Colors

Handling/Processing

Identification of Petitioned Substance

This Technical Evaluation Report discusses 18 substances used as colors in organic handling/processing: (1) beet juice extract color; (2) beta-carotene extract color; (3) black currant juice color; (4) black/purple carrot juice color; (5) blueberry juice color; (6) carrot juice color; (7) cherry juice color; (8) chokeberry—*Aronia* juice color; (9) elderberry juice color; (10) grape juice color; (11) grape skin extract color; (12) paprika color; (13) pumpkin juice color; (14) purple potato juice color; (15) red cabbage extract color; (16) red radish extract color; (17) saffron extract color; and (18) turmeric extract color. Identifying information for these 18 substances, including chemical names, color descriptions, and CAS numbers or other unique identifiers, is provided in Appendix 1.

Summary of Petitioned Use

The 18 colors that are the subject of this report are currently included on the National List of Allowed and Prohibited Substances (hereafter referred to as the National List) as nonorganically-produced ingredients in or on processed products labeled as "organic" when the substances are not commercially available in organic form (7 CFR 205.606). These colors are derived from agricultural products and must not be produced using synthetic solvents and carrier systems or any artificial preservative. The 18 colors can be grouped into three categories: anthocyanin colors (chokeberry-*Aronia* juice color, black currant juice color, black/purple carrot juice color, blueberry juice color, cherry juice color, red cabbage extract color, elderberry juice color, grape juice color, grape skin extract color, purple potato juice color, red radish extract color); carotenoid colors (beta-carotene extract color, carrot juice color, paprika extract color, pumpkin juice color, saffron extract color); and other colors (beet juice extract color, turmeric extract color). Colors are added to food products for various reasons: to enhance the attractiveness of the food, to assure uniformity of color, to add back color lost during processing, to intensify existing colors, to protect light-susceptible vitamins, and to preserve flavor (Delgado-Vargas et al., 2000; Mortensen, 2006).

Colors are used in many different food products. Carotenoids are used in fruit juices and other beverages, butter, margarine, soups, dairy products, meats, salad dressings, preserves, desserts, confectionery, syrups, pasta, and egg products and impart colors of red, orange, or yellow. Specifically, paprika extract is used in dairy products such as cheese, dairy-based drinks, desserts and edible ices; fermented fruit products; jams and jellies; and processed vegetables (Cantrill, 2008). Pumpkin juice color adds a strong yellow or orange color to cheese products and milk beverages (Muntean, 2005). Saffron, used in soups, cheese, cakes and other baked goods, and meat products, imparts a yellow color to these foods (Klaui and Bauernfeind, 1981). Anthocyanins are primarily used in fruit products such as fruit juices, jams, jellies, wines, frozen fruit, and maraschino cherries to add back color (variations of red, blue, purple, orange) lost during processing. Beet juice color is used in items such as yogurt, ice cream, meat products, baked goods, candies, jellies, and fruit cocktails (Delgado-Vargas et al., 2000). Turmeric is added to margarines, fat and oil products, bakery and dairy products, dry mixes, and cereals (Wrolstad, 2012).

Characterization of Petitioned Substance

Composition of the Substance:

Anthocyanin colors

Anthocyanins are a group of pigments responsible for the blue, red, and purple colors of many fruits and vegetables. Anthocyanins are composed of a pigment molecule called anthocyanidin, which is linked to a sugar molecule through a glycosidic bond (Mortensen, 2006). Six main anthocyanidin pigments are found at varying concentrations in 11 of the colors described in this report. Structures of these six anthocyanidin pigments are shown in Figure 1. The term anthocyanin is commonly used to describe the colors as a group, whereas the individual anthocyanin pigments are often referred to when describing the color and concentrations in various fruits and vegetables.

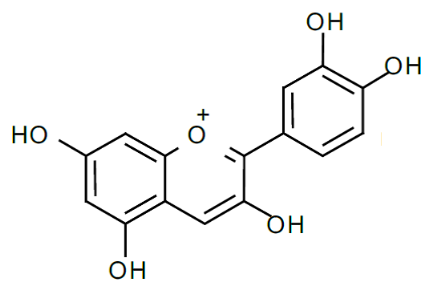
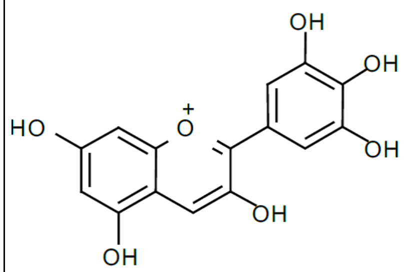
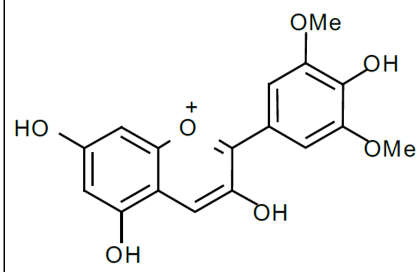
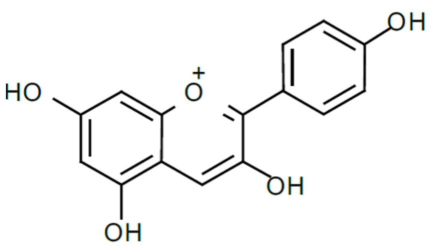
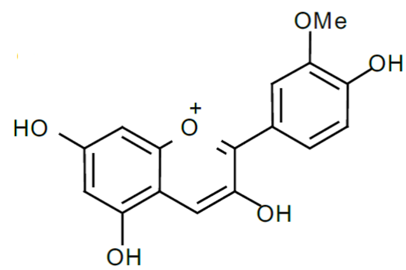
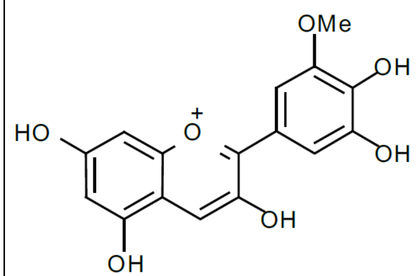
		
Cyanidin	**Delphinidin**	**Malvidin**
		
Pelargonidin	**Peonidin**	**Petunidin**

Figure 1: Chemical Structures of Six Anthocyanidin Pigments (Horbowicz et al., 2008)

Anthocyanin concentrations in fruits and vegetables generally range from 0.1–1.0% dry weight (Delgado-Vargas et al., 2000). The distribution of the different anthocyanins and thus the resulting hue, strength, and stability of color varies across different fruits and vegetables (Wrolstad, 2012). The actual color that the combined anthocyanin pigments express is also dependent on the pH of the solution. Red is favored at acidic (low) pH; purple or violet colors typically occur at neutral pH; and blues occur at moderately basic pH, turning to green or yellow at very high (basic) pH levels (Delgado-Vargas et al., 2000). Distributions of anthocyanidin pigments in various fruits and vegetable are shown in Table 1.

<u>Carotenoid colors</u>

Beta-carotene extract color, carrot juice color, black/purple carrot juice color

Four of the carotenoid colors contain beta-carotene: beta-carotene extract color, carrot juice color, black/purple carrot juice color (which contains both beta-carotene and anthocyanins), and paprika extract color. Beta-carotene is the most abundant carotenoid found in carrots and is made up of a hydrocarbon chain with a carbon ring at each end (Wrolstad, 2012). The structure of beta-carotene is shown in Figure 2. Beta-carotene concentrations are highest in carrots, with a reported mean value of 25.65 mg/100 g fresh weight (Holden et al., 1999; based on data from USDA-NCC Carotenoid Database for U.S. Foods).

Paprika extract color

The paprika extract color comes from paprika oleoresin, an oily extract from the paprika variety of chili peppers (*Capsicum annuum*) (Wrolstad, 2012). Paprika oleoresin may contain several pigment compounds depending on the formulation, including: capsanthin and capsorubin (red carotenoids); beta-carotene; and beta-cryptoxanthin, zeaxanthin, and antheraxanthin (yellow xanthophylls). Xanthophyll pigments are a subgroup of carotenoids, sometimes called oxycarotenoids (Klaui and Bauernfeind, 1981). Capsanthin is the main pigment in paprika and accounts for about half of the carotenoids in paprika (Mortensen, 2006). Paprika oleoresin added to food results in a bright orange to red-orange color (Rymbai et al., 2011). The structures of pigments in paprika oleoresin are shown in Figure 2.

Table 1: Anthocyanidin Pigment Levels in Raw Fruits and Vegetables[a]

Fruit/Vegetable	Levels of Anthocyanidin Pigments (mg/100 g)					
	Cyanidin	**Delphinidin**	**Malvidin**	**Pelargonidin**	**Peonidin**	**Petunidin**
Chokeberry, raw	**344.07**	0.65	1.22	0.98	0.08	2.79
Aronia/chokeberry juice concentrate[b]	**231.61**	ND	ND	ND	ND	ND
Black currant, raw	62.46	**89.62**	ND	1.17	0.66	3.87
Black currant juice	29.76	**45.27**	ND	ND	ND	ND
Blueberries, raw	8.46	35.43	**67.59**	0.00[c]	20.29	31.53
Carrot, black/purple[d]	**13.68–17.58**	ND–0.34	0.88–3.43	0.47–0.54	0.26–0.49	ND–0.32
Cherries, sweet raw	**30.21**	0.00[c]	0.00[c]	0.27	1.5	0.00[c]
Cabbage, red	**209.83**	0.10	ND	0.02	ND	ND
Elderberries, raw	**485.26**	0.00[c]	ND	0.02	ND	0.00[c]
Elderberry juice concentrate	**411.40**	ND	ND	ND	ND	ND
Grapes, red raw	1.16	2.27	**39.00**	0.02	3.62	1.97
Grape juice, red	**0.4**	0.10	0.08	ND	0.17	0.10
Potato, purple[d]	0.02–0.14	0.34–0.55	**2.70–4.77**	ND	0.3–0.83	13.99–29.72
Radish, red	0.00[c]	0.00[c]	0.00[c]	**63.13**	0.00[c]	0.00[c]

[a]Source is USDA (2014) unless otherwise noted; values are means or highest concentrations (bold) for each fruit/vegetable.
[b]Only juice concentrate listed
[c]Reported concentration of 0.00
[d]Source is Li et al., 2012
ND = not detected

Pumpkin juice color

Pumpkin (*Cucurbita* spp.) juice color contains the carotenoid pigments beta-carotene, alpha-cryptoxanthin, beta-cryptoxanthin, and lutein. Each of these compounds is made up of a hydrocarbon chain with carbon rings at both ends of the chain that vary in configuration (see Figure 2). One study reported that total carotenoids in pumpkin juice ranges from 3.7–19.7 mg/L. In this study, beta-carotene was the most abundant carotenoid in pumpkin juice color followed by lutein, alpha-cryptoxanthin, and beta-cryptoxanthin, which were present in similar amounts (Kreck et al., 2006).

Saffron extract color

Saffron extract color is extracted from the flowers—specifically the stigma—of the saffron crocus (*Crocus sativus*) (Mortensen, 2006; Timberlake and Henry, 1986). The pigment that gives saffron extract its deep yellow color is crocin. Crocin consists of a 20-carbon chain molecule called crocetin attached to two molecules of the sugar gentiobiose (Wrolstad, 2012). The structure of crocin is depicted in Figure 2.

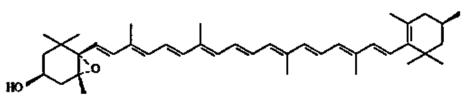
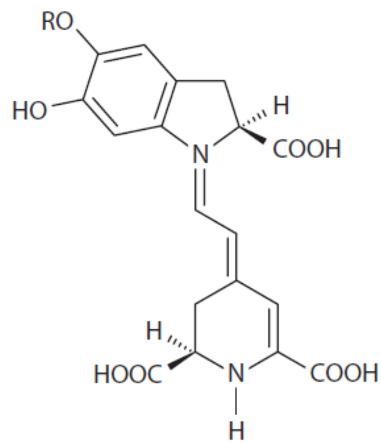
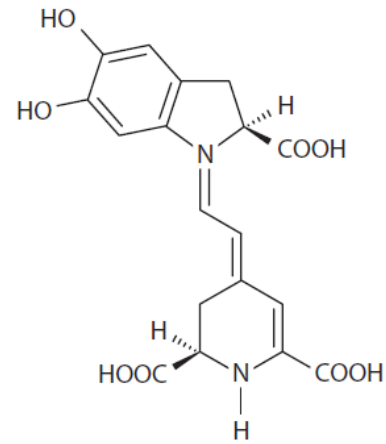
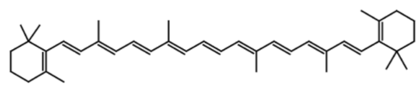
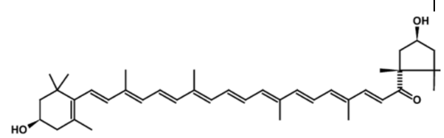
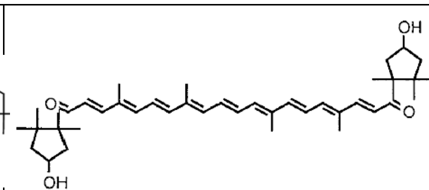
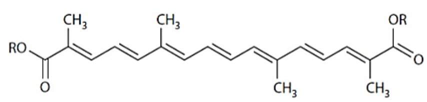
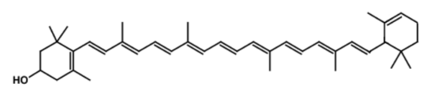
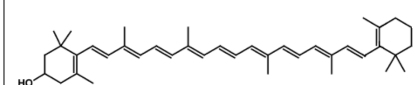
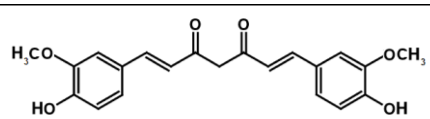
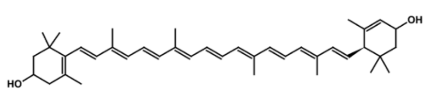
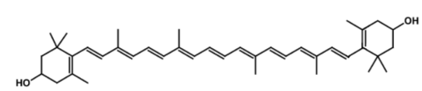
		
Antheraxanthin (Paprika Extract)	**Betanin** (R = glucose)	**Betanidin**
	Betacyanins (Beet Juice Extract)	
		
Beta-carotene (Multiple Carotenoids)	**Capsanthin (Paprika Extract)**	**Capsorubin (Paprika Extract)**
		
Crocin (Saffron Extract) (R = gentiobiose, a sugar)	**Alpha-cryptoxanthin (Pumpkin Juice)**	**Beta-cryptoxanthin (Pumpkin Juice, Paprika Extract)**
		
Curcumin (Turmeric Extract)	**Lutein (Pumpkin Juice)**	**Zeaxanthin (Paprika Extract)**

Figure 2: Chemical Structures of Carotenoid Colors and Betacyanins of Beet Juice (Kumagai et al., 1998; Mortensen, 2006; Phillip et al., 1996; Rymbai et al., 2011; Wrolstad, 2012)

<u>Other colors</u>

Beet juice extract color

Beet (*Beta vulgaris*) juice extract contains red pigments called betalains—also called betacyanins—which are glycoside pigments that are similar in structure to anthocyanins (Wrolstad, 2012). Betanin and betanidin are the two pigments that make up the betalains. Their structures differ in that a glucose molecule on the cyclic carbon chain of betanin replaces the hydrogen atom of betanidin (see Figure 2). Betanin is the most abundant component of the betalains and makes up 95% of the total pigment in beet extract (Rymbai et al., 2011).

Turmeric extract color

Turmeric rhizome (*Curcuma longa*) is the source of turmeric oleoresin, a common source for the pigment curcumin. Curcumin is used to give a yellow color to foods and is the principal coloring component of turmeric extract (Timberlake and Henry, 1986; Wrolstad, 2012). Turmeric contains 2.5–6% yellow pigments whereas oleoresin extracted from turmeric has a much higher concentration of pigments (up to 58%) (Mortensen, 2006; Rymbai et al., 2011). The structure of curcumin is depicted in Figure 2.

Source or Origin of the Substance:

The 18 colors that are the subject of this report and their plant sources are listed in Table 2. Several of the colors are made up of one or more anthocyanin pigments, present in varying amounts (Delgado-Vargas et al., 2000; USDA, 2014). Anthocyanins are responsible for the colors of many fruits, flowers, and leaves and are commonly found in higher plants (Wrolstad, 2012). Concentrations of the individual pigments can vary with growing conditions, and pigment color varies with pH (Delgado-Vargas et al., 2000).

Table 2: Vegetable and Fruit Sources of Colors Listed at 7 CFR 205.606(d)

Color Name	Plant Source	Plant Type/Part	Pigment Type(s) or Name
Beet juice extract color	*Beta vulgaris*	root vegetable	betalain
Beta-carotene extract color	*Daucus carota* or *Dunaliella salina*	root vegetable or algae	carotenoid
Black currant juice color	*Ribes nigrum*	fruit	anthocyanin
Black/purple carrot juice color	*Daucus carota*	root vegetable	anthocyanin, carotenoid
Blueberry juice color	*Vaccinium* sp.	fruit	anthocyanin
Carrot juice color	*Daucus carota*	root vegetable	carotenoid
Cherry juice color	*Prunus avium*	fruit	anthocyanin
Chokeberry-*Aronia* juice color	*Aronia* spp.	fruit	anthocyanin
Elderberry juice color	*Sambucus* spp.	fruit	anthocyanin
Grape juice color	*Vitis* spp.	fruit	anthocyanin
Grape skin extract color	*Vitis* spp.	fruit	anthocyanin
Paprika color	*Capsicum annuum*	fruit	oleoresin paprika (oil-soluble extract): carotenoid and xanthophyll
Pumpkin juice color	*Cucurbita* spp.	fruit	lutein
Purple potato juice color	*Solanum tuberosum*	root vegetable	anthocyanin
Red cabbage extract color	*Brassica oleracea*	leafy vegetable	anthocyanin
Red radish extract color	*Raphanus sativus*	root vegetable	anthocyanin
Saffron extract color	*Crocus sativus*	flower	carotenoid
Turmeric extract color	*Cucurma longa*	rhizome (type of root)	turmeric oleoresin (oil-soluble extract): curcuminoid

Anthocyanin colors

Various anthocyanin-containing fruits and vegetables, including black/purple carrot juice color

The word "anthocyanin" comes from two Greek words meaning "flower" and "dark blue." Anthocyanins are found in blue, red, and purple fruits and vegetables, representing a variety of shades and hues (Delgado-Vargas et al., 2000; Mortensen, 2006). As discussed in the previous section, anthocyanin pigments are all made up of an anthocyanidin pigment bonded to a glycoside sugar. There are about 25 known anthocyanidins, but due to the number of different anthocyanidin-sugar combinations, there are several hundred anthocyanins (Mortensen, 2006).

Carotenoid colors

Beta-carotene extract color, carrot juice color, black/purple carrot juice color
Carotenoids are the most widely distributed group of pigments. They are found in photosynthetic and nonphotosynthetic organisms: higher plants, algae, fungi, and bacteria. Carotenoids are responsible for many of the red, orange, and yellow colors of plants (fruits, vegetables, and flowers) and some animals (insects, birds, crustaceans, and fish). Black and purple carrots are unique in that they contain anthocyanins and carotenoid colors. Only microorganisms and plants can synthesize carotenoids; any carotenoids consumed by animals come from these two sources (Delgado-Vargas et al., 2000).

Approximately 600 carotenoid pigments have been identified although many more may exist considering the many carotenoids isolated from marine organisms (Holden et al., 1999). The total production of carotenoids in nature is estimated at 108 tons per year, comprised mostly of fucoxanthin from marine algae and lutein, violaxanthin, and neoxanthin from green leaves. Carotenoids are found in all green plants as a mixture of alpha- and beta-carotene, beta-cryptoxanthin, lutein, zeaxanthin, violaxanthin, and neoxanthin (Delgado-Vargas et al., 2000).

Paprika extract color
Paprika is a colorant and spice made from the dried fruit pods of the paprika pepper plant *Capsicum annuum*. Paprika oleoresin, the extract from the paprika fruit, is used both as a colorant and a culinary spice. When making the colorant, manufacturers use *C. annuum* varieties with low pungency (e.g., capsaicin, the source of the characteristic chili pepper heat) and limited flavor (Mortensen, 2006).

Capsanthin is the main pigment in paprika and can account for more than half of its carotenoids. Paprika also contains the orange–red pigment capsorubin and a number of yellow pigments as discussed in the *Composition of the Substance* section. Manufacturers prefer a high concentration of the orange–red pigments in paprika when it is used for colorant purposes, as yellow pigments can be obtained more efficiently from other sources. Very red paprika can be mixed with yellow carotenes or lutein to give a continuous range of yellow–orange–red colorants (Mortensen, 2006).

Pumpkin juice color
Pumpkin juice color is the pressed or extracted juice of the pumpkin squash (*Cucurbita* spp.). The fresh juice contains several carotenoids, but beta-carotene and lutein are found in the highest concentrations. In one study, lutein accounted for 13.7% of the total carotenoids and beta-carotene accounted for 52.3% of total carotenoids (Muntean, 2005).

Saffron extract color
Saffron, from the Arabic word meaning "yellow," is the dried stigma and style of the saffron crocus flower (*Crocus sativus*). Saffron is one of the earliest plant-based colorants used to add color to food (Klaui and Bauernfeind, 1981). The major pigment in saffron is the water-soluble compound crocin, the structure of which was shown in Figure 2 (Mortensen, 2006). Saffron production is extremely labor intensive because each stigma and style has to be hand-picked from the crocus flower. For this reason, saffron is one of the most expensive spices in the world, which limits its use as a colorant (Rymbai et al., 2011; Wrolstad, 2012). Nearly 36,000 saffron flowers are required to yield 1 pound of stigmas (Gohari et al., 2013). In Europe, saffron is not commonly regarded as a colorant, but is considered a spice (Mortensen, 2006). In Japan and China, gardenia fruit (*Gardenia jasminoides*) is used for the production of gardenia yellow, a colorant containing crocin. Gardenia yellow is not approved as a food colorant in the United States or European Union (Wrolstad, 2012).

Other colors

Beet juice extract color
Beet (*Beta vulgaris*) is a purple root vegetable which is the source of the beet juice extract color. The chemicals in beets that have pigment qualities are called betalains. Betalains are found in plants other than beet, but the beet is the only allowed source of betalain colorant in the United States and European Union. Betalains are made up of two groups of pigments: the red–purple betacyanins and the yellow betaxanthins. The red–purple betacyanins are the major pigments in beets, and betanin makes up 75–95%

of that pigment. Compared with anthocyanin pigments, beet color is more purple and brighter, and the color hue does not change with pH in the range 4–7. The major disadvantage of beet color is its low heat stability (Mortensen, 2006).

Turmeric extract color
Turmeric is the dried, ground rhizomes of the turmeric root, *Curcuma longa*. The name *Curcuma* is derived from the Arabic word kurkum, meaning "saffron." The pigment properties of turmeric are due to curcumin (the main pigment) and two other pigments that are derivatives of curcumin. Turmeric oleoresin, the turmeric extract that is used as a pigment, is made by extraction with organic solvents and may contain up to 58% pigment although a more typical range is 25–40%. The pigments may be further separated by multiple solvent washes and distillation from the oleoresin, yielding virtually flavor-free curcumin powder. The dried, powdered extract is also known as curcumin powder and can be more than 90% pigment (Mortensen, 2006; Stankovic, 2004).

Properties of the Substance:
Pigments are chemical compounds that absorb light in a specific wavelength range of the visible region. The specific color produced by the pigments is due to a structure on the pigment molecule called a chromophore. The chromophore captures some of the light energy, while the nonabsorbed light is reflected and/or refracted. This reflected or refracted light is captured by the human eye and generates neural impulses that are transmitted to the brain where they are interpreted as a color (Delgado-Vargas et al., 2000).

The pigments in this report are mixtures of several compounds that may vary depending on the composition of the fruit or vegetables from which they came. For this reason, the physical and chemical properties of the pigments will vary with source, season, use type, and processing methods. The exception to this rule is beta-carotene, which is the only singular chemical compound in this report. The chemical and physical properties of selected pigments are listed in Table 3.

Specific Uses of the Substance:
All of the substances discussed in this report are derived from fruit, vegetable, root, flower, or algal sources and are used to add color to various food products. These colorants may be considered dyes or pigments depending on their use. The terms "dye" and "pigment" may be used interchangeably, but they have different meanings. A dye is soluble (i.e., it dissolves) in the liquid media to which it is added, while a pigment is generally insoluble. For example, some carotenoids are considered dyes when they are added to oils, but considered pigments when they are added to water or water-based material. Given the various applications of the colorants in this report, the distinction between "dye" and "pigment" may be inconsistent depending on the use of the colorant (Mortensen, 2006). For this reason, the term "pigment" is used in this report to refer to the colorants in general.

Pigments are added to food to do one or more of the following (Delgado-Vargas et al., 2000):

- restore the original appearance of a food because of changes during processing and storage,
- intensify colors normally found in food,
- improve the appearance of the food if it will not be appetizing without additional color,
- ensure uniformity of color in the food and avoid variations in the color due to seasonal variations, and
- protect the flavor or any light-susceptible vitamins in food

Approved Legal Uses of the Substance:
The colors that are the subject of this report are currently included on the National List as nonorganically-produced agricultural products allowed as ingredients in or on processed products labeled as "organic" (7 CFR 205.606[d]). The listing further states that items listed at 205.606 may be used as ingredients in or processed products labeled as "organic" only when products are not commercially available in organic form.

Table 3: Physical and Chemical Properties of Selected Pigments

Pigment	CAS Number	Molecular Weight (g/mol)	Melting Point	Density	Water Solubility (mg/L)	Solubility
Anthocyanins[a]						
Cyanidin	525-58-5	322.6	NR	NR	NR	soluble in ethanol and water
Delphinidin	528-53-0	338.7	NR	NR	NR	soluble in ethanol and water
Malvidin	643-84-5	366.7	NR	NR	NR	soluble in water
Pelardonidin	134-04-3	306.7	NR	NR	NR	NA
Peonidin	134-01-0	336.7	NR	NR	NR	soluble in water
Petunidin	1429-30-7	352.7	NR	NR	NR	soluble in water
Carotenoids[b, c]						
Beta-carotene	7235-40-7	536.87	183 °C	1.00 at 20 °C	0.6	soluble in oil, fat solvents, and acetone
Lutein	127-40-2	568.88	196 °C	NR	insoluble	soluble in oil and solvents
Capsanthin	465-42-9	584.87	176 °C	NR	insoluble	soluble in acetone and ethanol
Crocetin[d]	42553-65-1	976.96	NR	NR	NR, soluble	very soluble in water
Other Colors[c]						
Betanin	7659-95-2	550.47	NR	NR	NR	water soluble
Curcumin	458-37-7	368.38	183 °C	NR	3.12	soluble in alcohol and acetic acid

[a]Source is EFSA, 2013
[b]Sources are EFSA, 2012 and HSDB, 2007
[c]Source is ChemIDPlus, 2014
[d]Sources are Abdullaev and Espinosa-Aguirre, 2004 and Sigma-Aldrich, 2014
NR = not reported
NA = not available

The history of color additive regulation is older than any other additive regulation with the exception of preservatives (Delgado-Vargas et al., 2000). Under the Federal Food, Drug, and Cosmetic Act (FFDCA), color additives are subject to approval before they can be used in food, drugs, cosmetics, and certain medical devices (with the exception of coal tar hair dyes). However, some fruit and vegetable pigments are exempt from certification, such as those listed at 21 CFR 73, "Listing of Color Additives Exempt from Certification." Many of the fruit and vegetable colors are included in the broad categories of "Fruit Juice" and "Vegetable Juice," defined in Sections 73.250 and 73.260, respectively. Fruit juice is defined as follows: "The color additive fruit juice is prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit. The color additive may be concentrated or dried." Vegetable juice is defined as follows: "The color additive vegetable juice is prepared either by expressing the juice from mature varieties of fresh, edible vegetables, or by the water infusion of the dried vegetable. The color additive may be concentrated or dried." The applicable FDA listing for each color, with its corresponding NOP listing, is presented in Table 4.

Table 4: FDA Listing of Color Additives Exempt from Certification

NOP Listing	FDA Listing at 21 CFR 73
Beet juice extract color	Dehydrated beets (beet powder)
Beta-carotene extract color	Beta-carotene
Black currant juice color	Fruit juice
Black/purple carrot juice color	Vegetable juice
Blueberry juice color	Fruit juice
Carrot juice color	Vegetable juice
Cherry juice color	Fruit juice
Chokeberry-*Aronia* juice color	Fruit juice
Elderberry juice color	Fruit juice
Grape juice color	Grape color extract
Grape skin extract color	Grape skin extract
Paprika color	Paprika oleoresin, paprika
Pumpkin juice color	Vegetable juice
Purple potato juice color	Vegetable juice
Red cabbage extract color	Vegetable juice
Red radish extract color	Vegetable juice
Saffron extract color	Saffron
Turmeric extract color	Turmeric, turmeric oleoresin

Action of the Substance:

All of the colors in this report are added to food products during handling or processing to alter the color of the food according to the needs of the food producer. Pigments such as the vegetable- and fruit-based colors in this report are chemical compounds that absorb specific wavelengths of light in the visible region. The color produced from each pigment is due to a molecule-specific structure called a chromophore. The chromophore is a specific section of a molecule that absorbs a portion of the energy from visible light. The nonabsorbed light is reflected and/or refracted and captured by the human eye. That light generates neural impulses that are transmitted to the brain where they are interpreted as a color (Delgado-Vargas et al., 2000).

Combinations of the Substance:

The pigments in this report are extracted from fruits, vegetables, flowers, roots, or algae with the intent of extracting only the material to be used as a pigment. For this reason, additional substances are not desirable in the final product. However, additional ingredients may need to be added to stabilize or preserve the pigments until they are used in handling or processing. The additional ingredients used with each of the pigments are described in Table 5.

Table 5: Additional Ingredients Added to Food Pigments[a]

Color	Additional Ingredients	Ingredients on National List
Anthocyanin colors	Sulfur dioxide use to decrease browning in presence of citric acid	Sulfur dioxide— for use only in wine labeled "made with organic grapes," provided, that, total sulfite concentration does not exceed 100 ppm.
Beet juice extract color	Citric acid used to extract color from beets, may remain after extraction; ascorbic acid (vitamin C) used to stabilize beet extract color	Citric acid—allowed for handling; Vitamin C—allowed for handling
Carotenoid colors	Protective coatings and/or antioxidant ingredients used to protect the pigment from degradation (Wrolstad, 2012); ascorbic acid (vitamin C) used as antioxidant to prevent fading; green tea polyphenols used to prevent discoloration (Delgado-Vargas et al., 2000)	Vitamin C—allowed for handling; green tea polyphenols not listed
Paprika color	Vegetable oil added to oleoresin to maintain consistency	Non-organic vegetable oil not listed
Purple potato juice color	Water, invert sugar (glucose/fructose syrup made from table sugar), citric acid	Citric acid—allowed for handling
Saffron extract color	Moisture added (to 5%) for stability during storage	NA
Turmeric extract color	None listed; extract is stable if it is kept in a dark and anoxic environment	NA

[a]Sources include Cantrill, 2008; Delgado-Vargas et al., 2000; Downham and Collins, 2011; and Raina et al., 1996
NA = not applicable

Status

Historic Use:

Anthocyanin colors

Anthocyanins are present in many types of edible and nonedible plants where they function as antioxidants and agents in photoprotection. As a result, they have been a part of the human diet for a very long time. Anthocyanins are present in fruits, vegetables, roots, bulbs, beans, and cereals. Anthocyanin pigments are abundant in wine, and pressed grapes are a common industrial source of additional anthocyanins. Researchers have reported that human consumption of anthocyanins ranges from 25–215 mg per person/day (Bridle and Timberlake, 1997).

Carotenoid colors

Carotenoids have been used as food colorants for centuries. Saffron, peppers (paprika), pumpkin, and carrots have carotenoids as their main color components. Colors from carotenoids have been widely used in the food industry. Carotenoids have many different preparations including colloidal suspensions, emulsions, and complexes with proteins. These varied preparations are used in multiple food products including margarine, butter, canned soups, fruit juices and beverages, dairy and related products, preserves and syrups, desserts and mixes, confections, salad dressings, meats, pasta, and egg products (Delgado-Vargas et al., 2000).

Other colors

Beet juice extract color

Beets have a long history of human consumption. Beets are consumed fresh or cooked, and some beet varieties are used for animal fodder or sugar production. The pigments in beets have been used since the mid-1800s and are also found in poke berries (*Phytolacca americana*) (Bauernfeind, 1981).

Pumpkin juice color

Pumpkin is an annual vine plant that is cultivated worldwide and is known for its edible flesh and seeds. The fruit is cooked as a vegetable, but can also be crushed to extract juice which may be drunk fresh or used as a coloring (Yadav et al., 2010).

Saffron extract color

Saffron was used in early human civilizations to provide a yellow color to food. The spice is used today to color foods such as rice dishes, and is one of the most expensive spices in the world (Delgado-Vargas et al., 2000).

Turmeric extract color

Turmeric has a long history of use as a spice and is grown and cultivated throughout tropical and subtropical regions of the world. The turmeric plant is native to India, where it plays a key role in seasoning blends for curry dishes (Stankovic, 2004).

"Colors derived from agricultural products" were added to the National List in 2007, and the listing was updated in 2010 to clarify that they must not be produced using synthetic solvents and carrier systems or any artificial preservative (USDA, 2010). The value of the natural food colors market was larger than the market for artificial colors for the first time in 2011. Global sales of natural colors were approximately $600 million in 2011, an increase of almost 29% 4 four years earlier. More recent estimates put the annual growth of the natural colors market at 3–4% annually. The food industry is the largest consumer of natural colors—accounting for 70% of the market share—with the remaining 27% in soft drinks and 3% in alcoholic beverages. The use of natural colors is highest in Europe, where 85% of new products launched between 2009 and 2011 used natural colorants (IFT, 2013).

Organic Foods Production Act, USDA Final Rule:

The 18 colors discussed in this report are included on the National List as nonorganically-produced agricultural products used as ingredients in or on processed products labeled as "organic" when the substance is not commercially available in organic form (7 CFR 205.606[d]).

International:

Canadian General Standards Board Permitted Substances List

The Canadian General Standards Board (CGSB) Permitted Substances List considers natural colorants, such as the substances described in this report, to be nonorganic ingredients not classified as food additives. Permitted colors must be from nonsynthetic sources only and cannot be produced using synthetic solvents or carrier systems and cannot include any artificial preservatives. The standards state that nonorganic ingredients may be used only when an acceptable nonsynthetic alternative is commercially unavailable (CGSB, 2011).

CODEX Alimentarius Commission

The CODEX Alimentarius Commission Guidelines for the Production, Processing, Labelling, and Marketing of Organically Produced Foods (GL 32-1999) states that only natural sources are allowed for coloring agents, including pigments. Individual colorants/pigments are not listed in the standards (CODEX, 2013).

European Economic Community Council Regulations

None of the colors discussed in this report are listed in the European Economic Community (EEC)

Council Regulation No. 889/2008 or 834/2007. Processed organic foods are discussed in EC No. 834/2007 (Articles 19 and 21) and EC No. 889/2008 (Article 21). Article 19 requires that all processed foods be produced mainly from ingredients of agricultural origin, but allows nonorganic agricultural ingredients to be used if they have been authorized for use in organic production in accordance with EC No. 934/2007 Article 21. Article 19 further states that "substances and techniques that reconstitute properties that are lost in the processing and storage of organic food, that correct the results of negligence in the processing of these products or that otherwise may be misleading as to the true nature of these products shall not be used"(EEC, 2007; EEC, 2008).

EC No. 834/2007 Article 21 states that the products and substances referred to in Article 19 should be subject to the objectives and principles for processed food listed in Article 21 of EC No. 889/2008. If the needed ingredients do not meet the criteria above, authorized alternatives are not available, and it would be impossible to preserve or produce the food without the ingredients, then the ingredients can be used. However, those ingredients must be found in nature and must have undergone only physical, biological, mechanical, enzymatic, or microbial processes. If products meeting this entire description are not available in sufficient quantities or qualities on the market, then the Commission would make an individual determination as to whether the ingredient should be allowed. EU Member States can also petition for ingredients meeting these criteria to be permitted.

Several of the colors are allowed for use as colorants in the European Union, and these are listed in Table 6.

Table 6: Colors with EU Numbers Allowed for Use in the European Union

Colors	EU Name	EU Number
Beet juice extract color	Beetroot red	E 162
Beta-carotene extract color	Beta-carotene	E 160a(ii)
Grape skin extract color	Anthocyanins	E 163
Paprika color	Paprika extract	E 160c
Saffron extract color	Saffron	no E-number
Turmeric extract color	Curcumin	E 100

Japan Agricultural Standard for Organic Production

The colors discussed in this report are not listed or discussed in the Japan Agricultural Standard (JAS) for Organic Production nor are the colors mentioned in the discussion of processing and handling. The Principle of Production of Organic Processed Foods in the standard states that, in the production of organically-processed foods, use of chemically-synthesized food additives and chemical agents should be avoided (MAFF, 2012).

International Federation of Organic Agriculture Movements (IFOAM)

The International Federation of Organic Agriculture Movements (IFOAM) 2014 Norms states that substances should "not be used solely or primarily as a preservative, to create, recreate or improve characteristics such as flavors, colors, or textures, or to restore or improve nutritive value lost during processing, except where the replacement of nutrients is required by law." The individual colors are not listed in the IFOAM Norms (IFOAM, 2014).

Evaluation Questions for Substances to be used in Organic Handling

Evaluation Question #1: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

As described in the *Properties of the Substance* section, the colors exhibited by the substances discussed in this report are dependent upon the specific chemical structures of the substances. Therefore, manufacturing and formulation processes generally are designed to maintain the integrity of the natural chemical structures of the colors. Chemical changes that may alter natural colors include oxidation and isomerization (a change of chemical conformation) due to light, heat, or pH changes. Resonance (the characterization of chemical conformations) and the likelihood of isomerization are the reasons for the instability of anthocyanin and carotenoid pigments. For example, the pH of anthocyanin pigment solutions can affect the equilibrium between colored and colorless pigments. A change in pH can shift the equilibrium and render them colorless (Delgado-Vargas et al., 2000).

Betalains, the pigments in beet juice extract, are very susceptible to chemical change from oxidation, which can result in color damage. Although betalains will retain their color at pH levels of 3.5–7 (the levels in most foods), they are susceptible to damage from oxygen, light, and moisture. Impacts related to these conditions can cause chemical changes affecting the color of betalain, which must be avoided by manufacturers in order to maintain the integrity of the pigment (Delgado-Vargas et al., 2000).
As another example, carotenoid compounds exist mainly in the *trans* form (a chemical conformation) in nature. Isomerization caused by excess light or heat changes the conformation of the pigment to the *cis* position. This change in chemical form decreases the intensity of the carotenoid color, for example, from bright orange to yellow in sweet potatoes (Chen et al., 1995; Eskin, 1979). Thus, the goal of extraction is to remove pigments without excessive isomerization thereby avoiding these types of chemical changes (Delgado-Vargas et al., 2000).

Many of the common extraction methods for colors involve solvent extraction of the pigments. Synthetic solvents are not permitted in organic processing and handling, so extraction methods for colors that involve synthetic solvents would not be permitted. Additional extraction methods using ethanol or supercritical fluid extraction are described for several of the pigments. The most prevalent methods of extraction for each group of colors are described below.

<u>Anthocyanin colors:</u>

Some methods of pigment extraction for the anthocyanin colors use dilute hydrochloric acid in methanol, which is reported to be the most effective method. However, hydrochloric acid is corrosive and methanol is toxic to humans. Consequently, other extraction methods are employed using ethanol and water, which are 80% and 27% as effective as using methanol, respectively (Castaneda-Ovando et al., 2009; Delgado-Vargas et al., 2000).

Anthocyanins are highly water soluble and are usually extracted for food use using water by soaking although lower alcohols such as ethanol are also used. Generally speaking, the most important source of anthocyanins in industrial applications is from grape pomace, the remains after grapes are pressed for wine production. Soaking is used to extract pigments from the wine grapes and the pomace is left to soak in water after pressing (Castaneda-Ovando et al., 2009). Given that the anthocyanin pigments are found in the skins of fruits and vegetables, it is possible that pigments from other fruits in this group could be extracted in the same manner (Delgado-Vargas et al., 2000; EFSA, 2013; Mortensen, 2006).

Researchers evaluated an aqueous extraction process for anthocyanins from sunflower. The researchers showed that extraction with sulfurous water (1000 ppm sulfur dioxide [SO_2]) was more effective than a traditional extraction method that uses ethanol, acetic acid, and water. The authors suggested that a possible reason for the improved extraction with SO_2 is the interaction of anthocyanins with bisulfite (HSO_3^-) ions, which improves the solubility of anthocyanins and its diffusion through the plant cell walls

(Gao and Mazza, 1996). This method has also been used with blackcurrants (Castaneda-Ovando et al., 2009; Delgado-Vargas et al., 2000).

Carotenoid colors:

Beta-carotene extract color, carrot juice color, black/purple carrot juice color

Generally, the extraction process for carotenoids requires the removal of the hydrophobic (fat-soluble) carotenoids from a hydrophilic (water-soluble) medium. Industrial extraction of carotenoids generally consists of shredding or milling, pressing, and solvent extraction of the pigments. The base material is milled or crushed and may be pelleted, and is then mixed with the synthetic solvent hexane and heated. Hexane in the pigment is eliminated by evaporation and vacuum distillation (Delgado-Vargas et al., 2000).

Supercritical fluid extraction (SFE) is another method used to extract carotenoids from carrots and algae (Borowitzka, undated; Herrero et al., 2006). SFE uses a gas (usually carbon dioxide) above its supercritical temperature and pressure (i.e., high temperature and pressure) to extract carotenoids and other compounds (Herrero et al., 2006). The best extraction results by Herrero et al. (2006) were obtained using 10% ethanol as a modifier. The fluid was held at 50 °C (122 °F) with the extraction pressure at 300 bar (296 atm). The resulting extract using SFE was higher in carotenoids and the process was faster than the traditional solvent extraction (Herrero et al., 2006).

Pressurized liquid extraction (PLE) is another method for carotenoid extraction. This method uses a solvent such as ethanol under increased temperature and pressure to extract carotenoids. One study employed this method to extract carotenoids from waste carrot material (Mustafa et al., 2012). An additional method employed in extraction of beta carotene from the algae *Dunaliella salina* involves using hot vegetable oil to aid the extraction (Borowitzka, undated).

Paprika extract color

The dried, ripe fruit of *Capsicum annuum* is used to manufacture paprika extract. Paprika extract is most commonly obtained by solvent extraction using hexane, which extracts all of the oil-soluble compounds. The solvent is evaporated from the extract following extraction (Cantrill, 2008) as in the extraction of other carotenoid compounds. Given that there are health concerns with hexane in food products and the fact that synthetic solvents cannot be used, other methods must be used for paprika extract color to be used in organic production. Supercritical fluid extraction (SFE) is also used for paprika extraction and requires less solvent inputs, uses a lower temperature, and can increase yields of paprika and other spice or color extracts (Machmudah and Goto, 2015).

Enzyme-assisted extraction is another method used for the extraction of paprika oleoresin and many other colors and flavors from fruits and vegetables, including *Aronia*/chokeberry, grapes, blueberries, carrots, and blackcurrant. This method uses the enzyme lipase as a pretreatment before distillation with water or solvent extraction. The advantage of this method is that less solvent is needed and the extraction time can be shortened. In addition, fruit and vegetable pressings (waste products from juice extraction) that have already been pressed for their juices can be treated with this method for extraction of colors (Sowbhagya and Chitra, 2010).

Other colors:

Beet juice extract color

The pigments from beets are not extracted; instead, the beetroots are pressed and the water is partially removed to yield a product that contains typically 0.5% pigments (Mortensen, 2006). The strained juice may then be sterilized by heat treatment (FAO, 1995). In the petition for the addition of beet juice color to the National List, the petitioner stated that no solvents are used in the extraction of beet juice and that processing is limited to physical processes and aqueous extraction (in water) (D.D. Williamson, Inc., 2007a).

Pumpkin juice color

Juice is extracted from pumpkin fruits by peeling and slicing the fruit into chunks and removing the seeds and placental tissue in the core of the fruit. From there, the fruit is chopped or pureed and pressed to produce the juice. The juice may also be obtained by using a commercial juicer. To further extract the carotenoids from the juice, the juice is filtered and solvents may be used to extract the pigments (Muntean, 2005). As an alternative to avoid solvent extraction, at this step, the color from the juice can be concentrated using vacuum evaporation, as is described in the petition for the addition of pumpkin juice color to the National List (GNT USA, 2007). The petitioner stated that water, glucose/fructose sugar (also called invert sugar), and citric acid may be used in this process to adjust the moisture level, sugar content, and pH of the juice (GNT USA, 2007).

Saffron extract color

The stigma and style of the saffron crocus are dried and ground, and water is used to extract the saffron pigment. Drying temperatures between 30–60 °C produce the highest carotenoid content when drying saffron (Delgado-Vargas et al., 2000). Crocin, the pigment from saffron, is one of the few water-soluble carotenoid pigments (Timberlake and Henry, 1986; Wrolstad, 2012).

Turmeric extract color

To manufacture turmeric extract color, the dried root of turmeric (*Curcuma longa*) is ground into powder and the colorant is extracted with a solvent. Several solvents may be used, including methanol, ethanol, and hexane. Carbon dioxide is also listed as a solvent, but it is not currently used in industrial applications (Stankovic, 2004). A different method is described in the petition for the addition of turmeric to the National List (D.D. Williamson, Inc., 2007b), whereby turmeric rhizomes are washed and cut into small pieces and soaked in vegetable oil. The pieces are agitated and the resulting liquid is drained. The liquid is then filtered and concentrated to yield an oil extract of turmeric (D.D. Williamson, Inc., 2007b). See Table 7 for information on extraction methods of the various colorants.

Table 7: Extraction Methods and Water/Oil Solubility of Pigments

Colorant	Pigment Name(s)	Water Solubility	Oil Used in Extraction?	Extraction Method Notes	Source
Anthocyanin colors	Cyanidin, delphinidin, malvidin, pelargonidin, peonidin, petunidin	Highly water soluble	No	Water or lower alcohols; aqueous extraction and spray drying; more soluble in alcohol than water; ethanol, acetic acid, water is traditional; SO2 in water aids extraction	Castaneda-Ovando et al., 2009; Delgado-Vargas et al., 2000; Gao and Mazza, 1996; Mortensen, 2006
Beta-carotene extract color	Beta-carotene	Not soluble	Yes	Extraction from carrots using pressurized ethanol extraction; extraction from algae using essential oil or hot vegetable oil or supercritical fluid extraction (SFE)	Borowitzka, undated; EFSA, 2012; Mustafa et al., 2012
Carrot juice color	Beta-carotene	Not soluble	No	Solvent extracted; also done with hot ethanol under pressure; example using carrot waste products	Mustafa et al., 2012
Paprika extract color	Canthaxanthin capsorubin; beta-carotene, beta-cryptoxanthin, zeaxanthin, and	No; soluble in oil	No	Organic solvent used in extraction; supercritical CO_2 also used; water-dispersible forms can be manufactured	Cantrill, 2008; Wrolstad, 2012

Colorant	Pigment Name(s)	Water Solubility	Oil Used in Extraction?	Extraction Method Notes	Source
	antheraxanthin				
Pumpkin juice color	Beta-carotene, lutein, alpha-cryptoxanthin, beta-cryptoxanthin	Pumpkins are 89% water by weight, but beta-carotene and lutein are not water soluble	No	Manual extraction by juicing and evaporation	Yadav et al., 2010
Saffron extract color	Crocin	Yes	No	Stigma and style are dried, powdered, and color is extracted using water; one of the few water-soluble carotenoids	Timberlake and Henry, 1986; Wrolstad, 2012
Beet juice extract color	Betanin, betanidin	Yes	No	More soluble in water than alcohol; citric acid also used to extract color; stable at pH range of 3.5–7	Delgado-Vargas et al., 2000; Mortensen, 2006; Timberlake and Henry, 1986; Wrolstad, 2012
Turmeric extract color	Curcumin	Water insoluble, slightly soluble in vegetable oil	No	Organic solvents: methanol, ethanol, hexane, others; also extracted by soaking in oil; may be dried to powder	D.D. Williamson, Inc., 2007b; Mortensen, 2006; Stankovic, 2004; Wrolstad, 2012

<u>Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.</u>

All of the colors that are the subject of this report are obtained from agricultural products including fruits, vegetables, roots, flowers, and rhizomes. The exception to this is beta-carotene extract, which is either obtained from carrots or the algae *Dunaliella salina* (Jaswir et al., 2011). Each of the colors is produced as a result of naturally-occurring biological processes. Extraction of the colors is described in the responses to Evaluation Question #1.

<u>Anthocyanin colors:</u>
Anthocyanins are produced within plants and function as pollination attractants and protective agents. Scientists believe that anthocyanins are dissolved in the cell sap within the vacuole of plant epidermis cells, where they provide color to flowers and fruits. Carotenoids are often present in the same plant organs as anthocyanins where they add complexity to color varieties in these plants (Bueno et al., 2012). Studies have shown that anthocyanins are produced in fruits during fruit ripening and, in the case of grapes, they are only produced in the skin of the fruit (Kennedy et al., 2006). All of the plants with anthocyanidin colors contain a mixture of the various anthocyanins as shown in Table 1.

<u>Carotenoid colors:</u>

Beta-carotene extract color, carrot juice color, black/purple carrot juice color, paprika extract color, pumpkin juice color, turmeric extract color

Carotenoid pigments are produced only in plants and algae, and all other life forms must obtain their carotenoids from plant or algal sources. It is thought that carotenoids played a role in the early development of photosynthesis in plants, specifically in modifying singlet oxygen (a highly reactive form of oxygen) to be used in the process. Furthermore, visual systems in animals utilize retinol, a metabolite of some carotenoids that is essential for these systems to operate (Klaui and Bauernfeind, 1981). Carotenoids in higher plants are derived from isopentenyl diphosphate and are produced in plastids by the methylerythritol phosphate pathway (Delgado-Vargas et al., 2000). Carotenoids are intracellular products and are usually located in the membranes of the mitochondria, chloroplasts, or endoplasmic reticulum. Due to their hydrophobic (fat-soluble) nature, carotenoids are most often found in lipids or other hydrophobic structures such as membranes (Jaswir et al., 2011).

Other colors:

Beet juice extract color
Betalains, the pigments found in beets that give them their red color, are created by a metabolic process within the plants. They are considered secondary metabolites and are derived from shikimic acid and the amino acid tyrosine (Delgado-Vargas et al., 2000). They are found in the flesh of the root and serve a similar purpose to anthocyanins, providing color and protecting against oxidative damage. Betalains are water soluble (Xiao-Hong et al., 2009).

Saffron extract color
Crocin biosynthesis occurs in the cytosol and endoplasmic reticulum of the saffron crocus (*Crocus sativus*) by way of the isopentenyl diphosphate pathway, similar to other carotenoid colors. Production of the pigments occurs in the flower of *C. sativus*, specifically in the stigma (the part of the pistil that receives the pollen) and style (the tube-like structure that connects the stigma to the rest of the flower). In many plants, the development of the stigma transitions from photosynthesizing organelles to pigment-containing organelles. In *C. sativus*, however, the pigment-containing organelles form without development of the photosynthesizing organelles (Gomez-Gomez et al., 2010).

Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

All of the substances discussed in this report are natural substances as they are derived directly from fruits, vegetables, rhizomes, or flowers. The specific fruits and vegetables from which each of the colors is derived are listed in Table 2. A synthetic form of beta-carotene exists, but is not considered in this report.

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

According to the FDA, a substance used to impart color is not eligible for determination as GRAS nor is it necessary to determine that the substance is GRAS if it is used as a colorant (U.S. FDA, 2004). The term "food additive," as defined in the Federal Food, Drug, and Cosmetics Act (21 USC 321, §201), specifically excludes color additives. In keeping with those regulations, none of the colors in this report are listed as GRAS, and there are no notices in the GRAS Notice Inventory considering their use as colorants. Several of the colors in this report are specifically listed in 21 CFR Part 73 as color additives exempt from certification, and if not listed specifically they are implicitly included in the broad categories of "fruit juice" and "vegetable juice," as defined at 21 CFR 73.250 and 21 CFR 73.260, respectively. The specific listing for each of the exempt color additives is provided in Table 4 in the *Approved Legal Uses of the Substance* section.

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

The primary technical function of the colors listed in this report is to add color to foods. Some of the colors have antioxidant activity and this is discussed in the response to Evaluation Question #7. The colors in this report sometimes require the addition of other compounds to stabilize them, which may require the addition of a preservative such as ascorbic acid (vitamin C), sulfur dioxide, or citric acid. These preservative additives are further described in Table 5.

Evaluation Question #6: Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

The substances described in this report are used to improve or replace the color of foods to which they are added as discussed in the section on *Specific Uses of the Substance*. The colors discussed in this report are exempt from certification according to 21 CFR Part 73 (see Table 4). The colorants in this report are added to various foods to recreate colors lost during processing or to augment, strengthen, or improve the colors of the food products (Delgado-Vargas et al., 2000). Simply adding the colorants to food products either changes or enhances the color of the food.

Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

The colors discussed in this report may affect the nutritional quality of the food to which they are added by increasing certain nutritional aspects. Many of the pigments have antioxidant and anti-inflammatory properties. Some of the pigments are the precursors to essential nutrients, and others may reduce the risks of cancer or cardiovascular disease. The health impacts of the colorants are summarized in Table 8.

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

The types of residues in natural colorants that may be harmful to human health include: aflatoxins, residual solvents used in extraction, pesticide residues, and heavy metal residues (Attokaran, 2011). U.S. FDA action levels exist for several, but not all of these residues, which FDA calls "poisonous or deleterious substances" (U.S. FDA, 2000). The FDA action levels for commodities represented by the fruits and vegetable sources of colorants in this report are presented in Table 11.

Aflatoxins

Aflatoxins are a group of toxins produced by fungal pathogens that commonly infect crops, including maize (corn). Exposure to significant amounts of aflatoxin can cause liver toxicity and in high amounts it can be fatal (CDC, 2012). One 2006 report from Brazil that examined paprika samples showed contamination of 82.9% of the samples with aflatoxin. The range of concentrations for aflatoxin B1 was 0.5–7.3 parts per billion (ppb), and the range for ochratoxin A (a type of aflatoxin) was 0.24–97.2 ppb (Shundo et al., 2009). For reference, the FDA action level for total aflatoxins in food is 20 ppb (U.S. FDA, 2005).

Heavy metals

FDA action levels exist for the heavy metals cadmium, lead, and mercury. However, no action levels exist for the agricultural products that are the subject of this report (U.S. FDA, 2000). There are standards for the arsenic, lead, and mercury for selected color sources listed at 21 CFR Part 73. Those standards are listed in Table 9.

Table 8: Health Impacts of Colorants

Color Name	Potential Health Impacts
Anthocyanin colors	Anthocyanin consumption is associated with many beneficial health impacts due to their strong antioxidant activity, including: anticarcinogenic activity, anti-inflammatory activity, prevention of cardiovascular disease, alleviation of diabetes, and obesity control (He and Giusti, 2010; Wrolstad, 2012). Epidemiological studies indicate that increasing anthocyanin consumption decreases the risk of cardiovascular disease, but the specific pharmacological mechanisms of action are still not known (Wallace, 2011). Purple potato flake extract was found to have antioxidant capacity and free radical scavenging activity in studies on rats (Han et al., 2006).
Beet juice extract color	Betacyanins from beets have high antioxidant capacity and have free radical scavenging properties. The impact of those properties on human health from dietary consumption of betacyanins has not been studied extensively (Cai et al., 2003; Wrolstad, 2012).
Carotenoid colors	Carotenoids alpha- and beta-carotene and beta-cryptoxanthin are converted in the body to retinol, which is further converted to retinal, a compound that is essential for normal vision, skin health, bone growth, and tooth remineralization (Holden et al., 1999; NLM, 2014). Beta-carotene and other carotenoid pigments have antioxidant activity that may be beneficial to human health, including inhibiting LDL cholesterol oxidation, reducing cancer risk, and improving cognitive development (Mustafa et al., 2012; Wrolstad, 2012). Studies in animals show that saffron has antitumor and cancer preventive activity (Abdullaev and Espinosa-Aguirre, 2004). Saffron also has strong antioxidant and anti-inflammatory activity based on studies in animals (Gohari et al., 2013).
Paprika extract color	Capsanthin, the main pigment in paprika extract, acts as a free-radical scavenger and may increase high-density lipoprotein (HDL) cholesterol, which can have a protective effect on cardiovascular disease (Aizawa and Inakuma, 2009).
Pumpkin juice color	Pumpkin juice color contains both beta-carotene and lutein, which can improve the nutritional quality of the food to which they are added. The nutritional benefits of beta-carotene are described above. Lutein and xeaxanthin (found in paprika extract) filter high-energy blue wavelengths of light and act as antioxidants in the eyes, helping to protect and maintain healthy cells. Consumption of lutein can help reduce the risk of age-related macular degeneration and cataracts (American Optometric Association, 2014).
Turmeric extract color	Curcumin is the biologically-active compound in turmeric extract color. Curcumin possesses anticancer and anti-inflammatory properties, which are linked to its strong antioxidant activity (Sharma et al., 2005; Wrolstad, 2012)

Table 9: Maximum Residues of Heavy Metals in Selected Color Sources

Color Source	Maximum Residue Level (21 CFR Part 73)		
	Arsenic (as As)	Lead (as Pb)	Mercury (as Hg)
Dehydrated beets (beet powder)	1 ppm	10 ppm	1 ppm
Canthaxanthin (in paprika)	3 ppm	10 ppm	1 ppm
Beta-carotene	3 ppm	10 ppm	not listed
Grape skin extract	1 ppm	10 ppm	not listed

Pesticide Residues

Fruit and vegetable products grown using nonorganic production methods may contain residues of conventional pesticides. These residues are limited by pesticide tolerances for food products, which are regulated by the U.S. EPA. The U.S. FDA tests food that is produced in the United States and food imported from other countries to ensure that the foods comply with pesticide tolerances (U.S. EPA, 2014).

The USDA conducts “market basket” surveys of produce each year and reports the results of those surveys in the Pesticide Data Program. Data from the 2010 USDA Pesticide Data Program showed that pesticides exceeding the tolerance levels were detected in 29 of the 11,644 samples tested. Of those 29 exceedances, 3 were in fruits and vegetable varieties similar to those that are the subject of this report. Two of the exceedances were in grapes (imidacloprid insecticide) and one exceedance (with two active ingredients) was in sweet bell peppers (fludioxonil and thiamethoxam fungicides) (see Table 10) (USDA, 2012). However, it is likely that the grapes are a variety intended for direct consumption (as is common in the market basket survey) and were not wine grapes used for the production of colorants. The sweet bell peppers in the report were also likely intended for direct consumption rather than those used for paprika colorant use. Regardless, it is possible that pesticide residues could be found in natural colorants.

Table 10: Pesticide Tolerance Exceedances in Fruits and Vegetable Types Used for Colorants[a]

Produce	Pesticide Active Ingredient	Detections/ Samples	Exceedances/ Samples	Range of Values (ppm)	Tolerance (ppm)
Grapes	Imidacloprid	357/745	2/745	0.004–2.3	1.0
Sweet bell peppers	Fludioxonil	2/744	2/744	0.055–0.059	0.01
Sweet bell peppers	Thiamethoxam	198/744	2/744	0.005–0.27	0.25

[a]Source is USDA, 2010

Residual solvents

According to FDA regulations for food additives and ingredients, hexane can be found in spice oleoresins (such as paprika oleoresin and turmeric oleoresin) at levels up to 25 ppm. Hexane is mentioned as a solvent used in extraction of both paprika and turmeric (Cantrill, 2008; Stankovic, 2004). Acetone is another solvent used in turmeric extraction, and FDA regulations for food additives permit 30 ppm of acetone in spice oleoresins. Other synthetic solvents used in extraction of spice oleoresins, as listed in the U.S. FDA additives regulations at 21 CFR 173.210–290, include: acetone (<30 ppm), ethylene dichloride (30 ppm), hexane (25 ppm), isopropanol (<50 ppm), methyl alcohol (<50 ppm), methylene chloride (<30 ppm), and trichloroethylene (<30 ppm). Given that synthetic solvents may not be used in organic processing, no amount of hexane would be expected to be present in these colors used for organic processing.

Table 11: FDA Action Levels for Poisonous or Deleterious Substances[a]

Substance Name	Commodity	Action Level (ppm)
Aflatoxins	Foods (general)	0.020
Aldrin & dieldrin	Beets (garden and sugar)	0.1
	Cabbage	0.03
	Carrots	0.1
	Peppers	0.05
	Potatoes	0.1
	Radishes	0.1

Substance Name	Commodity	Action Level (ppm)
	Small fruits and berries	0.05
	Squash (incl. pumpkin)	0.1
	Stone fruits (except Chickasaw, Damson, Japanese plums, and peaches)	0.03
Hexachlorobenzene	Brassica (cole) leafy vegetables (e.g., cabbage)	0.05
	Carrots	0.3
	Paprika	1.0
	Root and tuber vegetables (except carrots)	0.05
	Small fruits and berries	0.05
	Stone fruits (except Chickasaw, Damson, and Japanese plums)	0.05
Chlordane	Beets (with or without tops)	0.1
	Carrots	0.1
	Peppers	0.1
	Potatoes	0.1
	Radishes (with or without tops)	0.1
	Small fruits and berries (except cranberries, currants, elderberries, gooseberries, and olallieberries	0.1
	Squash	0.1
	Stone fruits (except Chickasaw, Damson, and Japanese plums)	0.1
DDT, DDE, & TDE	Beets (roots and tops)	0.2
	Carrots	3
	Grapes	0.05
	Peppers	0.1
	Potatoes	1
	Radishes (roots and tops)	0.2
	Small fruits and berries (except elderberries, grapes, and olallieberries)	0.1
	Squash	0.1
	Stone fruits (except Chickasaw, Damson, and Japanese plums)	0.2
Ethylene dibromide	Fruiting vegetables	0.00001
Heptachlor and heptachlor epoxide	Brassica (cole) leafy vegetables (e.g., cabbage)	0.01
	Cucurbit vegetables (e.g., squash)	0.02
	Fruiting vegetables	0.01
	Root and tuber vegetables	0.01
	Small fruits and berries	0.01
	Stone fruits	0.01

Substance Name	Commodity	Action Level (ppm)
Lindane	Root vegetables (includes beets, carrots, potatoes, radishes)	0.5
	Small fruits (includes blueberries, cherries, currants)	0.5

[a]Source is FDA, 2000

<u>Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).</u>

From a historical perspective, the first artificial dyes were based on fossil fuels and were developed from coal tar, which is a finite natural resource (Barrows et al., 2003). In contrast, colorants from fruit and vegetable agricultural sources are, by their very nature, a renewable resource (Bechtold and Mussak, 2009). The use of renewable resources such as fruits and vegetables for color production can have a decreased environmental impact if the agricultural production methods and extraction methods do not harm the environment or biodiversity.

The colors that are the subject of this report are normally produced in agricultural systems as food products for direct consumption. These products are produced not only to meet the demands of the food market but also the market for colorants. The methods used to cultivate any additional agricultural products for colorant use would dictate whether or not there would be an additional impact on the environment or biodiversity.

Mustafa et al. (2012) used waste carrots as a test source for carotenoid pigments processed using pressurized liquid extraction. The method utilizes waste products and is more efficient than other methods of extraction (Mustafa et al., 2012). Other color extraction processes such as enzyme extraction can utilize waste food products for color production (Sowbhagya and Chitra, 2010). Processes that utilize waste products are beneficial to the environment and biodiversity because they decrease waste and increase the efficiency with which materials are utilized, thus decreasing demand for the resource.

<u>Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).</u>

The colors in this report are associated with beneficial health effects due to their anti-inflammatory activity and antioxidant activity that could lead to decreases in cancer, cardiovascular disease, and other chronic diseases. These beneficial effects have been studied in animal models and in humans who are consuming the plant products (Mustafa et al., 2012; Wrolstad, 2012). Given the positive health effects that have been reported in studies associated with ingestion of the colorants in this report and the general knowledge that consumption of fruits and vegetables is beneficial to human health, it is unlikely that any of the colorants in this report would have adverse effects on humans. The beneficial health impacts of selected colorants are listed in Table 8 in the response to Evaluation Question #7.

<u>Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).</u>

Pigments are added to processed foods to replace color lost during processing or to augment existing colors for visual appeal (Delgado-Vargas et al., 2000). Alternative practices that would make the use of colors unnecessary would be use of cooking or processing methods that retain the native pigments in foods without subjecting them to the heat and pressure of processing. Natural colors are a quickly growing market segment for food coloring, indicating that those colorants are the preferred way to modify the colors of processed foods (IFT, 2013). Another alternative practice is to not add colors to processed foods and to educate consumers about the types of colors to expect in processed foods that have not been augmented with colorants.

Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

Anthocyanins:

Plant tissue culture is a potential source of production of anthocyanins given the expanding market of natural anthocyanins. Plant cell culture could ensure a continuous supply of uniform-quality anthocyanin pigments that are not produced by other biotechnological approaches. To date, no food colorant obtained by the use of plant tissue culture has been commercialized mainly because of low yield using this method (Delgado-Vargas et al., 2000).

Carotenoids:

Beta carotene, carrot juice extract color, black/purple carrot

An alternative source of beta-carotene is the fruit of the oil palm (*Elaeis guineensis*), which produces an oil rich in several different carotenes. The oil palm fruit is heated to extract the oil, which contains beta-carotene along with several other carotenes. The carotenes are extracted from the oil, which is used in making detergents or in other food applications. The beta-carotene from the oil palm is used for the same purpose as other beta-carotene (Mortensen, 2006). Organic palm oil is used in products manufactured by Newman's Own Organics such as baked goods and cookies (Newman's Own Organics, undated).

Annatto extract is another pigment that gives a yellow to red color to foods. Annatto was on the National List for use as a color until 2011 when it was removed. The NOSB Handling Subcommittee had sufficient evidence that enough organically-produced annatto was available to permit removal of nonorganically-produced annatto from the National List (USDA, 2011).

Paprika extract color, beet juice extract color

Another red pigment is cochineal/carmine extract. The scarlet red pigment is derived from the shells of female coccid insect *Dactylopius coccus* var. Costa, which are found on the prickly pear cactus. Cochineal is problematic because it causes allergic reactions. Several cases of anaphylaxis and urticarial (skin irritation) have been reported after ingestion of food pigmented with carmine (USDA, 2005).

Other Colors:

Pumpkin juice color

Organic marigold extract is another source of the carotenoid lutein, which is one of the main carotenoids in pumpkin juice color (Rao and Reddy, 2001; Sowbhagya and Chitra, 2010). In combination with other pigments that supply beta-carotene, marigold extract could replace the two main pigments provided by pumpkin juice color.

Saffron extract color

Crocin, the yellow pigment in saffron extract color, is also found in the fruit of the evergreen flowering plant *Gardenia jasminoides*. "Gardenia yellow" is the colorant produced from extraction of the fruits using alcohol or water. The colorant is allowed for use in food in both China and Japan, but not in the United States or Europe (Wrolstad, 2012).

Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

For all of the listed colorants, organically-grown (as opposed to conventionally-grown) vegetables and fruits can be used as an alternative source for the colorant. Manufacturers of the conventionally-grown colorants claim in their 2007 National List petition that the current supply of organic fruits and vegetables is insufficient to allow for colorant uses. It is unknown whether organic fruit and vegetable production has become sufficient since 2007. However if sufficient stocks of organically-grown fruits and vegetables used for colorants are now available or become available in the future, then the organically-grown fruits and vegetables can be used as alternatives for colors derived from conventional agricultural products.

Another alternative for increasing the supply of organic colorants is through the use of food waste material for production of pigments. Research has shown that enzyme-assisted extraction can be used on waste materials obtained from pressings of blueberry, blackcurrant, grapes, or orange peels. Enzyme-assisted extraction using these additional supplies of raw materials may increase the availability of organically-produced raw materials (Sowbhagya and Chitra, 2010).

Other organic agricultural products that can be used as alternatives include the following.

- Beta-carotene derived from organic palm fruit oil could substitute for beta-carotene derived from carrots (Mortensen, 2006; Newman's Own Organics, undated). The beta-carotene extracted from palm fruit is the same compound and could likely be used in the same manner.
- The yellow to red carotenoid pigments from organic annatto could be used as a replacement for some of the pigments in this report. Sufficient supplies of organic annatto are available such that nonorganic annatto was removed from the National List (USDA, 2011).
- Organic marigold extract is a source of the carotenoid lutein. Enzyme-assisted extraction of marigold was shown to decrease the amount of solvent needed and increase the yield of the extract (Sowbhagya and Chitra, 2010). Supercritical fluid extraction (SFE) could also be used to extract the lutein from marigold (Rao and Reddy, 2001).

Organic alternatives are not available for betalain pigments. Betalain pigments are only found in beets and poke berries (betanin only), but beets are the only plant source currently used as a food colorant (Bauernfeind, 1981; Wrolstad, 2012). Other red pigments could be used in place of the betalain pigments, but they may not have the same flexibility of use and persistence as the betalains.

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Appendix 1

Table A1: Colors Identification Table

Substance Name, as Listed at Section 205.606(d)	CAS Number(s)	CAS No. Listed in 205.606(d)	Chemical Name	Source	Color	Substance Name Under FDA Regulations, as Applicable	FDA CAS Number	FDA Identification Number (UNII)	INS Number	Explanation of Discrepancies
Beet Juice extract color	7659-95-2	Yes	betanin	TOXNET	red-yellow-light brown	beet juice; betanine	7659-95-2	Beet juice: IOZ32L9H3O; Betanine: 5YJC992ZP6	162	• No FDA CAS number given for the substance "beet juice." • CAS number query in the FDA databases returns "betanine." • “Beet juice” and “betanine” do not appear to be listed in 21 CFR. • Codex Alimentarius INS database substance name listed as "beet red."
Beta-carotene extract color	7235-40-7	Yes	beta-carotene	TOXNET	yellow-orange-red	beta-carotene	7235-40-7	Beta carotene: 01YAE03M7J	160a(ii)	• No observed discrepancies. • According to 21 CFR 1095, "The color additive [beta]-carotene may be safely used in coloring drugs generally, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice."
Black currant juice color	977038-70-2	No	currant juice, black	TOXNET	NA	currant juice, black	977038-70-2	Not provided	163(iii)	• CAS number for “black currant juice color” not included in the NOP listing, but identified in TOXNET and FDA searches for the
	528-58-5	Yes	cyanidin	TOXNET	blue-red	cyanidin chloride	528-58-5	2G4283G96U	NA	

Substance Name, as Listed at Section 205.606(d)	CAS Number(s)	CAS No. Listed in 205.606(d)	Chemical Name	Source	Color	Substance Name Under FDA Regulations, as Applicable	FDA CAS Number	FDA Identification Number (UNII)	INS Number	Explanation of Discrepancies
			chloride							color name. • No UNII number for "black currant juice color" provided in FDA databases. • Codex Alimentarius INS database substance name is "black currant extract." • Neither cyanidin chloride nor CAS no. 528-58-5 is listed in the FDA EAFUS database.
	528-53-0	Yes	delphinidin	TOXNET	blue-red	delphinidin	528-53-0	EM6MD4AEHE	NA	
	643-84-5	Yes	malvidin chloride	TOXNET	blue	malvidin	643-84-5	GL5KGZ4D8U	NA	
	134-01-0	Yes	peonidin chloride	TOXNET	purple-red	peonidin	134-01-0	D0O766G47B	NA	
	1429-30-7	Yes	petunidin chloride	TOXNET	purple-red	petunidin chloride	1429-30-7	WRK4Q8K2D8	NA	
	134-04-3	Yes	pelargonidin	TOXNET	orange	pelargonidin chloride	134-04-3	DFL6200791	NA	
Black/purple carrot juice color	NA	No	NA	NA	NA	NA	NA	NA	NA	• A search of "carrot juice, black" OR "purple" and other variations of the name did not yield CAS numbers or chemical names specific to this color in TOXNET, FDA databases, or Codex Alimentarius INS database. • Neither "cyanidin chloride" nor CAS no. 528-58-5 is listed in the FDA EAFUS database.
	528-58-5	Yes	cyanidin chloride	TOXNET	blue-red	cyanidin chloride	528-58-5	2G4283G96U	NA	
	528-53-0	Yes	delphinidin	TOXNET	blue-red	delphinidin	528-53-0	EM6MD4AEHE	NA	
	643-84-5	Yes	malvidin chloride	TOXNET	blue	malvidin	643-84-5	GL5KGZ4D8U	NA	
	134-01-0	Yes	peonidin chloride	TOXNET	purple-red	peonidin	134-01-0	D0O766G47B	NA	
	1429-30-7	Yes	petunidin chloride	TOXNET	purple-red	petunidin chloride	1429-30-7	WRK4Q8K2D8	NA	
	134-04-3	Yes	pelargonidin	TOXNET	orange	pelargonidin chloride	134-04-3	DFL6200791	NA	

Substance Name, as Listed at Section 205.606(d)	CAS Number(s)	CAS No. Listed in 205.606(d)	Chemical Name	Source	Color	Substance Name Under FDA Regulations, as Applicable	FDA CAS Number	FDA Identification Number (UNII)	INS Number	Explanation of Discrepancies
Blueberry juice color	NA	No	NA	NA	NA	NA	NA	NA	NA	• A search of "blueberry, juice" and other variations of the name did not yield CAS numbers or chemical names specific to this color in TOXNET, FDA databases, or Codex Alimentarius INS database. • Specific information is available for whole blueberry and other forms of blueberry (but not specifically for juice or extract). • Neither "cyanidin chloride" nor CAS no. 528-58-5 is listed in the FDA EAFUS database.
	528-58-5	Yes	cyanidin chloride	TOXNET	blue-red	cyanidin chloride	528-58-5	2G4283G96U	NA	
	528-53-0	Yes	delphinidin	TOXNET	blue-red	delphinidin	528-53-0	EM6MD4AEHE	NA	
	643-84-5	Yes	malvidin chloride	TOXNET	blue	malvidin	643-84-5	GL5KGZ4D8U	NA	
	134-01-0	Yes	peonidin chloride	TOXNET	purple-red	peonidin	134-01-0	D0O766G47B	NA	
	1429-30-7	Yes	petunidin chloride	TOXNET	purple-red	petunidin chloride	1429-30-7	WRK4Q8K2D8	NA	
	134-04-3	Yes	pelargonidin	TOXNET	orange	pelargonidin chloride	134-04-3	DFL6200791	NA	
Carrot juice color	NA	No	NA	NA	orange-yellow	carrot juice	Not provided	QXF936IX43	NA	• A CAS number is not provided for the substance "carrot juice." • However, "carrot juice color" is listed in the FDA database and ID number is available.
	1393-63-1	Yes	annatto pigment	TOXNET	yellow-orange	annatto extract	1393-63-1	6PQP1V1B6O	160b	• The Codex Alimentarius INS database number is general to the category of colors "annatto."
Cherry juice color	8012-99-5	No	cherry juice	TOXNET	red	cherry juice	8012-99-5	4XTQ10247Y	NA	• FDA provides a CAS number and UNII number for cherry juice. • CAS number 8012-99-5 was
	528-58-5	Yes	cyanidin	TOXNET	blue-red	cyanidin chloride	528-58-5	2G4283G96U	NA	

Substance Name, as Listed at Section 205.606(d)	CAS Number(s)	CAS No. Listed in 205.606(d)	Chemical Name	Source	Color	Substance Name Under FDA Regulations, as Applicable	FDA CAS Number	FDA Identification Number (UNII)	INS Number	Explanation of Discrepancies
			chloride							also listed on TOXNET for the substance name "cherry juice." • Neither "cyanidin chloride" nor CAS no. 528-58-5 is listed in the FDA EAFUS database.
	528-53-0	Yes	delphinidin	TOXNET	blue-red	delphinidin	528-53-0	EM6MD4AEHE	NA	
	643-84-5	Yes	malvidin chloride	TOXNET	blue	malvidin	643-84-5	GL5KGZ4D8U	NA	
	134-01-0	Yes	peonidin chloride	TOXNET	purple-red	peonidin	134-01-0	D0O766G47B	NA	
	1429-30-7	Yes	petunidin chloride	TOXNET	purple-red	petunidin chloride	1429-30-7	WRK4Q8K2D8	NA	
	134-04-3	Yes	pelargonidin	TOXNET	orange	pelargonidin chloride	134-04-3	DFL6200791	NA	
Chokeberry-*Aronia* juice color	NA	No	NA	TOXNET	NA	*Aronia melanocarpa* fruit juice; *Aronia nigra* fruit juice (black chokeberry)	NA	D2EVP827PJ	NA	• FDA provides a UNII number for several species of black chokeberry; however, no CAS number is provided in the FDA databases and no general CAS number was identified for chokeberry juice color. • Neither "cyanidin chloride" nor CAS no. 528-58-5 is listed in the FDA EAFUS database.
	528-58-5	Yes	cyanidin chloride	TOXNET	blue-red	cyanidin chloride	528-58-5	2G4283G96U	NA	
	528-53-0	Yes	delphinidin	TOXNET	blue-red	delphinidin	528-53-0	EM6MD4AEHE	NA	
	643-84-5	Yes	malvidin chloride	TOXNET	blue	malvidin	643-84-5	GL5KGZ4D8U	NA	
	134-01-0	Yes	peonidin chloride	TOXNET	purple-red	peonidin	134-01-0	D0O766G47B	NA	
	1429-30-7	Yes	petunidin chloride	TOXNET	purple-red	petunidin chloride	1429-30-7	WRK4Q8K2D8	NA	

Substance Name, as Listed at Section 205.606(d)	CAS Number(s)	CAS No. Listed in 205.606(d)	Chemical Name	Source	Color	Substance Name Under FDA Regulations, as Applicable	FDA CAS Number	FDA Identification Number (UNII)	INS Number	Explanation of Discrepancies
	134-04-3	Yes	pelargonidin	TOXNET	orange	pelargonidin chloride	134-04-3	DFL6200791	NA	
Elderberry juice color	NA	No	NA	TOXNET	NA	European elderberry juice	NA	Z4IFJ0AK1E	NA	• FDA provides a UNII number for the substance European elderberry juice, which lists elderberry juice as a synonym. • No CAS number is provided by FDA and no general CAS number was identified for elderberry juice color. • Neither cyanidin chloride nor CAS no. 528-58-5 is listed in the FDA EAFUS database.
	528-58-5	Yes	cyanidin chloride	TOXNET	blue-red	cyanidin chloride	528-58-5	2G4283G96U	NA	
	528-53-0	Yes	delphinidin	TOXNET	blue-red	delphinidin	528-53-0	EM6MD4AEHE	NA	
	643-84-5	Yes	malvidin chloride	TOXNET	blue	malvidin	643-84-5	GL5KGZ4D8U	NA	
	134-01-0	Yes	peonidin chloride	TOXNET	purple-red	peonidin	134-01-0	D0O766G47B	NA	
	1429-30-7	Yes	petunidin chloride	TOXNET	purple-red	petunidin chloride	1429-30-7	WRK4Q8K2D8	NA	
	134-04-3	Yes	pelargonidin	TOXNET	orange	pelargonidin chloride	134-04-3	DFL6200791	NA	
Grape juice color	NA	No	NA	NA	NA	grape color extract	977091-57-8	NA	Not listed	• "Grape juice color" listed at 21 CFR 73.169 as "grape color extract," a color additive exempt from certification, and described as an "aqueous solution of anthocyanin grape pigments made from concord grapes or a dehydrated water soluble powder prepared from the aqueous solution...contains the common components of
	528-58-5	Yes	cyanidin chloride	TOXNET	blue-red	cyanidin chloride	528-58-5	2G4283G96U	Not listed	
	528-53-0	Yes	delphinidin	TOXNET	blue-red	delphinidin	528-53-0	EM6MD4AEHE	Not listed	
	643-84-5	Yes	malvidin chloride	TOXNET	blue	malvidin	643-84-5	GL5KGZ4D8U	Not listed	
	134-01-0	Yes	peonidin chloride	TOXNET	purple-red	peonidin	134-01-0	D0O766G47B	Not listed	

Substance Name, as Listed at Section 205.606(d)	CAS Number(s)	CAS No. Listed in 205.606(d)	Chemical Name	Source	Color	Substance Name Under FDA Regulations, as Applicable	FDA CAS Number	FDA Identification Number (UNII)	INS Number	Explanation of Discrepancies
	1429-30-7	Yes	petunidin chloride	TOXNET	purple-red	petunidin chloride	1429-30-7	WRK4Q8K2D8	Not listed	grape juice, namely anthocyanins, tartrates, malates, sugars, and minerals, etc." • Neither "cyanidin chloride" nor CAS no. 528-58-5 is listed in the FDA EAFUS database.
	134-04-3	Yes	pelargonidin	TOXNET	orange	pelargonidin chloride	134-04-3	DFL6200791	Not listed	
Grape skin extract color	NA		NA	NA	NA	grape skin extract	11029-12-2	NA	163(ii)	• Listed at 21 CFR 73.170 as grape skin extract (enocianina) as a color additive exempt from certification. • Neither "cyanidin chloride" nor CAS no. 528-58-5 is listed in the FDA EAFUS database.
	528-58-5	Yes	cyanidin chloride	TOXNET	blue-red	cyanidin chloride	528-58-5	2G4283G96U	Not listed	
	528-53-0	Yes	delphinidin	TOXNET	blue-red	delphinidin	528-53-0	EM6MD4AEHE	Not listed	
	643-84-5	Yes	malvidin chloride	TOXNET	blue	malvidin	643-84-5	GL5KGZ4D8U	Not listed	
	134-01-0	Yes	peonidin chloride	TOXNET	purple-red	peonidin	134-01-0	D0O766G47B	Not listed	
	1429-30-7	Yes	petunidin chloride	TOXNET	purple-red	petunidin chloride	1429-30-7	WRK4Q8K2D8	Not listed	
	134-04-3	Yes	pelargonidin	TOXNET	orange	pelargonidin chloride	134-04-3	DFL6200791	Not listed	
Paprika color	68917-78-2		oleoresin paprika	TOXNET	reddish	paprika oleoresin (*Capsicum annuum L.)*	68917-78-2	X72Z47861V	160c	• FDA substance description at 21 CFR 73.345 describes paprika oleoresin as "...the combination of flavor and color principles obtained from paprika…" • However, it is also noted that "The definition of paprika oleoresin in this

Substance Name, as Listed at Section 205.606(d)	CAS Number(s)	CAS No. Listed in 205.606(d)	Chemical Name	Source	Color	Substance Name Under FDA Regulations, as Applicable	FDA CAS Number	FDA Identification Number (UNII)	INS Number	Explanation of Discrepancies
										paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for paprika oleoresin under section 401 of the act."
Pumpkin juice color	127-40-2		lutein	TOXNET	yellow	xanthophyll/ lutein	127-40-2	X72A60C9MT	161b	• "Pumpkin juice" not listed in EAFUS database; CAS 127-40-2 is listed as lutein/ xanthophyll. • *Tagetes* (Aztec marigold) meal and extract is listed as a color additive exempt from certification at 21 CFR 73.295. • INS number is for "luteins," and subcategories exist for luteins from *Tagetes erecta* (Aztec marigold), which are classified as 161b(i).
Purple potato juice color	NA		NA	NA	NA	Not listed in EAFUS or UNII databases.	Not listed	Not listed	Not listed	• "Purple potato juice" not listed individually in FDA databases or Codex Alimentarius INS database. • Neither "cyanidin chloride" nor CAS no. 528-58-5 is listed in the FDA EAFUS database.
	528-58-5	Yes	cyanidin chloride	TOXNET	blue-red	cyanidin chloride	528-58-5	2G4283G96U	Not listed	
	528-53-0	Yes	delphinidin	TOXNET	blue-red	delphinidin	528-53-0	EM6MD4AEHE	Not listed	
	643-84-5	Yes	malvidin chloride	TOXNET	blue	malvidin	643-84-5	GL5KGZ4D8U	Not listed	

Substance Name, as Listed at Section 205.606(d)	CAS Number(s)	CAS No. Listed in 205.606(d)	Chemical Name	Source	Color	Substance Name Under FDA Regulations, as Applicable	FDA CAS Number	FDA Identification Number (UNII)	INS Number	Explanation of Discrepancies
	134-01-0	Yes	peonidin chloride	TOXNET	purple-red	peonidin	134-01-0	D0O766G47B	Not listed	
	1429-30-7	Yes	petunidin chloride	TOXNET	purple-red	petunidin chloride	1429-30-7	WRK4Q8K2D8	Not listed	
	134-04-3	Yes	pelargonid in	TOXNET	orange	pelargonidin chloride	134-04-3	DFL6200791	Not listed	
Red cabbage extract color	NA	No	NA	NA	NA	Not listed in EAFUS database	Not listed	Cabbage (includes red): GW0W1Y9I97	163v	• "Red cabbage extract color" INS number is for "Red cabbage colour" [sic] • "Red cabbage extract color" not listed in FDA EAFUS. • Neither "cyanidin chloride" nor CAS no. 528-58-5 is listed in the FDA EAFUS database.
	528-58-5	Yes	cyanidin chloride	TOXNET	blue-red	cyanidin chloride	528-58-5	2G4283G96U	Not listed	
	528-53-0	Yes	delphinidi n	TOXNET	blue-red	delphinidin	528-53-0	EM6MD4AEHE	Not listed	
	643-84-5	Yes	malvidin chloride	TOXNET	blue	malvidin	643-84-5	GL5KGZ4D8U	Not listed	
	134-01-0	Yes	peonidin chloride	TOXNET	purple-red	peonidin	134-01-0	D0O766G47B	Not listed	
	1429-30-7	Yes	petunidin chloride	TOXNET	purple-red	petunidin chloride	1429-30-7	WRK4Q8K2D8	Not listed	
	134-04-3	Yes	pelargonid in	TOXNET	orange	pelargonidin chloride	134-04-3	DFL6200791	Not listed	
Red radish extract color	NA	No	NA	NA	NA	Not listed in EAFUS database	Not listed	Radish: EM5RP35463	Not listed	• "Red radish extract color" not listed in EAFUS database or INS database. • FDA UNII number is for radish (unspecified), not
	528-58-5	Yes	cyanidin chloride	TOXNET	blue-red	cyanidin chloride	528-58-5	2G4283G96U	Not listed	

Substance Name, as Listed at Section 205.606(d)	CAS Number(s)	CAS No. Listed in 205.606(d)	Chemical Name	Source	Color	Substance Name Under FDA Regulations, as Applicable	FDA CAS Number	FDA Identification Number (UNII)	INS Number	Explanation of Discrepancies
	528-53-0	Yes	delphinidin	TOXNET	blue-red	delphinidin	528-53-0	EM6MD4AEHE	Not listed	necessarily radish extract color. • Neither "cyanidin chloride" nor CAS no. 528-58-5 is listed in the FDA EAFUS database.
	643-84-5	Yes	malvidin chloride	TOXNET	blue	malvidin	643-84-5	GL5KGZ4D8U	Not listed	
	134-01-0	Yes	peonidin chloride	TOXNET	purple-red	peonidin	134-01-0	D0O766G47B	Not listed	
	1429-30-7	Yes	petunidin chloride	TOXNET	purple-red	petunidin chloride	1429-30-7	WRK4Q8K2D8	Not listed	
	134-04-3	Yes	pelargonidin	TOXNET	orange	pelargonidin chloride	134-04-3	DFL6200791	Not listed	
Saffron extract color	1393-63-1	Yes	annatto pigment	TOXNET	yellow-orange	saffron, extract (*Crocus sativus L.*); annatto	84604-17-1; 1393-63-1	Saffron: E849G4X5YJ; Annatto: 6PQP1V1B6O	160b	• FDA CAS number listed for "saffron, extract" is different than the CAS number listed by NOP. • CAS number query for 1393-63-1 in FDA database returns "Annatto pigment." • INS number for annatto extracts presented. • Saffron (*Crocus sativus L.*) listed in 21 CFR 182.20 as "essential oils, oleoresins (solvent-free), and natural extractives... generally recognized as safe."
Turmeric extract color	458-37-7	Yes	curcumin	TOXNET	yellow-orange	turmeric, extract (Curcuma longa L.); turmeric, oleoresin (Curcuma longa	84775-52-0; 129828-29-1	Turmeric extract: 856YO1Z64F	100(ii)	• FDA CAS numbers for "turmeric extract" are different from those provided by NOP. • Turmeric (*Curcuma longa L.*)

Substance Name, as Listed at Section 205.606(d)	CAS Number(s)	CAS No. Listed in 205.606(d)	Chemical Name	Source	Color	Substance Name Under FDA Regulations, as Applicable	FDA CAS Number	FDA Identification Number (UNII)	INS Number	Explanation of Discrepancies
						L.)				is listed in 21 CFR 182.20 as "essential oils, oleoresins (solvent-free), and natural extractives...generally recognized as safe."

NA = not available