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March 7, 2016

Dear Sen. Costello,

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 food, drugs, and cosmetics, including natural and synthetic colors. We are writing to you to oppose Senate Bill 199 and offer supporting information related to the intake of synthetic colors and the lack of strong scientific evidence of the need for a warning label.

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 feels strongly that requiring a warning label for food products in the state of Alaska containing FD&C colors is not only scientifically unwarranted, but would also be confusing and unhelpful to consumers, while cost prohibitive for food manufacturers wishing to do business in your state.

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 previous publications that Senator Wielechowski may be erroneously referencing to inform this proposed legislation.

IACM dismisses claims from a recent Center for Science in Public Interest (CSPI) report on FD&C colors as unfounded. The report offers no new information about the safety of FD&C colors and draws uninformed conclusions. The report also fails to provide any grounds that current levels are excessive relative to an objective measure against which it should be compared, even though such a measure, the Acceptable Daily Intake (ADI), does exist and stands well above all estimates of consumer intake. Its claims linking synthetic colors with possible negative health or behavior effects are not based on sound enough science to justify blanket changes to the rules governing how manufacturers can incorporate and label these colors in food and beverage products. IACM's position is supported by data that show that daily intake for the average person, including children, is far, far below the established conservative ADIs for safe consumption. The CSPI report stands in contrast to the collective scientific expert judgment and assessment of color safety by U.S., European and other international authoritative bodies, selectively ignoring scientific expert opinion.

You may also be aware of the McCann et al. study¹ published in 2007, in which two groups of young children were administered two different mixtures of synthetic colors and sodium benzoate (a commonly used food preservative) and their hyperactive behavior was evaluated using observational and behavior testing methods. 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

¹ McCann D, Barrett A, Cooper C, Crumpler D, Dalen L, Grimshaw K, Kitchin E, Lok K, Porteous L, Prince E, Sonuga-Barke E, O'Warner J, Stevenson J, 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. *The Lancet*, 370(9598), 1560-1567.

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 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 synthetic colors, there were “substantial individual differences in the response of the children to the additives.”

In the UK, where the McCann et al. study originated, consumer advocacy groups lobbied the Food Standards Agency (FSA) to enact a partial or total ban on all synthetic colors, and as a consequence, the UK FSA requested that the European Food Standards Agency (EFSA) Panel on Food Additives review the study and provide their expert opinion. In EFSA’s evaluation,² they found that the study provides only limited evidence that the two different mixtures of 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. EFSA did not comment on or propose a warning label. 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 or on the opinion of EFSA, but instead on a political decision taken by members of the European Parliament who chose to forsake the EFSA opinion of the safety of the colors. 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 McCann et al. study, but all earlier studies that asserted a link between consumption of FD&C 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 FD&C color additives and hyperactive behavior in children.³

Additionally, FD&C colors approved for use in the US 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

² EFSA (European Food Safety Authority), 2008a. Assessment of the results of the study by McCann *et al.* (2007) on the effect of some colours and sodium benzoate on children’s behaviour. Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC). Adopted on 7 March 2008. The EFSA Journal, 660, 1-54.

³ United States Food and Drug Administration (US FDA), 2011. Background Document for the Food Advisory Committee: Certified Color Additives in Food and Possible Association with Attention Deficit Hyperactivity Disorder in Children. FDA/CFSAN Meeting, March 30-31.

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 either individually or in combination.

Furthermore, none of the FD&C colors approved for use in the US are 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 FD&C color 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.

We would like to stress again that the conclusions of the McCann et al. study have not been corroborated further. Our industry has sponsored numerous safety studies, the results of which have been evaluated by FDA and international regulatory bodies. In fact, IACM has just completed an exposure study conducted with an independent expert organization, using actual FD&C color use level data from color manufacturers and users in our membership, and will publish the findings, which confirm that children exposure to FD&C colors is well below established ADIs, later this year. These studies confirm the safety of colors that have been approved for use in food in the US, the EU and elsewhere. We feel strongly that added colors play an important role in food, and they do so without posing a health risk to consumers.

To conclude, it is important to note that there has been no scientific indication of a causal association between the intake of color additives and hyperactive behavior. Simply put, consumers, including children, are not in any way at risk from the presence of color additives in foods and therefore a warning label is completely unnecessary. These color additives have been legally and safely used in the global market for many years. In addition, the industry's core objective is to ensure that their color additive ingredients are safe for consumption, and as such, follow extensive safety assessment processes that are respected internationally.

IACM feels strongly that governments, including the state of Alaska, should make regulatory decisions based on sound science, rather than respond to an emotionally charged public that may not understand the implication and unintended consequences resulting from such a decision. For this reason, warning statements for synthetic colors are not used in geographies that consider sound science in the development of policy, such as the United States, Canada, Australia, New Zealand, China or Japan.

We remain at your disposal to provide any additional information concerning the strong safety record of all of the color products sold by our member companies, including the scientific evidence that our colors are safe.

Sincerely,



Sarah Codrea
Executive Director

CC: Sen. Wielechowski