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FD&C Colors Are Safe: The International Association of Color Manufacturers (IACM) Position on Claims of a Link between the Intake of FD&C Food Colors and Hyperactive Behavior in Children

The color industry takes its responsibility for consumer safety seriously. In addition to complying with the US Food and Drug Administration (FDA) regulations for certification of colors, the industry has sponsored many safety studies, the results of which have been evaluated by the FDA and international regulatory bodies, including the Joint Expert Committee on Food Additives (JECFA) and the European Food Standards Agency (EFSA). These studies confirm the safety of FD&C colors, and as a result various coloring dyes have been approved for use in food, beverage, and other products in the U.S., the EU and elsewhere.

A petition to the FDA has been filed by the Center for Science in the Public Interest requesting that they revoke the approval of 8 FD&C food colors. CSPI has also requested that until approval of these food colors is revoked, a warning label be placed on food and beverage products containing these food colors. Finally, CSPI sent a letter to Rosa DeLauro (D-CT, Chairperson of the Agriculture-FDA Appropriations Subcommittee). In this letter, CSPI makes a number of requests, including the launching of an investigation, hearings, and federal funding for additional studies. They base their requests upon two published studies¹ that contend that there is a link between the intake of synthetic food colors and hyperactive behavior in children.

The scientific evidence does not support the petition submitted to the FDA. Reviews of several hyperactivity/synthetic food color studies have been conducted by US experts and by international regulatory bodies, and they have concluded that there is no correlation between the intake of synthetic food colors and hyperactivity among children.

Most recently, the European Food Safety Authority (EFSA), the chief regulatory authority for food products in the EU, reviewed the main study (McCann et al., 2007) upon which the CSPI bases their request, and they found that it 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 their initial public response to the CSPI actions, the FDA has indicated that they reviewed one of the studies that is cited in the petition, and the data did not provide sufficient cause to change the FDA conclusions that FD&C colors are safe for the general population. Further, the FDA supported the conclusions reached by EFSA in their review of the McCann et al., study. As a result, the FDA has not changed their current guidance statement on any relationship between synthetic food colors and hyperactive behavior. In essence, this guidance statement indicates that there is no correlation between the intake of synthetic food colors and childhood hyperactivity².

The data demonstrates that FD&C colors are safe for consumption.

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¹ (a) 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; (b) Schab D, Trinh N. (2004) Do Artificial Food Colors Promote Hyperactivity in Children with Hyperactive Syndromes? A Meta-Analysis of Double-Blind Placebo-Controlled Trials. *J Dev Behav Pediatr*. 25, 423-434.

² <http://www.cfsan.fda.gov/~dms/foodic.html#qa>.