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May 9, 2011

RE: Customs Union proposed warning labeling of specific colors in food products

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 regulation that includes a warning labeling requirement for color additives azorubine E122, yellow quinolinic E104, yellow "sundawn" FCF E110, red charming AC E129, ponseau 4R E124 and tartazine in food products. As we understand it, the proposal would require these food products to contain a label stating, "May cause negative influence to children activity and attention."

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 *2010 Consumer Perceptions of Food Technology Survey* the vast majority of surveyed consumers (82 percent) cannot think of any additional information they would like to see included on food labels that is not already required. Of the 18 percent who would like additional information, only one-fifth of those (or about 27 people) mention food ingredients in general, and none mention food colors specifically.

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 to the Customs Union 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 on many of these color additives, and stands ready to provide the Customs Union with appropriate data should the Customs Union undertake a risk assessment prior to requiring such a stringent risk management action.

Much of the data provided by IACM has formed the robust datasets that were the basis of the evaluations of these color additives by the US Food and Drug Administration and by the World Health Organization/United Nations Food and Agriculture Organization Joint Expert Committee on Food Additives (JECFA), which acts as the risk assessment body for the Codex Alimentarius. As a result of the US FDA evaluations, seven of these color additives 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.

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. However, IACM would like to briefly comment on a matter of potential significance to the use of color additives: the publication of a study (McCann et al., 2007) that implies a link between the intake of mixtures of color additives and a small increase in hyperactive behavior in two groups of children.[1]

Regarding the McCann et al. 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 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 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 European Food Safety Authority (EFSA), the chief risk assessment 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 artificial color additives 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. 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 Food and Drug Administration convened a two-day meeting of an independent Food Advisory Committee (FAC) 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

[1] 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.

there was no causal relationship between the intake of artificial color additives and hyperactive behavior.[2]

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 artificial 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. We therefore urge the Customs Union to base its regulations on sound science and reconsider its proposed warning label on colors in food products.

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.

IACM thanks you for considering these comments.

Sincerely,

John H. Cox
Acting Executive Director
International Association of Color Manufacturers

[2] The full FDA response and transcripts of this meeting are not yet available. In the interim, preliminary minutes are now available at:
http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/ucm250901.htm