

## MEMORANDUM

**From:** Joseph A. Levitt  
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**Re:** **FDA Issues Draft Guidance on Fruit and Vegetable Juice as Color Additives in Food**

The Food and Drug Administration (FDA) recently issued draft guidance regarding fruit juice and vegetable juice as color additives in food. The draft guidance explains that not all fruits or vegetables may be the source of a fruit or vegetable juice for color. The guidance also provides FDA's interpretation of key terms in the regulations to clarify the types of plant materials meet the requirements for fruit or vegetable juice for color. Comments on the draft guidance should be submitted by February 13, 2017. As with all draft guidance, this document is nonbinding, but does reflect FDA's current thinking on what is necessary to comply with the regulations.

### Background

Section 721 of the Federal Food, Drug, and Cosmetic Act (FFDCA) allows the FDA to list color additives for use in or on food so long as such additives are "suitable and safe" for their intended use. <sup>1/</sup> Unlike with food additives, however, there is no "generally recognized as safe" (GRAS) exemption for color additives. FDA must determine whether a color additive is suitable and safe before authorizing its use. In other words, FDA must pre-approve the use of any color additive.

Fruit and vegetable juices may be used as color additives so long as the juice comports with the color additive regulations in 21 C.F.R. § 73.250 (fruit juice) and 21 C.F.R. § 73.260 (vegetable juice). For fruit juice, the liquid must be "prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit." <sup>2/</sup> Similarly, vegetable juice color additives must be produced "either by expressing the juice from mature varieties of fresh, edible vegetables, or by the water infusion of the dried vegetable." <sup>3/</sup> Both regulations allow for fruit and vegetable juice color additives to be concentrated or dried. Fruit and vegetable juice for color also may contain diluents that are safe and suitable for use in color additive mixtures for coloring food.

### Interpretation of Key Terms

The draft guidance provides FDA's interpretation of key terms in the color additive regulations for fruit and vegetable juice for color. FDA explains that it is issuing the guidance in response to questions from industry regarding ambiguity in these terms. The draft guidance defines fruit and vegetables as the following:

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- <sup>1/</sup> 21 U.S.C. § 379e(b)(1).  
<sup>2/</sup> 21 C.F.R. § 73.250(a)(1) (emphasis added).  
<sup>3/</sup> 21 C.F.R. § 73.260(a)(1) (emphasis added).

- **“Fruit”** means “the ripened reproductive body of a seed-bearing plant or tree nut such as apple, orange, or almond.”
- 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 only used to prepare a tea or used as herbs or spices to be fruits or vegetables.

Under the regulations, the juice for color additives can be produced in one of two ways: (1) by “expressing the juice from mature varieties of fresh, edible” fruits or vegetables, or (2) by preparing a “water infusion of the dried” fruit or vegetable. The draft guidance offers the following relevant definitions:

- A **“mature”** fruit or vegetable “is ripe and at the physical state when it is eaten.”
- A **“fresh”** fruit or vegetable is one “in its raw state, and has not been frozen or subjected to any form of thermal processing or any other form of preservation.” The draft guidance further explains that fruits and vegetables may still be considered “fresh” even when they have undergone treatment with waxes or coatings, post-harvest approved pesticides, antimicrobials, and/or irradiation, so long as the treatment was in accordance with applicable regulations.
- **“Expressing the juice”** means “pressing or squeezing out the liquid from a raw 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.”

### **Criteria for “Edible” Plant Material**

Additionally, the draft guidance outlines what criteria should be considered in determining what constitutes an “edible” fruit or vegetable. FDA will consider three criteria:

- **Consumption as food.** FDA considers whether the fresh, mature fruit or vegetable is consumed as food (i.e., for its taste, aroma, or nutrient properties) rather than for medicinal or food decoration purposes.
- **Consumption amount and frequency.** FDA looks at how much and how often the fruit or vegetable is eaten, and whether that amount and frequency is similar to that of other commonly eaten fruits and vegetables.
- **History of safe consumption.** FDA examines whether the fresh, mature fruit or vegetable has been consumed by large and diverse populations for a significant period of time (typically 20 years or more). The fruit or vegetable must not have known detrimental health effects when consumed. Firms seeking to position a color made from fruit or vegetable juice as falling under the color additive regulation may rely on consumption data from foreign countries, but should support their contentions with well-publicized studies from peer-reviewed scientific and medical journals.

The draft guidance clarifies that not all fruits and vegetables—even those normally considered edible in common parlance—may lawfully be used to produce fruit or vegetable juice for color additives. For example, FDA notes that some plants could contain pesticide chemicals that are unsafe within the meaning of section 408(a) of the FFDCA, which would render the fruit or vegetable inedible. FDA also describes how a fruit or vegetable would be inedible if it were grown under environmental conditions that cause the plant to produce deleterious substances that could cause detrimental health effects.

FDA further explains that a firm only may use minimal processing methods to produce fruit and vegetable juice color additives. These minimal processing methods should not fundamentally alter the raw fruit or vegetable. The draft guidance lists the following as examples of minimal processing methods: 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. FDA does not consider the following to be minimal processing methods: aging, freezing, canning, pasteurizing, cooking or milling. Furthermore, a color additive cannot be used if the fruit or vegetable juice chemically reacts with another substance (unless otherwise authorized by another color additive regulation).

### **Premarket Consultations**

FDA provided in the draft guidance a link to the FDA website containing a chart of responses to questions regarding whether certain juices would be covered under the color additive regulations for fruit or vegetable juice. The chart summarizes the material from which the juice would be made, the date of the FDA letter, and a yes or no response to whether the juice from the relevant fruit or vegetable complies with §§ 73.250 or 73.260. If a firm has a question about whether a plant can produce fruit or vegetable juice suitable to make a color additive, it should first consult this list to see whether FDA has already made a decision regarding that plant.

If the plant is not on the chart, the agency encourages firms to contact the FDA Office of Food Additive Safety when unsure whether the fruit or vegetable is appropriate for producing juice used in color additives under §§ 73.250 or 73.260. FDA requests that the firm provide the information discussed in the draft guidance (e.g., consumption data and history), as well as the scientific name, common name(s), origin, cultivation state, and life-stage of the plant material from which the color additive will be derived. Furthermore, firms should explain which plant structure will be the fruit or vegetable and completely describe the color additive's manufacturing process.

### **Comments on the Draft Guidance**

The guidance is still in draft form. Companies producing color additives made from fruit or vegetable juice should carefully review the draft guidance and consider submitting comments to FDA.

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We will continue to monitor FDA's regulation of color additives. Please contact us if you have any questions.