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Fruit Juice and Vegetable Juice as Color Additives in Food: Guidance for Industry

Draft Guidance

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1200.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

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I. Introduction

Fruit juice and vegetable juice can be used under certain conditions as color additives in food under 21 CFR 73.250 (fruit juice) and 21 CFR 73.260 (vegetable juice). 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. This guidance is intended to help manufacturers determine whether a color additive derived from a plant material meets the specifications for fruit juice under § 73.250 or vegetable juice under § 73.260. This guidance, including our interpretation of the terms used in § 73.250 and § 73.260, is limited to these color additive regulations. This guidance does not address the use of fruit- or vegetable-derived color additives that are authorized under different color additive regulations or that are the subject of a color additive petition.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

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1 This guidance has been prepared by the Division of Petition Review, Office of Food Additive Safety, in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.
II. Background

Under section 721 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), FDA may list a color additive\(^2\) for use in foods only if we find that the color additive is suitable and safe for the intended use (21 U.S.C. 379e). The term “color additive” is defined in section 201(t) of the FD&C Act as any material, not exempted under section 201(t) of the FD&C Act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting a color thereto (21 U.S.C. 321(t)). This definition applies whether or not color additives when used in food have nutritive or other functions in addition to imparting color. For a material otherwise meeting the definition of color additive to be exempt from section 721 of the FD&C Act on the basis that it is used (or intended to be used) solely for a purpose or purposes other than coloring, the material must be used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. (It is not enough to warrant exemption if conditions are such that the primary purpose of the material is other than to impart color (21 CFR 70.3(g).)

FDA must determine whether a color additive is suitable and safe for its intended use before authorizing its use. A color additive is deemed unsafe under section 721(a) of the FD&C Act unless its use conforms to a color additive regulation issued by FDA for such use or to the terms of an authorized exemption, and a food is deemed to be adulterated if it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a) of the FD&C Act (21 U.S.C. 379e(a)).

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 a color additive (see 21 CFR 70.3(f)). Therefore, in 1966, we amended the color additive regulations by listing fruit juice as a color additive for use in food, provided that the liquid is expressed from mature varieties of fresh, edible fruits or is a water infusion of the dried fruit (31 FR 1063 at 1065; January 27, 1966). We also listed vegetable juice as a color additive for use in food, provided that the liquid is expressed from mature varieties of fresh, edible vegetables (31 FR 1063 at 1065; January 27, 1966). We later amended the color additive regulation for vegetable juice in response to a color additive petition to provide for the water infusion of dried vegetables as a color additive for use in food (60 FR 52628 at 52629; October

\(^2\) Unlike a “food additive,” there is no “generally recognized as safe” statutory exemption for a “color additive.” Section 201(t) of the FD&C Act, (21 U.S.C. 321(t). See also FDA’s definition of “color additive” at 21 CFR 70.3(f).
The final rule also amended the regulations for fruit juice and vegetable juice to provide for the safe use in food of dried fruit juice and dried vegetable juice (60 FR 52628 at 52629).

III. Fruit Juice and Vegetable Juice Authorized as Color Additives Under 21 CFR 73.250 and 73.260.

Our color additive regulations define “fruit juice” as a color additive prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit (21 CFR 73.250). Similarly, our color additive regulations define “vegetable juice” as a color additive prepared either by expressing the juice from mature varieties of fresh, edible vegetables, or by the water infusion of the dried vegetable (21 CFR 73.260). Both regulations specify that these color additives may be concentrated or dried and may contain diluents that are safe and suitable for use in color additive mixtures for coloring food.

As described above, we have a statutory duty to ensure the safety of the use of color additives before authorizing the use in our color additive regulations. The underlying premise of § 73.250 and § 73.260 is that the safety of fruit juice and vegetable juice as color additives for use in food is assured by the fact that the fruit or vegetable from which the color additive is derived has been safely consumed as food, such that there would not be safety concerns in using the juice or water soluble color components from the fruit or vegetable as a color additive.

We have received inquiries from industry regarding whether certain color additives made from various plant materials meet the specifications in our fruit juice or vegetable juice color additive regulations. These inquiries have led to questions as to what we mean by the terms used in these color additive regulations.

Therefore, for purposes of this guidance, we interpret the terms in §§ 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.

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3 FDA is providing a summary of our responses to these inquiries on its website at [http://www.fda.gov/downloads/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/UCM532389.pdf].
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).

We do 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? We do not consider parts of plants used for medicinal or food decoration purposes to be evidence of consumption as food.

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4 We have listed spices such as paprika and turmeric as color additives separately (see § 73.340 Paprika, § 73.345 Paprika oleoresin, § 73.600 Turmeric, and § 73.615 Turmeric oleoresin.)
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- 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?\(^5\)

- 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?

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\(^6\); 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 within the meaning of section 408(a) of the FD&C Act (21 U.S.C. 346a(a)). In addition, the plant could be grown under environmental conditions which cause the plant to produce a deleterious substance which could cause detrimental health effects.

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\(^5\) The reference amounts customarily consumed for fruits and vegetables are found in Table 2 of 21 CFR 101.12. For example, the reference amounts for all other fruits (except those listed as separate categories), fresh, canned, or frozen, per eating occasion for the general food supply are listed in FDA’s regulations as 140 grams.

\(^6\) Fresh-cut fruits and vegetables are those that have been altered in form by peeling, slicing, chopping, shredding, coring, pitting, or trimming, with or without washing or other treatment, prior to being packaged for use by the consumer or a retail establishment. Fresh cutting is a minimal-processing method that can be used to isolate plant material from which a fruit juice or vegetable juice color additive will be derived. For example, pitting is required prior to expressing fruit juice from mature, edible flesh and outer skin (mesocarp and pericarp) of elderberries and chokeberries or prior to dehydrating the fruit for water infusion because the pit (woody seed/stone or endocarp) contains cyanide, a glycoside poison.
Importantly, manufacturers are responsible for ensuring that their products meet all applicable FDA requirements before they are introduced into U.S. interstate commerce.

IV. Premarket Consultations

If you are unsure whether a color additive that is derived from plant material and that is intended for use in food meets the identity for fruit juice or vegetable juice in §§ 73.250 or 73.260, we strongly encourage you to consult with FDA’s Office of Food Additive Safety by providing us information that addresses the considerations listed above. You should also identify the scientific name, common name(s), origin, cultivation state, and life-stage of the plant material from which the color additive will be derived, and which plant structure will be declared the mature, fresh, edible fruit or vegetable, as well as a complete description of the manufacturing process for the color additive. On request, a color additive master file may be established as a repository for information that you may reference in future submissions. If we determine through the consultation process that a color additive does not meet the specifications for fruit juice or vegetable juice in §§ 73.250 or 73.260, you may submit a color additive petition for such use. We encourage petitioners to meet with us early in the petition process to discuss the safety data that will be needed and to obtain other information that will result in a better quality petition. In addition, you should follow the procedures set forth in the relevant guidance documents that are available on FDA’s website when requesting a pre-petition consultation and preparing a color additive petition.

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