

**CHAPTER 09 - FOOD AND COLOR ADDITIVES**

<b>SUBJECT:</b>  IMPORTED FOODS - FOOD AND COLOR ADDITIVES (FY/09/10/11)	<b>IMPLEMENTATION DATE</b>  Upon Receipt
	<b>COMPLETION DATE</b>  SEPTEMBER 30, 2011
<b>DATA REPORTING</b>	
PRODUCT CODES	PRODUCT/ASSIGNMENT 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))  Industry 13 (non-IMS products) Report under PAC 03803	09006A Food Additives  09006B Color Additives  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. Report all analytical results into the Field Accomplishment and Compliance Tracking System (FACTS).

PACs 09006A and 09006B - For imported foods and color additives, use these PACs to report label reviews and samples collected and analyzed.

**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 applicable 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 and certification exempt color additives. The Act and its implementing regulations are 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 color additives, including both certified color additives and certification exempt color additives, are considered to be "artificial colors." Only color additives 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.

The definition of "color additive" at 21 CFR 70.3(f) states that food ingredients which contribute their own natural color when mixed with other foods are not regarded as color additives. But where a food substance such as beet juice is deliberately added for its color, it is a color additive. The term "artificial color," as defined in 21 CFR 101.22, includes any "color additive" as defined in 21 CFR 70.3(f). Therefore, even though a substance like beet juice is a natural substance, it is an "artificial color" when added to a food deliberately for its color.

Food color additives subject to certification (synthetic organic color additives) are listed in 21 CFR 74, Subpart A and 21 CFR 82, Subpart B. Color additives subject to certification 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 additives exempt from certification i.e., "exempt" color additives, FD&C 721(a)(1)(B)(ii), are listed in 21 CFR 73, Subpart A.

The Nutritional Labeling and Education Act of 1990 (NLEA) and its regulations require the declaration by name of all color additives subject to certification 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 for butter, cheese, and ice cream

Butter, cheese and ice cream are exempt from color additive declaration requirements [section 403(k) of the Act] except for FD&C Yellow No. 5 (See CFR 101.22(k)(3) and 74.705(d)(2) for additional details).

### FD&C Red No.3 straight colors and lakes

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)]. FD&C Red No.3 **lakes** [described in 21 CFR 82.51] are not permitted in foods. See Part V for additional information concerning products found to contain FD&C Red No. 3.

### Cochineal extract and carmine

Note: A new required labeling has been proposed for cochineal extract and is expected to be finalized in 2008. See <http://www.cfsan.fda.gov/~lrd/cf731100.html>

### Sulfiting Agents

Examples: sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite, and potassium metabisulfite

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<sub>1</sub>), such as enriched flour because sulfites destroy the nutrient; and
- Meats.

See 21 CFR Part 182, Subpart D.

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 or otherwise 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)].

See CP 7304.004 - Pesticide and Industrial Chemicals in Domestic Foods for guidance concerning the fungicidal use of sulfites. Sulfites may be used as a fungicide to prevent grey mold or bunch rot on domestic or imported grapes during shipment and storage. The long-term storage necessary to extend the availability of grapes often involves repeated sulfite treatment. See 40 CFR 180.103 and 40 CFR 180.159 for approved use of sulfites on grapes.

(DO NOT use PAC 09006A for the fungicidal use of sulfites.)

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

### Antioxidants

The common antioxidants (fats, and oils) permitted in foods are BHA (butylated hydroxyanisole), Ionox-100 (4-hydroxymethyl-2,6-di-*tert*-butylphenol), TBHQ (2-(1,1-dimethylethyl)-1,4-benzenediol), THBP (2,4,5-trihydroxybutyrophenone), and Propyl Gallate (propyl 3,4,5-trihydroxybenzoate).

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**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 \(RPM\)](#), 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.

**Emerging Issues**

1. Foods to which drugs or biological products have been added, e.g., Aceyt1-CoA and Lactoferrin. Section 912 of the FDA Amendments Act of 2007 amended Section 301(II) of the Federal Food, Drug, and Cosmetic Act by prohibiting the introduction of any food into interstate commerce to which has been added an approved drug, licensed biological, or a drug or biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. For exceptions to this prohibited act, please see section 301(II) of the Act.

**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 the "Sampling Priority" within the "Program Priority list": 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). (This information is based on historical and current data, Center and District intelligence).

Below is the **Program Priorities** 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 <http://alpha.ora.fda.gov/fiars/fiars.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.**

Updates of the Program Priorities may be found at <http://inside.fda.gov/ProgramsInitiatives/Food/FieldPrograms/UCM015393.html>

PROGRAM PRIORITIES

<u>Foods to Focus On</u>	<u>Potential Country of Origin</u>	<u>Compliance Programs, Import Alerts &amp; Bulletins</u> <u>CPGs General Information</u>	<u>Sampling Priority</u>
<b>Food Additives</b>			
<u>Presence of unlabeled Sulfites in "fresh" or processed foods</u>			
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	See Import Alert#99-21, "DETENTION WITHOUT PHYSICAL EXAMINATION AND SURVEILLANCE OF FOOD PRODUCTS CONTAINING SULFITES" at website: <a href="http://alpha.ora.fda.gov/www_fiars/files/ia9921.lst">http://alpha.ora.fda.gov/www_fiars/files/ia9921.lst</a>	#
Dried or in jars: hearts of palm	People's Republic of China, Taiwan, Thailand, Vietnam, Singapore, the Philippines, India or Pakistan	See Import Alert#99-21, "DETENTION WITHOUT PHYSICAL EXAMINATION AND SURVEILLANCE OF FOOD PRODUCTS CONTAINING SULFITES" at website: <a href="http://alpha.ora.fda.gov/www_fiars/files/ia9921.lst">http://alpha.ora.fda.gov/www_fiars/files/ia9921.lst</a>	#
Bamboo	China Hong Kong Taiwan Thailand	See Import Alert#99-21, "DETENTION WITHOUT PHYSICAL EXAMINATION AND SURVEILLANCE OF FOOD PRODUCTS CONTAINING SULFITES" at website: <a href="http://alpha.ora.fda.gov/www_fiars/files/ia9921.lst">http://alpha.ora.fda.gov/www_fiars/files/ia9921.lst</a>	#
Dried, candied or preserved Ginger (any form except fresh); Coconut (aka macapuno)	Australia China Vietnam	See Import Alert#99-21, "DETENTION WITHOUT PHYSICAL EXAMINATION AND SURVEILLANCE OF FOOD PRODUCTS CONTAINING SULFITES" at website: <a href="http://alpha.ora.fda.gov/www_fiars/files/ia9921.lst">http://alpha.ora.fda.gov/www_fiars/files/ia9921.lst</a>	#
Dried garlic (any form except fresh)	China		

<u>Foods to Focus On</u>	<u>Potential Country of Origin</u>	<u>Compliance Programs, Import Alerts &amp; Bulletins</u> <u>CPGs General Information</u>	<u>Sampling Priority</u>
Sun-dried tomatoes	Turkey and Italy	See Import Alert#99-21, "DETENTION WITHOUT PHYSICAL EXAMINATION AND SURVEILLANCE OF FOOD PRODUCTS CONTAINING SULFITES" at website: <a href="http://alpha.ora.fda.gov/www_fiars/file/s/ia9921.lst">http://alpha.ora.fda.gov/www_fiars/file/s/ia9921.lst</a>	Sulfites #
Crackers & biscuits Dried radish	Republic of Korea		
Seafood products (frozen shrimp, prawns, conch, frozen lobster tail and meat, dried abalone,	Brazil Cayman Islands China El Salvador Honduras France Iran Republic of Korea Mexico Nigeria Switzerland Thailand Trinidad & Tobago Venezuela		
<u>Chloropropanols in food containing hydrolyzed vegetable proteins in Asian style sauces</u>			
Asian-style sauces and soy sauces; foods containing hydrolyzed vegetable proteins	China Hong Kong Philippines Taiwan Thailand Vietnam	CPG (Sec. 500.500) "Guidance levels for 3-MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces" Notice of Availability of CPG Published on 3/31/08 (73 FR 16861)	#
<u>Unapproved food additives declared in the ingredient statement on labeling</u>			
Labeled foods with two or more ingredients	All foreign sources	For Additive Labeling see CPG 7117.01 at <a href="http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg500-100.html">http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg500-100.html</a> For "GRAS" Additives see CPG 7117.12 at <a href="http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg500-200.html">http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg500-200.html</a>	#

<u>Foods to Focus On</u>	<u>Potential Country of Origin</u>	<u>Compliance Programs, Import Alerts &amp; Bulletins</u> <u>CPGs General Information</u>	<u>Sampling Priority</u>
		For Additive Labeling For Safe Use see CPG 7117.13 at <a href="http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg500-250.html">http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg500-250.html</a>	
<u>Conventional foods that contain an ingredient whose use is neither approved nor Generally Recognized as Safe (GRAS)</u>			
Conventional foods with two or more ingredients	All foreign sources	Prior to taking samples, the field should confer with ORA Headquarters and if necessary ORA Headquarters should confer with CFSAN food additive contact (see Part VI, Page 3) for assistance.	#
<u>Unapproved food additives</u>			
Foods with two or more ingredients	All foreign sources	For a list of approved food additives, see <a href="#">21 CFR 172</a> for conditions under which food additives may be safely used under conditions of good manufacturing practice.	#
Conventional foods containing Stevia leaves and extract of Stevia leaves (stevioside) including: Fruit & vegetable concentrate alfalfa drink, pickled radish, salted radish, Biscuits	Brazil Japan Republic of Korea	See IA #45-06, AUTOMATIC DETENTION OF STEVIA LEAVES, EXTRACT OF STEVIA LEAVES, AND FOOD CONTAINING STEVIA at website: <a href="http://alpha.ora.fda.gov/www_fiars/files/ia4506.lst">http://alpha.ora.fda.gov/www_fiars/files/ia4506.lst</a> 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 <a href="http://www.cfsan.fda.gov/~dms/ds-ingrd.html">http://www.cfsan.fda.gov/~dms/ds-ingrd.html</a> <a href="http://www.cfsan.fda.gov/~dms/supplmnt.html">http://www.cfsan.fda.gov/~dms/supplmnt.html</a>	#

<u>Foods to Focus On</u>	<u>Potential Country of Origin</u>	<u>Compliance Programs, Import Alerts &amp; Bulletins</u> <u>CPGs General Information</u>	<u>Sampling Priority</u>
Conventional foods containing Kava		See Consumer Advisory at website: <a href="http://www.cfsan.fda.gov/~dms/addskava.html">http://www.cfsan.fda.gov/~dms/addskava.html</a> &	#
Foods containing undeclared/illegal sweeteners (saccharin cyclamates) including: Sugar free strawberries in light syrup, peanuts in shell, preserved cabbage, dried sweet potato, dried fruit, fruit juices, licorice flavored melon seeds, preserved radish, fruit preserves	Bulgaria China Hong Kong Malaysia Mexico Thailand	See IMPORT ALERT #45-07, "DETENTION WITHOUT PHYSICAL EXAMINATION OF FOOD PRODUCTS CONTAINING ILLEGAL/UNDECLARED SWEETENERS" at website:  <a href="http://alpha.ora.fda.gov/www_fiars/files/ia4507.lst">http://alpha.ora.fda.gov/www_fiars/files/ia4507.lst</a>  <a href="http://alpha.ora.fda.gov/www_fiars/files/ia2104.lst">http://alpha.ora.fda.gov/www_fiars/files/ia2104.lst</a>	#
<b><u>COLOR ADDITIVES</u></b>			
<u>Non-permitted color additives</u>			
Foods containing <i>Carthamus tinctoris</i> L. (aka safflower extract, "American saffron"), a non-permitted color	Canada France Peoples Republic of China Thailand		#

<u>Foods to Focus On</u>	<u>Potential Country of Origin</u>	<u>Compliance Programs, Import Alerts &amp; Bulletins</u> <u>CPGs General Information</u>	<u>Sampling Priority</u>
additive, Including: Frozen desserts Beverages soups Broths Loose Tea Food coloring	United Kingdom India Pakistan		
Foods containing Sudan I, a non-permitted color additive  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 recom. 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		#
Non-declared FD&C Yellow No.5  FD&C Yellow No.5, must be identified on the food label or the product is adulterated. A product found to contain Tartrazine when this color is not declared as an ingredient should be	All foreign sources	See Import Alert 45-02 at website: <a href="http://alpha.ora.fda.gov/www_fiars/files/ia4502.lst">http://alpha.ora.fda.gov/www_fiars/files/ia4502.lst</a>	#

<u>Foods to Focus On</u>	<u>Potential Country of Origin</u>	<u>Compliance Programs, Import Alerts &amp; Bulletins</u> <u>CPGs General Information</u>	<u>Sampling Priority</u>
evaluated and added to the I.A 45-02.			
Ponceau 4R	All foreign sources	See Import Alert 45-02 at website: <a href="http://alpha.ora.fda.gov/www_fiars/files/ia4502.lst">http://alpha.ora.fda.gov/www_fiars/files/ia4502.lst</a>  Ponceau 4R is a non-permitted 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.	#

Note: Conditions in which problems may occur regarding the above foods to focus on are as follows:

Food additives: labeling deficiencies, GMP deficiencies, unapproved food additives, and potential severe illness from long term exposure (cancer causing agents);

Color additives: GMP deficiencies, non-permitted color additives, non-declared color additives, and potential severe illness from long term exposure (heavy metal).

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](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

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 #. The current Import Alert for color additives in food products is [Import Alert 45-02](#).

In addition, see DFI Food Bulletin # 9: "Collection of Samples for Color Violations under C.P.7309.006-Imported Foods-Food and Color Additives", #. 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 Additive Status List (formerly Appendix A of the IOM) that is posted on CFSAN Intranet at [www.cfsan.fda.gov/~dms/opa-appa.html](http://www.cfsan.fda.gov/~dms/opa-appa.html).

B. Sample Collection

1. Collect labels for review of imported food products:

- a) When the ingredient labels identify certifiable colors with: ONLY their European "E" color designation (e.g., E104 additive); by a color index number (e.g., C.I. 15985); by an International Numbering System (INS) number; 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. Refer to the Summary of Color Additives Listed for Use in the United States in Food, Drugs, Cosmetics, and Medical Devices posted on CFSAN Intranet at #.

**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 additive 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 additive solely in terms of "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 an exempt color additive.

C. Sample Sizes

1. For color additive samples consult the current edition of the IOM Chapter 4 (Chart 9), "Sample Schedule for Color Containing Products, Color Additives";
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 per National Sample Distributor (NSD).

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 03R824**.

**PART IV - ANALYTICAL**

In lieu of a Color Expert, a field laboratory may recommend an analyst for a Color Specialist, who must be approved by the Division of Field Science (DFS) and CFSAN's Office of Cosmetics and Colors (OCAC). For the criteria contact George Salem of DFS. The recommendation should include the analyst's work experience in color additives as well as relevant 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 Specialist.

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

**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, 17<sup>th</sup> 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, 6<sup>th</sup> Edition, or earlier editions as referenced in the appropriate regulations in 21 CFR 170-199;
- Antioxidants in Fats and Oils: AOAC 16<sup>th</sup> Edition, (983.15), or most current edition;
- Sulfites - AOAC 16<sup>th</sup> 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 16<sup>th</sup> 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 method is listed in the 18<sup>th</sup> 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, 13<sup>th</sup> 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;
- Kava kava in food, use of 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). **Analytical Method Development for the Determination of Kava in Functional Foods**, L.S. de Jager, G.A. Perfetti, G.W. Diachenko, OFAS, CFSAN, FDA, College Park, MD.

(Methods for kava are recommended and not required.)

#### 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, 17<sup>th</sup> edition of AOAC, Chapter 46, or most current edition of AOAC;
- Sudan I - AOAC 988.13 (AOAC 17<sup>th</sup> ed. Vol.2, 46.105) method. Consult with CFSAN analytical contact prior to analysis if there are questions about the appropriate methodology.

**Note:** A check analysis is **not** required for those analyses performed by a Color Expert or Color Specialist as designated by DFS and OCAC (see Part IV page 1) for either Detention or DWPE recommendations.

Attempt to identify any non-permitted or unlisted color(s) present. If they are found, a check analysis confirming the identity must be conducted. 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.

**For DWPE recommendations based on laboratory detection of an undeclared or non-permitted color, an original and check analyses that are specific to the color additive must be performed for each product being recommended.**

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](http://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 (FD&C Red No. 3 lakes are not permitted in foods); Citrus Red No. 2; FD&C Red No. 40 and lakes; FD&C Blue No. 1 and lakes; FD&C Blue No. 2 and lakes; FD&C Green No. 3 and lakes; Orange B; and FD&C Yellow No. 5 and lakes.

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, FD&C Red No.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 go 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 encourages the field to be aware of detention recommendation patterns that could develop into broad-based DWPEs and encourages the field to consult ORA Headquarters and if necessary ORA Headquarters should consult the CFSAN Labeling Compliance Team 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 detention without physical examination see the [RPM Chapter 9](#), Subchapter "Detention Without Physical Examination".

**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 an unapproved food or non-permitted 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 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 certified. For additional information see the RPM, Chapter 9, "[Exhibit 9-5](#)". The Field should contact ORA Headquarters for guidance and ORA Headquarters should contact the CFSAN regulatory contact, CFSAN/DE/Labeling Compliance Team, HFS-608 for direction if a special circumstance arises.

**2. 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.

**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](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 Internet at <http://www.cfsan.fda.gov/~dms/opa-appa.html>

Regulatory Procedures Manual (RPM), Chapter 9 at [www.fda.gov/ora/compliance\\_ref/rpm/default.htm](http://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](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](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](http://www.fda.gov/ora/fiars/ora_import_ia2604.html);
- IA#28-07, Detention Without Physical Examination of Coumarin in Vanilla Products Extracts-Flavorings-Imitations, [http://www.fda.gov/ora/fiars/ora\\_import\\_ia2807.html](http://www.fda.gov/ora/fiars/ora_import_ia2807.html);
- IA#45-02, Detention Without Physical Examination and Guidance of Foods Containing non-permitted Colors; [http://www.fda.gov/ora/fiars/ora\\_import\\_ia4502.html](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](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](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](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](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](http://www.fda.gov/ora/fiars/ora_import_alerts.html)

Compliance Policy Guides at [http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm)

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

### 3. Import Alerts for Food & Color Additives

If an unapproved food or non-permitted 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), I.A. 99-21 (Food Additives) or any appropriate I.A. 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 for Direct Reference Authority:**

**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, reagents, 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%.

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**

Section 500.500 Guidance Levels for 3-MCPD (3-Chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces

**Note:** The final CPG still is not posted in the Manual. You can access the copy filed with Dockets @ <http://www.accessdata.fda.gov/scripts/oc/ohrms/dailylist.cfm?yr=2008&mn=3&dy=31>

[Click on The Guidance under the paragraph for the FR notice.](#)

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** - Wanda Honeyblue, CFSAN/OC/DFP&G/FPB, HFS-615, Telephone (301) 436-2174, Fax (301) 436-2657 or [Wanda.Honeyblue@fda.hhs.gov](mailto:Wanda.Honeyblue@fda.hhs.gov)

**Regulatory Questions** - Felicia Binion-Williams, CFSAN/OC/DE/LCT, HFS-608, Telephone (301) 436-2566, Fax (301) 436-2716 or [Felicia.Binionwilliams@fda.hhs.gov](mailto:Felicia.Binionwilliams@fda.hhs.gov)

**ORA/Division of Import Operations and Policy (HFC-172):** Andrew J. Seaborn Telephone (301) 443-6553 FAX (301) 594-0413 or [Andrew.Seaborn@fda.hhs.gov](mailto:Andrew.Seaborn@fda.hhs.gov)

**Food Additive Questions** - Celeste Johnston, CFSAN/OFAS/DPR, HFS-265, Telephone (301) 436-1282, Fax (301) 436-2972 or [celeste.johnston@fda.hhs.gov](mailto:celeste.johnston@fda.hhs.gov)

**Analytical:**

- **Food Additives** - Dr. Gregory Diachenko, CFSAN/ORS/DAC/, HFS-705, Telephone (301) 436-1898, FAX (301) 436-2634 or [Gregory.Diachenko@fda.hhs.gov](mailto:Gregory.Diachenko@fda.hhs.gov)
- **Food Additives** - Timothy Begley, CFSAN/ORS/DAC/MDb, HFS-706, Telephone (301) 436-1893, Fax (301) 436-2634 or [Timothy.Begley@fda.hhs.gov](mailto:Timothy.Begley@fda.hhs.gov)
- **Color Additives** - Alan Scher, CFSAN/OCAC/DCCT/CTT, HFS-106, Telephone (301) 436-1139, FAX (301) 436-2961 or [Alan.Scher@fda.hhs.gov](mailto: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 [gsalem@fda.hhs.gov](mailto:gsalem@fda.hhs.gov)

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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. &.