DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 310, 318, 319, and 381

[Docket No. 88–026P]

RIN 0583–AB02

Substances Approved for Use in the Preparation of Meat and Poultry Products

AGENCY: Food Safety and Inspection Service (FSIS), USDA.

ACTION: Proposed rule.

SUMMARY: FSIS is proposing to amend the Federal meat and poultry inspection regulations to harmonize and improve the efficiency of the procedures used by FSIS and the Food and Drug Administration (FDA) for reviewing and approving the use of substances in meat and poultry products. Under the proposed procedures, FSIS would no longer issue its own regulations listing substances it finds suitable for use in meat and poultry products. Instead, by agreement between USDA and the FDA, future FDA regulations would specify whether a substance approved for use in foods under the Federal Food, Drug, and Cosmetic Act (FFDCA) may be used in or on meat or poultry products. Current FDA regulations that approve the use of substances in foods generally and do not preclude meat and poultry uses will confer authority to use such substances in meat and poultry products unless expressly prohibited by USDA regulation.

Requests for meat and poultry uses of substances not permitted under title 9 or title 21 of the Code of Federal Regulations (CFR) would have to be made to FDA in the form of a petition for FDA approval. FDA is simultaneously publishing in this issue of the Federal Register a proposal that would amend the FDA regulations governing the review of petitions for the approval of food additives to provide for simultaneous review of such petitions by FSIS when meat or poultry product uses are indicated. This would permit FDA listings to specify whether, and if so under what conditions, such substances may be used in USDA-inspected meat and poultry products. Such listings would eliminate the need for separate FSIS rulemaking.

FSIS would limit any future, substance-specific rulemaking to prohibitions or limitations on meat or poultry uses of specific substances that may be necessary to protect the public under the Federal Meat Inspection Act (FMIA) or Poultry Products Inspection Act (PPIA). FSIS would continue to provide evaluations upon request as to whether substances permitted for general use under current regulations are suitable for specific uses in meat and poultry products.

FSIS proposes to adopt the position that substances that are listed in title 21, CFR, Parts 182 and 184, as generally recognized as safe (GRAS) for use in food generally, with no limitation other than good manufacturing practice, would be accepted by USDA as GRAS for use in meat, meat food products, and poultry products generally, unless otherwise restricted for such use by regulation in title 9, CFR. Other GRAS substances currently permitted for general food use would be evaluated by FSIS as to their suitability for specified uses in meat food products and poultry products on a case-by-case basis, in consultation with FDA as appropriate.

DATES: Comments must be received by February 27, 1996.

ADDRESSES: Written comments to: Diane Moore, Docket Clerk, Room 4352, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments, as provided under the Poultry Products Inspection Act (PPIA), should be directed to Mr. Ralph Stafko at (202) 720–8168. (See also ''Comments'' under **SUPPLEMENTARY INFORMATION**.)

FOR FURTHER INFORMATION CONTACT: Mr. Ralph Stafko, Deputy Director, Policy Evaluation and Planning Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; (202) 720–8168.

SUPPLEMENTARY INFORMATION:

Comments

Interested persons are invited to submit comments concerning this proposal. An original and two copies of written comments should be sent to the Docket Clerk's office at the address shown above and should refer to docket number 88–026P. Any person desiring opportunity for oral presentation of views, as provided under the PPIA, should make such request to Mr. Stafko at (202) 720–8168 so that arrangements may be made for such views to be presented. Copies of all comments submitted in response to this proposal will be available for public inspection in the office of the Docket Clerk between 8:30 and 1:00 a.m. and between 2:00 and 4:00 p.m., Monday through Friday.

Background

FDA and FSIS are both regulatory agencies mandated to protect consumers from adulterated or misbranded food products. FDA, under the FFDCA, is responsible for regulating foods generally. FSIS, under the FMIA and the PPIA, regulates products consisting wholly or in part of meat or poultry.

Products regulated by FSIS, for the most part, include those containing at least 2 percent cooked or 3 percent raw poultry or red meat. Products that contain meat or poultry only in condimental quantities or that historically have not been regarded as meat or poultry products are not regulated under the inspection Acts. Examples of such products are some cheese spreads with meat, close-faced sandwiches, bouillon cubes, and dried or dehydrated meat soups.

Even though FDA and FSIS have a common food safety mission, they have differing statutory mandates and carry out their individual statutory mandates in different ways. FDA relies primarily on the promulgation of and compliance with regulations to implement its mandate concerning substances intentionally added to food, such as food additives and color additives. FDA also relies on inspections of food manufacturing and storage facilities to enforce its statutory mandates relating to sanitation and conditions of manufacture and storage. Detection and seizure of violative products, and sanctions imposed on producers or manufacturers responsible for violations are based on evidence that violative product (or a component of the product) was introduced into interstate commerce.

The FMIA and PPIA (21 U.S.C. 601 et seq.; 21 U.S.C. 451 *et seq.*) require that meat and poultry products be inspected, and USDA inspection program personnel inspect such products before the products are placed in commerce. The USDA mark of inspection is placed only on those products found by USDA to be unadulterated and properly labeled. Thus, FSIS's primary enforcement activity is the conduct of inspection activities designed to prevent the production and distribution of adulterated or misbranded products. FSIS regulations on products under its jurisdiction are enforced primarily by inspectors and inspection program support staff on a plant-by-plant basis. Inplant FSIS personnel may retain suspect product and condemn adulterated product. In egregious cases, FSIS may withdraw inspection from plants.

This different approach to regulation, based on the statutes governing the activities of the respective agencies, has required FSIS and FDA, and their predecessor agencies, to work together closely to minimize the potential for

conflict, duplication of effort, or gaps in their regulatory schemes that could result in inadequate or inappropriate regulation.

Over the years, FDA has generally deferred to FSIS in matters concerning the regulation of meat, meat food products, and poultry products, despite its broad jurisdiction over all food. This approach is consistent with the proposition that in cases of possible jurisdictional overlap, an agency with a broad grant of statutory authority will normally defer to an agency with a more specific grant of authority. FSIS employs veterinarians, trained inspectors, and technical support staff to carefully and continuously oversee the production of these products. FSIS regulations and guidelines govern all aspects of meat and poultry food product that are subject to such inspection. These include regulations and guidance on substances that may be added to those products.

Since the 1958 Food Additives Amendment to the FFDCA, FSIS has come to rely on FDA in most matters concerning the safety of food and color additives and other substances that may be used in foods—including meat and poultry products. FDA has developed the scientific staff, the institutional expertise, and the regulatory structure to ensure the safety of substances that may be added to foods.

Over the years, FDA and FSIS have cooperated on food-ingredient issues on an as-needed, substance-specific, case-by-case basis. Nonetheless, because of their different regulatory needs, the two agencies' regulations governing the use of these substances in foods are cast in formats and terms that are not fully consistent with one another. This inconsistency causes difficulty and inconvenience to persons who need to refer to both agencies' regulations on approved substances and approved uses.

Furthermore, it is not clear from the regulations where one agency's jurisdiction ends and the other's begins. The public frequently sends FSIS requests for the use of new substances or new uses of substances that must be referred to FDA, and sends FDA requests involving meat or poultry uses that must be referred to FSIS.

Finally, FSIS's current regulations require that substances used in meat or poultry products be listed in FSIS regulations for those uses. The regulations further require that those wishing to establish a rule permitting meat or poultry product uses of a substance first must establish that it is safe for the intended use under the FFDCA, and second, that it is suitable for the intended use under the FMIA or PPIA (9 CFR 318.7(a) and 381.147(f)). As a result, both agencies conduct separate reviews and undertake separate rulemakings, sequentially, before a new meat or poultry use of a substance can be permitted. This proposed rule and a concurrent FDA proposed rule, appearing elsewhere in this issue of the Federal Register, are intended to harmonize and simplify the agencies' regulations on food ingredients by allowing FSIS to rely on FDA's listings for food ingredients, and to provide a basis for the eventual elimination of FSIS's separate listings from the CFR. There would be a single petition, joint reviews, and a single rulemaking procedure, as well as continuing consultation on related issues, to replace the current time-consuming, duplicative, sequential rulemaking procedures. The agencies would enter into a Memorandum of Understanding (MOU) concerning the specifics of the agencies' working relationship. A draft of this MOU appears as an appendix to this notice of proposed rulemaking.

The following review of the laws and regulations of the two agencies explains in more detail the agencies' relationship in this area of regulation.

History of Food Additive Regulation

The Food and Drugs Act of 1906 declared that food containing ''any added poisonous or other added deleterious ingredient which may render such article injurious to health'' was adulterated (PL 59–384, 34 Stat. 770), and that sale of adulterated food was a violation of law. The Meat Inspection Act, passed at the same time as companion legislation, mandated Federal inspection of meat and meat food products. Responsibility for implementing and enforcing both these laws was vested in the Secretary of Agriculture.

In 1938, the FFDCA expanded the scope of the Food and Drugs Act by, among other things, prohibiting the sale of foods that may be adulterated by substances other than added ingredients, such as by environmental contaminants, that could render the food injurious to the health of the consumer.

In 1940, responsibility for implementation and enforcement of the FFDCA was removed from the Secretary of Agriculture and was vested in the Administrator of the Federal Security Agency, which later became the Department of Health, Education, and Welfare (today, the Department of Health and Human Services). However, the authority to implement the meat inspection system was retained by USDA.

By the 1950's, it had become apparent that there were certain limitations in the authorities provided by the FFDCA. Among these was the lack of a provision requiring industry to pretest substances intended for use in food to determine the safety of such use. Also, in an enforcement action against a violative food, the burden of proof was on the Government to show that use of a food additive caused the food to be adulterated or misbranded.

To correct these and other problems, the Food Additives Amendment was passed in 1958. Processors were thenceforth required to prove that food additives were safe for their intended use before they could be used in food. FDA was required to determine the safety of food additives and regulate their use in foods.

The Food Additives Amendment of 1958 applies to substances added to all foods, including meat and poultry products subject to USDA inspection under the FMIA and the PPIA. The FMIA (21 U.S.C. 601 *et seq.*) and the PPIA (21 U.S.C. 451 *et seq.*) give USDA primary jurisdiction over meat and poultry products to a ensure product entering commerce is not adulterated or misbranded. FSIS has interpreted the Food Additives Amendment as giving FDA primary jurisdiction for the approval of food additives for use in meat and poultry products, while not precluding continued exercise of USDA/FSIS jurisdiction to *further* regulate the use of those substances in meat and poultry products under the FMIA and PPIA.

Section 1(m)(2) of the FMIA (21 U.S.C. 601(m)(2)) and section 4(g)(2) of the PPIA (21 U.S.C. 453(g)(2)) provide the Secretary of Agriculture with authority to regulate the use of food and color additives in meat and poultry products. Section 1(m)(2)(C) of the FMIA and section 4(g)(2)(C) of the PPIA provide that any meat or poultry carcass, part, or product is adulterated ''if it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA).'' Under section 409 of the FFDCA (21 U.S.C. 348), all food additives are deemed unsafe unless the FDA finds, by regulation, that they are safe for a particular use. Section 1(m)(2)(D) of the FMIA (21 U.S.C. 601(m)(2)(D)) and section 4(g)(2)(D) of the PPIA (21 U.S.C. 453(g)(2)(D)) provide that any meat or poultry carcass, part, or product is adulterated ''if it bears or contains any color additive which is unsafe within the meaning of section 721 of the

FFDCA.'' Under section 721 of the FFDCA (21 U.S.C. 379e), all color additives are deemed unsafe unless the FDA finds, by regulation, that they are safe for a particular use. Section 1(m)(2) of the FMIA (21 U.S.C. 601(m)(2)) and section 4(g)(2) of the PPIA (21 U.S.C. 453(g)(2)) also provide that the Secretary of Agriculture may issue regulations prohibiting the use of a food additive or color additive in a meat or poultry article in establishments receiving Federal meat or poultry inspection services.

The Secretary of Agriculture's authority under the FMIA to prohibit the use of substances in meat products that are otherwise permitted in foods by FDA was tested in *Chip Steak Co.* v. *Clifford Hardin* (332 F. Supp. 1084 (N.D. Cal. 1971), *aff'd.,* 467 F.2d 481 (9th Cir. 1972)). The plaintiffs demanded injunctive relief from the prohibition at 9 CFR 318.7(d)(2) against the use of sorbic acid and sorbates in cooked sausage. The court held that the legislative history of the FMIA showed that it was the intent of Congress to vest the Secretary of Agriculture with the authority to prohibit the use of substances in meat food products notwithstanding their designation as GRAS. The court noted that under the FMIA, the Secretary had the power to prohibit a substance for use in meat and meat products even if the substance is not adulterative under the food additive provisions of the FFDCA. Thus, the Secretary of Agriculture could impose restrictions for food ingredients in meat and meat food products that exceeded restrictions imposed by the Secretary of HHS.

At about the same time that this case was in progress, the Agency was involved in rulemaking to implement the Wholesome Meat Act (81 Stat. 584) and the Wholesome Poultry Products Act (82 Stat 791–808). Among the provisions in the new regulations were requirements for listing substances in the 9 CFR regulations before they could be used in meat, meat food, or poultry products. The relevant provisions, at 9 CFR 318.7(a)(1) and 381.147(f)(1) in the existing regulations, were adopted October 3, 1970, and May 16, 1972, respectively. They had the effect, along with the favorable district court decision, of strengthening the Administrator's authority to control the use of substances in meat and poultry products. Nothing in the current proposal would diminish that authority.

FDA Regulations

Meat and poultry product ingredients are subject to regulation by the FDA under the FFDCA. Such ingredients may be food additives, substances that are generally recognized as safe (GRAS) for use in food, color additives, or ingredients covered by prior sanctions.

The FFDCA defines a food additive as ''any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food * * *'' (21 U.S.C. 321(s)). Anyone wishing to use a new food additive must petition the FDA and obtain approval before using the substance in food. The sponsor must provide FDA with information demonstrating safety under the proposed conditions of use. The extent or amount of the data submitted will depend primarily on the nature of the substance and its intended uses.

FDA's food additive regulations are codified in several parts of title 21 of the Code of Federal Regulations. Part 170 contains general provisions. Part 171 specifies how food additive petitions are submitted and processed. Part 172 lists food additives approved for direct addition to food. Part 173 lists food additives permitted in food, e.g., enzyme preparation, microorganisms, solvents, and lubricants. Part 179 covers sources of radiation used to process food, included in the statutory definition of a food additive (21 U.S.C. 321(s)). Part 180 lists certain food additives to be used on an interim basis until such time as studies can be completed and data made available to resolve those safety issues if the Commissioner of Food and Drugs determines that the continued use of those substances presents no public health concern.

The definition of ''food additive'' excludes certain substances that are ''prior sanctioned,'' ''generally recognized as safe,'' or ''color additive'' substances. Prior sanctioned ingredients are those used in accordance with explicit sanctions or approvals granted prior to the enactment of the Food Additives Amendment in 1958. These prior sanctions may have been granted by FDA under the FFDCA (21 U.S.C. 321(s)(4)) or by USDA under the FMIA or the PPIA. Such ingredients, e.g., nitrites used in cured pork products, are exempt from the food additive provisions of the FFDCA.

A second exemption from the definition of ''food additive'' is ''generally recognized as safe'' or ''GRAS'' substances. These are defined by the FFDCA as substances generally recognized as safe among experts qualified by scientific training and experience to evaluate their safety. Designation as GRAS can come about in either of two ways: (1) By demonstration of common use of the substance in food prior to 1958 or (2) by scientific procedures.

GRAS substances include a variety of common food ingredients. Although FDA advises that it would be impracticable to list all substances that are generally recognized as safe for their intended use, many GRAS substances are specifically listed in Part 182 of title 21. In addition, FDA has formally affirmed certain substances as GRAS, and has listed their GRAS uses in Part 184 of title 21.

FDA may also find that a substance or a particular use of a substance is not generally recognized by qualified experts as safe for use in food. Such substances or uses may continue to be used under an ''interim food additive'' regulation (21 CFR 180) while specified studies are performed to resolve the safety question.

A ''color additive'' is a material that, ''* * * when added or applied to a food, drug, * * * or cosmetic, or to the human body or any part thereof, is capable * * * of imparting color thereto'' (21 U.S.C. 321(t)). As with food additives, only those color additives listed for use in food may be so used. Petitions must be submitted to FDA for any new color additive or uses along with appropriate safety data and other pertinent information.

FSIS Regulations

FSIS inspectors oversee the production of meat and poultry products and must assure that product is not adulterated or misbranded by the addition of unsafe or otherwise improper ingredients, or by contamination with substances used for other purposes in the plant. To assist in this activity, FSIS headquarters staff reviews and approves substances that may be used in meat and poultry products regulated under the FMIA and PPIA.

Substances added directly to products are strictly regulated. FSIS regulations provide that no substance may be used in the preparation of any meat or poultry product unless the use of the substance is approved by the Administrator and listed in the regulations, or the Administrator has approved use of the substance in a specific case (9 CFR 318.7(a)(1) and 381.147(f)(1)). The tables of substances in 9 CFR 318.7 and 381.147 list a variety of substances along with their general classification (e.g., ''antioxidant''), their intended function, the categories of products in which they may be used, and the permitted use levels. The tables supplement or complement the product

standards set forth in 9 CFR 319 and 9 CFR 381.155–171. In order to add a new substance to these listings, increase the permitted use level, or expand the category of products in which an approved substance may be used, FSIS amends these listings by notice-and-comment rulemaking.

FSIS provides guidance on the regulatory status of substances used in inspected establishments. In the course of day-to-day operations, FSIS staffs must respond to inquiries, from inspectors and others, about new uses of substances already approved, or the use of new substances not previously approved, and must determine whether such substances are safe and suitable before they are used in specific meat food or poultry products. Responses to these inquiries generally are made after review by FSIS's Product Assessment Division (PAD), or, if appropriate, the Facilities, Equipment, and Sanitation Division (FESD).

The PAD will assess the safety and suitability of direct and indirect additives. Its assessment involves primarily a determination of whether the substance has been previously approved for safety by FDA or USDA. If the substance is a food additive or color additive the safe use of which has not been approved by FDA, the inquiring party is directed to petition FDA. If it is a GRAS substance or is asserted to be prior-sanctioned, a determination of its status is made by PAD, in consultation with FDA, if appropriate.

PAD will also determine the functionality of substances proposed to be added to meat or poultry products, and reviews data on amounts needed to achieve the intended technical effect. PAD looks at the consistency of the proposed use with standards of identity that may apply, and whether the substance may be misused in some way to make product adulterated or misbranded. The Division will restrict uses as appropriate to prevent adulteration or misbranding.

PAD reviews labels for compliance with FSIS regulations, including ingredient and additive requirements, and must approve them before they are used on the packaging of meat and poultry products (9 CFR 317.4, 381.132). The Division is thus in a position to monitor, by looking at formulations, the ingredients intended to be used with each product. In addition, the Division conducts a voluntary review of proprietary mixes intended for use in meat food or poultry products.

Similarly, PAD reviews food-contact materials, such as processing aids, scalding agents, and chill tank additives. If these substances are found to be food additives or color additives as defined by the FFDCA, they also must be approved by FDA before USDA will approve them for use with inspected products. Other substances, some of which are not regulated under the FFDCA's food additive provisions, are nonetheless reviewed by FSIS on an ''as needed'' basis, before their use in or about inspected products is sanctioned. Inspectors, meat and poultry processors, food chemical and equipment manufacturers, and others require guidance on whether inspectors may view substances as potential adulterants of inspected product. Prior review by FSIS's technical staff normally will resolve the question. For example, review and approval for use in official establishments of specific sanitizing and cleaning agents, and of food-contact equipment and utensils, is done by the FESD.

FDA Rulemaking Processes

Current FDA rulemaking for food additive and GRAS listings is essentially a four-part process:

1. A petition for use of a new food additive, a new use or use level of an existing food additive is received with data demonstrating the safety of the intended use of the substance, or a petition for affirmation of a substance as GRAS is received with data or information demonstrating that the substance is GRAS;

2. A notice of proposed rulemaking (or a notice of the filed petition—the functional equivalent of a proposed rule) is published in the FR;

3. A review for safety and technical effect of the new substance, new use, or new use level of the substance is conducted by the FDA; and,

4. A final rule is published if FDA determines that the food additive use or use level is safe or if the substance is GRAS.

FDA listings normally do not specify whether permitted uses include uses in meat and poultry products or, if so, what conditions or restrictions apply to such uses. Because USDA has always (prior to the 1958 food additive amendments) regulated the safe use of substances in meat and poultry products, and because of the need for inspected establishments, inspection program personnel and others to have uniform guidance on what substances may be added to inspected product, USDA has historically listed such substance uses in its own regulations in title 9 of the CFR.

FSIS Rulemaking Procedures

Before July 1983, FSIS conducted its own notice-and-comment rulemaking, as needed, for the listing of substances approved for use in meat and poultry products. Industry representatives complained that these FSIS rulemakings largely duplicate FDA rulemaking. They asserted that FDA's food additive and GRAS substance affirmation proceedings address and fully resolve all questions regarding safety, if not functionality, of ingredients intended to be used in meat and poultry products. They argued that additional rulemaking by FSIS generated needless delays and expense, and often resulted in the withholding of ingredients from the marketplace for months or even years after all serious questions of safety had been resolved.

Furthermore, notice-and-comment rulemaking by FSIS duplicated FDA's rulemaking (concerning safety), resulting in needless expenditure of USDA resources. FSIS concluded that these complaints had merit and that, if a substance was already listed in title 21, the safety of such uses had, by law, already been determined by competent authority. The addition of a substance to title 9 should not require a full reassessment for the safety of such use by USDA. For those reasons, FSIS proposed to amend its procedures.

In July 1983, FSIS issued a final rule, ''Meat and Poultry Products; Approval of Substances'' (proposed June 2, 1982, 47 FR 23941; final July 19, 1983, 48 FR 32749). Under this rule, full notice-and-comment rulemaking was no longer required for FSIS to list in its regulations substance uses or use levels if such uses or use levels were consistent with those already approved by FDA. A final rule listing the substance use or use-levels could be promulgated without first proposing it for comment, provided that:

1. The substance was an approved food additive, color additive, or substance affirmed as GRAS and permitted for use in food under title 21;

2. The intended use was in accordance with any conditions specified in the FDA approval and would not violate any other applicable FDA requirement; and,

3. The Administrator of FSIS determined:

a. That FSIS concurred with FDA regarding the safety of the substance;

b. That the available data indicated that the use of the substance would have an appropriate technical effect on the product; and,

c. That the available data indicated that the substance would be used only in the amount reasonably required to accomplish its intended technical effect. (9 CFR 318.7 and 381.147.)

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

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.

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:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

2. Section 310.20 would be revised to read as follows:

§ 310.20 Saving of blood from livestock as an edible product.

Blood may be saved for edible purposes at official establishments provided it is derived from livestock, the carcasses of which are inspected and passed, and the blood is collected, defibrinated, and handled in a manner so as not to render it adulterated under the Federal Meat Inspection Act and regulations issued pursuant thereto. The defibrination of blood intended for human food purposes shall not be done with the hands. Anticoagulants specified in title 21 of the Code of Federal Regulations or in this subchapter may be used in lieu of defibrination.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

3. The authority citation for Part 318 would be revised to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

4. Section 318.1(d) would be revised to read as follows:

§ 318.1 Products and other articles entering official establishments.

* * * * *

(d) Containers of preparations which enter any official establishment for use in hog scalding water or in denuding of tripe shall bear labels showing the chemical names of the preparations. In the case of any preparation containing any of the chemicals which are specifically limited by title 21 of the Code of Federal Regulations, Parts 73, 74, 81, 172, 173, 179, 182, or 184, or by a regulation in this subchapter, as to amount permitted to be used, the labels on the containers must also show the percentage of each such chemical in the preparation and must provide dilution directions which prescribe the maximum allowable use concentration of the preparations.

* * * * *

5. Section 318.7 would be amended by revising the heading, paragraph (a) and paragraph (d)(2) to read as follows:

§ 318.7 Restrictions on the use of substances in meat and meat food products.

(a) (1) Substances permitted for use in meat and meat food product in title 21, CFR, shall be permitted for such use under this subchapter, subject to declaration requirements in Parts 316 and 317 of this subchapter, unless precluded from such use or further restricted in Parts 318 or 319 of this subchapter, or by the Administrator in specific cases.

(2) (i) No substance may be used in the preparation of any product, for any purpose, unless its use is authorized under title 21, CFR, as a direct food additive (Part 172), a secondary direct food additive (Part 173), source of radiation (Part 179), an interim-listed direct food additive (Part 180), a prior-sanctioned substance (Part 181), or listed as a Generally Recognized As Safe (GRAS) substance or (Part 182 or 184), or by a regulation in this subchapter.

(ii) No substance the intended use of which is to impart color in any product shall be used unless such use is authorized under title 21, CFR, as a color additive (Parts 73, 74, and 81), or by a regulation in this subchapter.

(3) Petitions to amend title 21 regulations to provide for meat or meat food product uses of substances used in the preparation of product, or substances used to impart color to product, shall be filed with the Food and Drug Administration, in accordance with the provisions of title 21 CFR part 71 or 171, as appropriate.

(4) Inquiries concerning the regulatory status under the Federal Food, Drug, and Cosmetic Act of any articles intended for use as components of, or in contact with, meat or meat food product, should be addressed to the Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C Street, SW., Washington, DC 20204.

(5) Inquiries concerning the suitability for use in specific meat or meat food products of substances that are not affirmed by FDA as GRAS or otherwise listed in 21 CFR part 182 or part 184, or of substances listed in title 21 regulations for general use in foods, or for use in meat or meat food products generally, including mixtures of such substances, should be addressed in writing to the Department of Agriculture, Food Safety and Inspection Service, Product Assessment Division, USDA, FSIS, RP, West End Court Building, Washington, DC 20250–3700. Copies of such correspondence, except for information on proprietary mixtures, will be placed in the public record. A list of proprietary substances and non-food compounds determined suitable for specified uses also may be obtained from the Product Assessment Division, at the same address.

* * * * *

(d) * * *

(2) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid shall not be used in cooked sausage or any other product; sulfurous acid and salts of sulfurous acid shall not be used in or on any product, and niacin or nicotinamide shall not be used in or on fresh product, except that potassium sorbate, propylparaben (propyl p-hydroxybenzoate), calcium propionate, sodium propionate, benzoic acid, and sodium benzoate may be used in or on any product only as provided in 21 CFR or by a regulation in this subchapter.

* * * * *

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

6. The authority citation for 9 CFR Part 319 would be revised to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 319.100 [Amended]

7. Section 319.100 would be amended by removing ''§ 318.7(c) (1) and (4) of this subchapter'' in the first sentence and replacing it with ''a regulation permitting that use in this subchapter or in 21 CFR Chapter I, Subchapter B.''

§ 319.106 [Amended]

8. Section 319.106 would be amended by removing ''in accordance with 318.7(c)(4) of this subchapter'' in paragraph (d)(2) and replacing it with ''a regulation permitting that use in this subchapter or in 21 CFR Chapter I, Subchapter B.''

§ 319.140 [Amended]

9. Section 319.140 would be amended by removing ''§ 318.7(c)(4) of this subchapter'' in the second and third sentences and replacing it with ''a regulation permitting that use in this subchapter or in 21 CFR Chapter I, Subchapter B.''

§ 319.145 [Amended]

10. Section 319.145 would be amended by removing ''in the chart following § 318.7(c)(4),'' in paragraph (a)(4) and replacing it with ''in a regulation permitting that use in this subchapter or in 21 CFR Chapter I, Subchapter B'' and in paragraph (b)(6) by removing ''the chart of substances in § 318.7(c)(4) of this subchapter.'' and replacing it with ''a regulation permitting that use in this subchapter or in 21 CFR Chapter I, Subchapter B.''

§ 319.180 [Amended]

11. Section 319.180 would be amended by removing ''§ 318.7(c)(4) of

this chapter,'' in the first sentence of paragraph (a) and the first sentence of paragraph (b) and replacing it with ''a regulation permitting that use in this subchapter or in 21 CFR Chapter I, Subchapter B.'' and by removing ''§ 318.7(c)(4) of this subchapter.'' in the first sentence of paragraph (e) and replacing it with ''a regulation permitting that use in this subchapter or in 21 CFR Chapter I, Subchapter B.''

§ 319.303 [Amended]

12. Section 319.303 would be amended by removing ''§ 318.7(c)(4) of this subchapter'' from the second sentence of paragraph (a)(3) and replacing it with ''a regulation permitting that use in this subchapter or in 21 CFR Chapter I, Subchapter B.''

§ 319.700 [Amended]

13. Section 319.700 would be amended by removing ''§ 318.7(c)(4) of this chapter'' in paragraph (a)(4), paragraph (a)(5), and paragraph (a)(6), and replacing it with ''a regulation permitting that use in this subchapter or in 21 CFR Chapter I, Subchapter B''; by removing ''§ 318.7(c)(4) of this chapter,'' from the first sentence of paragraph (a)(7) and replacing it with ''21 CFR Parts 73, 74, or 82,''; and removing ''§ 318.7(c)(4) of this chapter,'' from the first sentence of paragraph (a)(9) and the first sentence of paragraph (a)(10) and replacing it with ''a regulation permitting that use in 21 CFR Chapter I, Subchapter B.''

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

14. The authority citation for 9 CFR Part 381 would be revised to read as follows:

Authority: 21 U.S.C. 450, 21 U.S.C. 451–470, 7 CFR 2.18, 2.53.

15. Section 381.147 would be amended by revising paragraph (f) to read as follows:

§ 381.147 Restrictions on the use of substances in poultry products.

* * * * *

(f)(1) Substances permitted for use in poultry product in 21 CFR chapter I shall be permitted for such use under this subchapter, subject to declaration requirements in Subparts M and N of this subchapter, unless precluded from such use or further restricted in Subparts O and P of this subchapter, or by the Administrator in specific cases.

(2)(i) No substance may be used in the preparation of any product, for any purpose, unless its use is permitted under 21 CFR chapter I as a direct food additive (Part 172), a secondary direct food additive (Part 173), a source of radiation (Part 179), an interim-listed direct food additive (Part 180), or is a prior-sanctioned substance (Part 181), or is a GRAS substance listed in Part 182 or Part 184, or is otherwise permitted by a regulation in this subchapter.

(ii) No substance the intended use of which is to impart color in any product shall be used unless such use is authorized under 21 CFR chapter I as a color additive (Parts 73, 74, and 82), or by a regulation in this subchapter.

(iii) Petitions to amend title 21 regulations to provide for poultry product uses of substances used in the preparation of product, or substances used to impart color to product, should be sent to FDA, in accordance with the provisions of 21 CFR part 71 or 171, as appropriate.

(iv) Inquiries concerning the food or color additive status under the Federal Food, Drug, and Cosmetic Act of any articles intended for use as components of, or in contact with, poultry product, should be addressed to the Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C St., SW, Washington, DC 20204.

(v) Inquiries concerning the suitability for use in specific poultry products of substances that are not affirmed by FDA as GRAS or otherwise listed in 21 CFR part 182 or part 184, or of substances listed in title 21 regulations for general use in foods, or for use in poultry products generally, including mixtures of such substances, should be addressed in writing to the Department of Agriculture, Food Safety and Inspection Service, Product Assessment Division, USDA, FSIS, RP, West End Court Building, Washington DC 20250. Copies of such correspondence will be placed in the public record, except for correspondence concerning proprietary mixtures. A list of proprietary substances and non-food compounds determined suitable for specified uses may be obtained from the Product Assessment Division, at the same address.

* * * * *

§ 381.120 [Amended]

16. Section 381.120 would be amended by removing ''§ 381.147'' from the fourth sentence and from the sixth sentence and replacing it with ''a regulation permitting that use in this subchapter or in 21 CFR Chapter I, Subchapter B.''

§ 381.132 [Amended]

17. Section 381.132 would be amended by removing ''§ 381.147'' from paragraph (c)(3)(iii)(D) and replacing it with ''a regulation permitting that use in this subchapter or in 21 CFR Chapter I, Subchapter B.''

§ 381.171 [Amended]

18. Section 381.171 would be amended by removing ''§ 381.147 of this part'' from the first and second sentences of paragraph (b) and replacing it with ''a regulation permitting that use in this subchapter or in 21 CFR Chapter I, Subchapter B.''

Done, at Washington, DC, on: December 21, 1995.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

Appendix

Note: This appendix will not appear in the Code of Federal Regulations.

Memorandum of Understanding (MOU) Between the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA) and the U.S. Food And Drug Administration (FDA), U.S. Department of Health and Human Services (USDHHS)

Regarding the Approval of Food Additives, Color Additives, and other Substances Used in Meat and Poultry Products

I. Purpose

This agreement establishes the working relationship and procedures to be followed by FSIS and FDA in responding to requests for the approval of the use of substances subject to regulation by the FDA and intended for use in meat and meat food products (hereinafter known collectively as meat products) and poultry products regulated by FSIS.

II. Background

The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), and the Federal Food, Drug, and Cosmetic Act (FFDCA) provide FSIS and FDA, respectively, with the authority to determine the safety, wholesomeness, and accurate labeling of foods. The Food Additives Amendment of 1958 to the FFDCA (21 U.S.C. 348) gives FDA the authority to determine the safety of food additives prior to their marketing. The Color Additives Amendment of 1960 (21 U.S.C. 379e) grants FDA premarket review authority comparable with these amendments to the FFDCA for color additives intended for use in foods, drugs, cosmetics, and medical devices. FDA has assumed primary authority over the approval of the use of food additives and color additives used in foods. FSIS has retained authority under the FMIA and PPIA to further regulate uses of such FDA-approved substances in meat and poultry products, respectively, as needed, to ensure inspected products are not adulterated or misbranded.

The process for documenting approved uses of substances intended for use in meat and poultry products has required that such ingredients first be reviewed and approved by FDA (in the form of an FDA regulation), and then subsequently be reviewed and incorporated into FSIS regulations. FDA's

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

requesting approval of the use of substances in meat or poultry products.

5. When petitioned, conduct rulemaking that would permit under the FFDCA use of a substance in meat or poultry, including those restrictions or conditions of use in meat or poultry products that are recommended in writing by FSIS, and for which there are data or other information establishing that the use of the substance is safe and not deceptive. FDA will also consult with FSIS on any comments received on petitions regarding meat or poultry uses.

C. FSIS and FDA jointly agree:

1. That the officials of the two Agencies responsible for implementing the Agreement are:

At FSIS: the Administrator and Deputy Administrators (as may be designated); Director, Product Assessment Division; Branch Chief, Food Standards and Ingredients Branch.

At FDA: Director, Center for Food Safety and Applied Nutrition; Director, Office of Pre-Market Approval.

2. That the responsible officials will concur on rulemaking documents that, when published by FDA, will list or amend listings of substances permitted for use in meat and poultry products.

3. That the Administrator of FSIS and the Director, CFSAN, FDA, shall resolve problems and make decisions by consensus in areas of disagreement.

VI. Conflict Resolution

Each Agency reserves the authority to review, independently of the other, matters of concern to their respective authorities. However, written notice will be provided to the Commissioner of Food and Drugs and to the Under Secretary for Food Safety, USDA, of any rulemaking initiative not in keeping with the provisions of this MOU or about which there is an interagency disagreement, prior to public announcement of the rulemaking.

VII. Other Agreements

A. The provisions of this MOU are not intended to add to or detract from any of the authorities provided to either FDA or FSIS by the FFDCA, FMIA, or the PPIA, or the regulations by which these laws are implemented.

B. FSIS and FDA may enter into additional, separate agreements with each other as they deem appropriate to achieve the objectives of this MOU.

VIII. Duration of MOU

This Agreement becomes effective upon acceptance by both Agencies and will continue indefinitely. It may be modified by mutual written consent or terminated by either agency with a 30-day written notice to the other agency.

Signed:

_____

Director, CFSAN, FDA

_____

Date

_____

Administrator, FSIS

Guidelines for Acceptability Determinations for New Substances and New Uses of Substances in Meat and Poultry Products

The evaluation by FSIS of the acceptable use of a new substance or new use of a substance in meat and poultry products subject to this MOU will be based on the following conditions that must be addressed by the requester. The conditions set forth are in accordance with the provisions for use of substances in 9 CFR and 21 CFR.

1. The substance has a documented history of use in foods.

2. The substance is derived from food or a food ingredient and is not considered to be a chemical or synthesized additive.

3. The process for manufacturing the substance does not result in a severe alteration of the molecular structure resulting in the formation of a chemical residue whose safety has not been shown.

4. The safety of the substance has been evaluated by an independent authority and adequate safety data have been presented.

5. The suitability and efficacy of the substance have been shown through adequate data submission. The lowest level of the substance necessary to achieve the intended functional effect must be shown and the use cannot render the products to which the substance is intended for use adulterated or misbranded.

6. The FDA has determined the common or usual name of the substance(s).

7. FDA must concur with FSIS's determination of acceptability in order to allow use.

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 301, 304, 305, 306, 307, 318, 325, and 381

[Docket No. 95–008A]

RIN 0583–AB89

FSIS Agenda for Change: Regulatory Review

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Advance Notice of Proposed Rulemaking; Request for Comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) has begun a comprehensive review of its regulatory procedures and requirements to determine which are still needed and which ought to be modified, streamlined, or eliminated. This review is an integral part of the FSIS initiative to improve the safety of meat and poultry products by modernizing the Agency's system of food safety regulation. It also moves beyond the page-by-page review of FSIS regulations carried out earlier this year under the President's Reinvention of Government Initiative. A thorough review of FSIS's regulations is needed to prepare for implementation of the Agency's proposed Hazard Analysis and Critical Control Points (HACCP) regulations and a new food safety strategy that will reduce reliance on command-and-control regulations and increase reliance on science-based preventive measures and performance standards to improve food safety. This review and any changes in FSIS regulations that are necessary to make them compatible with HACCP will be completed prior to implementation of HACCP. FSIS invites comment from the public and all interested parties on the Agency's preliminary review of its regulations and specific suggestions on which regulations need to be eliminated or changed to be compatible with HACCP, and how they should be changed, or to achieve Reinvention of Government goals of having fewer, clearer, and more user-friendly regulations.

Some of the rulemakings needed to streamline existing requirements and carry out the FSIS food safety strategy are being initiated or effectuated in documents that appear elsewhere in this issue of the Federal Register: A proposed rule that would eliminate the FSIS prior approval system for substances added to meat and poultry products; a proposed rule that would facilitate marketing of nutritionally improved alternatives to standardized meat and poultry food products; and a final rule streamlining the prior approval system for meat and poultry labels.

As FSIS progresses in its comprehensive regulatory review, FSIS will publish further proposals to eliminate unnecessary regulations and modify remaining regulations, replacing, to the extent possible, command-and-control regulations with performance standards, clarifying the role of inspectors in enforcing those standards, and reorganizing and simplifying the regulations to make them easier to understand and use.

DATES: Comments must be received on or before February 27, 1996.

ADDRESSES: Please send an original and two copies of written comments to Policy, Evaluation, and Planning Staff, Attn: FSIS Docket Clerk, DOCKET No. 95–008A, Room 4352 South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments, as permitted under the Poultry Products Inspection Act, should be directed to the person listed under **FOR FURTHER INFORMATION CONTACT.**