NATCOL
NATURAL FOOD COLOURS ASSOCIATION

POSITION PAPER

NATCOL Position on Fruit & Vegetable Juice Colors in US

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Disclaimer

This NATCOL position, as drafted by NATCOL U.S. members, aims at providing support in understanding the U.S. regulations that govern color additives for use in food and their scope and application. It must be read in conjunction with the relevant legislation and regulations.

This position is not a substitute for legal advice, but represents common industrial practice concerning the classification, manufacture, use and labeling of fruit and vegetable juice as color additives. The ultimate official interpretation of the legislation is the exclusive reserve of the judicial powers i.e., the relevant courts of the U.S.

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I Introduction & Common Guidelines

Who is Natural Food Colours Association (NATCOL)

The Natural Food Colours Association (NATCOL) is the go-to organization for Natural Colors and Coloring Foods worldwide to grow customers and consumers' choice (www.natcol.org).

It represents companies and associations which provide Natural Food Colors and/or Coloring Foods for the food, feed and related industries. By so doing, NATCOL offers the appropriate forum for companies located all around the world to exchange on regulatory and scientific topics on Natural Colors and Coloring Foods.

As part of its plan to support the global industry, NATCOL established an official and functioning presence in the United States in 2020.

Current Situation

Section 721 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) grants the Food & Drug Administration (FDA) authority to list a color additive for use in or on foods by regulation if the Secretary of Health and Human Services finds that the color additive is safe and suitable for the intended use.

The FDA implements color additives, that go through regulatory approval, in either 21 CFR Part 73 or 21 CFR Part 74. 21 CFR Part 74 contains a list of color additives which are subject to certification, which are man-made and derived primarily from petroleum and coal sources. These are permitted only if they are from batches that FDA has evaluated for compliance to the regulations. Color additives listed in 21 CFR Part 73 are those which are exempt from certification, and are primarily derived from plant, animal, and mineral source. Examples of color additives listed under Part 73 are fruit juice and vegetable juice colors (21 CFR §73.250 & §73.260). The listings of fruit and vegetable juice as allowed color additives were first published in 1966 and have remained relatively unchanged.

The purpose of this document is to establish a NATCOL position that was drafted by NATCOL U.S. members for the compliance of color additives derived from plant materials which meet the specifications for fruit juice color under 21 CFR §73.250 or vegetable juice color under 21 CFR §73.260.

II Source Materials

Under the color additive regulation, fruit and vegetable juice colors are expressed from "mature varieties of fresh, edible" fruits and vegetables or by "water infusion of the dried" fruits and vegetables. As there is no legal definition of a "fruit" or a "vegetable," it is generally accepted that it must be the edible part of a plant that is used for human food, meaning consumed as a source of nutrients and calories. Plants used for herbal, medicinal or flavoring purposes (e.g. spices), are not considered to be an edible fruit or vegetable.

"Edible" fruits and vegetables are those which are commonly eaten and have a history of safe consumption over a significant period of time. Examples include carrots, pumpkins, blueberries, and red cabbage. Plants used for herbal, medicinal or flavoring purposes (e.g. spices), are not considered to be an edible fruit or vegetable.

For those fruits and vegetables that are less commonly consumed, manufacturers can seek FDA concurrence that they are considered edible fruits and vegetables and manufactured in accordance with 21 CFR §73.250 and §73.260 through the longstanding Informal Opinion (IO) letter process. Through Informal Opinion letters, FDA has expressly agreed that many fruits and vegetables such as chokeberry, purple corn, and various colors of carrots (yellow, red, orange, purple black) are edible fruits and vegetables and qualify for use as color additives for food.[i]

i See Letter from Aydin Orstan, Ph.D., Direct Additives Branch, Division of Petition Control, CFSAN, to Jerome W. Kinnison, Warner Jenkinson Company, Inc., May 11, 1994 (Purple corn); Letter from Aydin Orstan, Ph.D., Direct Additives Branch, Division of Petition Control, CFSAN, to Dr.-Ing. Horst Hoeck, GNT, Aug. 14, 1996 (Aronia melanocarpa or chokeberry); Letter from Aydin Orstan, Ph.D., Direct Additives Branch, Division of Petition Control, CFSAN, to Dr.-Ing. Horst Hoeck, GNT, May 5, 1997 (Daucus carota or different subspecies of the carrot with roots colored white, yellow, orange, red, purple, and black).

III Manufacturing and Formulation

The current regulations for fruit and vegetable juice color were purposely written to be inclusive such that any possible fruit and vegetable juice compliant with the set criteria could be used without expressed consent by the FDA and without submitting a separate color additive petition. As such, the regulations do not address in detail the types of processing that are appropriate for such colors.

Since these colors are, by definition, juice that is used for the purpose of coloring foods and beverages, an appropriate guiding principle is that if an ingredient is safe to be consumed as an edible juice product, it is also safe for the intended use as a color additive. Importantly, the term[1] Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.

The following non-exhaustive list of processing steps for juice are acceptable examples that should similarly be considered appropriate for production of a juice for color, such as:

- Pasteurization, Heating, Cooking
- Enzymatic treatment
- Freezing
- Drying
- Milling
- Water extraction
- Filtration
- Acidification
- Concentration

When in doubt, it is recommended to consult with FDA to have clear guidance on compliance with 21 CFR §73.250 and 21 CFR §73.260.

Additionally, as with all color additives exempt from certification, additional substances may be used as diluents in fruit and vegetable juice colors in accordance with 21 CFR §73.1. According to 21 CFR §73.1, color additives may safely use diluents which are either specifically listed within this regulation or one which is Generally Recognized as Safe (GRAS) as prescribed by such regulation.[ii] Furthermore, GRAS processing aids may be used under conditions set forth by the regulations.

ii 21 C.F.R. § 120.1(a) ("Juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.")

iii 21 CFR §§ 73.250(a)(2); 73.260(a)(2) "Color additive mixtures made with fruit [vegetable] juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods."

IV Usage

In practice, both 21 CFR §73.250 and 21 CFR §73.260 list color additives as those that "may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice" – which is widely understood across the industry as the practice where additives may only be used in an amount necessary to achieve its purpose.

To use a color additive in accordance with good manufacturing practices, for instance, would mean that a manufacturer would only use a vegetable juice for color or fruit juice for color in an amount that is enough to impart color, but not exceeding that limit. However, it is worth noting that certain foods or beverages for which a standard of identity has been established may restrict the use of color additives. Additionally, some ingredients used in color additive preparations may also have restrictions in a final food product, which should be noted to assist final food formulators.

V Labeling

As defined by FDA, a color additive is any material that is a dye, pigment, or other substance that can impart color to a food, drug, or cosmetic or to the human body. Food ingredients, such as cherries, green or red peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as color additives, but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a *color additive.*" (see 21 CFR §70.3(f)). Therefore, when fruit and vegetable juices are deliberately added to other foods to impart color, they are considered to be color additives and must comply with the relevant regulations and be appropriately labeled as such.

If a food contains a color additive not subject to certification, the ingredient statement must declare the color additive as per 21 CFR §101.22(k)(2). -The provision states a variety of ways in which these colors may be declared "Colored with _____"; or "_____ color" (the blank being filled in with the name of the color additive listed in the applicable regulation). Examples of appropriate labeling for fruit and vegetable juice colors are "Colored with Fruit Juice"; "Vegetable Juice for color"; "Colored with black carrot juice"; "Color added", or an equally informative statement which clearly indicates the addition of a color to a food, except where regulations require specific declaration of the color by common or usual name.

In the United States, any food to which color is added results in an artificially colored food this includes foods with added colors that are exempt from certification. As such, color additives, even those derived from natural sources, cannot be referred to as "natural color(s)", "naturally colored", or described by any similar terminology on food labels. It would, however, be permissible to make other claims about the source of added colors that do not suggest there are no added colors in the product.

Packaging and labeling requirements for color additives are outlined in 21 CFR §70 Subpart B. 21 CFR §70.25 provides that all color additives shall be labeled with sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by the regulations. In addition to all other information required by the act, labels for color additives shall state:

1. The name of the straight color or the name of each ingredient comprising the color additive if it is a mixture.
2. A statement indicating general limitations for the use of the color additive, such as "for food use only"; "for food, drug, and cosmetic use"; "for use in drugs for external application only."
3. Where regulations issued impose quantitative limitations for a general or specific use of a straight color, the amount of each such straight color in terms of weight per unit/volume or percent by weight.
4. An expiration date if stability data require it.

VI Safety

The safety of the materials produced and marketed under 21 CFR §73.250 & §73.260 is of utmost importance to NATCOL members. This paper outlines the common steps and interpretations that the industry commonly utilizes to underpin the safety of these products. The common steps taken by the industry to ensure the safety of products on the market are outlined in *Section II. Source Materials and III. Manufacturing and Formulations* above.

In terms of the regulations, there is a direct relationship between the safety of the color additives and the source materials which are derived from mature varieties of fresh or dry edible fruits and vegetables, or by the water infusion of the dried fruits and vegetables. The underpinning 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.

Additionally, the safety of these color additives is also governed by the FD&C Act and implementing regulations, requiring the industry to comply with:

1. Current Good Manufacturing Practice (cGMP) regulations for human food (21 CFR Part 117, Subpart B)
2. Preventive Controls for Human Food rule (21 CFR Part 117, Subparts C, D, F, and G). Food facilities are required to have a food safety plan in place that includes a hazard analysis and risk-based preventive controls to minimize or prevent the identified hazards. Color manufacturers have implemented quality systems to control the following:
   a. Potential biological hazards such as bacterial pathogens
   b. Potential chemical hazards such as pesticides, heavy metals, mycotoxins, allergens, or adulterants that may be intentionally introduced for purposes of economic gain
   c. Potential physical hazards (e.g. stones, sticks, plastic…)
3. Intentional Adulteration rule (21 CFR Part 121), requiring the establishment of food defense plans. Mitigation strategies set by the industry aim at preventing contamination intended to cause wide-scale harm to public health, including acts of terrorism targeting the food supply.

The industry utilizes hazard analysis and risk-based preventative controls, such as those outlined in HACCP principles, in the establishment of a quality control system to prevent adulteration. These food quality control systems help to prevent the adulteration of food through the establishment of procedures and programs which may include but are not limited to site security, approved raw material supplier programs, third party auditing, traceability, recall procedures, and tamper proof packaging.

Although not directly applicable to color additives, the FDA Juice Hazard Analysis and Critical Control Point (HACCP) regulations (21 CFR Part 120) are also used by members as a guidance to ensure the safety of fruit and vegetable juice colors.

Specific to pesticide residues, the Environmental Protection Agency (EPA) defines the pesticide residue tolerances for each agricultural commodity (40 CFR Part 180). Fruit and vegetable juice colors are required to comply with the applicable limits and NATCOL members have implemented risk-based monitoring activities to ensure compliance.

Similarly, levels of contaminants, e.g., heavy metals and mycotoxins, are monitored and controlled.

In closing, it is the "intended use" of a juice for the purpose of coloring food that changes its regulatory classification from a food to a color additive. All food safety considerations apply regardless of whether the juice ingredient is intended to be used as a beverage/juice or at much lower levels for consumption as a color.

VII Closing Statement

NATCOL U.S. members are very pleased to provide this NATCOL position as a resource to ensure that the key principles are clear and understandable for fruit & vegetable juice colors, which are important items for US food manufacturers, in accordance with the regulations published in the corresponding CFR. We recommend that this position is read in conjunction with the relevant legislation and regulations.

VIII Annex

The FDA has previously, and continues to, provide an official opinion upon request as to whether a color additive made from certain plant materials complies with the listed specifications for fruit juice or vegetable juice color regulations. Prior opinions can be requested from the FDA via a FOIA request (Freedom of Information Act).

The table below illustrates a few examples of source materials to which the FDA has previously provided an opinion regarding compliance to the fruit juice and vegetable juice color additive regulations. This list is not comprehensive. As noted above, any FDA opinions, including those on other source materials, can be obtained via the FOIA process.

Complies	Does not Comply
Calyx of roselle (Hibiscus sabdariffa)	
Carrots (Daucus carota varieties, including orange, red, purple/black)	Blue green algae, Spirulina (Arthrospira platensis)[1]
Sweet potatoes (tubers of Ipomoea batatas L.)	Gardenia blue[2]
Red radish (Raphanus sativus, root)	Safflower petals (Carthamus tinctorius L.)[3]
Red beets (Beta vulgaris spp.)	

1 Spirulina not traditionally consumed as a food, or considered a "vegetable". Has since been approved as color additive 21 CFR 73.530 Spirulina extract

2 Blue color (genipin) is formed by reaction and not expressed from the fruit.

3 Safflower petals, although extracted via water infusion, consumed in a tea does not fit the definition of an edible vegetable (or fruit) traditionally consumed as a food.

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