



1101 17th Street, NW • Suite 700 • Washington, DC 20036
T: 202-293-5800 E: info@iacmcolor.org
www.iacmcolor.org

May 27, 2014

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

Dear Sir:

The International Association of Color Manufacturers (IACM) is the trade association that represents the global color industry, which is comprised of manufacturers and end-users of coloring substances that are used in foods, including natural and synthetic colors. IACM appreciates the opportunity to provide the following comments and recommendations in response to the draft standard, "Additives Permitted for Use in Foodstuffs" notified by the Kingdom of Saudi Arabia under WTO SPS agreement (G/SPS/N/SAU/96).

IACM generally supports alignment with Codex standards, as we understand is the intent of the Saudi FDA in developing this standard. However, IACM is concerned that as proposed, the Standard would generate barriers to international trade.

IACM participates as a nongovernmental observer at the Codex Alimentarius Commission, particularly the Codex Committee on Food Additives (CCFA), which considers colors for inclusion in the General Standard of Food Additives (GSFA). IACM appreciates and supports that many developing countries, as well as countries that are revising their food law such as Saudi Arabia, look to Codex standards for guidance and to the GSFA as an example of a positive list of food additives. However, 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. 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 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.

There are currently 46 colors with draft and/or adopted provisions in the GSFA. Eight colors have a JECFA acceptable daily intake (ADI) of "not specified" and are listed in Table 3 of the

¹ CODEX STAN 192-1995

GSFA. 38 colors have a numerical ADI and are only listed in Tables 1 and 2 of the GSFA. There are a total of 1,895 draft and adopted provisions for colors in the GSFA. However, while there are 990 adopted provisions (973 for colors with numerical ADIs and 17 for Table 3 colors), there are 905 draft provisions (760 for colors with numerical ADIs and 145 for Table 3 colors). Those colors that have not completed the Step process for adoption are largely at Steps 4 and 7.

Provisions at Step 4 are indicative that the draft text for the provision has been prepared, circulated to member countries and all interested parties for comment. The draft and the comments are awaiting review at the Committee level before being sent to the Commission for review. Step 7 additives have already been endorsed by the Commission and agreed to be put forth for finalization and are simply awaiting finalization by the Committee.

Since the Committee has so many additives currently in the step process, the backlog is the reason for the additives, including many colors, not yet being adopted in the GSFA. Additionally, the further consideration of Step 7 color additives to be adopted has stalled as a result of the ongoing debate over Note 161, which is a procedural issue unrelated to safety. Therefore, IACM would strongly discourage Saudi Arabia from using solely the adopted provisions in the GSFA in developing its food law.

To provide some context to these numbers, if Saudi Arabia were to adopt the GSFA as a positive list, a number of colors approved via GSO 23/1998 would no longer be approved for use in the country. Additionally, colors which were previously allowed for use in GSO 23/1998 'in general' with no maximum limit will now be permitted per food category and with maximum permitted levels. We appreciate that the standard would allow for some additional colors via the proposed Annex Table 1A, but would note that the colors that would be disallowed under the proposed regulation, including but not limited to those outlined in the table below, are all approved in the US and/or EU, and have been evaluated by JECFA.

Additionally, the EU is currently re-evaluating all color additives, and as agreed at the recent CCFA meeting, JECFA will soon begin re-evaluating colors as well. So while there are no safety concerns for these or any of the colors currently approved for use in the GCC, their safety profiles will be further strengthened as a result of the EFSA and JECFA re-evaluations. Additionally, IACM would be pleased to provide studies demonstrating safety for any color additive upon request.

Gold	evaluated by JECFA in 1977
Litholrubine BK	re-evaluated by EFSA in 2010 evaluated by JECFA in 1986
Paprika	evaluated by JECFA in 2008
Saffron	evaluated by JECFA in 1985
Silver	evaluated by JECFA in 1977

Additionally, colors at Steps 4 and 7 of the GSFA would no longer be allowed, including:

Annatto extract, bixin and norbixin	evaluated by JECFA in 2006
Brilliant black PN	evaluated by JECFA in 1981 re-evaluated by EFSA in 2010
Tartrazine	evaluated by JECFA in 1964 re-evaluated by EFSA in 2009

In the draft standard, Annatto is listed only for use in butter, but it is traditionally used in a wide range of foods. JECFA evaluated Annatto in 2007, at which point it issued a revised ADI and new specifications. This has caused the need for CCFA to reconsider the draft provisions for Annatto, as is procedure. However, JECFA's concerns were not due to safety and the CCFA has not expressed that the reconsideration is due to safety concerns or anything other than procedure. Therefore, we would urge Saudi Arabia to maintain that Annatto be allowed for use generally.

Annex Table 1A lists natural colors allowed for use generally, which IACM supports. However, IACM is unclear how additives which are listed elsewhere in the proposal, such as Anthocyanins (grape skin extract), and those which are not listed elsewhere as they are currently not contained in the GSFA, such as Paprika, should be treated. We would suggest that Annex Table 1A is both clarified and expanded to indicate that colors listed in the Annex are allowed for use in foods generally, regardless of their status in the GSFA. We also note that Annex Table 1A contains two incorrect INS numbers: lycopene should be 160D, while lutein should be 161B.

Note 161

The adoption of all of the notes in the GSFA may not be appropriate for inclusion in a country or regional standard. For example, many colors have Note 161 attached, which states, "Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble." Note 161 makes little sense in the context of the GSFA, where references to national legislation should be avoided. Note 161 would also seem to make little sense for inclusion in a national legislation such as this proposal and we suggest that it be removed. We would further stress that it is the issue of Note 161 that has stalled the progress of color additive provisions moving forward within the GSFA and that we anticipate that the CCFA will turn its attention to the colors in the step process as soon as the issue is resolved.

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

The draft standard appears to add warning statements for Sunset Yellow and Allura Red. IACM feels it is inappropriate for warning statements for product labels to be included in an additives standard. If Saudi Arabia is intent on following the Codex model for its regulations, we would note that Codex has a separate Committee on Food Labeling, whose terms of reference include drafting provisions on labeling applicable to all foods; the consideration and endorsement of draft specific provisions on labeling prepared by the Codex Committees drafting standards, codes of practice and guidelines; to study specific labeling problems assigned to it; and to study

problems associated with the advertisement of food with particular reference to claims and misleading descriptions. This Committee currently maintains nine separate standards and guidelines related to labeling and has not considered the addition of warning statements for any colors as necessary for adoption into any Codex standards or the GSFA.

IACM feels strongly that requiring a warning label for food products containing certain food colors is scientifically unwarranted. Both Sunset Yellow and Allura Red have been approved for use in many countries, including the US and 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 confirmed its safety 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 Saudi Arabia 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 both domestic and international regulatory bodies. 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 colors 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. 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 reported.

Furthermore, 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.

Mechanism for Addition of Colors

It is unclear from the proposed regulation if Saudi Arabia is considering a mechanism for the adopting future versions of the GSFA and/or the addition of additives. As we stated above, IACM strongly discourages the adoption of the GSFA as a positive list as 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 safely colored products. The process for GSFA approval is too deliberate to allow for these colors to be added in a timely manner. Additionally, the color industry continues to re-evaluate approved colors to provide regulators and the public with assurance that the colors in use are safe. However, if Saudi Arabia moves forward with this regulation as proposed, 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 offer the alternative solution that since the regulation already references the EU and Codex standard that colors approved for use by either to be automatically approved. This would allow for greater harmonization of regulations and decrease trade barriers.

The proposal indicates that the regulation would be in force immediately, with a short timeline for compliance. Given the reformulations that would be necessary in order for companies to comply with the reduction in colors that would be available to import into the Saudi Arabian market if adopted as proposed, IACM strongly encourages a three year compliance period at minimum.

To conclude, IACM reiterates that the GSFA is a living document and adoption as a country's positive list would have enormous impact both on foods that would be legally available in the Saudi Arabia as well as create uncertainty in trade. IACM looks forward to further dialogue on this issue and would be happy to answer any additional questions.

Sincerely,



Sarah Codrea
Executive Director