accord with the MOU, would provide a basis for appropriate limitations on uses in meat and poultry products.

The Proposed Rule

Under this proposal, FSIS would discontinue duplicative rulemaking activity regarding food additive and GRAS substance uses in meat and poultry products. FSIS would amend the Federal meat and poultry products inspection regulations in 9 CFR, Parts 310, 318, 319, and 381 to include appropriate cross-references to title 21 listings of food additive and GRAS substances permitted for use in meat and poultry products.

Substances whose use is GRAS are exempt from the premarket approval requirements of the FFDCA and need not be listed in title 21 of the Code of Federal Regulations. For substances that have not been listed by FDA as GRAS in Parts 182 or 184 of title 21, FSIS will continue to consider, in consultation with FDA, a manufacturer's basis for claiming GRAS status and suitability for use in meat, meat food, or poultry products. Likewise, a manufacturer has the option of seeking advice from FSIS regarding the suitability for specific uses in meat, meat food, or poultry products for substances listed in title 21 only for general use in foods, or for use in meat, meat food, or poultry products generally. FSIS's responses and related correspondence would be available to the public, except that the formulation and process data for proprietary mixtures would be kept confidential. Parties requesting such evaluations would be advised to petition FDA when the requested use is not permitted under FDA's regulations.

In keeping with this approach, FSIS proposes that, as a matter of policy, all substances currently listed by FDA as GRAS in title 21 of the CFR, Parts 182 and 184, for use in food generally, with no limitation other than good manufacturing practice, be considered by USDA to be GRAS for use in meat, meat food product, and poultry product, unless otherwise restricted for such use by regulation in title 9 of the CFR. Uses of substances may be restricted by FSIS standards of identity or composition, or in specific cases where the inspection program determines that use may adulterate the product.

Existing FSIS regulations in 9 CFR 318.7 and 381.147 listing substances for various meat and poultry uses would not be immediately affected. However, FSIS plans to review its title 9 listings within the next 3 to 5 years, and to eliminate those that duplicate FDA's title 21 listings. FSIS and FDA believe that the public will be better served by having all permitted uses for food additives and GRAS substances consolidated in one place—listings in title 21 of the CFR—and intend to work toward that end. Because of resource constraints, at the present time FDA regulations in title 21 will be amended to accommodate meat and poultry uses only in response to a food additive, color additive, or GRAS affirmation petition.

All petitions for rulemaking to permit new substances or new uses or use levels of substances in foods—including meat and poultry products—would be sent to FDA. FDA would evaluate the petitions in consultation with FSIS if any prospective use of a food additive, color additive, or GRAS substance includes use in meat, meat food, or poultry products.

The proposed revisions of 9 CFR 310.20 and 318.1 are intended only for the purpose of including appropriate references to substance listings in title 21, CFR. They would not change the substantive requirements governing the saving of livestock blood or the labeling of containers. Similarly, the proposed revision of 9 CFR 318.7(d)(2) is intended only for the purpose of adding a reference to title 21, CFR, and would not change the prohibitions of and restrictions on the substance uses provided in that paragraph.

The proposed 9 CFR 318.7(a)(4), 318.7(a)(5) and 381.147(f)(2)(iv) are intended to provide addresses for inquiries concerning food or color additive status of substances intended for use in or in contact with meat or poultry products. The proposed 9 CFR 318.79(a)(5) and 381.147(f)(2)(v) are intended to provide addresses for inquiries on the suitability for use in meat or poultry products, of substances not listed in the title 21 regulations. These provisions are not intended as requirements for a petitioning or petition review process.

Appended to this proposed regulation is a copy of the draft Memorandum of Understanding between FDA and FSIS, which would provide for the administration of these provisions.

Executive Order 12866

This proposed rule has been reviewed under Executive Order 12866 and found to be significant, but not economically significant, within the meaning of the Executive Order (sec. 3(f)). It is significant because it is a novel, collaborative, inter-Agency approach to streamlining regulation. It decreases regulatory and paperwork burdens on society by proposing an alternative to the current Government process of approving substances for use in foods.

This proposal would replace the current Government processes for approving substances and their uses in meat and poultry products, involving consecutive rulemakings by FDA and FSIS, with a ''one-stop'' procedure whereby sponsors of new food additive or other substance uses in meat and poultry products would have to petition only the FDA. FDA would conduct any required rulemaking on the matter in consultation with FSIS. FDA's rule would then specify any uses or use restrictions unique to meat or poultry products, thereby permitting use of the substance under the FMIA and PPIA.

This proposal embodies the regulatory philosophy and principles of Section 1 of the Executive Order and was the result of a review of existing regulations consistent with the direction in section 5. It modifies existing FSIS regulations concerning the approval of substances to be added to meat, meat food, and poultry products that have been found to result in needless duplication of effort and expenditures by Government and the regulated industry. These regulations necessitate sequential rulemakings by FDA and FSIS to permit a new substance or a new use of a previously approved substance to be used in meat, meat food, or poultry products. The costs to industry and Government of these rulemaking procedures includes the costs to industry arising from a several years' delay in the introduction of new food additives or new food products. These costs create a disincentive for technological innovation and new product development. The existing process, therefore, has a negative effect on economic growth.

Benefit-Cost Assessment

The public benefits conferred by the rulemaking include, principally, those associated with the more timely regulatory approval of substances added to foods and the benefits of the substances themselves. The benefits of substances added to meat and poultry products include the technical effects on the characteristics of food products, the uses of the substances in food processing, and a greater variety of foods in the marketplace. Public health benefits can include the greater availability of food through preservation techniques and improved food safety through, for example, antimicrobial treatment of raw product and the use of curing solutions in processed products. The benefits conferred by the availability of substances and their uses would be marginally increased by this rulemaking.