

# MEMORANDUM OF UNDERSTANDING Between The FOOD SAFETY AND INSPECTION SERVICE UNITED STATES DEPARTMENT OF AGRICULTURE And The FOOD AND DRUG ADMINISTRATION UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

MOU Number 225-00-2000

Amendment 1

## I. Purpose

This agreement establishes the working relationship to be followed by the United States Department of Agriculture, Food Safety Inspection Service (FSIS), and the United States Department of Health and Human Services, Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) (individually referred to as “a Participant” and collectively referred to as “the Participants”) when responding to requests for input or submissions (i.e., petitions or notifications) for the use of food additives, including sources of radiation and food contact substances (FCS), generally recognized as safe (GRAS) substances, prior-sanctioned substances, and color additives subject to FDA regulation and intended for use in the production of FSIS-regulated meat, poultry, and egg products.

## II. Definitions

- A. Food Additive: Defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(s)) 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 (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.<sup>[1]</sup>
- B. Food Contact Substance: Defined in section 409(h)(6) of the FD&C Act as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.
- C. GRAS Substance: Defined in section 201(s) of the FD&C Act as a substance, generally recognized among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.
- D. Prior-sanctioned Substance: A substance with an explicit approval granted for its use in food prior to September 6, 1958, by FDA or USDA pursuant to the FD&C Act, the Poultry Products Inspection Act (PPIA), or the Federal Meat Inspection Act (FMIA).
- E. Color Additive: Defined in section 201(t) of the FD&C Act (21 U.S.C. § 321(t)) as a material which (A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto.
- F. Food Ingredient: For the purpose of this document, the term “food ingredient” includes any and all substances defined in A-E above.

- G. Suitability: Relates to the effectiveness of the ingredient or substance in performing the intended purpose of use and the assurance that the conditions of use in an FSIS-regulated establishment will not result in an adulterated product or one that misleads consumers.
- H. Acceptability Determination: Process by which a new ingredient or substance or a new use of an ingredient or substance is deemed safe and suitable in the production of meat, poultry, and egg products.
- I. Meat: Defined in 9 CFR 301.2 as the part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing.
- J. Poultry: Defined in 9 CFR 381.1 as any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or squabs, also termed young pigeons from one to about thirty days of age), whether live or dead.
- K. Egg product: Defined in 9 CFR 590.5 as any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products.

### III. Background

- A. The FMIA, the PPIA, and the Egg Products Inspection Act (EPIA) (hereinafter collectively referred to as the “USDA Acts”) provide FSIS with the authority to regulate establishments that process meat and poultry and plants that process egg products. The USDA Acts also provide FSIS with the authority to determine the safety, wholesomeness, and accuracy of the labeling of meat, poultry, or egg products or existing amenable species under the USDA Acts, as well as future products or species that may be added under the USDA Acts.
- B. Food ingredients used during the production of meat, poultry, and egg products are subject to regulation by FDA under the FD&C Act. However, FSIS also has jurisdiction to regulate the use of those food ingredients used in the production of meat and poultry products under the FMIA (21 U.S.C. 601(m)(2)), PPIA (21 U.S.C. 453(g)(2)), and the EPIA (21 U.S.C. 1033(a)(2)). FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products in accordance with applicable FSIS laws, regulations, and policies.
- 9 CFR part 424 prescribes rules for the preparation or processing of meat and poultry products. The rules are intended to prevent the adulteration and misbranding of meat and poultry products in official establishments. 9 CFR 424.21 covers the general use of food ingredients. Paragraph (c) of section 424.21 provides a chart of approved ingredients for use in the preparation of meat and poultry products, provided they are used for the purpose indicated and within the limits of the amounts stated. Paragraphs (a) and (b) of 9 CFR 424.22 cover certain other permitted uses of ingredients in meat, while 9 CFR 424.22(c) permits the use of irradiation in meat and poultry products. 9 CFR 424.23 lists prohibited uses of ingredients in meat and poultry products.
  - 9 CFR 590.435 prescribes rules for the manufacture or preparation of egg products. The rules are intended to prevent the adulteration and misbranding of egg products in official egg products plants.
  - A comprehensive listing of substances authorized for use in the production of meat, poultry, and egg products is available to inspection program personnel in FSIS Directive 7120.1, *Safe and Suitable Ingredients used in the Production of Meat, Poultry and Egg Products*, on FSIS’s website. The list includes substances under titles 9 and 21 of the CFR and substances with safe and suitable acceptability determinations made by FDA and FSIS. The list of authorized substances is also available separately on FSIS’s website.

C. The FD&C Act provides FDA with the authority to determine the safety, wholesomeness, and accurate labeling of food.

- Section 409 of the FD&C Act (21 U.S.C. 348) requires premarket approval of food additives, including Food Contact Substances (FCS) and sources of radiation used to treat food. Under section 409, any person may submit to FDA a food additive petition that includes data and information that the petitioner believes establish that the food additive is safe under its intended conditions of use (i.e., that there is reasonable certainty that the substance is not harmful under the intended conditions of use (21 CFR 170.3(i)). If, based on the data and information in the petition, FDA finds that the food additive is safe under the conditions of its intended use FDA promulgates a regulation specifying the conditions under which the additive may be safely used.
- A manufacturer or supplier of an FCS may submit a Food Contact Notification (FCN) in accordance with 21 CFR 170.101, notifying FDA of the identity, intended use and limitations of the FCS, and of its determination that the intended use of such FCS is safe (see section 409(h) of the FD&C Act). Unless FDA objects to the FCN, or if the notifier withdraws the FCN within the 120 day review period, the FCN becomes effective. An FCS that has been shown to be safe, through the submission of an FCN to which FDA did not object, is added to the Inventory of Effective FCNs on FDA's website. Effective FCNs are exclusive to the manufacturer or supplier of the FCS identified in the inventory.
- The FD&C Act requires food substances or new uses of approved food substances to be approved by FDA prior to marketing unless the substance is prior-sanctioned or GRAS for its intended use. The FD&C Act and FDA's implementing regulations in 21 CFR 170.30 have several criteria that must be met before the intended use of the substance in food can be GRAS. In general, GRAS status is based on the views of qualified experts, either through (1) scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. GRAS status requires common knowledge about the use of the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food. When GRAS status is based on scientific procedures, the same quantity and quality of scientific evidence is required for the substance as is required to obtain approval of a food additive, and, in addition, that evidence must be generally available. Any person may notify FDA of an independent determination of GRAS status through FDA's voluntary GRAS notification program.
- Section 721 of the FD&C Act (21 U.S.C. 379e) requires premarket review and listing of color additives. Under section 721 of the FD&C Act, any person may submit to FDA a color additive petition that includes data and information that the petitioner believes establish that the intended use of the color additive is safe, and that it is suitable for its intended use. If, based on the data and information in the petition, FDA finds that the color additive is suitable and safe under the conditions of its intended use,, FDA promulgates a regulation specifying the condition under which the color additive may be safely used (see section 721(b); 21 CFR 71.20).

#### **IV. Substance of the Agreement**

A. This is a collaborative FSIS-FDA memorandum of understanding (MOU) regarding food ingredients intended for use in FSIS-regulated products, i.e., in the production of meat, poultry, and egg products at FSIS-regulated establishments.

This MOU between FSIS and FDA covers the following circumstances

1. When a person requests FDA approval of a food additive or color additive that specifies an intended use in or on a meat, poultry, or egg product.
2. When a person requests FDA approval of a food additive or color additive that is intended for use in or on food generally, but does not specify whether it is intended for use in or on a meat, poultry, or egg product.
3. When a person submits a notification that a substance is GRAS for an intended use in or on a meat, poultry, or egg product

4. When a person submits a notification for a food contact substance intended for use on or likely to become a component of a meat, poultry, or egg product.
  5. When a person requests an acceptability determination from either Participant regarding the use of a food ingredient in or on a meat, poultry, or egg product.
  6. When a person contacts either Participant with an inquiry about the use of a food ingredient in or on a meat, poultry, or egg product.
- B. The Participants agree to cooperate and collaborate, to the extent practicable, on the review of submissions each Participant receives regarding the use of food ingredients used in the production of or on a meat, poultry, or egg product.
- C. The Participants further agree that the details of this cooperative relationship are to be fully elaborated in a set of mutually agreeable standard operating procedures (SOP). The established SOP is attached to this MOU in Appendix A. This SOP will provide consistency in the processing of the relevant petitions and notifications regardless of which Participant receives the petition or notification. As appropriate, the Participant that is consulted about a pending petition or notification will provide its evaluation on the relevant parts of the petition or notification to the other Participant in accordance with the procedures established in the SOP.

The Participants jointly agree:

1. That the officials of the Participants responsible for implementing this MOU are: At FSIS: Director, Office of Policy and Program Development, Risk, Innovations, and Management Staff (or his/her designee).  
At FDA: Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (CFSAN) (or his/her designee).
2. That, prior to making a public announcement of a rulemaking affecting the subject matter of this MOU, each Participant will give to the other Participant the opportunity to comment (the Director of CFSAN, FDA, and the Administrator of the FSIS, USDA) on that rulemaking. This includes rulemakings which affect any of the following that are intended for use in or in the production of meat, poultry, or egg products: food additives, including sources of radiation and food contact substances, GRAS substances, prior-sanctioned substances, and color additives.
3. That the Administrator of FSIS and the Director of CFSAN shall resolve any interagency disagreements through internal negotiations.

## **V. General Provisions**

- 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 FD&C Act, FMIA, PPIA, or EPIA, or the regulations promulgated by each agency under such authorities. Each agency reserves the authority to review, independently of the other, matters of concern to their respective authorities.
- B. Information Sharing
1. The Participants recognize that exchanged information may contain any of the following types of information and as such must be protected from unauthorized use and disclosure: (1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(C) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal laws and their implementing regulations (e.g., Trade Secrets Act (18 USC 1905), the Privacy Act (5 USC 552a), other FOIA exemptions not mentioned above (5 USC 552(b)), the Federal FD&C Act (21 USC 301 *et seq.*), and the Health Insurance Portability and Accountability Act (HIPAA), (Pub. L. 104-191)).
  2. Pursuant to section 301(j) of the FD&C Act (21 USC 331(j)), FDA will not reveal to FSIS any method or process which is entitled to protection as a trade secret.

3. Under 21 CFR 170.102, a FCN is not available for public disclosure during the 120-day period of FDA's review of the FCN.

4. Participants will follow the process for information sharing and exchange in Appendix B of this MOU.

#### C. Information Safeguards:

1. The Participants will establish proper safeguards to ensure that non-public information shared under this MOU shall be used and disclosed solely in accordance with applicable laws and regulations and the procedures established in the SOP.
  - a. Proper safeguards shall include the adoption of policies and procedures to ensure that the information shared under this MOU shall be shared and used consistent with the Trade Secrets Act ((18 U.S.C. 1905), the FD&C Act ((21 U.S.C. 301 *et seq.*), the Privacy Act of 1974 ((5 U.S.C. 552a), the Freedom of Information Act ((5 U.S.C. 552), the confidentiality provisions of the Food Security Act of 1985 ((7 U.S.C. 2276), the confidentiality or non-disclosure provisions of any other agreement entered into by a Participant, and other applicable Federal laws and their implementing regulations.
  - b. Proper safeguards will protect against unauthorized use and disclosure of the non-public information shared or exchanged pursuant to this MOU and such safeguards are necessary for effective implementation of this MOU.
  - c. Access to the information shared or exchanged under this MOU shall be restricted to authorized Participants' employees, agents, and officials who require access to perform their official duties in accordance with the uses of information as authorized by this MOU and its appendices. Such personnel shall be advised of (1) the confidential nature of the information, (2) safeguards required to protect the information, and (3) the administrative, civil, and criminal penalties for noncompliance contained in applicable Federal laws. Contractors, their subcontractors, and agents requiring access to the non-public information shared or exchanged under this agreement will be required to sign a business associate agreement by which they will commit to keep the information confidential.
  - d. The Participants agree to notify promptly each other of any actual or suspected unauthorized disclosure of any information shared pursuant to this MOU.
  - e. The Participant who has received shared information (requesting Participant) will promptly notify the contact person or designee of the sharing Participant of any attempt by a third party to obtain shared non-public information by compulsory process, including, but not limited to, a FOIA request, subpoena, discovery request, or litigation complaint or motion.
  - f. If a Participant that has received information under this MOU receives a FOIA request where there are responsive records which originated with the other Participant, this Participant will refer the FOIA request to the other Participant for it to respond directly to the FOIA requestor. In such cases, the Participant which received the FOIA request will notify the FOIA requestor that it has referred the FOIA request to another agency and that a response will issue directly from that agency.
  - g. The requesting Participant will notify the sharing Participant before complying with any judicial order that compels the release of shared non-public information, so that the Participants may determine the appropriate measures to take, including, where appropriate, legal action.

#### VI. Resource Obligations

This MOU represents the broad outline of the Participants' intent to enter into collaborative efforts in areas of mutual interest to the Participants. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This

MOU does not affect or supersede any existing or future agreements or arrangements between the Participants. This MOU does not create binding, enforceable obligations against any Participant. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which the Participants operate.

**VII. Liaison Officers**

- A. To facilitate the activities carried out under this MOU, FDA and FSIS will establish liaisons
  
- B. Participants may designate a new liaison at any time by notifying the other Party’s administrative liaison in writing. If, at any time an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the Participants will name a new liaison within two weeks and notify the other Participant through the designated administrative liaison

**VIII. Term, Termination, and Modification**

This agreement will become effective when signed by all participating partners, in this case FDA and FSIS, and will continue in effect unless modified by mutual written consent at any time or terminated by either party upon a 30-day advance written notice to the other. This MOU supersedes the Memorandum of Understanding (MOU number 225-00-2000) dated January 31, 2000.

[1]The definition of a food additive does not include: (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or (2) a pesticide chemical; or (3) a color additive; or (4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to the FD&C Act, Federal Meat Inspection Act (FMIA), or the Poultry Products Inspection Act (PPIA); or (5) a new animal drug; or (6) an ingredient in or intended for use in a dietary supplement.

APPROVED AND ACCEPTED FOR FOOD SAFETY AND INSPECTION SERVICE	APPROVED AND ACCEPTED FOR FOOD AND DRUG ADMINISTRATION
By _____	By _____
Title <u>Assistant Administrator</u>	Title <u>Deputy Director for Scientific Operations</u>
<u>Office of Policy and Program Development</u>	<u>Center for Food Safety and Applied Nutrition</u>
Date _____	Date _____

**Appendix A**

**STANDARD OPERATING PROCEDURES**

**For the Working Relationship Established in MOU 225-00-2000 between the United States Department of Agriculture, Food Safety Inspection Service,  
and the United States Department of Health and Human Services, Food and Drug Administration**

**I. Purpose:**

This document describes the Standard Operating Procedure (SOP) for memorandum of understanding (MOU) 225-00-2000 between the United States Department of Agriculture, Food Safety Inspection Service (FSIS), and the United States Department of Health and Human Services, Food and Drug Administration (FDA). This SOP outlines FSIS and FDA’s working relationship for the listing, approval, or notification of food additives, including food contact substances and sources of radiation, GRAS substances, prior-sanctioned substances, and color additives used in the production of meat, poultry, and egg products.

**II. Applicability:**

This SOP applies to personnel at both FSIS and FDA.

This SOP incorporates the definitions in Section II of MOU 225-00-2000.

### **III. Procedures:**

#### **A. When FDA receives a petition for the approval of a food or color additive that specifies an intended use in the production of meat, poultry, or egg products:**

1. FDA will inform the petitioner in writing that such petition will also be evaluated by FSIS.
2. In accordance with the regulations for color additive petitions and food additive petitions (21 CFR 71.1 and 171.1, respectively), upon filing of the petition, FDA will forward a copy of the petition or relevant portions thereof to FSIS for simultaneous review.
3. FDA and FSIS will consult with one another, as necessary and appropriate, regarding issues associated with the petitioned use of the substance or source of radiation in the production of meat, poultry, or egg products.
4. FSIS will, within 60 days of their receipt of the petition, provide a written response to FDA relating FSIS's determination of the suitability of the food or color additive for the intended use.
5. FDA will inform the petitioner of any concerns expressed by FSIS regarding the suitability of use of the substance or source of radiation in the production of meat, poultry, or egg products.
6. When appropriate, FDA will include in any regulation that results from such a petition the specific use in the production of meat, poultry, or egg products that FDA determines to be safe. FDA will consider any restrictions or conditions on the use in the production of meat, poultry, or egg products that FSIS recommends in writing, provided that such restrictions or conditions are consistent with sections 409 and 721 of the FD&C Act (21 U.S.C. §§ 348 and 379e).
7. FDA will, before publication, advise FSIS of any new listing or approval regulation in Title 21 of the Code of Federal Regulations regarding a substance or source of radiation for use in the production of meat, poultry, or egg products, including conditions of use, use restrictions, or labeling provisions.

#### **II. When FDA receives a petition for approval of a food or color additive that is intended for use in or on food generally, but that does not specify whether this general use includes use in the production of meat, poultry, or egg products:**

1. FDA will contact the petitioner and clarify whether the requested use in food includes an intended use in the production of meat, poultry, or egg products.
2. If the petitioner wishes the intended use in food to include use in the production of meat, poultry, or egg products, FDA will request that the petitioner so inform FDA in writing and provide FDA with an additional copy of the petition, if not already submitted in electronic format. FDA and FSIS will jointly review the petition for the intended use in the production of meat, poultry, or egg products, as described in subsection A of this agreement.
3. If the petitioner does not wish the intended use in food to include use in meat, poultry, or egg products, FDA will request that the petitioner so inform FDA in writing. Any regulation that FDA issues in response to the petition will explicitly exclude the use of the additive in the production of meat, poultry, or egg products.

#### **III. When FDA receives a GRAS notice regarding the use of a substance in the production of a meat, poultry, or egg product:**

1. FDA will inform the notifier in writing that such notice will also be evaluated by FSIS to determine the suitability of the use of the substance in the production of meat, poultry, or egg products.
2. FDA will provide FSIS with copies of relevant data and information from the notice.

3. FDA and FSIS will consult with each other, as necessary and appropriate, regarding issues associated with the notified use of a substance in meat, poultry, or egg products.
4. FSIS will, within 60 days of their receipt of the GRAS notice, provide a written response to FDA relating FSIS's determination of the suitability of the GRAS substance for the intended use.
5. FDA will include in its written response to the notifier information regarding the notifier's responsibilities under the FMIA, PPIA, or EPIA, as appropriate. The FDA response may include concerns about the suitability of the use of the substance in the production of meat, poultry, or egg products and, when applicable, any restrictions or conditions of use in the production of meat, poultry, or egg products that FSIS recommends in writing, provided that such restrictions or conditions are consistent with sections 409 and 201(s) of the FD&C Act (21 U.S.C. §§ 348 and 321(s)). FDA will send FSIS a copy of FDA's written response to the notifier.

**IV. When FDA receives a food contact notification (FCN) regarding the incorporation of a food contact substance (FCS) likely to become a component of food that is jointly regulated by FDA and FSIS:**

1. After FDA completes its initial review and determines that the FCN is complete and likely to become effective, an acknowledgement letter is issued to the notifier.
2. FDA's acknowledgement letter will inform the notifier that the FCS used in the production of a meat, poultry, or egg product (e.g., antimicrobial wash) is also regulated by FSIS.
3. FDA's acknowledgement letter will ask the notifier to provide FSIS with a copy of this acknowledgement letter as well as his or her FCN to allow for concurrent evaluation by both agencies.
4. FSIS will, if more information is needed, engage in direct correspondence with the notifier and request that the notifier provide the requested additional information to both FSIS and FDA.
5. As appropriate, FDA and FSIS will both request that the notifier provide them with written consent for FDA and FSIS to discuss the information contained in the FCN and all correspondence and written discussions of oral summaries relating to the notification. If written consent is not provided, FDA and FSIS will discuss this information to the extent permissible under their authorities.
6. FDA and FSIS will consult with each other, as necessary and appropriate, regarding issues associated with the notified use of a substance likely to become a component of food that is jointly regulated by FDA and FSIS.
7. FSIS will, within 60 days of their receipt of the complete FCN from the notifier, provide a written response to the notifier and FDA relating FSIS's determination of the suitability of the FCS for the intended use.
8. Within 120 days of FDA's receipt of a complete FCN, the FCN will become effective unless an objection letter is issued by FDA to the notifier. The notifier is ultimately responsible for obtaining a suitability determination from FSIS if the FCN involves meat, poultry, or egg products before the ingredient can be used in a meat, poultry, or egg product.

**V. When FDA receives a petition or notification for a food ingredient that specifies an intended use in a food product that could fall under the jurisdiction of FSIS because it may be made with meat or poultry, for example, soup:**

1. FDA will contact the petitioner or notifier and clarify whether the intended use of their food ingredient would fall under the jurisdiction of FSIS.<sup>[2]</sup>
2. If the intended use would fall under the jurisdiction of FSIS, FDA will follow the outlined procedures above for interacting with FSIS based on the program area.

**VI. When FSIS receives a request for an acceptability determination regarding the use of a food ingredient, including a FCS, in the production of a meat, poultry, or egg product and wishes to confirm the status of the intended use of the food ingredient under the FD&C Act:**

1. FSIS will consult, as necessary, with FDA on the requirements under the FD&C Act and its implementing regulations.
2. FDA will, within 60 days, provide a written response to FSIS. When appropriate, FDA will advise FSIS that a food additive petition, FCN, or color additive petition is necessary to accommodate the requested uses or recommend that FSIS direct the requester to discuss the substance or source of radiation's regulatory status with FDA.

**VII. When FDA receives a request for a suitability determination regarding the use of a substance in the production of a meat, poultry, or egg product:**

1. FDA will inform the requester in writing that such a request must be evaluated by FSIS.

**VIII. When FDA receives an inquiry regarding the use of a substance in a meat, poultry, or egg product:**

1. FDA will consult with FSIS, as appropriate.
2. FDA's response to the inquirer will, when appropriate, direct the inquirer to contact FSIS for more information regarding the inquirer's responsibilities under the FSIS' laws and regulations.

**IX. When FSIS receives an inquiry regarding the use of a substance in the production of a meat, poultry, or egg product:**

1. FSIS will consult with FDA, as appropriate.
2. FSIS's response to the inquirer will, when appropriate, direct the inquirer to contact FDA for more information regarding the inquirer's responsibilities under the FDA's laws and regulations.

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<sup>[2]</sup>Food containing less than 2% cooked meat or chicken and/or less than 3% raw meat, would fall under the jurisdiction of FDA.