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To whom it may concern:

The International Association of Color Manufacturers (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 natural and synthetic colors. IACM assists the industry in regulatory and scientific matters, and also participates as a nongovernmental observer at the Codex Committee on Food Additives (CCFA), which considers colors for inclusion in the General Standard of Food Additives (GSFA). IACM appreciates the opportunity to provide the following comments and recommendations in response to the WTO notification of amendments to GSO 23/1998, "Colouring Matter Used in Foodstuffs."

As you know, food regulations in many countries provide lists of approved food additives, including colors, for various food categories, acceptable levels of use and specifications for these materials. Unfortunately, these lists, food categories and specifications are non-harmonized around the world which makes it very difficult for international trade of many food products. Major developed countries such as the US and Europe have had detailed food and color additive regulatory systems in place for many years, which has led to non-harmonized standards. We appreciate that the GCC is establishing regulations for the use of color in food products and that it is looking to the GSFA and to the EU regulation as guidance. We would also advise you to consider the US regulatory process as an additional reference point. However, we want to note that the GSFA is a living document, and that the Codex process is very deliberate, and as such not all additives, including colors, which are approved in countries such as the US and the EU have made it through the Codex approval process for inclusion in the GSFA. Since their current omission 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 the US and the EU, as well as in the Codex GSFA, when developing color regulations.

IACM has a few specific concerns with the amendments that the GCC is proposing to its 2008 regulation, specifically the removal of Tartrazine and Carmoisine/Azorubine as accepted color additives and the addition of a warning label for Sunset Yellow and Allura Red.

Benefits of Colors

In foods, added colorants perform important functions. They are used to offset color loss that can occur due to exposure to light, air, temperature extremes, moisture and storage conditions. Color additives enhance colors that occur naturally, they correct natural variations in color, and they provide a colorful identity to foods that would otherwise be virtually colorless. Artificial color additives are preferred over natural colors in some applications due to their specific coloring ability, uniformity, stability, and intensity of color. Currently, there are some applications in food production for which there are not suitable natural color alternatives to artificial colors such as Tartrazine and Carmoisine (Azorubine).

Tartrazine (E 102)

Tartrazine is a color additive approved for use in the United States and in Europe. Tartrazine is also approved in many countries globally, including but not limited to Australia, Brazil, Canada, Central American Customs Union, Chile, China, Eurasian Customs Union, Hong Kong, India, Japan, Korea, Malaysia, Mexico, New Zealand, Philippines, Singapore, South Africa, Taiwan and Vietnam. Tartrazine is used to provide a yellow or green (when blended with other colors such as Brilliant Blue or Green S) color to a wide variety of products, including ice cream, confectionary, pastries, cookies, beverages, snack foods, condiments, spreads, cereal, rices, noodles, and chewing gum.

The Joint FAO/WHO Joint Expert Committee on Food Additives (JECFA), which acts as the risk evaluation body for Codex Alimentarius, has evaluated the safety of Tartrazine used as a coloring agent in food and has established an acceptable daily intake (ADI) of 0-7.5 mg/kg bw per day based on the extensive toxicological information indicating Tartrazine does not possess carcinogenic potential.

In 1975 and 1984, the EU Scientific Committee for Food (SCF), evaluated the safety of Tartrazine and also established an ADI of 0-7.5 mg/kg bw per day based on the extensive toxicological information available [SCF, 1975 and 1984]. In 2009, the European Food Safety Authority (EFSA), the successor to the EU SCF and the chief risk assessment authority for food products in the EU, 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.

In the US, Tartrazine is a certified color, which means that the US Food and Drug Administration (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[1]), and established an ADI of 0-5 mg/kg bw per day for FD&C Yellow 5 (Tartrazine) based on 2-year bioassays in Charles River CD-1 mice and albino rats (CD) (in utero exposure) and a 2-year bioassay in dogs. FDA maintains the status of Tartrazine as a color subject to certification.

These bodies consider the material to be safe and as such there is no reason to disallow the use of the material in food products.

<u>Azorubine (Carmoisine) (E 122)</u>

Azorubine (Carmoisine) 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, India, Malaysia, Mexico, New Zealand, Philippines, Singapore, South Africa and Vietnam, and has previously been evaluated by JECFA in 1983 and the EU SCF in 1984. Both committees established an ADI of 0-4 mg/kg bw/day. The SCF and also the JECFA evaluations concluded, based on in vivo and in vitro studies available at that time, that Azorubine (Carmoisine) does not show any genotoxic activity.

EFSA's Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel) re-evaluated the additive in 2009 and concluded that the current available data do not provide reason to revise the established ADI of 0-4 mg/kg bw/day.

[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=74.705

Labeling - Sunset Yellow (E110) and Allura Red (E 129)

IACM feels strongly that requiring a warning label for food products containing certain food colors is not only scientifically unwarranted, but would also be confusing and unhelpful to consumers. According to the International Food Ingredient Council Foundation's 2012 Consumer Perceptions of Food Technology Survey[2], consumers are generally satisfied with information currently provided on food labels. Seventy-six percent say they cannot think of anything additional they would like to see on the label.

Both Sunset Yellow and Allura Red have been approved for use in many countries, including the US, in Europe, and internationally by JECFA. Their safety for use in food in Europe was re-affirmed as recently as 2011 for Sunset Yellow and just last year, 2013, for Allura Red. Internationally, JECFA re-evaluated Sunset Yellow in 2011 and Allura Red in 2006, and confirmed that they are both safe for use in food.

IACM takes the continuing demonstration of the safety of color additives as its top mission. We believe that the regulation of these additives that will most benefit consumers relies on sound, thorough science and risk assessment and management practices that utilize this science and consider input from all stakeholders. IACM would like to offer our assistance in providing data should a safety evaluation of color additives be planned. IACM or its predecessor organization, the Certified Color Manufacturers of America (CCMA), has sponsored a large number of metabolism, toxicology, carcinogenicity, genotoxicity, and reproductive/developmental toxicity studies, and stands ready to provide appropriate data should the GCC undertake a risk assessment prior to requiring such a stringent risk management action as requiring a warning label.

Much of the data provided by IACM have formed the robust datasets that were the basis of the evaluations of these color additives by US FDA and by JECFA. As a result of US FDA evaluations, both Sunset Yellow and Allura Red are allowed for use at levels consistent with Good Manufacturing Practices (GMP) within the United States. As a result of JECFA evaluations, full specifications and ADI levels for both of these food colorants have been established. JECFA has established an ADI of 4 mg/kg bw/day for Sunset Yellow and of 12.5 mg/kg bw/day for Allura Red.

Additionally, Sunset Yellow and Allura Red have been studied extensively to determine whether they can cause a variety of types of reactions in people who consume food containing these additives. The most thorough scientific review of this subject is contained in the textbook, Food Allergy: Adverse Reactions to Foods and Food Additives [Stevenson, 2008]. In Chapter 31 of Food Allergy, Stevenson reviews the data on both azo and non-azo dyes and finds significant inaccuracies with many of the reported studies, including overstated and excessive claims of adverse effects caused by dyes. Except for a rare patient who experiences urticaria, dermatitis and allergic vasculitis, or perhaps mild asthma, these dyes were concluded to be safe [Stevenson, 2008]. Furthermore, as recently as 2010, EFSA reviewed all reported cases and evidence related to alleged and rare instances of allergic reactions and concluded that they are unlikely to be triggered by oral consumption of food colors, including Sunset Yellow, either individually or in combination. For Allura Red, EFSA concluded that no data on sensitivity are available, and no well-documented cases of intolerance reactions after oral exposure have been

[2] http://www.foodinsight.org/Content/5438/FINAL%20Executive%20Summary%205-8-12.pdf

reported.[3]

Despite assertions to the contrary, neither Sunset Yellow nor Allura Red is carcinogenic. This has been shown in numerous scientific studies. In addition, the presence of any contaminants derived from the manufacturing process is negligible and below any level of possible concern. In the US, every batch of Sunset Yellow and Allura Red is analyzed and certified as safe for use by FDA, and this testing is conducted before the batch can be used in any product sold in the US.

Issues Related to Hyperactivity

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 of the specific color additives or the ban of Tartrazine or Azorubine/Carmoisine. However, IACM would like to briefly comment on a matter of potential significance to the use of color additives: the publication of a study that implies a link between the intake of mixtures of color additives and a small increase in hyperactive behavior in two groups of children.[4]

Regarding the McCann et al., 2007 study, two groups of young children were administered two different mixtures of artificial color additives and sodium benzoate (a commonly used food preservative) and their hyperactive behavior was evaluated using observational and testing methods. One of the mixtures contained the colorants Sunset Yellow, Azorubine/Carmoisine, Tartrazine, Ponceau 4R, and the preservative sodium benzoate. The other mixture contained Sunset Yellow, Azorubine/Carmoisine, Quinoline Yellow, Allura Red, and sodium benzoate. The authors reported that statistical analysis of the results indicated that one of the mixtures appeared to increase hyperactive behavior in a group of 3-year old children, but not in a group of 8-9-year old children. The other mixture was not reported to increase hyperactive behavior in the group of 3-year old children, but was reported to produce a small increase in hyperactive behavior in the group of 8-9-year old children. The statistical analysis suggested that, if taken collectively, hyperactive behavior in children taking the test mixture increased roughly eight percent relative to children not administered the mixtures. Additionally, the authors noted that even within those groups of children that were administered the test mixtures of artificial color additives, there were "substantial individual differences in the response of the children to the additives."

The United Kingdom Food Safety Authority requested that the EFSA review the McCann et al., 2007 study. In their evaluation, they found that the study provides only limited evidence that the two different mixtures of artificial color additives and sodium benzoate tested in the study had a small and statistically significant effect on children selected from the general population.[5] They further indicated that the effects were not statistically significant for the two mixtures in both age

[3] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the re-evaluation of Allura Red AC (E 129) as a food additive on request from the European Commission. EFSA Journal 2009; 7(11):1327. [39pp.].doi:10.2903/j.efsa.2009.1327. Available online: www.efsa.europa.eu.

[4] McCann D, Barrett A, Cooper A et al. (2007) Food additives and hyperactive behavior in 3-year-old and 8/9-year-old children in the community: a randomized, double-blinded, placebo-controlled trial. Lancet, 370, 1560-1567.

[5] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the re-evaluation of Azorubine/Carmoisine (E 122) as a food additive on request the European Commission.

groups, and that since mixtures and not individual additives were tested, it was not possible to ascribe the observed effects to any individual compounds. Finally, they indicated that the clinical significance of any reported effects remains unclear.

As a result, EFSA concluded that the study was not of sufficient significance to warrant a re-evaluation of the regulatory status of the colors tested. 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. In fact, the US government has expressed its concerns regarding EU's action to the World Trade Organization.

More recently, 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 label, 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.[6]

IACM strongly 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.

Therefore, IACM does not support specific labeling requirements for Sunset Yellow or Allura Red. As indicated above, there are only anecdotal published reports of allergic responses to these colors, and the only studies that have been reported were flawed or did not yield conclusive results. Drawing specific attention to these colors may induce undue concern about their safety. Additionally, the current labeling provisions are sufficient to assist individuals that may have general concerns about their potential sensitivity to food colors and other additives. IACM strongly believes that the rationale for any ingredient labeling requirement should be supported by strong, conclusive scientific evidence. Therefore, we believe that specific labeling requirements for Sunset Yellow and Allura Red should not move forward unless and until data are firmly established to support such a measure.

Mechanism for Addition of Colors

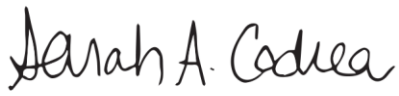
It is unclear from the proposed regulation if the GCC is considering a mechanism for the addition of colors to its positive list. In addition to the opportunity to add colors that may not already be included in the GCC regulation, innovative color manufacturers are continuing to identify new uses and new colors that will allow product manufacturers to provide consumers with a greater variety of colored products. Additionally, the color industry continues to re-evaluate approved colors to provide regulators and the public with assurance that the colors in

[6] Meeting transcript available at: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/UCM255119.pdf

use are safe. For these reasons, 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 to be automatically approved. This would allow for greater harmonization of regulations and decrease trade barriers.

We remain at your disposal to provide any additional information concerning the strong safety record of all of 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,



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