 CFR 182 and 184, if permitted for general use in or on foods (which includes meat and poultry) in accordance with good manufacturing practice, unless meat or poultry uses of the substances are otherwise precluded;

d. GRAS substances found by FSIS to be suitable for specified meat and poultry uses on the basis of information and data submitted by petitioners to FSIS. Factors affecting FSIS findings of suitability include:

(1) Existing FDA GRAS listings, which need not explicitly permit but may not preclude the specific use in meat or poultry products; and

(2) Concurrence of FSIS with the petitioner and FDA acceptance of FSIS's determination.

e. FDA food additive, color additive, GRAS, and prior-sanctioned substance listings promulgated after this proposal becomes final that provide for meat and poultry uses.

Requests for use of substances not authorized for use in meat and poultry products must be made to FDA in the form of a petition to amend FDA food additive, color additive, or GRAS affirmation regulations, as appropriate. Specifically, this is required when the substance: (1) is not expressly listed for meat and poultry uses in title 9, CFR, or in title 21, CFR, Parts 172–180; (2) is not a GRAS substance listed in Part 182 or 184 of title 21 for general use in foods; and (3) cannot be demonstrated to FSIS to be GRAS for particular meat or poultry uses.

The working relationship between the two agencies, as set forth in the memorandum of understanding (MOU) between them, would ensure FDA and FSIS collaboration on any petition that includes a use in meat or poultry products.

The Administrator of FSIS would retain legal authority to prohibit or restrict the use of specific substance(s) in meat or poultry products by notice-and-comment rulemaking, but is not expected to have to exercise that authority on a regular basis because FDA's statutory authority, exercised in