Color additive manufacturers pleased with FDA exposure study

By **Stephen Clapp**
Published: August 27, 2014 10:42 PM

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

FDA earlier this month unveiled results of a color additive exposure study in a poster displayed at the American Chemical Society's annual meeting in San Francisco. All exposure estimates for seven controversial synthetic organic dyes used as color additives "are well below the acceptable intake levels established by FDA," the agency concludes in a poster titled "Exposure Estimate for FD&C Colors for the U.S. Population."

The seven additives include FD&C Blue No. 1, Blue No. 2, Green No. 3, Red No. 3, Red No. 40, Yellow No. 5 and Yellow No. 6. They first came to international attention in a Southampton (UK) University study in 2007 that 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."

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

Responding to CSPI's petition, FDA convened its Food Advisory Committee (FAC) 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 that a causal link between children's consumption of FD&C color additives and behavioral effects hadn't 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.

FDA then conducted a robust exposure assessment of the FD&C colors approved for general use in food. Foods that contain the colors were identified, grouped into broad food categories, and then matched with food codes from the combined 2007-2010 National Health and Nutrition Examination Survey (NHANES).

FDA says the levels of FD&C color additives in over 580 foods were determined using a high performance liquid chromatography (HPLC) method developed by FDA's Office of Cosmetics and Colors (OCAC). Dietary exposures from the use of each FD&C color additive in food were estimated for the U.S. population aged 2 years or more, children aged 2-5 years, and teenage boys aged 13-18 years.

IACM looks forward to 14-day study

IACM notes that FDA also plans to estimate exposure using 14-day food consumption data as well as reassessing the safety studies conducted on FD&C color additives to determine if additional safety studies are needed before issuing a publication in a peer reviewed journal early next year.

“We are pleased that FDA has undertaken such a comprehensive study on FD&C colors additives and confirmed that exposure to these colors is well below the acceptable daily intake levels,” says Sarah Codrea, IACM executive director, in a news release yesterday. “This work, in combination with recent work undertaken by the European Food Safety Authority (EFSA) also finding that consumer exposure estimates are well below acceptable daily intake levels, reinforces our industry’s view that when used at the levels needed to achieve an appropriate technical effect, these colors do not pose safety concerns.”

“We also look forward to hearing more on the results and FDA’s next steps from FDA chemist Diana Doell, Ph.D., who will be presenting on this topic at IACM’s upcoming Global Color Conference in Chicago, IL,” adds Codrea.