The public benefits of regulating food additives generally would not change. These include, principally, the prevention of adulteration or misbranding of food products. Consumers are provided assurance that the products they buy do not contain substances whose use ought, for various reasons, to be prohibited, or substances that have been approved have not been used improperly in foods. Such benefits would not be affected by this proposed rulemaking because FDA would continue to conduct food safety reviews of substances proposed for use in foods, including—in consultation with FSIS—meat and poultry products, and FSIS would continue to exercise its in-plant inspection and other regulatory authorities to prevent the marketing of adulterated or misbranded meat and poultry products.

Therefore, elimination of the duplicative FSIS rulemaking process involved in approving substances for use in meat and poultry products could save the regulated industry about $600,000 a year over and above the savings the Government itself would realize in administrative costs.

Other, albeit less calculable benefits arise through the removal of a disincentive to innovate. With the potential expansion of uses of approved food additives and other substances that could result from the easing of the current regulatory burden, new product development and marketing could be encouraged.

Executive Order 12778

This proposed rule has been reviewed pursuant to Executive Order 12778, Civil Justice Reform. This proposed rule would provide for the use in meat and poultry products of substances approved by FDA and listed in 21 CFR for such uses, and would eliminate the requirement in the current 9 CFR 318.7(a) and 381.147(a) listing of such uses in 9 CFR 318.7(c)(4) or 381.147(f)(4).

States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any requirements with respect to federally inspected premises and facilities, and operations of such establishments, that are in addition to, or different than, those imposed under the FMIA or PPIA. States and local jurisdictions are also preempted under the FMIA and PPIA from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat or poultry products that are in addition to, or different than, those imposed under the FMIA or the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat or poultry products that are misbranded or adulterated under the FMIA or PPIA or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. States and local jurisdictions may also make requirements or take other actions that are consistent with the FMIA and PPIA, with respect to any other matters regulated under the FMIA and PPIA.

Under the FMIA and the PPIA, States that maintain meat and poultry inspection programs must impose requirements on State-inspected products and establishments that are at least equal to those required under the FMIA or PPIA. These States may, however, impose more stringent requirements on such State-inspected products and establishments.

In the event of its adoption, no retroactive effect would be given to this proposed rule, and applicable administrative procedures must be exhausted before any judicial challenge to the application of these provisions. Those administrative procedures are set forth in 9 CFR 306.5, 318.21(h), 381.35, and 381.153(h).

Effect on Small Entities

The Administrator, FSIS, has determined that the proposed amendments would not have a significant economic impact on a substantial number of small entities. Obtaining approval for the use in meat and poultry products of new substances or for new uses of previously approved substances would be simpler, faster, and less costly for both industry and the Federal Government than under the current system.

FSIS now may approve for use in meat or poultry products only those substances that have been previously reviewed for safety and approved for such use by FDA. Under the proposed amendments, separate petitions to FSIS would no longer have to be submitted. FSIS would permit substances to be used in products under its jurisdiction on the basis of FDA's title 21 regulations permitting such uses. Those substances not authorized for meat and poultry use under existing FDA regulations would require only one petition for rulemaking—to FDA. (For a substance that is not affirmed by FDA as GRAS or otherwise listed in 21 CFR part 182 or 184, or a substance listed by FDA for general food use, manufacturers would have the option of requesting that FSIS evaluate the manufacturer's assertion of the GRAS status of the substance and its suitability for a specified use in meat and poultry products.)

FSIS is currently receiving about six petitions per year for the approval of substances for use in meat and poultry products. Most of these petitions are from large commercial entities. Although the reduction in costs from the proposed rule would be significant, but unknown, for prospective petitioners, the number of such entities is not substantial. Therefore, the proposed amendments would not have a significant effect on a substantial number of small entities.

Furthermore, all users of the Federal regulations concerning the addition of substances to foods should benefit by having fewer, clearer regulations. Thus, there would be a reduction in the duplication of effort and attendant costs for all concerned.

Paperwork Reduction Act

FSIS has determined that the proposed rulemaking would entail no new information collection from the regulated industry or other private entities. Rather, the effect of the rulemaking would be to substantially reduce the information collection from private sources concerning proposed uses of substances in meat or poultry products. Persons seeking Federal Government approval of substances for use in meat or poultry foods would only have to petition FDA, rather than both FDA and FSIS, as they now do. Thus, a current, duplicative information collection requirement would be eliminated.

List of Subjects

9 CFR Part 310

Animal diseases, Meat inspection.

9 CFR Part 318

Food additives, Meat inspection.

9 CFR Part 319

Food grades and standards, Meat inspection.

9 CFR Part 381

Food grades and standards, Meat inspection, Poultry and poultry products.

For the reasons set forth in the preamble, FSIS proposes to amend Parts 310, 318, 319, and 381 of title 9, Code of Federal Regulations, as follows:

PART 310—POST-MORTEM INSPECTION

1. The authority citation for Part 310 would be revised to read as follows: