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May 1, 2017

*Via Electronic Transmission*

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Food and Drug Administration Docket Number FDA-2016-D-4120: Availability of Draft Guidance for Industry; Fruit Juice and Vegetable Juice as Color Additives in Food, (December 14, 2016)

To Whom It May Concern:

On behalf of the International Association of Color Manufacturers (IACM), we appreciate the opportunity to submit comments in response to the Food and Drug Administration's (FDA) notice of availability of draft guidance for industry on fruit juice and vegetable juice as color additives in food (81 *Fed. Reg.* 90267, Dec. 14, 2016).

## I. Introduction

IACM is the trade association that represents the global color industry, comprised of manufacturers and end-users of coloring substances that are used in foods, including certified and exempt from certification colors. IACM members create and use colors for a wide variety of food and beverage products.

## II. Overview of FDA's Draft Guidance

On December 14, 2016, FDA published draft guidance for industry entitled "Fruit Juice and Vegetable Juice as Color Additives in Food" (81 *Fed. Reg*. 90267, Dec. 14, 2016) and FDA established a docket to receive information and comments on this draft guidance. This draft guidance has been prepared by the Division of Petition Review, Office of Food Additive Safety, in the Center for Food Safety and Applied Nutrition at the FDA and the agency's stated intent is to "help manufacturers determine whether a color additive derived from plant material meets the specifications for fruit juice under §73.250 or vegetable juice under §73.260" because FDA had received numerous inquiries from industry regarding whether certain plant-derived materials were covered under these regulations (81 *Fed. Reg.* 90267, at 90268, Dec. 14, 2016).

FDA's draft guidance explains that the agency has a statutory obligation to ensure the safety of the use of color additives before FDA may authorize such a use under their color additive regulations. FDA maintains on page 5 of the draft guidance that,

> "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."

As such, FDA prepared and published this draft guidance to interpret certain terms in §73.250 and §73.260 in response to industry inquiries regarding the suitability of certain plant-derived materials under these regulations. Interested parties, including members of the color and food industry, have submitted requests to FDA over the years to obtain clarification on whether certain color additives made from various fruit and vegetable plant material meet the specifications of FDA's fruit juice and vegetable juice color additive regulations. This recently published draft guidance is intended to provide details to the interpretations that FDA has previously provided to industry via informal opinion letters.

Specifically, in its draft guidance, FDA provides the agency's interpretation of the terms "fruit" and "vegetable," "mature," "fresh," "expressing the juice," "water infusion of the dried fruit or vegetable" and "edible." Additionally, FDA requests in its draft guidance that industry stakeholders consult with FDA where questions exist regarding whether a plant-derived material meets the specifications of these color additive regulations. In conjunction with the publication of the draft guidance, FDA also posted on its website a summary table of the informal opinions FDA has previously issued in response to stakeholder inquiries regarding the applicability of §73.250 and §73.260 to certain materials. This is the first time that FDA has made any information related to these informal opinion letters so accessible, although the contextual and pertinent details are not provided in the summary table and are still only available via Freedom of Information Act (FOIA) request.

## III. Executive Summary of IACM's Comments

By publishing draft guidance offering FDA's interpretation of the fruit and vegetable juice regulation that in many instances is inconsistent with widely accepted industry practice and/or other FDA regulations, IACM suggests that FDA is regulating through guidance and is in violation of the Administrative Procedure Act (APA). Similarly, the suggestion that companies engage in premarket consultations is not required by the regulation, and by suggesting it in guidance, FDA is creating a situation whereby a premarket consultation would become the de facto regulatory process to determine whether their product meets the regulation – this is a major change and should be addressed via regulation, not guidance.

IACM will also comment on some differences in how FDA treats colors derived from fruit juice and vegetable juice as opposed to many of its key trading partners, which puts the color and food industry at a disadvantage globally by reducing the domestic industry's ability to innovate and by also creating trade barriers. Additionally, IACM offers examples of where this guidance is overly burdensome and out of line with typical accepted practice, both by industry and other governmental bodies.

Food colors are of great benefit to both consumers and processors. First, food color is an important property of foods that adds to a person's enjoyment of eating. Consumers already expect certain foods to contain added color and appreciate the benefits of added color including: offsetting color loss due to exposure to light, air, temperature extremes, moisture and storage conditions; correcting natural variations in color; enhancing colors that occur naturally but at levels weaker than those usually associated with a given food; providing a colorful identity to foods that would otherwise be virtually colorless; enhancing the flavor expectations of food; and most importantly to provide an appealing variety of wholesome and nutritious foods that meet consumer expectations and demands. Many consumers selecting natural foods already select foods with added color derived from natural sources. Colors meeting the fruit juice and

vegetable juice regulation are often considered in this purchasing decision by both consumers and the industry, and we urge FDA to consider the impact its draft guidance may have on the availability of safe fruit juice and vegetable juice color additives.

## IV. IACM's Specific Comments to FDA's Draft Guidance

### a. FDA Guidance Should Not be Used to Bind the Regulated Industry

A federal agency may not make binding law except in accordance with the authorities and procedures established by Congress. Specifically, agencies may make binding law only through rulemaking, which must be made in accordance with the notice-and-comment procedures set forth in section 553 of the APA.[1] The APA defines a rule as:

> "The whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret or prescribe law or policy or describing the organization, procedure or practice requirements of an agency…"[2]

Rules are generally and broadly classified as either legislative or nonlegislative. Legislative rules are those which an agency promulgates via APA's required notice-and-comment rulemaking. With legislative rules, agencies typically must amass a significant rulemaking record, are required to seek public participation in the development of the rule and must take the time to develop a basis and purpose justifying the rule.[3] Nonlegislative rules are those that are issued by an agency outside of the APA's procedural requirements and often are comprised of interpretative rules (i.e., provide an agency's interpretation of a statute or regulation) or agency policy statements.

Agencies often choose to communicate agency policy through the publication of guidance. Agency guidance notably lacks the procedural safeguards of notice-and-comment rulemaking that protect both regulated entities and regulated beneficiaries. Although agency guidance constitutes informal agency thinking regarding a topic, where guidance was not issued pursuant to §553 of the APA, and therefore is not binding legally, it may nevertheless be binding as a practical matter if the agency or regulated industry treats it as dispositive of the issue it addresses.

On December 14, 2016, FDA published in the Federal Register, its draft guidance document, "Fruit Juice and Vegetable Juice as Color Additives in Food." FDA explains in the introduction to its draft guidance, that the intent of this guidance is to assist the industry when determining whether a plant-derived color additive meets the specifications of the fruit juice color additive regulation at 21 CFR §73.250 or the vegetable juice color additive regulation at 21

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[1] 5 U.S.C. §553; *see* also *Chrysler Corp. v. Brown,* 441 U.S. 281, 302-03 (1979); *Batterton v. Marshall*, 648 F.2d 694, 701 (D.C. Cir. 1980) ("Advance notice and public participation are required for those actions that carry the force of law.").

[2] 5 U.S.C. §551(5).

[3] *See* 5 U.S.C. §553(c); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43, 57 (1983).

CFR §73.260. However, the draft guidance goes well beyond merely clarifying regulatory terms used in FDA's juice color additive regulations. For example, in the draft guidance, the agency suggests that to meet the specifications for fruit or vegetable juice color additive, the plant derived material must be "minimally processed," a term undefined in current FDA regulation. Furthermore, the agency also goes so far as to specify juice production methods that may be inappropriate to produce color additives under the fruit and vegetable juice color additive regulations. Neither the fruit nor vegetable juice color additive regulations as promulgated at 21 CFR §73.250 and §73.260 respectively contain either a formal definition of "minimal processing" or an express listing, itemization or prohibition of certain juice production methods. Since the fruit and vegetable juice color additive regulations are silent as to what typical juice processing methods are appropriate or might qualify as minimal sufficient to meet the regulations' specifications, any attempt by the FDA to define, categorize or otherwise establish such requirements, should not be memorialized in draft guidance, but instead, as required by law, must be done through notice-and-comment rulemaking. As a result, FDA's draft guidance suggests that the agency would implement its fruit and vegetable juice color additive regulations such that only those materials that meet its informal definition of minimally processed would qualify under the existing regulations, which applies an inappropriate binding norm on the regulated industry since such regulatory action would be based on draft guidance rather than rules established by proper notice-and-comment rulemaking.

Additionally, the draft guidance includes a reference to a static summary table listing FDA's informal disposition of stakeholder inquiries regarding the suitability of certain plant derived materials under the fruit and vegetable juice color additive regulations. As is discussed more fully below, the summary table itself fails to provide sufficient context to allow the reader to fully understand the agency's rationale for its informal opinion as to whether a certain material may be added to food in the U.S. under the current regulations. IACM members have confirmed that since the draft guidance was published, finished food and beverage manufacturers have taken FDA's summary table and used it to apply a concrete prohibition on the use of any material listed as "no." Since the summary table does not provide any context or a synopsis of the basis for FDA's informal opinion as to that material, the agency has in effect created a binding norm upon which the color industry must abide.

Although FDA's intent may have been to clarify certain terms used in both the fruit and vegetable juice color additive regulations, the practical effect of the draft guidance has been to bind the color industry outside the required notice-and-comment rulemaking process required by the APA. As such, IACM respectfully requests that FDA revoke the draft guidance.

### b. <u>Reference to FDA's Summary Table of Informal Opinions Should be Removed from the Draft Guidance and from FDA's Website</u>

In its draft guidance, FDA expounds on certain terms used in the fruit juice and vegetable juice color additive regulations because, the agency explains, it has received numerous inquiries from industry asking whether certain color additives made from various fruit and vegetable plant materials meet the specifications set forth in FDA's fruit juice or vegetable juice. Within its draft guidance, FDA provided a link [4] to a table listing the informal opinion letters

[4]http://www.fda.gov/downloads/forIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/UCM532389.pdf

where FDA issued an informal opinion to these inquiries. IACM has obtained the informal opinions listed in the FDA summary table linked to in the draft guidance via FOIA. It is clear through review of the informal opinions that FDA's thoughts on how to interpret the regulation has evolved over the years. Additionally, IACM notes that there are some materials included in the earliest informal opinions by FDA not included in the table.

However, FDA's summary table does not provide a link to or otherwise provide access to the actual informal opinions listed in the table or otherwise provide any analysis, synopsis or annotation of the FDA's informal opinion or the agency's basis underpinning its informal opinion regarding the suitability of the plant material under the existing regulations. Neither does the summary table provide any details regarding the request that gave rise to the opinion, nor the robustness or scope of the information provided by the requester in support of its request. FDA's summary table provides only a simple "yes" or "no" indication of whether the plant material at issue in the inquiry meets the specifications in the fruit juice or vegetable juice color additive regulation. By providing only a "yes" or "no" indication, and for the example of hibiscus, not explaining that this was an instance of FDA's interpretation resulting in a change of opinion, FDA creates uncertainty in the regulated community, who must now guess of the rationale applied by FDA. In many instances, it appears that FDA's issue is not with the material itself, but with the specific processing. Without providing that detail, a manufacturer is left uncertain whether a material, seemingly manufactured in accordance with the regulations, and with data on hand supporting that it has been widely used in and consumed as food in the U.S., would be acceptable. Would that company then be required to request a consultation with FDA to continue using a material that is designated as a "no" in the table? To do so appears to be discriminatory and does nothing more than suggest FDA will arbitrarily enforce the regulation. Additionally, regardless of FDA's intent, IACM members confirm that the table is being referenced by some as a positive list for what materials are acceptable or not under Secs. 73.250 and 73.260 despite FDA's assertion that the guidance is only draft and should be considered non-binding. The public can also view this information and make a misinformed decision as to a product's safety. For these reasons, IACM requests that FDA remove the table from its website and remove references to it from the draft guidance.

### c. FDA's Criteria for Determination of Whether a Fruit or Vegetable is "Edible" Should be Revised

The fruit juice and vegetable juice regulations promulgated in 1966 only require that the color additive juice be obtained from mature varieties of fresh, edible fruits and vegetables, and FDA has consistently concluded that to qualify as a source for fruit or vegetable juice color additives, the source material must be a commonly edible fruit or vegetable. FDA has stated, "We want to emphasize that Sec. 73.250 and Sec. 72.260 (the vegetable juice regulation) apply only to mature varieties or fresh, edible fruits or vegetables, respectively. Therefore, we would not consider a juice expressed from a portion of a fruit or vegetable that is not normally consumed, such as lemon skins or flowers, to be a listed color additive…" (Orstan, 1994). FDA came to the same conclusion about safflower petals stating that "Plants used only for herbal, medicinal, flavoring (for example spices) or coloring purposes are not considered to be edible vegetables (Rulis, 1997).

However, we would suggest that nothing in the regulations or preamble, or even within FDA's informal opinion letters, proposes a more specific definition for the term "edible," and we believe that current law does not support FDA's interpretation of whether a fruit or vegetable is

edible as outlined in the draft guidance.

We thereby assert that by offering specific criteria in draft guidance of determining whether a fruit or vegetable is "edible," FDA is inappropriately establishing legal criteria in the draft guidance not in accordance with the APA. Even if FDA were never to finalize this guidance, by issuing this information in draft guidance, FDA is establishing a new standard, not based in regulation, to which industry will be held both by the agency and by the market.

IACM has interpreted the regulations and FDA's informal opinions to indicate that while a fruit or vegetable may not be commonly cultivated or consumed in food in the U.S. due to its not yet been "discovered" as a food item, the regulations would still allow such fruit juice or vegetable juice as color additives exempt from certification under Secs. 73.250 and 72.260. In response to an inquiry about the use of chokeberry juice as a color additive, FDA stated, "The available information indicates that: (1) The fruit of *Aronia melanocarpa* was used for food by Native Americans, (2) the same fruit has been a commercial crop for food use in Finland, Russia and several eastern European countries since the 1940s, and (3) the juice obtained from the fruits has been sold in the U.S. for several years. Therefore, we conclude that the fruit of *Aronia melanocarpa* may be considered an edible fruit and color additives prepared in compliance with 21 CFR 73.250 may be used under that regulation to color foods sold in the U.S." (Orstan, 1996).

To address the specific guidance laid out by FDA, IACM asserts that neither the regulations nor informal opinions offered by FDA provide adequate details to require a sufficiently large or geographically diverse human population, nor should FDA require, without promulgating an amendment to the regulations, that industry demonstrate a lack of "detrimental health effects" or provide several well publicized studies to support the safety of consumption. IACM feels that there is no precedence for precluding significant use by another geographically diverse population outside the U.S. in determining a history of safe use. Many exotic fruits and vegetables that are not common in the U.S. have been safely used in many other countries for many years and can provide manufacturers with a broader palate to satisfy consumer demand for naturally derived color.

However, if a manufacturer relies on history of consumption outside of the U.S., FDA's draft guidance would require that the manufacturer not only establish a history of safe use, but also provide scientific studies from the peer-reviewed literature to establish safe use. IACM believes that manufacturers who source fruit or vegetable juice from countries outside of the U.S., where there is significant history of safe consumption of that fruit or vegetable juice, should not have to meet a higher burden of proof by providing scientific peer-reviewed articles to establish safety of a food that already has been consumed safely by diverse populations. Such requirements seem to discriminatorily suggest that fruit or vegetable juice sourced from outside of the U.S. should meet some higher threshold for safety or be subject to its own color additive petition. Additional support for this conclusion can be found in FDA's regulation of food substances "generally recognized as safe" (GRAS). The agency allows data on food consumption outside of the U.S. to be used to establish GRAS status in the U.S. (21 CFR 170.30; 53 *Fed Reg*. 16544. 10 May 1988; *Fmali Herb v. Heckler*. 715 F.2d 1389 (9$^{th}$ Cir. 1983)). Even though the GRAS concept does not apply to color additives, the principle of FDA recognizing foods consumed outside of the U.S. as relevant to U.S. regulation should apply with respect to juice from fruits and vegetables used as color additives.

Additionally, FDA's parenthetical in the draft guidance that 20 years of history of consumption is generally necessary to determine history of safe use for fruits and vegetables appears to be arbitrary with no basis in science, and is inconsistent with the type of information necessary for other food sources. As the guidance is currently drafted, FDA is creating a threshold for establishing safe use of fruit juice and vegetable juice as color additives that would be more appropriately handled through notice and comment rulemaking. History of safe consumption should be specific based on the situation rather than defensible because of an arbitrary period of safe use. If FDA were to maintain this requirement to establish a history of safe use, the agency should provide the precedent upon which it is based.

**d. <u>FDA's Argument that Juice Products be Minimally Processed to Meet the Specifications of the Color Additive Regulations is too Narrowly Construed</u>**

IACM feels that FDA is also regulating through guidance because it creates and relies on a legally undefined term, "minimal processing," as a basis for determining whether a color additive derived from fruit juice or vegetable juice meets the specifications of the existing regulations.

IACM and its members have interpreted the first two elements of FDA's fruit juice and vegetable juice color additive regulation, first that the color additive must be a juice and second that the method of production must be expression or water infusion, to require that a fruit or vegetable juice color additive must be produced in a manner consistent with typical fruit juice production processes. To this interpretation, we feel that two FDA definitions are relevant. First, the FDA regulation permitting the use of fruit juice and vegetable juice as color additives, which generally states that fruit or vegetable juice is prepared either by expressing the juice from mature varieties of fresh, edible fruit or vegetables, or by water infusion of the dried fruit or vegetables. FDA has also defined juice in the context of its juice hazard analysis critical control point (HACCP) regulations as follows: "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." 21 CFR 120.1(a).

As FDA's regulation on fruit juice and vegetable juice as color additives were developed more than fifty years ago, the regulation was implemented prior to the development of many aspects of modern, typical juice production. However, given the lack of detail previously available from FDA on the production of fruit and vegetable juice for color additive uses, the color industry has looked to FDA's regulations on several fruit juices, as well as FDA's regulations on HACCP for juice and accompanying policies and procedures to confirm that juice color additives used in accordance with the fruit juice and vegetable juice color regulations are produced consistent with typical juice production methods.

The draft guidance fails to consider modern fruit and vegetable processing procedures that do not adversely affect safety and in some instances, are required steps to ensure safety. FDA states in the draft guidance that, "importantly, manufacturers are responsible for ensuring that their products meet all applicable FDA requirements before they are introduced into U.S. interstate commerce" yet steps taken to meet these requirements would in some instances be disallowed by this guidance. Additionally, if no processing of the juice is allowed beyond those mentioned in this guidance, it not only poses a safety risk to consumers, but also eliminates any uses of powdered juices for use as colors in solid foods. This guidance would only then apply to

juice as a liquid for use in beverages, which is not only unreasonable, but contradictory to the specifications of the regulations, which allow for drying. For these reasons, IACM urges FDA to support specific process steps that industry consider to be necessary and consistent with safe and modern juice processing.

We would note that FDA has been reluctant to define the term “minimal processing” in regulation, seeking input on the topic just last year in a request for comments and information on the use of the term “natural” in the labeling of human food products (Docket Number FDA-2014-N-1207). FDA has also indicated that produce undergoing commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g. via a “kill step”) is enough to provide exemption from the Food Safety Modernization Act (FSMA) Final Rule on Produce Safety (80 FR 74353), thereby acknowledging that some processing is important for the safety of such food products.

IACM offered a list of processes that we felt could be considered by FDA to be appropriate minimal processes for a “natural color” in our comments to Docket Number FDA-2014-N-1207. Among these processes were some that are key to the safe production of fruit juice and vegetable juice color additives, including freezing, drying, filtration, hydrolysis, heating, and enzymatic processes. Other important processes for these color additives and which are routinely used in the juice industry include concentration and clarification. We respectfully note that given FDA’s current position that all color additives are artificial, which includes fruit juice color and vegetable juice color, holding these colors to a standard of processing beyond what is considered natural in most jurisdictions seems especially burdensome and restrictive and beyond the scope of what was intended by the regulations. Additionally, IACM members feel strongly that FDA’s approach to minimal processing as outlined in the draft guidance is beyond generally accepted industry practice and inconsistent with other FDA and other agency guidance.

We feel that FDA should remove any ruling, explanation or definition of what constitutes appropriate minimal processing from the guidance. As safe and efficient processes have and continue to evolve, FDA should be flexible rather than prescriptive in its allowance of appropriate minimal processing for fruit juice and vegetable juice color additives. As such, IACM would like to provide further information on why some processes are crucial to the production of color additives from fruit and vegetable juice, and in many cases, are required or encouraged by other FDA regulations on juice. IACM also requests clarification on whether FDA’s intent is to focus on processing that takes place in juice production itself or once the extraction process takes place and whether an extract from a concentrate juice is covered by the proposed definition of “water infusion of the dried fruit or vegetable.”

The application of heat is a critical aspect of modern juice production, utilized in the production of fruit and vegetable juice color additives to accomplish several things. Heat is necessary to stabilize the development of the color of the juice which, in instances such as with apple juice and orange juice, will naturally progress to brown and black if allowed to continue. The application of heat is also provided for in producing pasteurized orange juice, “to reduce substantially the enzymatic activity and the number of viable microorganisms.” 21 CFR 146.140 FDA permits the use of heat in the production of lemon juice, noting that the juice… “may be preserved by heat sterilization…or so processed by heat, before or after sealing, as to prevent spoilage,” 21 CFR 146.114, with similar language offered for canned prune juice production 21 CFR 146.187. Additionally, apple juice is produced by the maceration and pressing of various

varieties of apples, and the juice is often further treated with enzymes and centrifugal clarification to remove carbohydrates and pectin. It is then pasteurized for packaging or for dehydration for concentrate. The brown color is stabilized by heat processing during pasteurization that deactivates the enzymes. Heat may also be utilized to concentrate a juice blend for later reconstitution and/or standardization.

In addition to the examples offered above, it is necessary that raw materials and juices used for coloring would often need to be pasteurized, frozen, cooked or spray dried to make them safe for transportation to food manufacturers who would then need to store them on site until needed in a finished good and also because a processing plant is not always close to point of harvesting. Typical juice production processes often include milling and natural enzymatic reactions during processing, which can be necessary steps to obtain color to be used in amounts consistent with good manufacturing practices (GMP). For example, to produce elderberry juice color, like the example provided previously as allowable in the production of apple juice, enzymatic treatment is required to remove product turbidity caused by large molecular weight materials like cellulose and pectin. Filtration is also required to remove large and small particles after the extraction process. We also note that in the case of cooking, juice from some fruits, such as tamarind, are traditionally prepared this way. Unlike citrus that needs only to be cut and squeezed, the traditional way of extracting juice from the tamarind is to boil it in water until the skins burst, which takes about 20 minutes, and to mash the fruits either with a fork, or more practically, with a mashing instrument to squeeze the pulp, before straining and mashing once more. In the case of aging, juice from some fruits, such as prune, are aged from other fruits, such as plum. FDA should also consider the need for preservation, for without it, colors derived from fruit juice and vegetable juice would be at risk for microbiological contamination. It is not clear from the guidance whether these processes necessary for juice production would be allowed.

As you know, the U.S. juice industry is regulated by 21 CFR Part 120 and as such adheres to the regulation's requirements, including the establishment of a HACCP plan, which requires 5-log pathogen reduction. Heat processing is a key part of this program, utilized to address safety issues consistent with the HACCP regulations to produce fruit juice and vegetable juice. As this regulation was developed more than 20 years after the agency's fruit and vegetable juice color additive regulations, it reflects many aspects of modern juice production and provides more current thinking on important safety issues. As further defined in the Guidance for Industry: Juice HACCP Hazards and Controls Guidance First Edition; Final Guidance issued on March 3, 2004, pasteurization means a heat treatment sufficient to destroy vegetative cells of pathogens. The guidance includes pasteurization as an accepted pathogen control measure and includes comments on published studies on pasteurization processes for controlling pathogens in juice. Indeed, most modern juice processors choose to use pasteurization to achieve the requirements of this section. Other processes that may be included in the HACCP plan are pH adjustment during and after the extraction process and filtration, both of which contribute to the safety of many fruit and vegetable juices. Therefore, the disallowance of these processes could have food safety implications for consumers of these fruit and vegetable juice color additives.

We also note that there are a myriad of international standards and guidance that juice processors adhere to, and which color manufacturers engaged in the manufacturing of additives derived from fruit juice and vegetable juice, also look to for guidance. These include, but are not limited to the FAO 2001 Agriculture Services Bulletin #146 "Principles and Practices of Small to

Medium Scale Juice Processors;[5] " Codex General Standard for Fruit Juices and Nectars (Codex Stan 247-2005)[6], and the EU Council Directive 2001/112/EC of 20 September 2001 relating to fruit juices and certain similar products intended for human consumption[7]. We encourage FDA to consider these documents as models of what processes should be considered as necessary for the safe production of juice given that juice processors and color manufacturers do business globally.

For these reasons, IACM feels that FDA's current thinking is not in alignment with the view of the global marketplace on fruit and vegetable juice based colors, which places an undue burden on the U.S. food and color industry, and which we will discuss in more detail in the next section.

## V. Inconsistencies with FDA approach vs. major trading partners

The U.S. is the only industrialized nation that considers fruit juice and vegetable juice as color additives. Many jurisdictions have instead promulgated regulations in recognition that colors derived from sources such as fruit juice and vegetable juice are outside the scope of what is traditionally considered to be a food or color additive. This difference in approach puts the U.S. color and food industry at a disadvantage globally by reducing the domestic industry's ability to innovate and by creating trade barriers.

For example, the European Commission's Standing Committee on the Food Chain and Animal Health has recently adopted guidance to specify that coloring ingredients can be considered coloring foods rather than coloring additives if they are derived from fruits, vegetables, herbs or other foods that are legally considered foods or food ingredients in the EU. The guidance also says they should be processed by simple, traditional food preparation processes without selective extraction.

These guidance notes[8] are intended to assist industry in distinguishing between products that are food ingredients with coloring properties and additives intentionally added for color. This guidance was relevant as there was no allowance in the EU regulation on color additives[9] for fruit or vegetables juice colors outside of the anthocyanins color additives. In fact, the EU directive specifically acknowledges that these types of colors are not additives but instead are considered food ingredients that nonetheless still contribute color when incorporated into a processed food.

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[5] Available online at http://www.fao.org/3/a-y2515e.pdf.

[6] Available online at http://www.fao.org/fao-who-codexalimentarius/sh-proxy/zh/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCODEX%2BSTAN%2B247-2005%252FCXS_247e.pdf

[7] Available online at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3Al21132.

[8] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_guidance_additive-eu-rules.pdf

[9] Regulation (EC) No 1333/2008

The UK's Food Standards Agency published a 'food additive legislation-guidance notes definition of color,' which provides further clarification:

> Colors add or restore color in a food. They are not substances that are normally consumed as foods by themselves or used as characteristic ingredients of foods. This Regulation is not intended to catch products such as fruit juices (for example, elderberry juice added to yoghurt) or tomato concentrates. These would be regarded as ingredients, to be labelled as such, even when added principally for coloring purposes.[10]

The EU guidance notes makes a differentiation between whether a color has been obtained via "selective extraction" or using typical juice processing techniques.

> Provided that these foods or food ingredients retain their essential characteristics, foods with coloring properties should not be regarded as food colors whether used in the raw state or in a processed form, e.g. by concentration, drying, cooking or milling. For example spinach used in the manufacture of noodles as such or dried or in the form of concentrated juice, without a selective extraction of pigments, would be considered as a food ingredient and not as a food color. On the other hand if pigments are 'selectively extracted' from the spinach and added to noodles in order to add color, then these are regarded to be food additives (i.e. food colors - chlorophylls and chlorophyllins (E140)).[11]

Canada has also recently addressed the issue of concentrates and crude extracts used for coloring. Like in the U.S., industry can request an opinion on whether a concentrate or extract would be considered a coloring agent, but again in the absence of a regulation specific to fruit juice and vegetable juice as color additives, Health Canada considers those extracts that are not highly purified via techniques such as selective extraction to be non-additive coloring ingredients. This approach is like that adopted by Europe to differentiate between coloring foods and color additives.

Based on the guidance recently issued by the EU and Canada acknowledging that there are instances where colors derived from fruit juice and vegetable juice should not be classified as color additives and subject to the premarket review process, IACM questions why the U.S. is taking the opposite approach with this draft guidance. As drafted, this guidance would require colors derived from fruit juice and vegetable juice that are produced using typical juice processing techniques and where the ratio of coloring principle to other constituents is not substantially different than for the source material to undergo a similar level of premarket review as any other color additive. Given the resources involved with this process, both from industry and the agency, IACM would instead encourage the agency to consider the adoption of a similar approach, including the recognition of the same typical processes, which would enable the U.S. to be more in line with other major jurisdictions.

## VI. Conclusion

[10] http://www.food.gov.uk/multimedia/pdfs/guidance.pdf (Section 4, page 18)

[11] https://ec.europa.eu/food/sites/food/files/safety/docs/fs_food-improvement-agents_guidance_additive-eu-rules.pdf (page 4)

If the agency feels that uncertainties in the fruit juice and vegetable juice color additive regulations must be addressed through guidance, we encourage that it be done through a collaborative process with the regulated industry. As the agency noted in a January 31 constituent update,

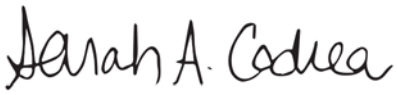
> "FDA is not the only source of guidance documents on best practices for compliance with regulatory requirements. Associations or organizations associated with a specific industry…also draft guidance documents to capture the best practices to produce food…in a way that helps to ensure their safety in accordance with federal regulations."

Due to the intrinsic challenges with obtaining information historically on how FDA was interpreting the fruit juice and vegetable juice regulations, as that information was only available by requesting an informal opinion to the agency, which was then only available to the individual requesting the opinion unless obtained via FOIA, IACM understands why the agency may think that a guidance document to offer FDA's interpretation to the entire regulated industry would be helpful. However, in this case, the guidance as offered does not reflect current industry practice or provide recognition that is necessary to produce color additives extracted in a manner to ensure their safety in accordance with federal regulations.

Therefore, we reiterate our request to FDA to revoke the draft guidance. We additionally urge FDA to accept IACM's December 2013 offer to collaborate with the association and with industry to develop guidance or modify the existing regulations to help ensure safe fruit and vegetable juice color additives meeting modern, typical juice processing methods remain available for use in the U.S.

IACM appreciates the opportunity to comment and urges your consideration of these important matters as you consider guidance for industry on fruit juice and vegetable juice as color additives in food. We look forward to further dialogue with the agency on this issue of significant importance to the color industry.

Sincerely,



Sarah A. Codrea
Executive Director