

have found the ingredients to be safe and suitable in the production of products that are subject to such standards, and if the standards and other applicable regulations already allow the use of these types of ingredients in the preparation or processing of the products.

FSIS has determined that conducting rulemaking to amend individual food standards of identity to permit the addition of new ingredients on a case by case basis is not an efficient use of Agency resources and results in unnecessary delays for the use of safe and suitable binders and antimicrobial agents by meat and poultry establishments. Therefore, the objectives to be accomplished by this direct final rule is to provide for efficient use of Agency resources and to provide establishments greater flexibility in the formulation of meat and poultry products with a standard of identity and composition in 9 CFR parts 319 and 381 which already permit the use of ingredients of these types.

With the implementation of this direct final rule, establishments that prepare or process meat or poultry food products for which a standard of identity or composition provides for the use of binders or antimicrobial agents will be able to choose from a larger number of antimicrobial agents or binders than at present when formulating their products. Even though the standardized products will be permitted to contain these new antimicrobial agents or binders, the products will continue to be identified by the same standardized product names. The establishments thus would benefit from continued consumer acceptance of their products.

Executive Order 12988

This direct final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This direct final rule: (1) Preempts all state and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Executive Order 12866 and Regulatory Flexibility Act

This direct final rule has been reviewed under Executive Order 12866. It has been determined to be not significant for purposes of E.O. 12866 and therefore, has not been reviewed by the Office of Management and Budget (OMB).

Effect on Small Entities

Costs associated with this direct final rule will be voluntary. Establishments can be expected to assume such costs only if it would be profitable for them to do so. The direct final rule will not mandate any changes in the way meat food or poultry products are produced or labeled. The rule will increase the availability to establishments of antimicrobial agents and binders that may be added to standardized meat food and poultry products without prolonged regulation development processes to amend food standards. Establishments that choose to prepare or process products that contain antimicrobial agents or binders will continue to incur the normal costs of production, labeling, and marketing.

This direct final rule will not impose any new requirement on small entities but will provide them with greater flexibility in the use in their products of antimicrobial agents and binders. The decision to use a new antimicrobial agent or binder in the production of standardized meat and poultry products is strictly voluntary. The rule could benefit as many as 1,150 federally inspected establishments. Most of these establishments—almost 900—are small operations, each employing fewer than 500 persons. If States operating meat or poultry inspection programs for products in intrastate commerce that are “equal to” the Federal program for products in interstate commerce issue similar regulatory amendments, an additional 1,100 establishments could benefit. Nearly all the State-inspected establishments are small business entities.

Paperwork Requirements

Abstract: Establishments choosing to take advantage of the flexibility of this rule by changing their product formulations to include different antimicrobial agents or binders would have to change their labels. In most cases, the label changes will be subject to the provisions for generically approved labeling in 9 CFR 317.5 and 381.133 because the changes will apply to products with standards of identity. That means that the label changes would not entail prior review and approval by FSIS before the new labels could be used. In most cases, the changes involved will be limited to changes in the statement of ingredients. A small percentage of the establishments affected by this rule may find that they need to revise and revalidate their HACCP plans.

Estimate of Burden: FSIS estimates that it will take at most one hour to

develop a modified label. As many as 300 federally inspected establishments, principally establishments that manufacture products that are heat-treated, not-fully-cooked, and not shelf-stable would be more likely to consider changes, such as the addition or substitution of an antimicrobial agent, that might entail a reassessment of their HACCP plans. For example, an establishment wishing to add an antimicrobial to its product formulation, or substitute another approved antimicrobial for one that the establishment is already using, may have determined that such a change in product formulation would improve product safety. If so, FSIS estimates that it may take up to two hours for an establishment to reassess its HACCP plan as a result of a formulation change.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this direct final rule, FSIS will announce it and make copies of this **Federal Register** publication available through the FSIS Constituent Update. FSIS provides a weekly Constituent Update, which is communicated via Listserv, a free e-mail subscription service. In addition, the update is available on-line through the FSIS web page located at <http://www.fsis.usda.gov>. The update is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent Listserv consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through the Listserv and Web page, FSIS is able to provide information to a much broader, more diverse audience.

For more information contact the Congressional and Public Affairs Office, at (202) 720-9113. To be added to the free e-mail subscription service (Listserv) go to the “Constituent Update” page on the FSIS Web site at <http://www.fsis.usda.gov/oa/update/update.htm>. Click on the “Subscribe to the Constituent Update Listserv” link, then fill out and submit the form.

List of Subjects

9 CFR Part 319

Food Standards, Meat Inspection.