



April 10, 2009

International Trade and Cooperation Team
Korea Food and Drug Administration
#194 Tongilro, Eunpyeong-gu
122-704, Seoul Korea
Email: wtokfda@kfda.go.kr

RE: Proposed Draft Standards for Quality Certification of Children's Favorite Food, G/SPS/N/KOR/315

Proposed Amendments to Standards and Specifications for Food Additives, G/SPS/N/KOR/316

Dear Sir or Madam:

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 artificial colors. We are writing to you to offer further information and to express our concerns related to the draft notifications referenced above that propose to ban the use of a number of specific food colorants and their aluminum lakes in food categories that are commonly consumed by children.

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. Prohibiting the use of this important class of food colorants would have a detrimental effect upon many segments of the food industry. Similarly, aluminum lakes of these colors have unique applications that can not be replaced given current technology.

IACM takes the continuing demonstration of the safety of food color additives as its top mission, and we believe that the regulation of food colors that is of most benefit to

consumers relies on sound, thorough science and risk assessment and management practices that utilize this science and consider input from all stakeholders.

In considering the draft notification G/SPS/N/KOR/315 and G/SPS/N/KOR/316, IACM has concerns that no risk assessment has been carried out. As IACM understands it, such risk assessments are required by the World Trade Organization Sanitary and Phytosanitary (SPS) Measures Agreement.¹ Such a risk assessment would also be consistent with international harmonization practices through the Codex Alimentarius.

IACM would like to offer our assistance in providing data to the KFDA should a safety evaluation of colors 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 on many of these colors, and stands ready to provide the KFDA with appropriate data should the required risk assessment be planned.

Much of this data has formed the robust datasets that were the basis of the evaluations of these colors by the US FDA and by the World Health Organization/United Nations Food and Agriculture Organization Joint Expert Committee on Food Additives, which acts as the risk assessment body for the Codex Alimentarius. As a result of the US FDA evaluations, 7 of these colors and their aluminum lakes are allowed for use at levels consistent with Good Manufacturing Practices (GMP) within the United States. As a result of the JECFA evaluations, full specifications for each of the food colorants listed within the draft notifications referenced above have been established and, where appropriate, acceptable daily intake (ADI) levels have been established. The JECFA evaluations have also led to the development of food additive provisions within the Codex General Standard for Food Additives for many of the cited food colorants and in several different food categories.

As mentioned above, IACM is unaware at this time of any specific, new risk assessments that have been conducted that have formed the basis for the proposed prohibition of the cited food colors. However, IACM would like to briefly comment on two matters of potential significance to the use of food colorants. The first is the recent JECFA evaluation of aluminum (all sources), and the second is the publication of a study that implies a link between the intake of mixtures of food colors and a small increase in hyperactive behavior in two groups of children.²

Regarding aluminum, JECFA evaluated the available data for aluminum (from all sources), and concluded that additional studies were required to support its safe use. As a result, JECFA established a provisional tolerable weekly intake (PTWI) of 1 mg/kg bw, and requested additional data to support the safety of aluminum. In response, several groups, including IACM, are supporting additional studies on aluminum salts and aluminum-containing food additives. IACM, in particular, has sponsored a bioavailability study that will support the safety of aluminum lakes. All of the newly collected data will

¹ The SPS Agreement requires members to “base their sanitary or phytosanitary measures on international standards...where they exist.” (WTO SPS Measures Agreement, Article 3).

² McCann D, Barrett A, Cooper A et al. (2007) Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomized, double-blinded, placebo-controlled trial. *Lancet*, 370, 1560-1567.

be supplied to JECFA, and IACM anticipates that JECFA will re-evaluate aluminum (all sources) in 2011. In the interim, IACM would consider it premature to invoke specific prohibitions on any aluminum-containing food additives.

Regarding the McCann et al. study, two groups of young children were administered two different mixtures of artificial colors 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 FCF, Carmoisine, Tartrazine, Ponceau 4r, and the preservative sodium benzoate. The other mixture contained Sunset Yellow FCF, Carmoisine, Quinoline Yellow, Allura Red AC, 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 8% 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 colors, there were "substantial individual differences in the response of the children to the additives."

The United Kingdom Food Safety Authority requested that the European Food Safety Authority (EFSA), the chief regulatory authority for food products in the EU, review the McCann et al., study. In their evaluation, they found that the study provides only limited evidence that the two different mixtures of synthetic colors and sodium benzoate tested in the study had a small and statistically significant effect on children selected from the general population. They further indicated that the effects were not statistically significant for the two mixtures in both age 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.

In addition to the EFSA evaluation of the McCann et al., study, Food Standards Australia New Zealand (FSANZ) has carried out a preliminary evaluation of this work.³ FSANZ agreed with the EFSA opinion of the study, and further suggested that they had no concerns based on an intake study that was recently completed in Australia and which found that the use of food colorants resulted, in general, in intakes that were significantly below the JECFA-established ADIs.

IACM strongly asserts that the results of the McCann et al., study do not provide support for a ban on food colors. As the authors of the 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.

³ <http://www.foodstandards.gov.au/newsroom/factsheets/factsheets2008/effectsofartificialc3893.cfm>

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

IACM thanks you for considering these comments.

Sincerely,

Sean Taylor
Scientific Director
International Association of Color Manufacturers