approval of food additives and color additives is based on reviews of data and other information establishing the safety of the substance for its intended use in food. To approve a food additive, the Agency must also determine that the food additive achieves its intended technical effect; to approve a color additive, the Agency must also determine that the color additive is suitable for its indended use. However, these criteria are not sufficient to establish the suitability of such additives for use in meat or poultry products. Subsequent FSIS approval is based primarily on review of data regarding the efficacy and suitability of the substance for its intended use in meat and poultry products that FSIS regulates under the FMIA and PPIA. FSIS requires data that support the lowest level of the subject substance(s) needed to achieve the intended effect. FSIS is charged with ensuring the safety of inspected products. However, with respect to the safety of food and color additives that may be used in those products, FSIS defers to FDA determinations under the FFDCA.

In light of the foregoing regulatory context, FDA and USDA/FSIS have concluded:

A. The duplicative, sequential approval process for substances intended for use in meat and poultry products is unnecessarily cumbersome, time-consuming, and costly to all parties involved, and has fostered confusion over the relationship between FDA and FSIS regulations.

B. Consolidation and harmonization of the Agencies' approvals in this regard will result in fewer and more consistent Federal approval regulations for substances used in food, and will provide simpler and less expensive procedures for petitioners seeking approval of substances under the FMIA and PPIA.

C. This Memorandum of Understanding should clarify the Agencies' working relationship and, in particular, provide procedures whereby:

1. In situations where FSIS's Title 9 and FDA's Title 21 regulations do not specifically address the intended use of a particular substance for meat or poultry products, any interested party may request that FSIS evaluate the status of such use. FSIS will conduct a review and determine whether the use is acceptable in meat or poultry products, including whether the use is approved under the FFDCA. Under the terms of this MOU, FSIS would seek FDA's concurrence with FSIS's review and conclusions. If FDA does not concur that the use is approved under the FFDCA, the petitioner would be required to submit a food additive or color additive petition to FDA requesting that FDA's regulations be amended to accommodate the requested use.

2. In situations in which FDA receives a petition for the use of a substances or a use of a substance that is not approved under the FFDCA, a petitioner shall prepare and submit a food additive petition or a color additive petition only to FDA. FDA will consult with FSIS regarding petitions for meat and poultry use and, under the terms of this MOU, FSIS concurrence would be required for the approval of the use of substances intended for use in meat and poultry and that are codified in Title 21 of the Code of Federal Regulations.

D. This agreement and these procedures are not intended to erode the existing authority of FDA or of FSIS to provide guidance on the status and conditions of use of substances intended for use in meat and poultry.

III. Scope

This agreement between FSIS and FDA concerns procedures for Federal approval of food additives, color additives, and other food ingredients that are regulated by FDA under the FFDCA and may be used in meat and poultry products that are subject to the FMIA and the PPIA. This agreement further provides for the review and classification, as needed, of substances asserted to be exempt from regulation under the FFDCA because they are generally recognized as safe, or are covered by a prior sanction.

IV. Collaborative FSIS—FDA Approvals of Substances Intended for Use in Meat and Poultry Products

A. Petitions for FDA approval of Substances Intended for Use in Meat and Poultry Products.

Relevant portions of petitions submitted to FDA for the use of new substances or new uses of approved substances will be shared with FSIS by FDA when the proposed use specifically includes use in meat and poultry products. FSIS will provide advice to FDA, in writing, on any criteria, restrictions, conditions of use, or prohibitions FSIS believes necessary concerning use of the substance in products subject to the FMIA and the PPIA.

B. Requests for FSIS Determination on Acceptability of Substance Uses in Meat and Poultry Products.

FSIS routinely provides advice and counsel to individuals and issues guidance on the status and conditions of use of substances in products under its regulatory purview. Requests for a determination of the acceptability of substances may result in the need for rulemaking when: (1) FSIS standards of identity and composition preclude the use of a substance; or (2) there is concern about the suitability of a substance for the intended use because the substance has never been used in meat or poultry before, or the applications of the substance are new, e.g., a new meat, meat food, or poultry product category.

Requests for a determination of acceptability of new substances and new uses of substances in meat and poultry products are currently submitted by the requester (e.g., an ingredient manufacturer, meat or poultry processor, or trade group) to FSIS. FSIS will continue to require that a request for an acceptability determination for the use of a new substance in meat or poultry or for the new use of an approved substance be supported by information and technical data that establish that: (1) the use of the substance will not render the product in which it is used adulterated or misbranded and (2) the proposed use of the substance is at the lowest level necessary to accomplish the intended technical effect(s) in each category of the product in which the substance will be used.

Under the terms of this memorandum, when FSIS receives a request for a determination on whether the use of a substance in meat or poultry will be permitted, FSIS will evaluate the request and render a determination of acceptability (i.e., safety and suitability). In instances where the use of the requested substance is not explicitly authorized by FDA regulations, FSIS will consult with FDA concerning FSIS's evaluation of the regulatory status of the food ingredient. If FDA has no objection to FSIS's determination, FSIS, through its Product Assessment Division (PAD), will amend Agency directives and other guidance materials to reflect the approved use. If FDA objects to FSIS's determination, the request will be denied and the requester will be advised to petition FDA to amend FDA's regulations to permit the use of the substance at issue.

V. The Agreement

A. FSIS will:

1. Receive requests for evaluation of the acceptability of new substances and new uses of approved substances for use in meat and poultry products subject to the FMIA and PPIA.

2. Through the activities of the PAD, review all data submitted in support of requests for ingredient use and, in consultation with FDA, make acceptability determinations on use in meat and poultry products. FSIS's Regulatory Programs will seek written concurrence from FDA's Center for Food Safety and Applied Nutrition on FSIS acceptability determinations before use is granted and the substance is listed in FSIS directives or other guidance material. If use of a substance is not found to be acceptable, the requester will be advised to submit a petition to FDA to approve the use of substance in meat or poultry products.

3. Forward to FDA all food and color additive petitions and petitions for affirmation of GRAS status for use of such substances in meat or poultry products.

4. Respond in a timely manner to inquiries from FDA regarding petitions or requests for approval of the use of food additives, color additives, or GRAS substances or new uses of such substances in meat and poultry products regulated under the FMIA and PPIA.

5. Continue to provide advice and counsel on, and clarification of, the acceptability and uses permitted under the FMIA and PPIA of substances used in meat and poultry products.

B. FDA will:

1. Receive petitions for approval of substances intended for use in foods, including meat or poultry products regulated under the FMIA and PPIA.

2. Advise interested persons if a petition is needed to amend FDA regulations to accommodate the requested uses.

3. Advise FSIS of any new substance listings in Title 21 concerning use restrictions or conditions of use, and common or usual names of substances intended for use, in meat or poultry products.

4. Provide FSIS, PAD, with copies of relevant information from petitions and accompanying data submitted by petitioners