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Regulatory Alert: FDA Publishes Guidance on Fruit and Vegetable Juice as Color Additives in Food

Guidance on Meaning of Key Terms Provided

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On Tuesday, December 15, 2016, the U.S. Food and Drug Administration (FDA) published draft guidance for industry entitled "Fruit and Vegetable Juice as Color Additives in Foods." The agency is requesting comments on the draft guidance by February 13, 2017.

Fruit juice and vegetable juice may be used as color additives pursuant to 21 CFR § 73.250 and 21 CFR § 73.260 respectively. The color additive "fruit juice" is defined in § 73.250 as the juice expressed from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit. Similarly, the color additive "vegetable juice" is defined in § 73.260 as the juice expressed from mature varieties of fresh, edible vegetables, or by the water infusion of the dried vegetable. The fact that plant material can be eaten does not necessarily mean that juice from such plant material meets the specifications of these regulations. The Guidance does not address the use of fruit- or vegetable-derived color additives that are authorized under different color additive regulations such as beet juice or that are the subject of a color additive petition.

FDA does not regard food ingredients, such as cherries, green or red peppers, and orange juice, which contribute their own natural color when mixed with other foods to be color additives. However, when a food substance, such as beet juice, is deliberately used as a color, as in pink lemonade, it is considered a color additive.[1]

FDA issued the guidance to respond to a number of questions relating to whether certain color additives made from various plant materials meet the specifications in the fruit juice or vegetable juice color additive regulations. These inquiries have led to questions as to what the Agency means by the terms used in these color additive regulations.

FDA interprets the terms in 21 CFR §§ 73.250 and 73.260, as follows:

"Fruit" and "Vegetable"

A "fruit" is the ripened reproductive body of a seed-bearing plant or tree nut such as apple, orange, or almond.

[1] 21 CFR § 70.3(f).

A "vegetable" is the part of plant whose fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are consumed in a manner consistent with other common vegetables such as beets, onions, sweet potatoes, celery, lettuce, corn, squash, peppers, broccoli, carrot, and spinach, including the fleshy fruiting body of a fungus (such as white button or shiitake mushrooms).

FDA does not consider plant parts used only to prepare a tea or used as herbs or spices (such as in small amounts for flavoring purposes) to be a fruit or a vegetable.

"Mature"

A mature fruit or vegetable is ripe and at the physical state when it is eaten.

"Fresh"

"Fresh" means that the fruit or vegetable is in its raw state, and has not been frozen or subjected to any form of thermal processing or any other form of preservation. However, fruits and vegetables are still considered "fresh" if they have been treated with waxes or coatings, post-harvest approved pesticides, antimicrobials, and/or irradiation in accordance with applicable regulations.

"Expressing the juice"

Expressing the juice is the act of pressing or squeezing out the liquid from a raw fruit or vegetable.

"Water infusion of the dried fruit or vegetable"

Water infusion of the dried fruit or vegetable is the extraction of the pigmented components of the dehydrated fruit or vegetable using potable water.

"Edible"

The following criteria should be considered in determining whether a fruit or vegetable is "edible":

Consumption as food: Is the mature fruit or vegetable consumed for its taste, aroma, or nutrient properties in its "fresh" state? FDA does not consider parts of plants used for medicinal or food decoration purposes to be evidence of consumption as food.

Consumption amount and frequency: Is the amount customarily consumed per eating occasion, and frequency of consumption, similar to that of other commonly eaten fruits and vegetables?

History of safe consumption: Has the mature and fresh fruit or the mature and fresh vegetable been consumed by a large, geographically diverse human population over a significant period of time (i.e., generally for 20 years or more) without known detrimental health effects? If relying

primarily on consumption outside of the United States, are there well-publicized studies such as those in peer-reviewed scientific and medical journals that support the safety of its consumption?

Minimal Processing: Only minimal processing methods may be used for the production of the color additives fruit juice and vegetable juice. Such processing does not fundamentally alter a raw fruit or vegetable.

Examples of minimal processing steps include:

Washing with a potable water rinse; fresh cutting; and drying to remove the majority of the original water content either naturally, by sun drying, or through the use of specialized dryers or dehydrators.

Minimal processing would not include: aging, freezing, canning, pasteurizing, cooking or milling.

If the expressed juice of a fruit or vegetable or the water infusion of a dried fruit or vegetable is chemically reacted with another substance (such as extracts produced using solvent extraction, acid hydrolysis, and enzymatic processes), the resulting color additive does not conform with §§ 73.250 or 73.260 and could not be used for coloring food unless authorized for the intended use by another color additive regulation.

There may be circumstances under which a fruit or vegetable that is normally regarded as edible should not be used as a plant material for producing fruit juice and vegetable juice color additives. For example, a plant material could contain a pesticide chemical that is unsafe. In addition, the plant could be grown under environmental conditions which cause the plant to produce a deleterious substance which causes deleterious health effects.

Specific Plant Materials

FDA has received inquiries from industry regarding whether certain color additives made from various plant materials would meet the specifications in the fruit juice or vegetable juice color additive regulations. Below is a summary table of FDA responses to these inquiries:

Material from Which Juice Would be Made	Date of FDA Letter(s)	FDA Responses on Whether Certain Juices Would be Covered Under § 73.250 or § 73.260
Flowers of hibiscus (*Hibiscus spp.)*	5/11/1994	No
Purple corn (*Zea mays* L. many varieties of the Kculli line, mature kernels)	5/11/1994	Yes
Blue green algae, Spirulina (Arthrospira platensis)[1]	5/11/1994 3/6/1996	No
Safflower petals (*Carthamus tinctorius* L.)	5/11/1994 6/10/1997	No
Nettle and spinach leaf extracts (*Urtica dioica and Spinacia oleracea*, respectively)	7/26/1994	No
Calyx of roselle (*Hibiscus sabdariffa*)	3/24/1995 3/31/1995	Yes

[1] Spirulina extract was subsequently listed in a separate color additive regulation. For conditions of safe use, see §§ 73.530 and 73.1530 Spirulina extract.

Material from Which Juice Would be Made	Date of FDA Letter(s)	FDA Responses on Whether Certain Juices Would be Covered Under § 73.250 or § 73.260
Flower, fruit and/or seed of cape jasmine (gardenia, *Gardinia augusta*)	7/5/1996 7/24/2015	No
Chokeberry (*Aronia spp.*, berries)	8/14/1996	Yes
Black carrots (*Daucus carota* variety *atrorubens* Alef., roots)	5/5/1997	Yes
Gardenia fruit – crocin extract (*Gardenia augusta*, L., currently named *Gardenia jasminoides* Ellis)	6/11/1998	No
Grape extract (*Vitis spp.*, fruit)[2]	7/19/2002	No
Red sugar beets (*Beta vulgaris spp. vulgaris* var. *rubra*, roots)	11/20/2007	Yes
Red cabbage (*Brassica oleracea* var. *capitata* f. *rubra*, leaves)	11/20/2007	Yes
Purple sweet potato (*Ipomoea batatas* L. tuber)	11/20/2007	Yes
Red radish (*Raphanus sativus*, root)	11/20/2007	Yes
North American and European black elderberry (*Sambucus canadensis* and *Sambucus nigra* L., respectively, berries)	11/20/2007	Yes
Watermelon (*Citrullus lanatus*, fruit)	11/20/2007	Yes
Acai	11/20/2007	No
Kokum	11/20/2007	No
Red perilla (*Perilla frutescens* variety *crispa* forma *crispa* (common name *shiso*), and *Perilla frutescens* variety *crispa* forma *purpurea*, leaves)	2/29/2012 6/17/2015	Yes
Flowers of butterfly pea (*Clitoria ternatea*)	3/13/2015 8/24/2015	No
Huito fruit (*Genipa americana*, Jagua)	7/13/2015	No
Seeds of *Sorghum bicolor*, *(L.)Moench*	4/23/2015 9/11/2015	No
Red rhubarb petiole (*Rheum rhubarbarum*)	9/4/2015	Yes
Prickly pear fruit (*Opuntia ficus-indica*)	12/30/2015	Yes
Swiss chard stalk (*Beta vulgaris* L. ssp. *vulgaris* var. *cicla*)	12/30/2015	No
Wheatgrass (*Triticum aesitivum*, L.)	4/19/2016	No

[2] Grape color extract and grape skin extract were subsequently listed in separate color additive regulations. For conditions of safe use, see § 73.169 Grape color extract and § 73.170 Grape skin extract (enocianina).

Please contact Erik Lieberman at erl@liebermanpllc.com or 202.830.0300 if you have questions or would like additional information.