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March 8, 2019

Saudi Food and Drug Authority
SFDA - 3292 North Ring road Al Nafel Area Unt (1) - Riyadh 13312 - 6288
Via E-mail: SPSEP.Food@sfda.gov.sa

Re: GSO 05/FDS 2500 /2019

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 Kingdom of Saudi Arabia/The Cooperation Council for the Arab States of the Gulf draft Technical Regulation for "Additives Permitted for Use in Food Stuffs" as notified to the World Trade Organization.

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 synthetic and natural colors. IACM members create and use colors for a wide variety of food and beverage products. Color additives play an important role in food, and they do so without posing a health risk to consumers.

Codex GSFA is Not a Positive List

IACM generally supports the adoption of Codex General Standard for Food Additive (GSFA) provisions and the safety evaluations of food color additives by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). However, in adopting only those provisions, Saudi Arabia/The Cooperation Council for the Arab States of the Gulf is severely limiting the options for color available to the food and beverage industry. We respectfully request that you consider the scientific evidence available to support the addition of further color provisions as well as the evidence against a warning label. IACM is concerned that local restrictions on the use of safe and globally approved colors would generate barriers to international trade.

IACM participates as a non-governmental observer at the Codex Alimentarius Commission, particularly the Codex Committee on Food Additives (CCFA), which considers colors for inclusion in the GSFA. IACM appreciates and supports that many countries that are revising their food laws look to Codex standards for guidance and to the GSFA as an example of a positive list of food additives. The Codex process for establishing final provisions for maximum use levels is very slow, and as such not all additives, including colors, which are concluded to be safe by JECFA and approved in countries such as the United States (US) and the European Union (EU), have made it through the Codex process for inclusion in the GSFA. Additionally, it was not the intent of the creators of the GSFA for it to be adopted as a positive list at this stage of development. Footnote 1 of the GSFA states,

> Notwithstanding the provisions of this Section of the General Standard, the lack of reference to a particular additive or to a particular use of an additive in a food in the General Standard as currently drafted, does not imply that the additive is unsafe or unsuitable for use in food. The Commission shall review the necessity for maintaining this footnote on a regular basis, with a view to its deletion once the General Standard is

substantially complete.[1]

Since the current omission of some colors from the GSFA is not due to safety concerns, but instead due to the large number of additives waiting for completion of the step process, we encourage countries to consider color approvals in other regions, as well as in the Codex GSFA, when developing domestic color regulations. In the case of the draft Technical Regulation for "Additives Permitted for Use in Food Stuffs," IACM would encourage the adoption of color provisions allowed in Commission Regulation (EU) No 1129/2011 of 11 November 2011 Amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union List of Food Additives as well as consideration of those colors approved for use by the US Food and Drug Administration (FDA), for those colors where final provisions in the GSFA have not yet been adopted.

There are currently 47 colors with draft and/or adopted provisions in the GSFA (see Appendix 1). Eight colors have a JECFA acceptable daily intake (ADI) of "not specified" (i.e. an ADI was not considered necessary) and are listed in Table 3 of the GSFA. 39 colors have a numerical ADI and are listed in Tables 1 and 2 of the GSFA. There are currently 966 draft color provisions in the GSFA for colors pending for either Tables 1 and 2 or Table 3.

The Committee, via the GSFA Electronic Working Group (EWG), has, as of 2018, resumed working through these draft provisions, beginning with the 40 draft provisions in the confectionery food categories 5.2-5.4, and we expect those to be endorsed at the upcoming 51st CCFA meeting and adopted at the Codex Commission meeting this summer. We also anticipate the GSFA WG to include a new batch of draft color provisions in the mandate for the next GSFA EWG to consider over the course of the next year and to continue doing so until the completion of all draft or proposed draft color provisions. Therefore, IACM would strongly discourage using solely the adopted provisions in the GSFA in developing your food law and encourage you to consider also the draft provisions, in addition to considering the status of these colors in other regions, such as the EU and the US.

Additionally, in support of adopting those provisions currently draft in the GSFA, the EU just completed the re-evaluation of all color additives, and JECFA has recently completed re-evaluations for 8 synthetic colors. So, while there are no safety concerns for these or any of the colors currently approved for use in Saudi Arabia or the Gulf region, their safety profiles have been further strengthened as a result of the European Food Safety Authority (EFSA) and JECFA re-evaluations. IACM would be pleased to provide studies demonstrating safety for any color additive upon request. All available safety studies are cited in the EFSA opinions and JECFA monographs.

Importantly, among the colors that would no longer be allowed in most food categories under the proposed Saudi Arabia standard, include tartrazine, quinoline yellow, ponceau 4R and azorubine, along with natural colors such as spirulina extract, all of which are crucial to many food and beverage products and have completed safety evaluations.

Tartrazine

Tartrazine (INS 102) is a color additive approved for use in the United States and in Europe. Tartrazine is also approved in many other countries globally, such as Australia, Brazil, Canada, Central American Customs Union, Chile, China, Eurasian Customs Union, Hong Kong, Japan, Korea, Malaysia, Mexico, New Zealand, Singapore, South Africa, and Vietnam. Tartrazine is used to provide a yellow or green (when blended with other colors

[1] CODEX STAN 192-1995

such as Brilliant Blue) color to a wide variety of products, including ice cream, confectionary, pastries, cookies, beverages, snack foods, condiments, spreads, cereal, rice, noodles, and chewing gum.

JECFA has evaluated the safety of tartrazine used as a coloring agent in food and has established an ADI of 0-10 mg/kg bw per day. During the 82nd JECFA meeting on food additives held in June 2016, JECFA increased the previously established ADI for tartrazine from 0-7.5 to 0–10 mg/kg bw. It was also noted that, based on industry use data, estimated dietary exposures to tartrazine for children were below the upper bound (10 mg/kg bw) of the ADI and concluded that dietary exposure to the color does not present a health concern for any age group. In 2009, EFSA completed a re-evaluation of tartrazine and concluded that the current available data do not provide reason to revise the approval of tartrazine as food color additive or its established ADI of 0-7.5 mg/kg bw.

In the US, tartrazine is a certified color, which means that the US FDA assures that newly manufactured batches of the color meet the identity and specification requirements of their listing regulations. US FDA approved tartrazine as a food color additive for use in foods generally in 1969 (21 CFR 74.705) and continues to uphold the safety of this color based on current scientific updates.

Azorubine/Carmoisine

Azorubine (INS 122) is an azo dye that provides a red to maroon shade often used to provide color in yogurts, preserves, jams and jellies. It is allowed as a food additive in the EU, as well as in Australia, Brazil, Central American Customs Union, Chile, China, Eurasian Customs Union, Hong Kong, Malaysia, Mexico, New Zealand, Singapore, South Africa and Vietnam. JECFA evaluated the color in 1983 and established an ADI of 0-4 mg/kg bw. EFSA's Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) re-evaluated this color in 2009 and concluded that the current available data do not provide reason to revise the established ADI of 0-4 mg/kg bw.

Quinoline Yellow

Quinoline yellow (INS 104) is a bight greenish-yellow, water soluble dye with typical applications including beverages, confectionery, meat, bakery, dairy fats and oil, seafood, snacks, dry mixes and seasonings, fruit preparation and convenient food, approved for use in Europe and in many other countries. At its 82nd meeting, JECFA established an ADI of 0–3 mg/kg bw. The Committee also concluded that dietary exposure to quinoline yellow for children and all other age groups does not present a health concern. EFSA re-evaluated quinoline yellow in 2009 and established an ADI of 0.5 mg/kg bw.

Ponceau 4R

Ponceau 4R (INS 124) is a red dye that provides a dark red shade in applications such as beverages, confectionery, bakery, dairy fats and oil, meat, seafood, snacks, dry mixes and seasonings, fruit preparation and convenient foods. It is approved for use in the EU with an ADI up to 0.7 mg/kg bw (EFSA 2009) and permitted use levels have been defined in EU legislation (Directive 94/36/C). JECFA last evaluated ponceau 4R in 2011 and established an ADI up to 4 mg/kg bw.

Expansion of Natural Color Approval

IACM commends Saudi Arabia/The Cooperation Council for the Arab States of the Gulf for including Annex A to Table One (pg. 224 of the draft standard), which would allow certain natural colors to be used in foodstuffs in general. We would encourage the addition of other natural colors, particularly spirulina extract (INS 134), for which more safety information is

available below. The table should also include colors such as carthamus (safflower) yellow (INS 105), a newer natural yellow color that is currently subject to a color additive petition in the US and is already allowed in countries such as Korea and Japan as well as additional anthocyanin extracts (INS 163). For example, black carrot extract (INS 163(vi)) is being reviewed by the 87th JECFA meeting this summer and once an ADI is established, will be proposed for inclusion in the GSFA.

Spirulina Extract

Spirulina extract, a natural blue green extract, was approved by the US FDA in 2013 as an exempt from certification color limited to amounts consistent with good manufacturing practice (GMP) in response to two separate color additive petitions. The initial petition provided for the safe use of spirulina extract as a color additive in candy and chewing gum. The second petition expanded the safe use of spirulina extract to additional food categories including frostings, ice cream and frozen desserts, beverage mixes and powders, yogurts, custards, puddings, cottage cheese, gelatin, breadcrumbs, and ready-to-eat cereals (excluding extruded cereals).[2] The color additive as allowed in the US is prepared by the filtered aqueous extraction of the dried biomass of *Arthrospira platensis,* a protein-rich nutrition supplement for undernourished populations worldwide, and contains phycocyanins as the principal coloring components (21 CFR 73.530).

Spirulina extract was also recently reviewed at the 86th JECFA, which established a temporary ADI "not specified." This determination was based on the absence of toxicity in repeat-dose animal studies with spirulina extract and dried spirulina. The ADI "not specified" was made temporary due to the tentative nature of the specifications which will be finalized next year. The Committee concluded that this dietary exposure does not present a health concern. Once the specifications are made final, it will be proposed for addition to Table 3 of the GSFA.

In the EU, spirulina extract is typically considered a coloring food, which is a food ingredient used for coloring purposes. In order to distinguish between coloring foods and food color additives, in 2013, the European Commission adopted “guidance notes on the classification of food extracts with coloring properties.”[3]

These expert review bodies all consider these colorants to be safe and as such there is no reason to prohibit the use of these colors in food and beverage products in Saudi Arabia or the Gulf region.

Technical Corrections/Misalignment with the GSFA

IACM would offer a few technical corrections to the proposed standard as follows:

- In Annex A to Table 1:
  - INS 160b – Color name should be annatto extracts instead of lutein
  - INS 153 is the correct number for activated charcoal (vegetable carbon).
- Colors included in Annex A to Table 1: INS 160b, 100(i), 150a and 150b also have provisions listed in Tables 1 and 2. We would suggest striking those provisions from Tables 1 and 2 while keeping them in Annex A to alleviate potential confusion over

[2]https://www.federalregister.gov/documents/2014/04/11/2014-08099/listing-of-color-additives-exempt-from-certification-spirulina-extract

[3] https://ec.europa.eu/food/safety/food_improvement_agents/additives/eu_rules_en

whether a provision with a Maximum Level or the Annex A listing should take precedence.

- Allura red (INS 129) and sunset yellow FCF (INS 110) have been omitted from Food Categories 5.1.3, 5.1.4, 5.1.5, 5.2 and 5.3. Allura Red is listed in the Codex GSFA in each category at 300 mg/kg, while sunset yellow is listed in the Codex GSFA in 5.1.4 at 400 mg/kg and at 300 mg/kg in the additional omitted categories.

IACM does not understand why the proposed draft standard is out of alignment with the GSFA for some color additives, particularly allura red and sunset yellow in the chocolate and confection categories. If this disallowance was intended to potentially reduce the exposure of children to these colors, then this action is misguided. Bastaki *et al.* (2017) finds that intake for these colors in children is as low as 3% and 5% of their respective ADIs. Furthermore, concern related to possible association with hyperactivity in children as reported by McCann *et al*. (2007) has been determined unsubstantiated. Besides, for children to reach the intake assumed in the McCann *et al.* (2007) study (see below for further discussion of this study), they would have to consume foods and beverages that contain four different colors at maximum use levels, at daily amounts more than double that of the high consumers (95%), a clearly excessive and unrealistic scenario. Intake assessments have demonstrated that food color use as currently practiced in the US, EU, and elsewhere is safe and does not result in excessive exposure to the population, even at conservative ranges of food consumption and levels of use.

Warning Statement

IACM would strongly encourage the deletion of the warning statement for some synthetic colors. IACM is unaware at this time of any specific, new risk assessments that have been conducted that would form the basis for a risk management action such as the proposed labeling.

Much of the recent research activity on the topic of food additives, including color additives, and childhood behavior has been driven by research published by McCann *et al.* (2007), which is commonly referred to as the Southampton study because it was conducted by investigators at Southampton General Hospital in the UK. The Southampton study utilized mixtures of four food color additives and sodium benzoate as test articles. The study utilized sunset yellow, tartrazine, carmoisine and ponceau 4R in Mix A and used sunset yellow, carmoisine, quinoline yellow, and allura red in Mix B. McCann *et al.* (2007) utilized a double-blinded test article protocol. The magnitude of the effect size (i.e., standardized mean difference), of worsening of hyperactivity, for color additives reported and acknowledged by McCann *et al.* (2007) was miniscule.

The McCann *et al*. (2007) study was evaluated by the EFSA Panel on Food Additives, Flavourings, Processing Aids, and Food Contact Materials (EFSA, 2008) shortly after it was published. According to the EFSA Panel, the main limitations of the study include: the study investigated mixtures not individual colors, unverified validity of the novel behavioral scoring, small sample size, absence of information regarding a dose-response relationship, and the absence of a possible biological mechanism to explain behavioral changes. ESFA also noted that McCann *et al.* (2007) used an unconventional and inadequately justified statistical model. EFSA concluded that the evidence currently available did not substantiate a causal link between the individual colors and possible behavioral effects.

However, since 2010, the EU has also required a specific warning label for the Southampton study colors, saying that they may have effects on activity and attention in children. It is important to note that while the EU has required a warning label for the colors

included in the McCann *et al*. study, this requirement was not based on adequate scientific evidence or on the opinion of the risk assessors at EFSA, but instead on a political decision taken by members of the European Parliament.

Risk management response to the Southampton study outside of Europe differed. In March 2011 the US FDA convened a two-day meeting of an independent Food Advisory Committee (FAC), an expert panel of pediatricians, toxicologists, behavioral scientists, food scientists, and scientists in related fields, to review not only the Southampton Study, but all earlier studies that asserted a link between consumption of artificial color additives and hyperactive behavior in children. After two days of scientific discussion, presentations by researchers, and public comment by parents and stakeholders, the FAC recommended that no additional information, including a warning, was needed on a product label to ensure the safe use of colors. The Committee also agreed that there was no causal relationship between the intake of artificial color additives and hyperactive behavior in children. Other countries who also considered the merits of the Southampton Study have rejected the merit of a warning label for similar reasons.

IACM asserts that the results of the McCann *et al.* study and previous studies do not provide support for restrictions on the use or labeling of synthetic color additives on food products. As the authors of the McCann *et al.* study have already stated, much additional work remains to be done to establish whether the results can be reproduced and to understand the significance of any validated results. This important work must be carried out prior to any further consideration as to whether there are risk assessment or risk management implications.

In summary, there is no positive association between consumption of synthetic colors and behavioral problems in children. There is no evidence that supports the claim that a warning label will result in any significant health benefits. Perception of benefit without the support of scientific evidence cannot be adequate justification for a regulatory decision that limits choice.

<u>Mechanism for Addition of Colors</u>

It is unclear from the proposed regulation if Saudi Arabia/The Cooperation Council for the Arab States of the Gulf is considering a mechanism for the addition of colors to its positive list that may not already be included in the GCC regulation. Innovative color manufacturers are continuing to identify new uses and new natural colors that will allow product manufacturers to provide consumers with a greater variety of colored products. For this reason, IACM would stress that it is advisable to have a regulatory mechanism whereby the list of colors included in the regulation can be updated to add substances. We would also suggest since the regulation already references the EU and Codex standard, that the regulation should reference colors approved for use by either regulatory body to be automatically approved. This would allow for greater harmonization of regulations and decrease trade barriers.

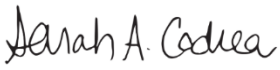
However, if Saudi Arabia/The Cooperation Council for the Arab States of the Gulf will not consider referencing the EU and/or Codex Standard to allow for an automatic update mechanism, IACM encourages you to add the following clause to the standard: "*This list of permitted additives is not a closed list and other food additives will be permitted based on their safety and permissibility on a case by case basis.*" This would allow for companies to petition for specific color provisions that are crucial to their business in the Gulf region to be added to the standard.

<u>Enforcement Date</u>

IACM recommends that the deadline for enforcement of the updated standard is at least 24 months, in accordance with international practices for grace periods that are normally given for such broad-spectrum regulations that require re-formulation and label changes. A timeline of at least 24 months would provide operators of food and beverage products, particularly those which are exported from countries such as the US and EU, to implement the changes and avoid business challenges, cost implications and business disruptions.

We remain at your disposal to provide any additional information concerning the strong safety record of all the artificial color additives that are produced or used by our member companies, including the scientific evidence that our colors are safe. In the interim, we strongly urge that the scientific evidence that colors are safe be considered in a manner consistent with harmonized international standards.

Sincerely,



Sarah Codrea
Executive Director

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Appendix 1 – Color Additives with Provisions Approved in the GSFA, EU and/or US

Color	INS #	GSFA Adopted Provisions	GSFA Provisions in Step Process	GSFA Table 3	EU Approved	US Approved
Curcumin	100(i)	2	84		E100	21CFR73.615
Riboflavins	101(i-iii)	71			E101(i-ii)	21CFR73.450
Tartrazine	102	4	71		E102	21CFR74.705
Quinoline Yellow	104	2	56		E104	
Carthamus Yellow	105				Colouring food	pending
Sunset Yellow FCF	110	63			E110	21CFR74.706
Carmines/Cochineal Extract	120	76	1		E120	21CFR73.100
Azorubine (Carmoisine)	122	2	58		E122	
Amaranth	123	2	39		E123	
Ponceau 4R	124	50	1		E124	
Erythrosine	127	6	1		E127	21CFR74.303
Allura Red AC	129	52			E129	21CFR74.340
Indigotine	132	51			E132	21CFR74.102
Brilliant Blue FCF	133	58			E133	21CFR74.101
Spirulina extract	134				Colouring Food	21CFR73.530
Chlorophylls	140		23	*	E140(i)	
Chlorophylls & Chlorophyllins, copper complexes	141(i-ii)	57			E141(i-ii)	21CFR73.125
Fast Green FCF	143	36				21CFR74.203
Caramel I	150a	1	23	*	E150a	21CFR73.85
Caramel II	150b	1	53		E150b	21CFR73.85
Caramel III	150c	80	2		E150c	21CFR73.85
Caramel IV	150d	71	2		E150d	21CFR73.85
Brilliant Black	151	1	57		E151	
Vegetable Carbon	153				E153	
Brown HT	155	1	58		E155	
Carotenoids	160a(i), 160a(iii), 160e, 160f	79	1		E160a(i) E160a(iii) E160e	21CFR73.90 21CFR73.95
Carotenes, Beta-, vegetable	160a(ii)	89			E160a(ii)	21CFR73.95
Carotenes (Algae)	160a(iv)				E160a(iv)	21CFR73.95
Annatto extracts	160b	3	93		E160b	21CFR73.30
Paprika extract	160c		82		E160c	21CFR73.340 21CFR73.345
Lycopene, Synthetic	160d(i)		9	*	E160d(i)	
Lycopene, Tomato	160d(ii)		28	*	E160d(ii)	21CFR73.585
Lycopene, Blakeslea Trispora	160d(iii)		9	*	E160d(iii)	
Lutein from Tagetes Erecta	161b(i)	1	42	pending	E161b	
Lutein esters from Tagetes erecta	161b(iii)			pending		

Color	INS #	GSFA Adopted Provisions	GSFA Provisions in Step Process	GSFA Table 3	EU Approved	US Approved
Canthaxanthin	161g	34			E161g	21CFR73.75
Zeaxanthin, Synthetic	161h(i)	1	33			
Beet Red	162		24	*	E162	21CFR73.40
Anthocyanins: Grape Skin Extract Blackcurrant Extract Purple Corn Color Red Cabbage Black carrot extract Red Radish	163(ii-vii)	67 (Grape Skin Extract)			E163	21CFR73.170
Calcium Carbonate	170(i)	19	1	*	E170	21CFR73.70
Titanium Dioxide	171		17	*	E171	21CFR73.575
Iron oxides	172(i-iii)	32	1		E172	21CFR73.200
Potassium aluminum silicate-based pearlescent pigments	176(i-iii)				E171 with E555	21CFR73.350

*Indicates inclusion in GSFA Table 3

Full list of pending provisions prepared for and available as an Information Document at each CCFA meeting. Most recent version available: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-51%252FINF%252Ffa51_info_01e.pdf

Colouring Food is defined by the “Guidance Notes on the Classification of Food Extracts with Colouring Properties” http://ec.europa.eu/food/food/fAEF/additives/docs/guidance_en.pdf.

EU color additive specifications are defined in Commission Regulation (EU) No 23/2012

US regulations in 21 CFR can be found in the Electronic Code of Federal Regulations https://www.ecfr.gov/cgi-bin/text-idx?gp=&SID=3463c48f55ae08efd099682901bb9500&mc=true&tpl=/ecfrbrowse/Title21/21CIsubchapA.tpl