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