CHAPTER 09 - FOOD AND COLOR ADDITIVES

SUBJECT:	**IMPLEMENTATION DATE**
IMPORTED FOODS – FOOD AND COLOR ADDITIVES (FY/07/08) This program has completed a Good Guidance Practice clearance by CFSAN's ORP and OC/DFP/CPB in October 2006.	November 13, 2006 **COMPLETION DATE** SEPTEMBER 30, 2008

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
All Food Codes (except industry 16, Seafood and Industry 50 (Color Additives)	09006A Food Additives
All Food Codes (except industry 16, Seafood and Industry 45-46 (Food Additives)	09006B Color Additives
Industry 13 (non-IMS products) Report under PAC 03803	03R833 (Entry Review) 99R833 (Filer Evaluation) 03R824 (Follow-up to Refusal)

Note: Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted; (&) denotes one or more paragraphs were deleted; and (%) denotes an entire attachment was deleted.

FIELD REPORTING REQUIREMENTS

1. Field Hardcopy Worksheets to DIOP, HFC-170.
2. Report all analytical results into the Field Accomplishment and Compliance Tracking System (FACTS).

PACS 09006A and 09006B - use these PACS to report label reviews for import food and color additives. Samples collected and analyzed for import food and color additives are also to be reported against these PACS.

Note: Imported Seafood products are covered under the Import Seafood Products Program, C.P. 7303.844, and Chemotherapeutics in Seafood Program for drug residues in seafood, C.P. 7304.018, and related field assignments.

PART I - BACKGROUND

Imported food products must comply with all provisions of the Federal Food, Drug, and Cosmetic Act (the Act), including its regulations for food and color additives and the declaration of all certifiable color additives. The Nutrition Labeling and Education Act of 1990 (NLEA) combined with other regulations is the basis for sample collection and examination of samples of imported foods for unsafe and/or undeclared food additives, non-permitted or undeclared color additives, and food and color additives otherwise used in a manner not in compliance with applicable regulations.

General facts about color additives and their declaration

All food colors, including both certified color additives and exempt color additives are considered to be “artificial colors.” Only artificial colors that are listed in the CFR and meet its requirements may legally be used in food products in the U.S. All other artificial colors are non-permitted.

Food colors subject to certification (synthetic organic colors) are listed in 21 CFR 74, Subpart A and 21 CFR 82, Subpart B. Certifiable color additives that have not been batch certified by FDA are non-permitted colors [FD&C 721(a)(1)(B)(i)], and they may not legally be used in food products.

Food color exempt from certification (i.e., “exempt” color additives) are listed in 21 CFR 73, Subpart A.

NLEA and its regulations require the declaration by name of all certifiable color additives on food labels [21 CFR 101.22(k)(1)]. Exempt color additives (listed in 21 CFR 73, Subpart A) are required to appear in the ingredients declaration by name, as artificial color, as artificial color added, as color added, or by an equally informative term [21 CFR 101.22(K)(2)].

Exemptions

Butter, cheese, and ice cream are exempt from color declaration requirements except for FD&C Yellow No. 5 (See CFR 101.22(k)(3) for additional details).

FD&C Red No. 3 is currently permitted for use in foods only when used in the form of the **straight** color additive [21 CFR 81.10(u)]. **"Lakes"**[within the meaning of 21 CFR 82.51] of this color additive are not permitted in foods manufactured since January 29, 1990. See Part V for additional information concerning products found to contain FD&C Red No. 3.

Sulfiting Agents

Sulfiting agents as chemical preservatives in food products are prohibited on foods in the following categories:

- Fruits/vegetables intended to be served raw to consumers or sold raw to consumers, or to be presented to consumers as fresh;
- Foods recognized as a source of thiamin (vitamin B_1), such as enriched flour because sulfites destroy the nutrient; and
- Meats.

For more detailed information on sulfiting agents see, http://www.cfsan.fda.gov/~dms/fdpreser.html.

The use of sulfiting agents as chemical preservatives in foods (other than the aforementioned categories) is Generally Recognized As Safe (GRAS) when used in accordance with Good Manufacturing Practices (GMPs). However, a sulfiting agent used as a preservative and/or present in food at levels that will have a functional or technical effect, must be declared on the label. Sulfites present as incidental additives (with no functional or technical effect) at 10 ppm or greater must be declared [21 CFR 101.100(a)(4)].

Sulfur dioxide used as a fumigant for table grapes is officially defined as a pesticide and is required by the U.S. Environmental Protection Agency (EPA) to be at less than detectable levels (less than 10 ppm). For additional details see “Sulfites: An Important Food Safety Issue” at http://www.cfsan.fda.gov/~dms/fssulfit.html.

PART II - IMPLEMENTATION

OBJECTIVES

- To collect and analyze imported foods as necessary for food and color additives.

- To utilize the Import Alert procedures outlined in Chapter 9 of the Regulatory Procedures Manual (RPM) to detain without physical examination (DWPE) entries of products previously found non-compliant with the requirements of the Act and its regulations concerning food and color additives. In addition, to consider appropriate broad-based actions against importers, shippers, manufacturers and countries when detention patterns warrant.

PROGRAM MANAGEMENT INSTRUCTIONS

Direct label reviews, sample collections and sample analyses of imported foods for unsafe food additives and for non-permitted or undeclared color additives.

PROGRAM PRIORITIES

1. Collect samples based on past problem areas, import alerts, bulletins, and district intelligence;
2. Conduct sample collections of imported food products having a known or suspected potential for food and color additive deficiencies; and
3. Conduct label review of imported food products for potential food and color additive deficiencies (see the current ORA Field Workplan for district obligation).

Below is a **Priority List** of past food and color additives problem areas that the district should use to guide its sampling. Some of these are addressed in specific Import Alerts at **www.fda.gov/ora/fiars/ora_import_alerts.html**.

Note: This is not an exhaustive listing of all the potential food categories [food and color additives] that may be non-compliant of the Act and similarly, the list of countries of origin is not intended to be exhaustive.

I. Presence of unlabeled Sulfites in "fresh" or processed foods;
[See Import Alert#99-21 at website:
http://www.fda.gov/ora/fiars/ora_import_ia9921.html]

Foods to Focus On	**Potential Country of Origin**
Dried Fruits and Vegetables: Apricots, guava, mango, jack fruit, persimmon, quince, bananas, peaches, plums, pears, dates, winter melon, cassava, golden raisins, lotus root, lily flower, eggplant, potatoes, sweet potatoes	People's Republic of China, Taiwan, Thailand, Vietnam, Singapore, the Philippines, India or Pakistan
Dried or in jars: Bamboo, hearts of palm	Same as above
Dried, candied or preserved: Ginger	Same as above
Any form (except fresh): Coconut (aka macapuno)	Same as above
Dried garlic (any form except fresh)	China
Sun-dried tomatoes	Turkey and Italy

II. Foods containing Carthamus tinctoris L. (aka safflower extract, "American saffron"), an unapproved color additive.
[See Import Alert#45-02 at website:
http://www.fda.gov/ora/fiars/ora_import_ia4502.html]

Foods to Focus On	**Potential Countries of Origin**
• Frozen Desserts • Beverages • Soups • Broths • Loose Tea • Food Colorings	• Canada • France • Peoples Republic of China • Thailand, • United Kingdom • India • Pakistan

III. Foods containing Sudan I, an unapproved color additive;
[See Import Alert 45-02 at website:
http://www.fda.gov/ora/fiars/ora_import_ia4502.html]

If Sudan I is declared on the label, analysis is not required. Sudan I may also be declared as "Sudan Red I" and is identified as (C.I. 12055), C.I. Solvent Yellow 14, or CAS 842-07-9. There are reports of products containing undeclared Sudan Red I. Analysis of products suspected of containing undeclared Sudan Red I is required to support a regulatory recommendation.

Foods to Focus On	Potential Countries of Origin
• Hot Chili Products • Sauces (e.g., tomato based) • Pasta/Noodles • Tomato Ketchup • Spices and spice mixes (e.g., chili powder, tandoori, paprika) • Couscous	• All foreign sources

IV. Chloropropanols in food containing hydrolyzed vegetable proteins (e.g. soy sauce, other "Asian style" sauces).;

Do not collect samples until directed by CFSAN and ORA via field assignment.

V. Non Permitted/Undeclared FD&C Yellow No.5;

FD&C Yellow No.5, though not classified as an allergen, should be associated with labeling of "safe use of foods" . A product found to contain this color when it is not declared as an ingredient should be evaluated and is a good candidate to be added to the Import Alert 45-02.

VI. Conventional foods that contain an unsafe dietary supplement-type ingredient whose use is neither approved nor generally recognized as safe;

The Center is interested in the referral of conventional foods containing dietary ingredients, when the product is labeled as a dietary supplement. However, prior to taking samples the field should confer with the CFSAN food additive contact for instructions.

VII. Unapproved food additives declared in the ingredient statement on labeling; [see below the following Compliance Policy Guides (CPGs) for guidance]

- For Additive Labeling see CPG 7117.01 at **http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg500-100.html**
- For "GRAS" Additives see CPG 7117.12 at **http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg500-200.html**
- For Additive Labeling For Safe Use see CPG 7117.13 at **http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg500-250.html**

VIII. Unapproved food additive and color additive uses

Stevia is not approved for use in conventional foods (tea, chips). Stevia is not subject to food additive regulations when labeled as a dietary supplement or when used as a dietary ingredient in a dietary supplement [within the meaning of Section 201 (ff) of the Act]. For more detailed information on dietary supplements and dietary ingredients, to http://www.cfsan.fda.gov/~dms/ds-ingrd.html.

Ponceau 4R is an "unapproved" color additive in any food. It is a major food color additive in the European Union (E.U.) but not approved for use in the U.S.

IX. Unapproved Food additives permitted for direct addition to food for human consumption

For a list of the Common Food Additives and specifically antioxidants, see Subpart B-Food Preservatives. See 21 CFR 172 for conditions under which food additives substances may be safely used under conditions of good manufacturing practice.

Note: Undeclared allergens are not included in this priority list because they are covered within the Domestic and Import NLEA, Nutrient Sample Analysis, and General Food Labeling Requirements Program, C.P. 21005. For additional information see Sec. 555.250 (CPG 7117.13) at **http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg500-250.html**.

PART III - INSPECTIONAL

Inspectional

No inspections are scheduled under this program.

Import Sample Collection

See Part I- Appendix III of the ORA Workplan for the current listing of color and food additive servicing laboratories.

A. General Information

Refer to RPM Chapter 9, Subchapter "Import Information Directives" for procedural guidelines about FDA Import Alerts and Import Bulletins or via the ORA/DIOP Intranet site at #. The current Import Alert for color additives in food products is Import Alert 45-02.

In addition, see the June 16, 2004 DFI Food Bulletin: "Collection of Samples for Color Violations under C.P.7309.006-Imported Foods-Food and Color Additives", **at #.** It was issued to clarify the type of sample that is necessary depending on the potential deficiencies that are discovered by the investigator during the field exam, (see sample collection) and to provide information on the status of color additives to assist the field in making sampling decisions.

Refer to the Food and Color Additive Status List (formerly Appendix A of the IOM) that is posted on CFSAN Intranet at www.cfsan.fda.gov/~dms/opa-appa.html.

B. Sample Collection

1. Collect labels for review (operation 41,) of imported food products:
   a) When the ingredient labels identify certifiable colors with: ONLY their European "E" color designation (e.g., E104); by a color index number (e.g., C.I. 15985); or by a trade or common/usual name of the color additive (e.g., Sunset Yellow FCF);

OR

   b) If the label identifies a color not permitted by color additive regulation for use in food products in the U.S.

Note: Laboratory confirmation is not required for the above mentioned deficiencies. See I.A. 45-02 for the latest information.

2. Collect physical samples of products that:
   a) Have color but have no obvious source of corresponding color listed on the label. Collect samples for analyses for synthetic organic color (e.g. a blue appearing food declaring only FD&C Red No.40 and yet, it is not obvious what is imparting the blue color to the product);

OR

   b) If the label identifies a color solely in terms of "permitted color", "color added", or "artificial color", for determination if the product actually contains a color that is subject to certification instead of only an exempt color.

C. Sample Sizes

1. For color additive samples consult Chapter 4 (Chart 9), "Sample Schedule for Color Containing Products, Color Additives", of the current edition of the IOM;
2. For food additive samples collected for a quantitative analysis to determine the amount of a food additive present (e.g. sulfites), collect a total of 10 subs, 1 lb minimum per sub,(see ANALYTICAL section for additional information);
3. No single sampling schedule is feasible for all additives and food containing them. As a general rule, collect a representative sample of the same amount of finished food as would be required for a filth analysis;
4. If unusual sampling situations arise not addressed by the above guidance, contact the servicing laboratory for color analysis and for qualitative food additive analysis sample size guidance. Contact CFSAN program office for quantitative food additive sample size information.

D. Sample Shipment

Submit samples for food and color additives analyses to your district's servicing laboratory. For additional information on servicing laboratories, please refer to current fiscal year ORA Field Workplan for the appropriate analyzing laboratory.

- Antioxidants in fats and oils analyses can be performed by the district's servicing lab. The common antioxidants permitted in foods are BHA, Ionox-100, NDGA, TBHQ, THBP, and Propyl Gallate.

E. Sample Flag

The following Problem Area Flags (PAF) should be used to identify attributes to be analyzed for samples collected:

- **Color Additives – PAF: COL**
- **Food Additives – PAF: FAD**

F. Entry Review

Operational time spent on entry review for this program should be reported under **PAC code 03R833**.

G. Filer Evaluation

Operational time spent on filer evaluation for this program should be reported under **PAC code 99R833**.

H. Follow-up to Refusal

Operational time spent on follow-up to refusal of entry due to color and/or food additive deficiencies should be reported under **PAC code 03R823**.

PART IV - ANALYTICAL

This compliance program provides certain authorities to a Field Color Expert (usually designated by their Position Description). For laboratories that do not have a Field Color Expert, laboratory management may recommend experienced color analysts as Color Specialists, who, if approved, can then be permitted similar authorities.

Color analyses performed by a Field Color Expert or Color Specialist do not require a check analysis for either detention or DWPE recommendation. Analyses not performed by a Field Color Expert or Color Specialist do require a check analysis.

Recommendations for Color Specialists must be approved by the Division of Field Science (DFS) and CFSAN's Office of Cosmetics and Colors (OCAC). For the criteria required, contact George Salem of DFS. The recommendation should include the analyst's work experience in color additives as well as relevant formal and on-the-job color training. DFS, in collaboration with CFSAN/OCAC, will prepare and distribute a Standard Operation Procedure Manual (SOP) detailing qualifications, roles and responsibilities, and application procedures for field Color Specialists.

A. Analytical Methodology

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 analytical contact prior to analysis if there are questions about the appropriate methodology. Please refer to section 2.3.3.1 (Chapter 2) of the ORA Laboratory Manual (LM) for instances where a check analysis is necessary.

1. **Food Additives:**
   - AOAC, Official Methods of Analysis, 17th Edition, Chapters 47 and 48, or the most current AOAC edition;
   - Food Additives Analytical Manual, Vol. I and II, 1983 and 1987;
   - Food Chemicals Codex, 4th Edition, or earlier editions as referenced in the appropriate regulations in 21 CFR 170-199;
   - Antioxidants in Fats and Oils: AOAC 16th Edition, (983.15), or most current edition;
   - Sulfites - AOAC 16th Edition, (990.28), Optimized Monier-Williams Method. (Final Action, 1994) Monier-Williams titrimetric results with gravimetric confirmation must be used to provide either initial analysis or the check analysis;
   - Sulfites- All Food except for dried garlic: AOAC 16th Edition, (990.28), Optimized Monier-Williams Method. (Final Action, 1994). Other methods such as those found in a current edition of the AOAC Official Methods of Analysis may be used if the method is known to give results comparable to the values obtained with the optimized Monier-Williams Method; however, Monier-Williams titrimetric results with gravimetric confirmation must be used to provide

either the original analysis or the check analysis.

- For Dried garlic: Liquid Chromatographic Method described in Journal of AOAC International, **86**(3), 2003, pp.544-550.

- 3-Chloro-1, 2-propanediol (3-MCPD)-AOAC, Official Method 2000.01 (First Action, 2000). This is a new method and not listed in the 17th edition. This method was validated by a collaborative trial according to criteria of the AOAC, described in Journal of AOAC International, **84**:455-465.
- Coumarin in food, AOAC, Official Methods of Analysis, 13th edition of AOAC (1980), or most current edition of AOAC

- Kava kava in food, use the method described in the "LC-UV and LC-MS analysis of food and drink products containing kava." Food Additives and Contaminants, **21**(10), pp.921-934 (2004).

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.

2. Color Additives:

- AOAC, Official Methods of Analysis, 17th edition of AOAC, Chapter 46, or most current edition of AOAC;

- Sudan I – AOAC 988.13 (AOAC 17th ed. Vol.2, 46.105) method. The Color Technology Branch (CTB) at CFSAN is evaluating other methods to include an LC/MS/MS technique that should be able to detect trace levels (3pmm) of Sudan I in products. Consult with CFSAN analytical contact prior to analysis if there are questions about the appropriate methodology.

Note: For either Detention or DWPE recommendation a check analysis is not required for color analyses performed by a Field Color Expert, or Color Specialist as designated by DFS and OCAC (see Part IV page 1). A check analysis is required when the original analysis is NOT performed by a Filed Color Expert or Color Specialist.

Attempt to identify any non-permitted or unlisted color(s) present. If they are found, a check analysis confirming color identity is required unless the original analysis was performed by a Field Color Expert or Color Specialist. If one non-permitted or unlisted color is confirmed, identification of the remaining color components in the product is not necessary for initiating a detention recommendation. However, as resources permit, the identification and confirmation of the other color(s) present would improve the agency's database concerning color usage abroad. 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);

Nutrition Labeling and Education Act (NLEA) of 1990 requires the declaration of all color additives subject to certification by name. If undeclared certifiable colors are found in a sample, perform a check analysis to confirm the presence of at least one undeclared

certifiable color additive (in the absence of evidence that the color is from a certified lot). If multiple undeclared certifiable color additives are found by original analysis, the district may exercise discretion with regard to performing check analysis for each color additive.

The original or check analysis for the identification of non-permitted or undeclared color additives should always include visible spectra of the isolated color additive, ideally under acidic, basic, and neutral conditions. Standard reference spectra in the same solvent as those for the isolated color should be attached to the analytical worksheets. Confirmatory analysis should include different characterizing data (e.g., TLC R_f-values, HPLC retention times). TLC confirmation should include either tables of R_f-values, or high quality reproductions of the TLC plates with spots and streaks clearly encircled and labeled. The colors of the spots and streaks should also be reported, especially if black and white reproductions are submitted. 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.

The official method for the identification of a color additive is by UV/VIS spectra. In the case of possible agency action based on the presence of a non-permitted color additive in a product, resulting analytical worksheet should include UV/VIS spectra by either the original or the check analyst. If both analyses are by a color specialist, then one of the two methods used should include UV/VIS spectra.

- Do not routinely quantitate the color(s) for which no limits have been established; and

- The analyst must describe the color(s) of the product in the product description section of the analytical worksheet.

The analyst should be aware of the list of approved color additives at www.cfsan.fda.gov/~dms/opa-appa.html. The following color additives below are not permitted and are ones that you may come upon:

- Amaranth (C.I. 16185, EEC No. E123, formerly certifiable as FD&C Red No. 2);

- Azorubine (C.I. 14720, EEC No. E122, formerly certifiable as Ext. D&C Red No. 10); also called Azo Rubine and Carmoisine;

- Rhodamine B (C.I. 45170, chloride and stearate salts formerly certifiable as D&C Red No.19 and D&C Red No.37);

- Ponceau 4R (C.I. Acid Red No. 18, C.I. 16255, EEC No. 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); and

- Quinoline Yellow (resembles C.I. 47005, EEC No. E104, C.I. Acid Yellow No. 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 at this

time. In European and other countries, primarily disulfonated quinoline yellow may be used as a color additive in foods.

The following color additives **are** authorized by regulation (see 21 CFR Part 74) for safe use in food products, only when the color additives are from batches that have been certified by the FDA:

- FD&C Red No. 3 (Red lakes are not permitted in foods); 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; and FD&C Yellow No. 5.

Entries found containing the following color additives should be considered for detention if the label does not declare the color additive subject to certification (see 21 CFR Part 74, Subpart A). The laboratory worksheets should not convey erroneous information. **Analytically,** we cannot determine if a color additive subject to certification has in fact been certified. Analysts should report their findings as written on food labels as follows:

- E129, C.I. 16035, Allura Red AC (certifiable as FD&C Red No.40);
- E133, C.I. 42090, Brilliant Blue FCF (certifiable as FD&C Blue No.1);
- C.I. 12156 Solvent Red 80 (certifiable as Citrus Red No.2, for use only for coloring the skins of oranges that are not intended or used for processing;
- E127, C.I. 45430, Erythrosine (certifiable as FD&C Red No.3, may be used only if added as a straight color, Red 3 lakes are not permitted in foods);
- C.I. 42053, Fast Green FCF (certifiable as FD&C Green No.3);
- E132, C.I. 73015, Indigotine (certifiable as FD&C Blue No.2);
- C.I. 19235, Acid Orange 137 (certifiable as Orange B, may be used only in coloring sausage casing or surfaces);
- E110, C.I. 15985, Sunset Yellow FCF (certifiable as FD&C Yellow No.6); and
- E102, C.I. 19140, Tartrazine (certifiable as FD&C Yellow No.5).

Be aware of the presence and the possible separation of subsidiaries 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 FACTS report.

B. Analytical Reporting

- Report all analytical results into the Field Accomplishment and Compliance Tracking System (FACTS) as appropriate or applicable using the following Problem Area Flags (PAF) and Program

Assignment Codes (PAC).

- **Color Additives** – PAC 09006B
  PAF: COL

- **Food Additives** - PAC 09006A
  PAF: FAD

Questions about entering data into FACTS should be directed to your district's lead FACTS user.

PART V - REGULATORY/ADMINISTRATIVE STRATEGY

For detailed information concerning detentions and DWPE recommendations refer to the RPM Chapter 9.

One of the goals of this import program is to obtain sufficient evidence to support broad-based enforcement strategies. These would include Import Alerts for Detention Without Physical Examination (DWPE) for importers, shippers, manufacturers, and countries. CFSAN is requesting the field to be aware of detention recommendation patterns that could develop into broad-based DWPEs by consulting CFSAN, Import Branch Chief and/or the regulatory contact when these situations arise. For example, districts should consider recommending more stringent enforcement action against problem importers when these importers do not routinely monitor the compliance of products they import. Chapter 9 of the Regulatory Procedures Manual (RPM) contains a section on Priority Enforcement Strategy for Problem Importers.

Note: All Detention Without Physical Examination (DWPE) recommendations should be forwarded to DIOP, HFC-170 with accompanying documentation, to include laboratory work sheets. Refer to I.A. 45-02 for further instructions. To remove firms from automatic detention see the RPM Chapter 9, Subchapter "Automatic Detention".

Sampled Lots

Do not release a sampled lot until the analyses are completed. Follow the directions in the RPM Chapter 9. Districts **should consider a detention recommendation of** a sampled lot without analyses if the product labeling declares a non-permitted food or color additive in the ingredient statement.

Specimen Charge

Follow the directions in the RPM, Chapter 9, "Exhibit 9-5" and the appropriate Import Alert listed in Part VI-References.

FIELD INSTRUCTIONS FOR DETENTION OR DWPE RECOMMENDATIONS

1. Imported Products with European Named Colors

Many products bear ingredient labels identifying certified colors 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) 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 certified. For additional information see the RPM, Chapter 9, "Exhibit 9-5". Contact import regulatory, CFSAN/DE/Imports Branch, HFS-606 for direction if a special circumstance arises.

2. Imported Products with FD&C Red No.3

Only the **straight** dye 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.

3. Import Alerts for Food & Color Additives

If a non-permitted food or color additive is detected, in addition to detaining the specific entry, the district should initiate a DWPE recommendation to be added to I.A. 45-02(Color Additives) or I.A. 99-21 (Food Additives) covering the specific manufacturer and product. For the current import alerts for food and color additives see Part VI, reference. Such recommendations are to be routed to DIOP as instructed in the RPM Chapter 9.

"See FDA internet, Color Additives page, for a list of firms requesting color certification within the last two years at **http://www.cfsan.fda.gov/~dms/col-comp.html**.

4. Analytical Requirements For Laboratories When Considering A Detention or DWPE Recommendation

The lab must meet the following conditions:

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

a) Requirements for Labs:
The district has appropriate equipment, apparatus, regents, methods and standards;

b) Requirements for Colors:
A Color Expert or Color Specialist performed and/or reviewed all analyses. The Color Specialist concluded that official or appropriate methods were correctly used and that all the analyses support the finding of the cited violation (s); and

c) Requirements for Foods:
Sulfite labeling violations in imported foods, with the exception of Allium (e.g., garlic, onion) and Brassica (e.g., cabbage, broccoli) vegetables, and isolated soy protein, and provided that the following criteria are met:
   - o Both the original and the check analyses are conducted using the Monier-Williams Method on a composite of all subs collected;
   - o The average of all original and check analyses are greater than 50 ppm (as sulfur dioxide); and
   - o The results of all original and check analyses agree within 30%.

PART VI – REFERENCES, PROGRAM CONTACTS AND ATTACHMENT

REFERENCES

The most current IOM and other inspectional guides are available via ORA's web site at http://www.fda.gov/ora/inspect_ref/iom/iomtc.html . Also, check the appropriate DFI Guide to Inspection Manuals, for correct sample size at ORA: Inspection References Inspection Guides Start Page.

The Food Additive Status List (formerly Appendix A of the IOM) is posted on CFSAN Intranet at **www.cfsan.fda.gov/~dms/opa-appa.html**

Regulatory Procedures Manual (RPM), Chapter 9 at
www.fda.gov/ora/compliance_ref/rpm/default.htm

Import Alerts as follows:

- IA#21-04, Detention Without Physical Examinations and Increased Surveillance of Dried Fruits, http://www.fda.gov/ora/fiars/ora_import_ia2104.html
- IA#23-02, Detention Without Physical Examination of Melon Seeds, http://www.fda.gov/ora/fiars/ora_import_ia2302.html;
- IA#26-04, Detention Without Physical Examination of Expressed Mustard Oil, http://www.fda.gov/ora/fiars/ora_import_ia2604.html;
- IA#28-07, Detention Without Physical Examination of Couramin in Vanilla Products Extracts-Flavorings-Imitations, http://www.fda.gov/ora/fiars/ora_import_ia2807.html;
- IA#45-02 (in revision), Detention Without Physical Examination and Guidance of Foods Containing non-permitted Colors; http://www.fda.gov/ora/fiars/ora_import_ia4502.html;
- IA#45-06, Automatic Detention of Stevia Leaves, Extract of Stevia Leaves, and Food Containing Stevia, http://www.fda.gov/ora/fiars/ora_import_ia4506.html;
- IA#45-07, Detention Without Physical Examination of Food Products Containing Illegal/Undeclared Sweeteners, http://www.fda.gov/ora/fiars/ora_import_ia4507.html;
- IA#99-20, Detention Without Physical Examination of Imported Food Products Due To NLEA Violations http://www.fda.gov/ora/fiars/ora_import_ia9920.html; and
- IA#99-21, Detention Without Physical Examination and Surveillance of Food Products Containing Sulfites, http://www.fda.gov/ora/fiars/ora_import_ia9921.html.

In addition, Import Alerts and Import Bulletins can be accessed via the FDA Import Alerts Retrieval System (FIARS) at
www.fda.gov/ora/fiars/ora_import_alerts.html

Compliance Policy Guides at
http://www.fda.gov/ora/compliance_ref/cpg/default.htm

Compliance Program Guidance Manual (CPGM) at
http://www.fda.gov/ora/cpgm/default.htm

See below the following CPGs concerning food and color additives:

- **Nitrates**

Section 540.200	Chubs, Hot Process Smoked with Added Nitrite - Adulteration Involving Food Additives, Sodium Nitrite (CPG 7108.15)
Section 540.500	Tuna, Sable, Salmon, Shad - Smoked Cured, Adulteration Involving Food Additives, Sodium Nitrite (CPG 7108.18)

- **Other Food Additives**

Note: Acid –hydrolyzed Protein: A CPG is being developed on Asian-style sauces and Acid-hydrolyzed protein that contain 3-MCPD (3-Chloro-1, 2-propanediol) at levels of concern. Districts should not collect samples at this time; coverage will be conducted by a CFSAN directed field assignment.

Section 578.600	Unapproved Additives for Exported Grains (CPG 7104.08)
Section 500.200	Food Additives - "GRAS" (CPG 7117.12)
Section 510.200	Brandy Containing Methyl Alcohol - Food Additive (CPG 7119.09)
Section 457.100	Pangamic Acid and Pangamic Acid Products Unsafe for Food and Drug Use (CPG 7121.01)

- **Color Additives**

Section 550.625	Oranges - Artificial Coloring (CPG 7110.21)
Section 585.825	Sweet Potatoes - Dyeing of Yellow and Red Varieties (CPG 7114.26)
Section 545.200	Confectionery Decorations (Nutritive and Non-Nutritive) (CPG 7117.03)
Section 587.200	Uncertified or Delisted Colors in Foods for Export - (e.g., FD&C Red #2) (CPG 7127.02)
Section 587.300	Colors for Foods, Drugs, and Cosmetics (CPG 7127.03)

- **Additives - labeling**

Section 500.100	Additives - Labeling with Adequate Directions for Many Uses (CPG 7117.01)
Section 500.250	Food Additives - Labeling: Directions Necessary for Safe Use (CPG 7117.13)
Section 500.300	"Approved by FDA" - Use of Phrase Objectionable in Marketing or Labeling of a Food Additive (CPG 7117.09)
Section 555.800	Polysorbates 20, 40, 60, 65, 80, 85 - Common or Usual Names (CPG 7120.09)
Section 587.100	Label Declaration of Artificial Color (CPG 7127.01)

PROGRAM CONTACTS

General Program Questions – Glenn Bass, CFSAN, Office of Compliance, Division of Field Programs, Compliance Programs Branch, HFS-636, Telephone (301) 436-2774, Fax (301) 436-2415 and **glenn.bass@fda.hhs.gov**

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ORA/Division of Import Operations and Policy (HFC-172) contact: Ted Poplawski Telephone (301) 594-3849, FAX (301) 594-0413 and **ted.poplawski@fda.hhs.gov**

Color Additive Questions – Richard Jewell, CFSAN, Office of Cosmetics and Colors, Division of Cosmetics and Compliance, HFS-125, Telephone (301) 436-1345, Fax (301) 436-2975 and **richard.jewell@fda.hhs.gov**

Food Additive Questions – Andrew Zajac, CFSAN, Office of Food Additive Safety, Division of Petition Review, HFS-265, Telephone (301) 436-1267, Fax (301) 436-2972 and **andrew.zajac@fda.hhs.gov**

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- **Food Additives** - Dr. Gregory Diachenko, CFSAN, Office of Food Additive Safety, DCRER, HFS-245, Telephone (301) 436-1898, FAX (301) 436-2634 and **gregory.diachenko@fda.hhs.gov**

- **Color Additives** – Alan Scher, CFSAN, Office of Cosmetic and Colors, DCCT/CTB, HFS-106, Telephone (301) 436-1119, FAX (301) 436-2961 and **alan.scher@fda.hhs.gov**

- **General Methods Contact** - George Salem, ORA/Division of Field Science, HFC-141, Telephone (301) 827-1031, FAX (301) 443-6388 and **george.salem@fda.hhs.gov**

PART VII - CENTER RESPONSIBILITY

The Director, Office of Food Additive Safety, in collaboration with the Director, Office of Cosmetics and Colors has the responsibility to prepare periodic formal evaluations of this compliance program. When completed and cleared, the evaluation will be available for Agency personnel on CFSAN's OC Intranet site #. Additionally, the evaluations should appear on CFSAN's Internet website.