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Food and Drug Administration – Center for Food Regulation and Research  
Department of Health  
Civic Drive, Filinvest City, Alabang 1781  
Muntinlupa, Philippines  
Via E-mail: [info@fda.gov.ph](mailto:info@fda.gov.ph)

Re: Revised Regulatory Guidelines Concerning Food Additives and Processing Aids  
WTO G/TBT/N/PHL/199

To whom it may concern,

The International Association of Color Manufacturers (IACM) is the trade association that represents the manufacturers and end-users of coloring substances that are used in foods, including natural and synthetic colors. IACM participates as a nongovernmental observer at the Codex Alimentarius Commission, including at the Codex Committee on Food Additives (CCFA), which considers colors for inclusion in the General Standard of Food Additives (GSFA).

We are writing to provide comment on the draft for comments (dated 23 May 2017) of the revised regulatory guidelines concerning food additives, and processing aids, which would cancel and replace Bureau Circular No. 2006-016 of 18 October 2006 providing an updated list of food additives accepted for use in the Republic of the Philippines. Additionally, we are providing comment on what we perceive to be an associated issue impacting the use of lake colors in the Philippines.

### **Limitations of the GSFA**

IACM appreciates and supports that many countries, such as the Philippines, that are revising their food law, look to Codex standards for guidance. However, the process for achieving adoption into the GSFA is slow and limited both by resources and time, and as such, not all additives, including many colors that are approved in countries such as the US and the EU have made it through the Codex step 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.<sup>1</sup>

There are currently more than 1,800 draft and adopted provisions for colors in the GSFA. Those colors that have not completed the Step process for adoption are largely at Steps 4 and 7. For provisions at Step 4, the draft text for the provision has been prepared and 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. A full list of pending provisions is prepared for and available as an Information Document at each CCFA meeting. The most recent version is available online.<sup>2</sup>

In reviewing the draft regulation, it appears that the Philippines is proposing to implement the tables of the GSFA consisting of only adopted additives as a positive list. If so, this proposal would result in a ban and/or restriction on many color additives that are currently approved for use in the Philippines, including amaranth, annatto extracts, azorubine, brilliant black PN, brown HT, curcumin, ponceau 4R, quinoline yellow and tartrazine, colors which are all widely approved and commonly used on a global basis, and for which a replacement may not be readily available. In fact, adopting the GSFA would leave the Philippines with limited options for approved natural and synthetic yellows in which to provide color in food categories beyond soups and broths and flavored fluid milk drinks. This limitation would also put the Philippines out of alignment with many of its trading partners, including the United States and Europe.

Most importantly, there is no scientific basis for which to reduce provisions for or ban any of these colors, particularly given that they were all recently re-evaluated and re-affirmed for their safe use by the European Food Safety Authority (EFSA) and are currently undergoing re-evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Additionally, omission of these colors from the GSFA as adopted is not due to safety concerns, but instead due to the substantial time it takes to finalize review and for completion of the step process.

Therefore, IACM maintains that there is no reason for the Philippines to disallow the use of a color or a use already approved due its position at Steps 4 or 7 (awaiting final adoption) rather than Step 8 (adopted) and strongly encourages the Philippines to continue to allow those colors evaluated by JECFA and determined to be safe with provisions pending adoption, particularly as they are currently allowed in the Philippines and there is no indication that the Philippines is concerned about the safety of these colors. Adoption of color provisions at Steps 4 and 7 would also allow for a much broader spectrum of yellow colors,

In reviewing the regulation, which states that the latest Codex GSFA and its future revisions/amendments/updates shall be adopted automatically but that requests or proposals for new and/or revision of food additives provisions in the GSFA shall follow the Codex procedure for consideration for the entry and review of food additives provisions in the GSFA, it is unclear whether such a mechanism would exist in this proposal, or if achieving adoption into the Codex GSFA through the Codex procedure is the only avenue for approval in the Philippines.

IACM would also encourage the Philippines to include a mechanism for the adoption of new

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<sup>1</sup> CODEX STAN 192-1995

<sup>2</sup> [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FX-711-49%252FINF%252Ffa49\\_info\\_01e.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FX-711-49%252FINF%252Ffa49_info_01e.pdf)

additives that may not yet be adopted into the GSFA. As indicated previously, the process from proposing a new additive into the GSFA takes time, due to competing priorities for the GSFA working group and the CCFA. Once an additive has been reviewed by JECFA and an acceptable daily intake (ADI) has been established, or conversely, JECFA considers the additive having an ADI of “not specified” indicating it will be added to Table 3 of the GSFA, it should be viable for consideration by the Philippines FDA.

### **Restriction of Lakes**

Additionally, it has recently come to our attention that the allowance of aluminum lakes of colors is being restricted in the Philippines due to the incorrect perception that lakes are not allowed under the Codex GSFA and concerns about exposure. As you may know, lake is the term for pigments for food made by extending water-soluble dyes onto a substrate of alumina hydrate, which results “in a water-insoluble colo[u]r which has advantages for use in e.g. food products containing oils and fats, or products lacking sufficient moisture to dissolve the water-soluble colo[u]rs”, such as coatings.<sup>3</sup> The EFSA opinion on the safety of aluminum from dietary intake goes on to note that “aluminium lakes are used at a level up to 950 mg/kg in confectionery and fine bakery wares mostly in decorations, icing, coatings and fillings.”

There are no separate provisions for aluminum lakes of colors in the GSFA as lakes do not have separate INS numbers from straight colors, but aluminum lakes are considered in the definition of color additives in JECFA color specifications (“May be converted to the corresponding aluminum lake in which case only the General Specifications for Aluminium Lakes of Colouring Matters applies.”<sup>4</sup>) and therefore the GSFA provisions for the associated straight color include their corresponding aluminum lakes under the same INS number. There is no need for lakes to be listed separately in the GSFA, and to do so would cause confusion since the ADI for a color considers and covers combined uses of both lakes and straight dye. This is also the reason that exposure assessments do not separately review lakes from their straight color component.

IACM understands the Philippines may have concerns of excessive aluminum exposure. IACM members appreciate and share these concerns. In fact, there was a discussion on aluminum exposure at the CCFA that took place about five years ago in the context of potential safety concerns due to high exposure to aluminum from a variety of sources. However, since that time, refined assessments submitted to JECFA found that combined average consumer intakes of aluminum in Australia, Europe, US, and other countries are below the established provisional tolerable weekly intake (PTWI). Any instances of exceedance of the PTWI have consistently been shown to be a result from other specific functions of aluminum additives that are unrelated to applications of color lakes. To reduce exposure to aluminum, the Philippines would be advised to look at major sources of aluminum exposure such as sodium aluminosilicate (INS 554), found in cereals and related products, and which has been demonstrated to contribute a significant percentage of a country’s reported aluminum exposure. In fact, the CCFA recommended that the provisions for INS 554 be revoked after this review.<sup>5</sup> EFSA’s opinion also reviewed the various routes of exposure to aluminum and concluded that it is not possible to

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<sup>3</sup> Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials on a request from European Commission on Safety of aluminium from dietary intake. The EFSA Journal (2008) 754, 1-34

<sup>4</sup> [http://apps.who.int/iris/bitstream/10665/44788/1/WHO\\_TRS\\_966\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44788/1/WHO_TRS_966_eng.pdf)

<sup>5</sup> CX/FA 13/45/8 of December 2012; Codex Committee on Food Additive, Forty-fifth session; Recommendations for Provisions for Aluminium Containing Food Additives of the GSFA.

distinguish between the specific sources of aluminum, which is also naturally occurring in food and drinking water. In comparison, exposure to aluminum by color lakes is minimal at best and limiting their use in the Philippines will do little to address concerns with aluminum exposure.

In addition, the industry has conducted safety studies including a bioavailability study,<sup>6</sup> which showed miniscule bioavailability (absorption), while another study<sup>7</sup> showed absence of neurological effects. Upon review of all safety data, JECFA does not have any remaining safety concerns as long as “provisions for food additives containing aluminum included in the Codex General Standard for Food Additives should be compatible with the revised PTWI for aluminum compounds of 2 mg/kg body weight as aluminum from all sources.”<sup>8</sup> Additionally, as described above, exposure to lakes is self-limiting, as there are only certain types of food products, such as confectionary frostings and coatings, where use of a lake is preferred over a dye. Additionally, as lakes are more expensive for manufacturers to produce, they are only used in applications where it is necessary to do so to achieve the appropriate technological effect.

EFSA has taken this model in its recent assessment of lakes and has set forth specific colors which may be used in the form of lakes, as well as specific food categories and corresponding aluminum maximum limits, in Commission Regulation (EU) No 380/2012 of 3 May 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use levels for aluminum-containing food additives. As EFSA maintains a tolerable weekly intake (TWI) for aluminum of 1 mg/kg body weight/week, then following this model would ensure that the Philippines would not exceed JECFA's PTWI.

To conclude, lakes are not listed as separate additives in the GSFA for the reasons outlined above. However, they are considered safe by JECFA, if total exposure (from all food sources) falls within the PTWI of 2 mg/kg for aluminum that was established at the 74th JECFA in 2011. The contribution of color lakes to aluminum exposure is very low relative to other contributors of aluminum intake. Via the specifications set by JECFA for aluminum lakes of coloring matters and the reference to lakes in the associated straight color specifications, lakes are not in fact excluded from the GSFA, nor is their use banned by countries implementing the GSFA to regulate food additives.

We appreciate the opportunity to provide comment and remain at your disposal for further discussion on the matters raised in our letter.

Sincerely,



Sarah Codrea  
Executive Director

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<sup>6</sup> Priest, N. (2010) The Bioavailability of Ingested Al-26 Labelled Aluminium and Aluminium Compounds in the Rat: FD&C Red No. 40. GNP-121100-REPT-001, Unpublished report to the International Association of Color Manufacturers.

<sup>7</sup> Pennington, J.A., and Schoen, S.A. 1995. Estimates of dietary exposure to aluminium. *Food Addit. Contam.* 12:119-128.

<sup>8</sup> <http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=6179>