CHAPTER 09 – FOOD AND COLOR ADDITIVES

SUBJECT:	**DOMESTIC AND IMPORT FOOD ADDITIVES AND COLOR ADDITIVES**
IMPLEMENTATION DATE:	UPON RECEIPT
Product Codes:	All Food Codes [except Industry 16 (seafood)] and Industry 50 (Color Additives) All Food Codes [except Industry 16 (seafood)] and Industry 45-46 (Food Additives)
Product/Assignment Codes:	09006C Color Additives 09006F Food Additives

FIELD REPORTING REQUIREMENTS:

Report all domestic sample collections and analytical results into the Field Accomplishment and Compliance Tracking System (FACTS). Report all import samples in System for Entry Review and Import Operations (SERIO).

Report all inspections into eNSpect. Scan product labeling and any product brochures into eNSpect as an exhibit.

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Change History

Item	Change	Date
Issuance	CP 7309.006 initial issuance	10/28/2019
Minor Updates	• PART III – INSPECTIONAL #1, B Sample Size • PART VI – REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS, #3, p.28	12/07/2023
Minor Updates	• PART VI – REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS, #3, p.28	06/06/2024

Item	Change	Date
Minor Updates	• Updated to reflect organizational changes. • Added specific Import field reporting requirements. • Added clarifying language. • Updated, added, and removed hyperlinks. • Updated interacting compliance program names. • Removed analytical information related to samples analyzed for sulfite levels. • Removed color additive "ECC No." references. • Clarified why some COL samples receive additional ELE analysis. • Added potential regulatory responses. • Updated PART V – REGULATORY/ADMINISTRATIVE STRATEGY to reflect current OCIC consultation and OE case routing. • Updated, added, and removed associated import alerts. • Updated program contacts.	05/13/2025

PART I - BACKGROUND

Public health issues have been associated with food additives, color additives, and undeclared ingredients in food. For example, the Food and Drug Administration (FDA) identified food that contained undeclared sulfites that can cause allergic reactions in sensitive individuals. The Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations are the basis for sample collection and examination of food for food additives, food contact substances, and color additives that may be unsafe, undeclared, nonpermitted, and/or used in a manner that is not in compliance with applicable regulations. This compliance program includes instructions for monitoring of food for food additives, food contact substances, color additives, and the declaration of all certified and certification-exempt color additives.

General Information About Food Additives, Color Additives, and Food Contact Substances

Section 201(s) of the FD&C Act defines "food additive" as any substance where the intended use may result or reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristic of any food. This includes any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food and any source of radiation intended for any such use. Therefore, if any substance added to food is not "generally recognized as safe" (GRAS) under its intended conditions of use, sanctioned prior to 1958, or otherwise excluded from the definition, it would be considered a food additive.

Section 201(t)(1) of the FD&C Act defines "color additive" as any substance that imparts color to FDA-regulated products. Many different types of substances are used as color additives. Some are soluble organic dyes and insoluble pigments, while others are plant extracts, spices, and mineral compounds. "Straight colors" are dyes that have not been mixed or chemically reacted with any other substance. "Lakes" are insoluble pigments formed by chemically reacting straight colors with precipitants and substrata. "Mixtures" are color additives combined with other non-colored components by simple mixing. Substances that impart color by using optical properties such as those achieved by layered particles (i.e., mica) are also color additives. The FDA does not consider any color additives to be "natural" constituents in foods because they are artificially added. Therefore, both certified and certification exempt color additives are considered "artificial colors." Food ingredients that contribute their own colors to food, such as strawberries, green or red peppers, or chocolate, are not considered color additives (21 CFR 70.3(f)) provided that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned (21 CFR 70.3(g)).

Pre-approval of food additives and color additives is required by the FDA before they can be used in food and, for color additives, in other FDA-regulated products (drugs, cosmetics, and certain medical devices). To obtain approval for use of a new food additive or color additive, an interested person may petition the FDA and submit data demonstrating its safety. Regulatory requirements for food additive and color additive petitions may be found in 21 CFR part 171 and 21 CFR part 71, respectively. A substance that is GRAS under its intended conditions of use is excluded from the definition of "food additive," and thus is not subject to pre-approval under the FD&C Act. "GRAS" is not an inherent property of a substance. The use of a substance is concluded to be GRAS for a certain technical effect, for use in certain foods, and at a certain level in those foods. There is no GRAS exemption for the use of color additives.

A partial list of GRAS substances may be found in 21 CFR parts 182, 184, and 186. Some prior-sanctioned food ingredients are listed in 21 CFR part 181. Since 1997, FDA has administered a GRAS Notification Program whereby a person may inform FDA of a conclusion that the use of a substance is GRAS. FDA's GRAS Notification Program is voluntary; therefore, a company may independently conclude that the use of an ingredient is GRAS and choose not to inform FDA about its GRAS conclusion. This is known as an independent GRAS conclusion. However, a company is still responsible for ensuring that the GRAS food ingredients the company manufactures, distributes, or offers for sale in the United States are safe and lawful within the meaning of FD&C Act.

In 2016, to strengthen oversight of food ingredients, the FDA issued a final rule (81 *FR* 54960) detailing the criteria for concluding that the use of a substance in human or animal food is GRAS. Unlike food additives, GRAS substances are not subject to FDA pre-market approval; however, they must meet the same safety standards as approved food additives. Additionally, the FDA issued its final determination that partially hydrogenated oils (PHOs) are not GRAS for any use in human food (80 FR 34650; June 17, 2015). See Attachment A for additional information.

Section 409(h)(6) of the FD&C Act defines "food contact substance" as any substance 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 a technical effect in such food. More information on food contact substances can be found at FDA.gov: Packaging & Food Contact Substances.

The Food Contact Substance Notification Program replaced the petition process (in 1997) as the primary means for authorizing new uses of food additives that are considered food contact substances (e.g., indirect additives). Most indirect additives and some secondary direct additives (e.g., processing aids) are reviewed under the Food Contact Substance Notification Program. Effective food contact notifications (FCNs) are listed on the FDA website (Inventory of Effective Food Contact Substance Notifications). The listed FCNs are manufacturer-specific.

Regulations

Regulations for food additives directly added to food are found in 21 CFR part 172. Regulations for secondary direct food additives (those that have a technical effect during processing but not in the finished food) are found in 21 CFR part 173. Regulations for indirect food additives (those that come into contact with food but are not added directly and are not intended to have a technical effect in food) are found in 21 CFR parts 174-178. Indirect food additives are substances used in food-contact articles and include adhesives and components of coatings (21 CFR part 175), paper and paperboard components (21 CFR part 176), polymers (21 CFR part 177), and adjuvants and production aids (21 CFR part 178). Additional indirect additives that are authorized through the food contact substance notification program or that are exempted from regulation as food additives in accordance with 21 CFR 170.39 *Threshold of Regulation (TOR) exemptions for substances used in food-contact articles* are listed in separate inventories on FDA's website (FCN inventory and TOR inventory). Per 201(s) of the FD&C Act, when used on food, sources of irradiation are considered "food additives". Regulations for permitted sources of radiation used for inspecting and treating food are found in 21 CFR part 179.

Permitted color additives are listed in 21 CFR parts 73, 74, 81, and 82. The color additives listed in 21 CFR part 73 are exempt from certification. This category generally includes substances derived from plant or mineral sources and, in one case, an insect source. The color additives listed in 21 CFR parts 74, 81, and 82 are synthetic organic dyes, pigments, and lakes. These color additives are

required to be batch certified, which means that FDA chemists test a sample from each new batch to ensure compliance with the corresponding color additive specifications. Seven color additives that are synthetic organic dyes are permitted for general use in foods: FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Yellow No. 6. All except FD&C Red No. 3 may be used as components of aluminum lakes, also permitted for general use in foods. The requirements for chemical identity, specifications, permitted uses, and restrictions are included in the individual listing regulations.

Food ingredients must be declared on food labels in accordance with the regulations in 21 CFR part 101. Declaration of all color additives on food labels is required under the Nutritional Labeling and Education Act of 1990 (NLEA) and its implementing regulations. Under 21 CFR 101.22(k)(1), the color additives subject to certification and have been documented to be certified are required to be declared by their listed names (for example, FD&C Blue No. 1 or FD&C Red No. 40 Aluminum Lake). Appropriate abbreviations may be used (for example, Blue 1 or Red 40 Lake) and alternative names may be declared in parentheses, such as the European E numbers or Colour Index (C.I.) numbers. Under 21 CFR 101.22(k)(2), most color additives listed in Part 73 not subject to certification may be declared on food labels as "Artificial Color," "Artificial Color Added," "Color Added," or by an equally informative term that makes clear that a color additive has been used in the food. They also may be declared as "Colored with _____" or "_____ Color," with the blank filled in by the listed name. Under 21 CFR 101.22(k)(3), when a color additive has been added to butter, cheese, or ice cream, the color additive does not have to be declared in the ingredient list unless declaration is required by a regulation in 21 CFR parts 73 or 74. Cochineal extract, carmine, and FD&C Yellow No. 5 are specifically required to be declared on all food labels under 21 CFR 73.100(d) and 21 CFR 74.705(d).

Under 21 CFR 70.25, color additives marketed to product manufacturers ("bulk" color additives) must be labeled with their listed names, general limitations (e.g., "for food use only" or "for food, drug, and cosmetic use"), any quantitative limitations, an expiration date (if stability data require it), other special labeling, if appropriate (e.g., "Do not use in the area of the eye"), and certification lot numbers if the color additive is required to be certified (with certain exceptions; see 21 CFR 70.25(d)). Under 21 CFR 80.39, manufacturers of certified color additives must keep certain records, which are subject to FDA inspection.

PART II - IMPLEMENTATION

1. **Objectives**

- To collect and analyze domestic and import samples per the "Program Sampling Priorities Table (Domestic and Import)" to determine if they are in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act).
- To conduct label examinations of domestic and imported foods.
- To enforce food additive and color additive regulations for products that are not in compliance with the FD&C Act.

2. **Program Management Instructions**

- **Inspection Priorities**

  Domestic and foreign inspectional priorities for compliance with food additive and color additive regulations are covered under the Preventive Controls and Sanitary Human Food Operations Compliance Program (CP). However, specific instructions pertaining to label review and color additive manufacturer inspections are provided in this compliance program (see Part III).

  Foreign Supplier Verification Program (FSVP) inspections for food additive and color additive importers will be covered by FSVP inspection compliance program or assignment.

  Inspection of color additive manufacturers subject to 21 CFR part 117 (Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (cGMP & PCHF)) will be identified in the Food Safety Modernization Act (FSMA) High risk (HR)/Non- High Risk (NHR) workplan.

- **Label Exams and Sample Collection Priorities**

  Priorities for domestic and import label exams and sample collections should focus on the "Program Sampling Priorities Table (Domestic and Import)." Further, import label exams and sample collections should focus on products from firms that are not included in existing Import Alerts (IAs) (see Part V). If label examinations or samples of imported food products that are not already on IA are found to be violative, the division should recommend addition of the foreign firm and/or product to an IA for Detention Without Physical Examination (DWPE) or revision of an existing IA.

- **Planning instructions**
  - Domestic and foreign inspections will be targeted under the Preventive Controls and Sanitary Human Food Operations CP for each fiscal year.
  - Sampling under this compliance program will be planned and directed in the Sample Collection Operation Planning Evaluation (SCOPE) program.
  - For-cause samples can only be collected during domestic inspections of manufacturing establishments.

- Prior to conducting import label exams or sample collections, review the "Program Sampling Priorities Table (Domestic and Import)" and any appropriate IAs or Import Bulletins (IB). Conduct label reviews of imported food products for potential food additive and color additive deficiencies based on historical and current data. Focus on sample collections of imported food products when there is known or suspected potential for food additive and color additive deficiencies.

- **Interactions between compliance programs**

  This compliance program may have some interactions with the following CPGMs. Use the appropriate PAC when reporting sample collections under this compliance program.

  - Preventive Controls and Sanitary Human Food Operations CP, 7303.040 - Inspections for food and color additives are subject to the cGMP & PCHF rule and covered under the Preventive Controls and Sanitary Human Food Operations CP.
  - Import Foods - General, 7303.819
  - General Food Labeling Requirements and Labeling-Related Sample Analysis – Domestic and Import, 7321.005
  - Cosmetics (Domestic and Import), 7329.001
  - Seafood Processor, Products, and Importer Inspection Program, 7303.842
  - Milk Safety, 7318.003
  - Toxic Elements in Food and Foodware, and Radionuclides in Food - Domestic and Import, 7304.019
  - Pesticides and Industrial Chemicals in Food - Domestic and Import, 7304.004
  - Foreign Supplier Verification Programs and Inspections, 7303.878

- **Resource instructions**

  - Resources for sample collections, analyses, import label exams, and emerging issues for food additives and color additives are provided in the OII Field Workplan.
  - Resources will be allocated through a prioritization process.

- **Interactions with other Federal agencies, State and local counterparts, and foreign authorities**

  - Divisions will collaborate with commissioned State agencies to make them aware of the requirements of the program (in advance of the beginning of the program) and deadlines for deliverables. Divisions will offer State agencies an opportunity to accompany FDA inspections/sample collections or assist as necessary.
  - States may share their analytical data with FDA. After reviewing the results, FDA may consider follow-up.
  - Memorandum of Understanding (MOU) 225-99-2001 exists between FDA and the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA) to facilitate an exchange of information between the agencies about establishments and

operations that are subject to the jurisdiction of both agencies. FSIS should report undeclared color additives FD&C Yellow No. 5, cochineal extract, and carmine and undeclared sulfites (https://www.fda.gov/about-fda/domestic-mous/mou-225-99-2001).

- MOU 225-00-2000 exists between the FDA and FSIS, USDA to serve as a joint effort to respond to requests for sanctioning the use of food ingredients and sources of radiation intended for use in the production of meat products and poultry products (https://www.fda.gov/about-fda/domestic-mous/mou-225-00-2000-amendment-1).
- MOU 225-88-2000 exists between the FDA and The Bureau of Alcohol, Tobacco, and Firearms and Explosives to clarify the enforcement responsibilities regarding alcoholic beverages that are considered adulterated (e.g., contains an unapproved food additive) under the FD&C Act (https://www.fda.gov/about-fda/domestic-mous/mou-225-88-2000).

PART III - INSPECTIONAL

1. **Operations**

A. Inspections

Inspections of food facilities and color additive manufacturers subject to 21 CFR part 117 are performed under the Preventive Controls and Sanitary Human Food Operations Compliance Program.

Inspections of food additive and color additive FSVP importers will be covered by the FSVP inspection compliance program or assignment.

Specific instructions for routine inspectional coverage pertaining to food additives and color additives are provided below:

i. Food Additives

During inspections of manufacturing facilities for compliance with food additive regulations investigators should:

- refer to the Investigations Operation Manual (IOM), Section 5.8.6.3, "Food Additives" for routine inspectional instructions
- refer to the Substances Added to Food inventory for a searchable list of food additives inclusive of short notations on use limitations for each additive
- focus primarily on unauthorized and illegal food additives (safrole, thiourea, etc.) and those restricted to the amounts permitted in finished foods
- check products containing Aspartame/NutraSweet for the required statement (21 CFR 172.804(d)(2))
- check products for sulfites and sulfite ingredient declaration
- follow the instructions in Attachment A if the investigator finds a manufacturer using PHOs or a PHO-containing ingredient

ii. Food Additive Manufacturers

Establishment inspections of firms manufacturing food additives are reviewed by the FDA at the following three levels: Primary Manufacturer - firms that synthesize or manufacture additives (Codex products); Secondary Manufacturer or Mixer (Formulators) - firms that compound premixes containing the additive(s) for specific industries; and Finished Food Processor (User) - firms that incorporate the additive as a component of finished food.

Further information is available in OII's "Guide to Inspections of Manufacturers of Miscellaneous Food Products - Volume II."

iii. Color Additives in Food Products

During inspections of food manufacturing facilities for compliance with color additive regulations investigators should:

- refer to the IOM, Section 5.8.6.4, "Color Additives" for routine inspectional coverage

- refer to the Regulatory Status of Color Additives for current information that will enable determination of the status and limitations of most color additives likely to be encountered in establishments
- determine whether color additives are used as ingredients in accordance with existing regulations or tolerances in food that are consumed by sensitive populations, or considered high risk, or have larger manufacturing volume
- check for the color additive ingredient declaration and put emphasis on certified color additives, cochineal extract/carmine, and others identified in the Program Sampling Priorities Table (Domestic and Import)
- be aware that firms might use unlisted or restricted color additives through ignorance of changes in regulations; by deliberately using up old stock to avoid financial losses; and/or using technical grades of color additives because they are cheaper

Inspections may generate for-cause sample collection (see Sample Collections below). Voluntary corrections should be encouraged during inspections.

For color additives required to be certified, check whether certified lots are being used. This cannot be determined analytically. The validity of certification information can be checked by accessing the online Color Certification Database system. Certification lot numbers should be declared on the labeling of bulk color additives that have been certified by the FDA. Check the labeling of the color additives and color additive mixtures used as ingredients against the requirements of 21 CFR 70.25 and 80.35(b).

21 CFR 101.22(k) and CPG 7127.01, section 587.100 should be used as directions for the declaration of both certified color additives and color additives exempt from certification on food labels.

The NLEA requires that all certified color additives used in food be declared by the name of the color additive listed in 21 CFR 74 or 82. Abbreviations for certified colors may be declared in accordance with 21 CFR 101.22(k)(1). Also, use 21 CFR 74.705 for the declaration of FD&C Yellow No. 5. Color additives exempt from certification must be declared in accordance with 21 CFR 101.22(k)(2), except use 21 CFR 73.100 for the declaration of cochineal extract and carmine.

FD&C Red No. 3 is currently permitted for use in foods only in the form of the straight dye. “Lakes” of the dye have not been permitted in FDA-regulated foods since January 29, 1990, but they are permitted for food use in other countries. Due to analytical difficulties in distinguishing between the straight dye and its lakes when in a food matrix, the suspected use of FD&C Red No. 3 lake in a domestic food should be documented at the manufacturer through record collection and observations.

iv. Color Additive Manufacturers

Color additive manufacturer inspections are conducted to ensure compliance with current regulations including requirements for packaging, labeling, storage, documentation of cGMP, and recordkeeping for distribution of color additives.

Inspections of selected color additive manufacturing firms will be conducted under the Preventive Controls and Sanitary Human Food Operations CP.

During the inspections:

- compare requests for certification with those documents maintained at the selected firm
- review the manufacturers' certified color batch distribution records
- for-cause, official samples of certified colors may be collected for verification of certification (see Section C below for sampling and shipping instructions)

B. Sample Collections

General Information (domestic and import)

Refer to current SCOPE for number of food additive and color additive samples to collect. Select samples per the "Program Sampling Priorities Table (Domestic and Import)."

In addition, sample collections for food additives and/or color additives should:

- cover food consumed by vulnerable populations (i.e. infants, elderly persons, persons with weakened immune systems, etc.)
- prioritize emerging issues related to food additives and color additives
- focus on foods that are more highly consumed among the U.S. population
- **do not** collect dried garlic
- target larger volumes or repeated small volume shipments
- include scanned labels (or clear photographs) for review of food products, when the label identifies a color not permitted by a color additive regulation for use in food products in the United States. Do not collect a physical food sample.
- include a photograph(s) of the label for all samples collected for analysis (ensure that pictures are clear and taken from all sides of the label)
- Specify in the Collection Report (CR) if the sample was collected for sulfites, non-nutritive sweeteners, benzoates/sorbates, vanilla extract authenticity, or other analysis. If other, please contact the Human Foods Program (HFP) OLOAS Program Coordinator prior to shipping to learn which laboratory can analyze the sample.

Further, when considering food samples, collect products that:

- contain color additives that have methods for analysis (e.g., certified color additives, cochineal extract/carmine, and others identified in the Program Sampling Priorities Table (Domestic and Import)
- have color, but have no obvious source of corresponding color listed on the label, for analyses for synthetic organic colors (e.g., a blue appearing food declaring only FD&C Red No. 40, and it is not obvious what is imparting the blue color to the product)

- have labels identifying color solely with a term such as "permitted color," "color added," or "artificial color," for determination if the product actually contains a color additive that is subject to certification instead of only exempt colors

NOTE: When investigators encounter situations where PHOs are declared as an ingredient in the food label or labeling of human food, or when PHOs are being used in the manufacture of human foods, refer to the instructions in Attachment A.

Import Sample Collection

In addition to information under "General Information," consider the following instructions for import sample collection:

- For Entry Review and Label Examinations refer to IOM Subchapter 6
- Refer to Regulatory Procedures Manual (RPM) Chapter 9, Subchapter "Import Information Directives" for procedural guidelines about FDA Import Alerts and Import Bulletins.
- When selecting samples, investigators should focus on products from firms that are not included in existing Import Alerts (IAs). Refer to Part VI for a link to relevant existing IAs.

Collect labels for review of food products, rather than physical samples for analysis, when the ingredient labels identify:

- certifiable colors not using the certified name
- European "E" color designation (e.g., E104 additive)
- a Color Index number (e.g., C.I. 15985)
- an International Numbering System (INS) number
- a trade or common/usual name (e.g., Sunset Yellow FCF)

Note: Do not target labels for review which list the certified name *in addition to* the "E" color, Color Index number, INS number or trade or common/usual name. Laboratory confirmation is not required for the above labeling deficiencies.

For-cause Sample Collection during inspection

If it is determined that for-cause food additive or color additive samples will be collected during an inspection, refer to the following instructions:

- For food additive samples, if a physical sample of the finished product containing the additive is collected, always collect a physical sample of the pure additive and its label.
- Do not collect samples of food products containing a suspected FD&C Red No. 3 lake for analysis. Due to analytical difficulties, the straight dye and its lakes, when in a food matrix, cannot be distinguished. The suspected use of FD&C Red No. 3 lake should be documented at the manufacturer through record collection and observations.

- Color additive samples must be collected in plastic/glass jars and the containers must be securely sealed with tape around the lid to prevent moisture pickup and to prevent dye from escaping.
- If certified color additives are found at the food manufacturing facility, if possible, collect up to five official samples of different certified color additives. Official samples for verification of certified colors should be sent to

  OCS, OCAC, Division of Color Certification and Technology,
  Color Certification Branch (CCB), HFS-107
  Attn: Amelia Morris
  4300 River Road, College Park, MD 20740

Sample Size:

- See IOM Sample Schedule Chart 9 for general sample size information for collecting samples of **color additives** to determine whether non-permitted color additives are present.
- No single sampling schedule is available for all **food additives** and foods containing them. Samples should consist of **ten (10) randomly selected subsamples** from a single lot. Each subsample should be **8 ounces** or more. If the lot consists of individual "consumer size" containers, collect 10 randomly selected containers. If the consumer size is less than 8 oz, collect enough units per sub to make up 8 oz. If the lot consists of bulk size containers, collect 10 subsamples of at least 8 ounces each. Do not co-mingle the subsamples collected from bulk containers.

  For domestic samples only, unless an exemption applies as specified in **IOM Chapter 4 (21 CFR 2.10(b))**, collect an additional 10 subsamples as a **702(b)** sample portion, of equal portions from the same lot. If 10 additional subsamples of the same lot are not available, collect as many as possible as a 702(b) portion, preferably a minimum of 5 subsamples **from the same lot**.
- If unusual sampling situations arise that may not be addressed by the above instructions, contact your Supervisory Consumer Safety Officer (SCSO) or the HFP Compliance Program Monitor (see Part VI).

Sample Shipping:

The investigator should ship product samples to a servicing laboratory per the Lab Servicing Table (LST) Dashboard.

2. **Reporting**

Report resources utilized for sample collection using the following Program Assignment Codes (PACs) and Problem Area Flags (PAF):

PAC	PAF	PAF Description
09006C	COL	Color Additives
09006F	FAD	Food Additives

PART IV - ANALYTICAL

1. **Analyzing Laboratories**

   Refer to the current LST Dashboard for Food Additive and Color Additives to determine the analyzing laboratory.

   Official dye samples for verification of certified colors will be analyzed by OCS, OCAC, Division of Color Certification and Technology, Color Certification Branch (CCB).

2. **Analyses to be Conducted**

   Samples will be analyzed for food additive (FAD) or color additive (COL).

   If Sudan I is declared on the label, analysis is not required. However, to support regulatory action of products suspected of containing undeclared Sudan Red I, analysis is required.

   For-cause samples will be analyzed according to the description in the collection report.

   The division can have Direct Reference Authority (DRA) for either Detention or Detention without Physical Examination (DWPE) recommendations if the analyses are performed by a **qualified analyst.** A check analyst is not required to perform an additional analysis, if two different analytical techniques are used by the qualified analyst.

   An analyst must meet the criteria below to be considered a qualified analyst:

   - a minimum of two-year experience as a color additive analyst (preferably consecutive time/experience equivalent)
   - worked on 75 samples or more per year for two years
   - analyzed a minimum of five samples per year for different product types (e.g., beverage, candy, bakery, and seafood products)
   - attended Color Additive training course and passed proficiency test sample at the end of the course
   - participated in at least one National Quality Assurance Check Sample with good results
   - familiar with current status and use limitations of color additives
   - familiar with different color additive nomenclature and labeling requirements
   - reviews and evaluates analytical work performed by private laboratories
   - provides regulatory guidance and training to FDA and non-FDA personnel

3. **Methodology**

Food Additives

Sample Preparation for All Foods

All samples will be analyzed on a composite basis. Prepare a composite by thoroughly mixing together equal portions (usually 50g-100g) from each sub sample. The original and check portions will be taken from the same composite.

Analytical Methods

Use methodology appropriate for the product as well as the additive for which the product is being tested. Various analytical methodology sources are available for food additives and food additive combinations in addition to those listed below. Consult with the CFSAN ORS analytical contact (see Part VI) prior to analysis if there are questions about the appropriate methodology.

NOTE: Please refer to Section 2.3.3.1 (Chapter 2) of the Field Science Laboratory Manual (LM) for instances where a check analysis is necessary.

- AOAC, Official Methods of Analysis, 17th Ed., or the most current Ed., Chapter 47 and 48.
- Food Additives Analytical Manual, Vol. I and II, 1983 and 1987.
- Food Chemicals Codex, 11th Edition, or earlier editions as referenced in the appropriate regulations in 21 CFR 170-199.
- Antioxidants in Fats and Oils: AOAC, 17th Ed, or most current Ed., 02, "Antioxidants in Oils and Fats, Liquid Chromatographic Method.
- Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry: Collaborative Study (https://doi.org/10.5740/jaoacint.17-0033; see also the Compendial method C004 https://www.fda.gov/media/114411/download) which should be used for analysis. If questions regarding the use of the method arise, please contact the Sulfite SME, Katie Carlos, katherine.carlos@fda.hhs.gov.
- For sulfite samples analyzed with the LC-MS/MS method listed above, no check analysis is required. The samples should be analyzed in duplicate. A percent relative difference should be calculated for the two extracts and the percent difference should be less than 20%.
- 3-Chloro-1,2-propanediol (3-monochloro-1,2-propanediol, 3-MCPD): AOAC, Official Method 2000.01 (First Action, 2000). This method is listed in the 18th edition. This method was validated by a collaborative trial according to criteria of the AOAC, described in Journal of AOAC International, 84 (2001) 455-465.
- Coumarin in food, AOAC, Official Methods of Analysis, 13th edition of AOAC (1980), or most current edition of AOAC.
- Lowri S. de Jager, Gracia A. Perfetti, Gregory W. Diachenko, Determination of coumarin, vanillin, and ethyl vanillin in vanilla extract products: liquid chromatography mass spectrometry method development and validation studies, Journal of Chromatography A, 1145 (2007) 83-88.
- Laila Ali, Gracia Perfetti, and Gregory Diachenko, Rapid Method for the Determination of Coumarin, Vanillin, and Ethyl Vanillin in Vanilla Extract by Reversed-Phase Liquid

Chromatography with Ultraviolet Detection, Journal of AOAC International 91 (2008) 383-386.

Color Additives in Domestic and Imported Foods

Sample Preparation for All Foods

All samples will be analyzed on a composite basis (as needed) by thoroughly mixing subsamples together (usually 50g-100g). If composited, the original and check portions may be taken from the same composite.

Analytical Methods

Use methodology appropriate for the color additive being tested. Various analytical methodology sources are available for color additives in addition to those listed below. Consult with the Office of the Chief Scientist, OCAC analytical contact prior to analysis if there are questions about the appropriate methodology.

- AOAC, Official Methods of Analysis, 17th Ed. or the most recent Ed., Chapter 46
- Sudan I: Laboratory Information Bulletin (LIB) 4583 or Genualdi, S.; MacMahon, S.; Robbins, K.; Farris, S.; Shyong, N.; DeJager, L. "Method Development and Survey of Sudan I-IV in Palm Oil and Chilli Spices in the Washington D.C. area". Food Additives & Contaminants: Part A, 2016 33 (4), 583-591.
- Carbon Black: LIB 4485.
- Table olive adulteration by copper salts: LIB 4621.
- Color additives in foods: LIB 4498, LIB 4537, and LIB 4643.

NLEA requires the declaration of all certified color additives by name or appropriate abbreviation (21 CFR 101.22(k)(1)). If undeclared certifiable colors are found in a sample, perform check analyses to confirm the presence of each undeclared certifiable color additive as appropriate depending on the investigational evidence developed (see Part III).

- When a certifiable color additive is not declared on the label, it cannot be determined whether FDA certified it for use in food products without evidence that the color additive came from a batch that has been certified (e.g., FDA certification lot number, record review, investigational observations that a certified color additive was at the manufacturing site and/or used in the finished product, etc.).
- The original or check analyses for the identification of non-permitted/ non-listed or undeclared color additives should include visible spectra of the isolated color additive, ideally under acidic, basic, and neutral conditions, when possible, or other definitive identification against a standard. Standard reference spectra in the same solvents as those for the isolated color should be included in the analytical worksheets. Confirmatory analyses should include at least two lines of characterizing data (e.g., UV-Vis spectra, TLC Rf-value, HPLC retention times, etc.). TLC confirmation should include either tables of Rf-values or high-quality reproductions of the TLC plates with spots clearly circled and labeled. The color of the spots and streaks should also be reported. In addition, spots should be checked under UV light. The presence or absence of fluorescence as well as the visual color of the

fluorescence should be reported to support the identity of fluorescent dyes. HPLC retention times should include matching spectra against standards.

- If non-permitted/ non-listed color(s) are found, a check analysis must be performed. If the original analyses are performed by a **qualified analyst**, then one of the two methods used should include UV/VIS spectra. Spectra should be included by either the original or the check analyst. If one non-permitted/ non-listed color is confirmed, identification of the remaining color components in the product is not necessary.
- Attempt to identify any non-permitted/ non-listed color (s) present.
  - As resources permit, the identification and confirmation of the other color(s) present would improve the agency's database concerning color usage.
  - If the color cannot be identified, at least two lines of characterizing data (e.g., UV-Vis spectra, TLC Rf-value, HPLC retention times, etc.), submitted by both analysts, should be included to show that the data does not match any permitted color additives.
- Be aware of the presence and possible separation of subsidiary and isomeric dyes, which are permitted in many of the FD&C colors (see 21 CFR Part 74). Their presence may be more evident when high-resolution techniques are employed such as HPLC and HPTLC. Excessively high levels of subsidiaries in Tartrazine, Sunset Yellow FCF, and Allura Red AC may indicate the use of non-certified batches of these dyes and should be noted as a possibility on the analytical screen.
- Do not quantitate the color additives unless limits have been established.

Color additives authorized by regulation for safe use in food products are FD&C Red No. 3, Citrus Red No. 2, FD&C Red No. 40, FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, Orange B, FD&C Yellow No. 5, and FD&C Yellow No. 6. The color additives must be from batches that have been certified by the FDA. Analytically, it cannot be determined that a color additive in a food matrix subject to certification has in fact been certified. Therefore, conclusions should not simply state "contains FD&C Yellow No 5." Analysts should report their findings as follows:

- Allura Red AC (C.I. 16035, E129, certifiable as FD&C Red No. 40)
- Brilliant Blue FCF (C.I. 42090, E133, certifiable as FD&C Blue No. 1)
- Citrus Red 2 (C.I. 12156, no EU designation, certifiable as Citrus Red No. 2 for use only for coloring the skins of oranges that are not intended or used for processing); the common name for Citrus Red No. 2 is C.I. Solvent Red 80.
- Erythrosine (C.I. 45430, E127, certifiable as FD&C Red No. 3)
- Fast Green FCF (C.I. 42053, certifiable as FD&C Green No. 3)
- Indigotine (C.I. 73015, E132, certifiable as FD&C Blue No. 2)
- Orange B (C.I. 19235, no EU designation, certifiable as Orange B for use only in coloring frankfurter and sausage casings)
- Sunset Yellow FCF (C.I. 15985, E110, certifiable as FD&C Yellow No. 6)

- Tartrazine (C.I. 19140, E102, certifiable as FD&C Yellow No. 5)

Refer to the Regulatory Status of Color Additives for current information that will enable determination of the status and limitations of **most** color additives likely to be encountered in establishments. For a complete list of approved color additives see: Summary of Color Additives for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices.

Be aware that the following color additives are not listed by FDA for use in food products in the United States but are approved in other countries.

- Amaranth (C.I. 16185, E123, formerly certifiable as FD&C Red No. 2).
- Azorubine (C.I. 14720, E122, formerly certifiable as Ext. D&C Red No. 10); also called Azo Rubine and Carmoisine.
- Ponceau 4R (C.I. Acid Red 18, C.I. 16255, E124, no certifiable equivalent); also called Cochineal Red A, Brilliant Scarlet 3R and Brilliant Scarlet 4R, but not Brilliant Scarlet which is a different color (C.I. 15585:1, formerly certifiable as D&C Red No. 8).
- Rhodamine B (C.I. 45170, chloride and stearate salts formerly certifiable as D&C Red No. 19 and D&C Red No. 37).
- Quinoline Yellow (C.I. 47005, E104, C.I. Acid Yellow 3, C.I. Food Yellow 13).
- In the United States, primarily monosulfonated Quinoline Yellow is certifiable as D&C Yellow No. 10 for use in drug and cosmetics but is not permitted in foods. The Quinoline Yellow allowed in European and other countries is the primarily disulfonated form of the color additive.

The field should also be aware of the inappropriate use of certain color additives in food products, e.g., the use of drug and cosmetic (D&C) or external drug and cosmetic (Ext. D&C) color additives or of FD&C Red No. 4, which is not listed for food use despite the FD&C designation.

4. Reporting

Report all analytical results (food additives and color additives) into Field Accomplishment and Compliance Tracking System (FACTS) using the following Problem Area Flags (PAF) and Program Assignment Codes (PACs):

PAC	PAF	PAF Description
09006C	COL ELE[1]	Color Additives
09006F	FAD	Food Additives

[1] When green olives are analyzed for COL, they potentially receive both COL and ELE testing under PAC 09006C.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

The overarching program goal is to remove adulterated and misbranded products from the market and prevent the future entry of these products into commerce. During the development of a regulatory action it is imperative to establish JIVR (jurisdiction, interstate commerce, violation and responsible firm, person, and/or party) and supporting evidence. When sufficient evidence has been established to support adulteration and/or misbranding, divisions should use the following table to aid in determining the appropriate regulatory response.

Regulatory activities that should be considered for food additive and color additive violations:

FD&C Act Charge	**Possible Regulatory Response*** Domestic	**Possible Regulatory Response*** Import
Adulteration, Section 402(a)(2)(C)(i); the article appears to be or to bear or contain any unsafe **food additive**.	Untitled Letter (UTL) Warning Letter (WL) Regulatory meeting Recall Follow-up inspection Administrative Detention Seizure Injunction	Detention and refusal of entry Firm/product added to Import Alert (IA) DWPE letter
Adulteration, Section 402(c); the article appears to be or to bear or contain a **color additive** which is unsafe.	Untitled Letter (UTL) Warning Letter (WL) Regulatory meeting Recall Follow-up inspection Administrative Detention Seizure Injunction	Detention and refusal of entry Firm/product added to Import Alert (IA) DWPE letter

FD&C Act Charge	Possible Regulatory Response* Domestic	Possible Regulatory Response* Import
Misbranding, Section 403(i)(2); the article is fabricated from two or more ingredients but does not bear the common or usual name of each ingredient.	Untitled Letter (UTL) Warning Letter (WL) Regulatory meeting Recall Follow-up inspection Administrative Detention Seizure	Detention and refusal of entry Firm/product added to Import Alert (IA) DWPE Letter
Misbranding, Section 403(k); the article appears to bear or contain an undeclared artificial color additive.	Untitled Letter (UTL) Warning Letter (WL) Regulatory meeting Recall Follow-up inspection Administrative Detention Seizure	Detention and refusal of entry Firm/product added to Import Alert (IA) DWPE Letter

* **NOTE**: For unique or unusual evidence or questions regarding regulatory strategy, consider submitting a Compliance Intake and Consultation Form to HFP using the Division of Compliance Consultation regulatory contact listed in Part V for review prior to generating a case.

Consider referral to the State when:

There is no evidence of interstate commerce and/or if a violation is pervasive within a community and State involvement may be leveraged to move expeditiously.

Consider a regulatory meeting when:

The implicated domestic product does not pose a significant public health concern and the criteria for a regulatory meeting is met. See Regulatory Procedures Manual (RPM) Chapter 10-3.

Consider a recall when:

- Voluntary Recall - Violative product has been distributed outside the control of the manufacturer.
- Mandatory Recall - If a determination is made that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 or misbranded under 403(w) and the use of or exposure to such article will cause "serious adverse health consequences or death to humans or animals" (SAHCODHA), mandatory recall under section 423 should be considered.

Consider a follow-up inspection when:

A Class I recall was initiated for a sampled product (refer to the Preventive Controls and Sanitary Human Food Operations CP for detailed inspection instructions).

Consider administrative detention when:

A seizure is contemplated **and** the Agency needs to quickly gain control of the food while the seizure case is built.

Consider a seizure when:

The criteria is met per RPM Chapter 6, Section 6-1-2 General Guidelines for Seizures (i.e., the adulteration meets SAHCODHA).

Consider recommending Detention Without Physical Examination (DWPE) when:

- The criteria are met for DWPE (RPM Chapter 9-8).

  All DWPE recommendations should be forwarded to DIO Import Compliance Branch (Compliance Team) inbox in CMS with all accompanying documentation, to include laboratory work sheets (if applicable). For information regarding the removal of firms and/or products from DWPE, see the RPM Chapter 9-8-15 thru 9-8-19.

  See Part VI Reference R for a list of possible Import Alerts for consideration. This list is not exhaustive and subject to change.

- Review the criteria for each import alert before applying or recommending DWPE. For example:
  - IA 99-21, "Detention Without Physical Examination and Surveillance of Food Products Containing Sulfites" - Sulfites are not declared and analysis shows the presence of sulfites at levels greater than 10 ppm. A single violation is sufficient reason to recommend a firm/product for DWPE.
  - IA 99-45, "Detention Without Physical Examination of Food Products That Are or Contain an Unsafe Food Additive" - This import alert has been developed for food products, including dietary supplements, that have been imported or offered for

import into the United States that are adulterated under section 402(a)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 342(a)(2)(C)(i)] if it is or if it bears or contains any food additive that is unsafe within the meaning of section 409 of the FD&C Act [21 U.S.C. § 348].

- IA 45-02, "Detention Without Physical Examination and Guidance of Foods Containing Illegal and/or Undeclared Colors" - The product is labeled to contain non-permitted colors and/or the product labeling does not declare color additives as required, or color additives are not declared, and FDA analysis identifies a color additive which may be certifiable as an FD&C color.

Imported Products with European Named Colors

Many products bear ingredient labels identifying color additives subject to certification with their European name or ("E") color designation with a corresponding number (e.g., E104, E122, E123, and E124), by using a Color Index number (e.g. C.I. 15985), by using INS numbers, or using the trade or common name of the color additive (e.g. Sunset Yellow FCF). This suggests that the color additives used may not be from certified batches.

Imported Products with FD&C Red No.3

Only the **straight color** is permitted for use in foods [21 CFR 81.10(u)]. If the investigator or analyst has reason to suspect that an imported product contains a **lake** of FD&C Red No. 3 (for example if there is a past non-compliant history for the manufacturer/shipper/commodity), request additional information from the broker/importer.

When division compliance is considering adding a firm for DWPE under DRA, check that the laboratory analysis has met the following conditions:

When DRA is granted, HFP concurrence is assumed. See Direct Reference page for a complete and current list of DRA granted by HFP.

a) Requirements for Labs:

The division has appropriate equipment, apparatus, reagents, methods and standards.

b) Requirements for Color Analyses:

A qualified analyst performed and/or reviewed all analyses. The qualified analyst concluded that official or appropriate methods were correctly used and that all the analyses support the finding of the cited violation(s).

c) Requirements for Sulfite Analyses:

A sulfite labeling violation (with the exception of isolated soy protein) has been identified and the following criteria are **also** met:

- Analysis was performed on a composite of all subs collected.

- Determination of Sulfite in Food by Liquid Chromatography Tandem Mass Spectrometry: Collaborative Study (https://doi.org/10.5740/jaoacint.17-0033; see also the Compendial method C004 https://www.fda.gov/media/114411/download) should be used for analysis. If questions regarding the use of the method arise, please contact the Sulfite SME, Katie Carlos, katherine.carlos@fda.hhs.gov. For sulfite samples analyzed with the LC-MS/MS method listed above, no check analysis is required. The samples should be analyzed in duplicate. A percent relative difference should be calculated for the two and the percent difference should be less than 20%.
- The average of all original and duplicate extracts analyses is greater than 50 ppm (as sulfur dioxide).
- The results of all original and duplicate analyses agree within 20% with the exception of products containing Allium (e.g., onion) and Brassica (e.g., cabbage or broccoli) vegetables on their ingredient list.

Note: If the above conditions are met, no submission of lab analysis (e.g., analytical worksheets) for HFP review is required for the types of deficiencies cited.

Sampled lots

Do not release a sampled lot until the analyses are completed. Follow the directions in the RPM Chapter 9.

However, Divisions **should consider a detention recommendation of** a sampled lot without analyses if the product labeling declares an unapproved food additive or non-permitted color additive in the ingredient statement.

Specimen charge

The available import charge codes for a violation, with associated charge statements and statutory citations, may be found on the Import Detention Violation Codes page and/or a relevant IA.

Foreign Supplier Verification Programs for Food Importers (FSVP) Enforcement Discretion for Food Contact Substances

The FSVP regulation applies to importers of food and the food they import into the United States, unless there is an exemption. Importers of food contact substances are subject to the FSVP regulation. However, on January 4, 2018, FDA announced the availability of a guidance for industry entitled, "Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs." This guidance states that FDA intends to exercise enforcement discretion for importers of food contact substances with respect to the FSVP regulation. "Enforcement Discretion" means that FDA will not assess compliance with applicable regulatory requirements and will not base enforcement action on those requirements. FDA determined that because of certain characteristics related to the nature

of food contact substances, FDA's premarket review and oversight of food contact substances, and the regulatory framework for these substances, it is appropriate to exercise enforcement discretion with regards to the FSVP regulation. For more information, see the *Enforcement Discretion for Certain FSMA Provisions* fact sheet.

When the label review finds food(s) with PHOs declared on the label, follow the instructions provided in Attachment A.

PART VI - REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

1. **References**

Major guidance and reference materials pertaining to this program are listed below.

A. Program Sampling Priorities Table (Domestic and Import)
https://fda.sharepoint.com/sites/insideFDA-HFP-Office-of-Compliance-and-Enforcement/Program%20and%20Initiatives%20Documents/PAMB_Current%20Inspection%20and%20Collection%20Schedules/CP%207309.006%20Program%20Sampling%20Priorities%20Table%20(Domestic%20and%20Import).pdf

B. IOM Section 5.8.6.3 "Food Additives" through 5.8.6.4, "Color Additives", refer to the current edition of the IOM

https://www.fda.gov/media/166533/download?attachment

C. IOM Sample Schedule Chart 9 Sampling Schedule for Color Containing Products & Color Additives

https://www.fda.gov/media/166532/download?attachment

D. Guide to Inspections of Manufacturers of Miscellaneous Food Products - Volume II
https://www.fda.gov/miscellaneous-food-products-vol-2-996

E. Color Certification: Quick Links and FAQs
https://www.fda.gov/industry/color-certification/color-certification-faqs

F. Color Certification Database system
https://www.cfsanappsexternal.fda.gov/scripts/ocacapp/colorcert/lookup/default.cfm

G. Regulatory Status of Color Additives
https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=ColorAdditives

H. Summary of Color Additives for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices

https://www.fda.gov/industry/color-additive-inventories/summary-color-additives-use-united-states-foods-drugs-cosmetics-and-medical-devices

I. Substances Added to Food List

https://www.fda.gov/food/food-additives-petitions/substances-added-food-formerly-eafus

J. Generally Recognized as Safe (GRAS) Notification Program
https://www.fda.gov/animal-veterinary/animal-food-feeds/generally-recognized-safe-gras-notification-program

K. Packaging & Food Contact Substances (FCS)

https://www.fda.gov/food/food-ingredients-packaging/packaging-food-contact-substances-fcs

L. Enforcement Discretion for Certain FSMA Provisions

https://www.fda.gov/media/110052/download

M. Food Compliance Programs
https://www.fda.gov/food/compliance-enforcement-food/food-compliance-programs

N. OII Field Work Plan

FY 2025 OII Work Plan

O. Regulatory Procedures Manual (RPM)
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual

P. Note to Field Staff on PHO

https://fda.sharepoint.com/:b:/r/sites/insideFDA-ORA/Shared%20Documents/Field%20Guidance/CFSAN%20Notes%20to%20field%20staff%20Information%20for%20FDA%20staff%20-%20Partially%20Hydrogenated%20Oils%20(PHOs)%20are%20no%20longer%20GRAS%20v2.pdf?csf=1&web=1&e=FbebV2

Q. Manual of Compliance Policy Guides (CPG)

https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/manual-compliance-policy-guides

R. Import Alerts https://www.accessdata.fda.gov/cms_ia/ialist.html

- IA 45-02, "Detention Without Physical Examination and Guidance of Foods Containing Illegal and/or Undeclared Colors"
- IA 99-21, "Detention Without Physical Examination and Surveillance of Food Products Containing Undeclared Added Sulfiting Agents"
- IA 16-127, "Detention Without Physical Examination of All Seafood Due to Chloramphenicol"
- IA 16-129, "Detention Without Physical Examination of Seafood Products Due to Nitrofurans"
- IA 16-131, "Detention Without Physical Examination of Aquacultured, Shrimp, Dace, and Eel from China and Hong Kong SAR-Presence of New Animal Drugs and/or Unsafe Food Additives"
- IA 16-136, "Detention without Physical Examination of Aquacultured Shrimp and Prawns Products in all Market Forms from Peninsular Malaysia Due to Presence of Drug Residues from Unapproved Animal Drugs or the Presence of Unsafe Food Additives"
- IA 26-04, "Detention Without Physical Examination of Expressed Mustard Oil"
- IA 36-04, "Detention Without Physical Examination of Honey and Blended Syrup Due to Unsafe Drug Residues"
- IA 45-06, "Detention Without Physical Examination of Stevia Leaves, Crude Extracts of Stevia Leaves, and foods Containing Stevia Leaves and/or Stevia Extracts"
- IA 45-07, "Detention Without Physical Examination of Food Products Containing Illegal/Undeclared Sweeteners"
- IA 99-39, "Detention Without Physical Examination of Imported Food Products That Appear to Be Misbranded"

- IA 99-42, "Detention Without Physical Examination of Foods Due to Heavy Metal (Toxic Element) Contamination"
- IA 99-45, "Detention Without Physical Examination of Food Products That Are or Contain an Unsafe Food Additive"

2. **Attachments**

A. Partially Hydrogenated Oils (PHOs) Are No Longer GRAS

3. **Program Contacts**

A. General Program Contact

Alexandra Carrico, HFP/OCE/OCOI/DCI/Compliance Programs and Assignment Branch, Alexandra.Carrico@fda.hhs.gov, 313-393-8236

B. HFP Regulatory/Compliance Contacts

HFP/OCE/OCIC/Division of Compliance Consultation
HFP-OCE-Inquiries@fda.hhs.gov
Compliance Intake and Consultation Form

Tyra Wisecup, HFP/OCE/OE/DCFDSE/Critical Foods and Labeling Enforcement Branch
Tyra.Wisecup@fda.hhs.gov, 240-402-5854

Rob Genzel Jr., HFP/OCE/OE/DPIE/Imports Enforcement Branch
Rob.Genzel@fda.hhs.gov, 240-402-2708

C. Program Office Subject Matter Experts

Food Additives: Stephen DiFranco, HFP/OFCSDSI/OPMAS/DFI/Regulatory Management Branch, Stephen.Difranco@fda.hhs.gov, 240-402-2710

Food Additives: Jason Downey, HFP/OFCSDSI/OPMA/DAI/Regulatory Management Branch, Jason.Downey@fda.hhs.gov, 240-402-9241

Color Additives: Bhakti Petigara, OCS/OCAC/DCCT/Color Technology Branch, Bhakti.Petigara@fda.hhs.gov, 240-402-1025

D. Analytical Contacts

Food Additives: Katherine Carlos, HFP/OLOAS/OCT/DAC/Methods Development Branch, Katherine.Carlos@fda.hhs.gov, 240-402-1835

Color Additives: Bhakti Petigara, OCS/OCAC/DCCT/Color Technology Branch, Bhakti.Petigara@fda.hhs.gov, 240-402-1025

HFP OLOAS Program Coordinator (Food Additives and Color Additives): Lawrence Schaufler, HFP/OLOAS/ORTS/DSPC/Chemistry Branch

Lawrence.Schaufler@fds.hhs.gov, 303-231-2732

E. OII/Office of Import Operations (OIO)

OII/OIO/HFP Liaisons, OIIOIOHFPLiaisons@fda.hhs.gov

F. OII/Office of Human Food Inspectorate (OHFI)

Rina Vora, OII/OHFI/OGSHFI/DCSF/Human Food Program Expert Branch, Rina.Vora@fda.hhs.gov, 561-416-1065 (x1117)

PART VII - CENTER RESPONSIBILITIES

The Office of the Chief Scientist, Office of Cosmetics and Colors (OCAC) and the HFP Office of Food Chemical Safety, Dietary Supplements, and Innovation (OFCSDSI) will provide subject matter expertise in the maintenance and evaluation of this compliance program and provide guidance to the HFP Office of Compliance and Enforcement (OCE) with regard to program objectives, program priorities, relevant analytic questions, and recommended program changes. The OCE will lead the effort and work in conjunction with the OCAC and OFCSDSI to prepare routine compliance program reports, analysis, and recommendations. Evaluations will be conducted on a routine basis and will provide an overview of the compliance program objectives, accomplishments, as well as list recommendations for process improvement, highlight data patterns and trends to assist with planning, resource allocation, and the development of policy/guidance. The OCE will make these evaluations available internally to FDA.

In the interim of publishing evaluation reports, the OCE has provided standard data reports to assist the OCAC and OFCSDSI with ongoing efforts to review and track accomplishments. These data reports can be run annually or as frequently as needed. Instructions on how to access these reports are available at:

FACTS Accomplishments (sharepoint.com)

ATTACHMENT A - FY 2021 Partially Hydrogenated Oils (PHOs) are no longer generally recognized as safe (GRAS)[2]

Target Audience

SCSOs, Compliance Officers, CSOs, DIBs, DCBs and other food safety staff who may encounter situations, where partially hydrogenated oils (PHOs) are declared as an ingredient in the food label or labeling of human food, or when PHOs are being used in the manufacture of human foods.

Background

PHOs are no longer generally recognized as safe, or GRAS, for any use in human foods. On January 1, 2021, the agency's final compliance date allowing manufacturers to reformulate products to remove PHOs and sell or use up existing product inventories expired (83 FR 23358; May 21, 2018).

PHOs are the main dietary source of industrially produced (i.e., artificial) *trans* fat. Current scientific evidence links the consumption of artificial *trans* fat to significant human health risks, namely an increased risk of coronary heart disease (CHD). Based on the available scientific evidence and on the opinions of expert scientific panels, FDA concluded that there is no longer a consensus among qualified experts that PHOs are safe for human consumption (i.e., PHOs do not meet the GRAS standard).

June 2015 Declaratory Order

On June 17, 2015, the FDA issued its final determination that PHOs are not generally recognized as safe (GRAS) for any use in human food. We published a declaratory order in the Federal Register (80 FR 34650; June 17, 2015) that explained this determination and the following major provisions:

- PHOs are not GRAS for any use in human food.
- The order defines PHOs as those fats and oils that have been hydrogenated, but not to complete or near complete saturation, and with an iodine value (IV) greater than 4.
- This order does not apply to the use of PHOs as raw materials used to synthesize other ingredients.
- This order does not apply to the use of PHOs in animal food.
- The order established a compliance date of June 18, 2018, which is three (3) years after the date the order published in the Federal Register to give the food industry time to identify suitable replacement ingredients, to exhaust existing product inventories, and to reformulate and modify labeling of affected products.
- Any interested party may seek food additive approval for one or more specific uses of PHOs with data demonstrating a reasonable certainty of no harm of the proposed use(s).

Denial of Food Additive Petition

[2] This document was developed by the CFSAN Office of Compliance and Office of Food Additive Safety.

In addition to the extended compliance dates, on May 21, 2018, the FDA announced the denial of a food additive petition submitted in response to the June 2015 declaratory order. The petition requested that FDA permit the limited use of PHOs as carriers for color additives and flavoring agents, pan release agents for baked goods, and processing aids. FDA denied this food additive petition because the petitioner did not provide convincing evidence that petitioned uses of PHOs are safe (see 83 FR 23382).

Compliance Dates

On May 21, 2018, the FDA published a notification in the Federal Register that extended the compliance date beyond June 18, 2018, and stated that all foods containing unauthorized uses of PHOs after January 1, 2021, may be subject to FDA enforcement action (see 83 FR 23358;).

INSPECTIONS: Human food manufacturing operations that use PHOs

Firms should no longer be using PHOs (or ingredients containing PHOs) to manufacture human food. If a firm is observed using PHOs (or ingredients containing PHOs) to manufacture human food:

- Human food manufactured with PHOs are adulterated in that the food contains an unsafe food additive [see Section 402(a)(2)(C)(i)] of the Federal Food, Drug and Cosmetic Act (FD&C Act). Section 409 of the FD&C Act establishes that a food additive is unsafe for the purposes of Section 402(a)(2)(C)(i).
- This observation during an inspection is significant and warrants citing on a FDA Form 483.
- Document in the EIR any corrective actions the firm is taking to stop using PHOs.
- Field Offices should consult with the Human Foods Program (HFP), Office of Compliance and Enforcement if there are questions related to regulatory follow-up.

LABEL REVIEW: PHOs declared on product label

If a human food product declares PHOs on the label:

- After January 1, 2021, food containing PHOs is adulterated in that the food contains an unsafe food additive [see Section 402(a)(2)(C)(i)] of the FD&C Act. Section 409 of the FD&C Act establishes that a food additive is unsafe for the purposes of Section 402(a)(2)(C)(i).
- For imported food that declares PHOs, entries may be subject to detention/refusal. Contact the Human Foods Program (HFP), Office of Enforcement, Imports Enforcement Branch (IEB), if recommending that the foreign manufacturer and food product be placed on an Import Alert 99-45. A food that presumably does not contain PHOs but bears a label that declares PHOs as an ingredient is misbranded under section 403(a)(1) of the FD&C Act in that the label is false or misleading.

Field Offices should consult with the Human Foods Program (HFP), Office of Compliance and Enforcement if there are questions concerning regulatory follow-up based on misbranding related to PHOs.

Contacts:

Food ingredient questions	Mical Honigfort, HFP/OFCSDSI/OPMAS/DFI/RMB
Enforcement questions	Rob Genzel Jr., HFP/OCE/OE/DPIE/IEB
Labeling concerns	Lynn Szybist, HFP/NCE/ONFL/DFLS