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