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