Color additive manufacturers pleased with FDA's 14-day exposure study

By Stephen Clapp

Published: September 21, 2015 08:05 PM

The Washington, D.C.-based International Association of Color Manufacturers (IACM) is pleased with FDA's latest findings that all exposure estimates for seven FD&C colors are well below the acceptable daily intake (ADI) levels previously identified by the agency.

However, consumer advocates find small comfort in FDA's studies, which they say are based on ADIs established a long time ago and irrelevant to current concerns.

FDA last year unveiled an exposure assessment of the FD&C color additives using data from the analysis of approximately 600 representative food products and two-day food consumption data from the 2007-2010 National Health and Nutrition Examination Survey (NHANES).

However, the use of two-day food consumption data to assess chronic exposure "can lead to an overestimation of exposure, especially for foods that are not commonly consumed," IACM says on Sept. 17. "For this reason, data collected from a longer survey are considered to be more representative of actual consumption patterns in the U.S. The dietary exposure to FD&C color additives has been updated using 10-14 day food consumption data."

The trade association says data from the 10-14 day study "show that an adult or child would need to consume anywhere from 10 to 100 times or more of the estimated daily intake to reach the ADI level in their diet." FDA unveiled its **findings** during a poster presentation at the American Chemical Society's annual meeting, in Boston, late last month.

"FDA's findings confirm our long-held belief that colors added to foods and beverages are safe and used at levels well below previously determined acceptable levels," comments Sarah Codrea, IACM executive director. "The bottom line is the FDA agrees these ingredients are used at such small levels that they do not pose a threat to consumer health. We look forward to a comprehensive review of the FDA's findings when they are published in a peer-reviewed journal next year."

IACM says it plans to publish findings from its own exposure study using actual FD&C color use level data from color manufacturers and users in its membership.

CSPI keeps aim at color additives

Color additives have become a lightning rod for some critics in recent years. A 2007 study at Southampton (UK) University study found behavioral changes in children exposed to a mixture of dyes plus the preservative sodium benzoate.

In 2009, the European Union adopted legislation requiring a label warning on foods using the color dyes, stating that they "may have an adverse effect on activity and attention in children."

Responding to the Southampton study, the Washington, D.C.-based Center for Science in the Public Interest (CSPI) in 2008 submitted a citizen petition asking FDA to ban eight of the nine certified color additives allowed for use in food, as well as requested that warning labels be placed on food containing these color additives until FDA makes a final decision to ban these color additives.

FDA convened a Food Advisory Committee (FAC) meeting in March 2011 to consider the available relevant data on the possible association between children's consumption of these color additives in food and hyperactivity or other behavioral effects.

The FAC concluded a causal link between children's consumption of FD&C color additives and behavioral effects had not been established, and a warning label was unnecessary to ensure safe use of the color additives. However, the advisory committee recommended further research, including a comprehensive exposure assessment for these color additives, especially for children.

Lisa Lefferts, CSPI senior scientist, told *Food Chemical News* that some children can respond to very small doses of a single color additive or mixtures of several colors. "For children who consume a lot of dyed foods, the estimate of the amount of Red 40 alone exceeds the amount of total dyes sufficient to trigger hyperactivity and other adverse effects on behavior in some studies," she commented last year in response to FDA's two-day food consumption study. "The FDA is failing kids and parents by allowing the use of these purely cosmetic chemicals in food, which trigger behavioral problems in some children, as even FDA conceded in 2011," she said.