

## Europe reaffirms food dye safety ahead of FDA study

By HELENA BOTTEMILLER EVICH | 7/29/14 1:44 PM EDT

Just as the FDA is about to release a look at how much food dye Americans are consuming, European food safety officials are reaffirming the safety of several controversial synthetic chemicals used to make fruit snacks, sports drinks and cereals pop with bright colors.

Next month, FDA scientists are expected to present a summary of a new exposure assessment on color additives used in the U.S. at the American Chemistry Society meeting in San Francisco.

Concern had been growing for some time that certain synthetic food dyes might be contributing to hyperactivity in children. But in 2011, when FDA had an advisory committee look at the issue, it didn't find sufficient evidence linking food dyes to hyperactivity and recommended more research, including a comprehensive updated exposure assessment. To tackle that, FDA scientists determined the levels of colors in hundreds of different foods and then calculated dietary exposures for a number of age groups and subpopulations, especially children, based on an abstract of the research.

Asked about the new exposure assessment, an FDA spokesperson noted that the agency "carefully assesses color additives proposed for use in food to ensure they are safe for human consumption" and reiterated the findings of the 2011 Food Advisory Committee.

A first look at the results of the new assessment is set to be presented during a poster session Aug. 13.

Meanwhile, one of the major drivers of concern — Europe — has been turning down the alarms over some food colors in recent weeks, even boosting the consumption levels it deems safe in at least one case.

Since 2007, when a study out of the University of Southampton linked them to exacerbating hyperactive behavior in children, six food dyes have been the subject of much concern in Europe: Allura Red (Red 40), Ponceau, Tartrazine (Yellow 5), Sunset Yellow (Yellow 6), Quinoline Yellow and Carmoisine.

Unlike in the United States, products in Europe that carry these colors, collectively known as the Southampton Six, must include the warning label: "may have an adverse effect on activity and attention in children."

But there are signs the tide may be turning on safety concerns. Two weeks ago, the European Food Safety Authority's Panel on Food Additives and Nutrient Sources Added to Food (ANS) released its long-anticipated review of the safety of ubiquitous Yellow 6 and raised the acceptable daily intake (ADI) to 4 milligrams/kilograms of body weight per day.

The move was particularly significant because the ADI for Yellow 6 — used across the globe to color a range of food products from Kraft Macaroni & Cheese to Skittles — had in 2009 been lowered by EFSA to 1 mg/kg of body weight.

The International Association of Color Manufacturers, whose membership includes ingredient suppliers and manufacturers such as Hershey, Kraft Foods and Coca-Cola, welcomed the news.

“EFSA's exposure estimates also provide a strong indication that the consumer exposure to this color is not high, and this is strong evidence that our member companies use colors only at the levels needed to achieve an appropriate technical effect,” said Sarah Codrea, executive director of IACM, in an announcement applauding the report.

IACM noted that EFSA raised the ADI after reviewing more data, some of which was submitted by the association.

Then late last week, EFSA released an updated scientific opinion on Indigo Carmine, known in the U.S. as Blue 2, confirming the safety of the current ADI of 5 mg/kg of body weight per day. The color, which is not part of the Southampton Six, is used by manufacturers in such products as Froot Loops, where eye-popping colors are key.

The two recent reports, for Yellow 6 and Blue 2, follow a handful of others released by EFSA in the past few years, including those for Amaranth (Red 2) and Allura Red. The EFSA panel released a scientific assessment for Red 40 in June 2013 that maintained its ADI of 7 mg/kg of body weight but also called for more science to clear up some uncertainties.

“EFSA recommends that new tests be carried out to address uncertainties related to the possible genotoxicity (that is, the ability of a substance to damage DNA, the genetic materials of cells) of Allura Red AC,” the agency said at the time. “This recommendation applies to the so-called ‘sulphonated mono azo dyes,’ a group of six chemically-related food colours including Allura Red AC. Based on the results, EFSA's experts will, if necessary, reconsider existing ADIs for these substances.”

But even with the reports from EFSA, IACM isn't under any illusion that the results are going to rescind the requirement for warning labels.

“This isn't going to change that,” Codrea noted.

The reassessments are also not likely to dampen concerns raised by consumer and health advocacy groups like the Center for Science in the Public Interest.

“As on other issues, EFSA is sticking its head in sand when it ignores problems with food ingredients,” said Michael Jacobson, executive director of CSPI, in an email when asked about EFSA’s safety assessments. “The European Parliament, which appears to have a more cautious attitude regarding health concerns, requires a notice on most packaged foods that contain dyes warning consumers that dyes trigger hyperactivity in sensitive children.

“Yes, parents should protect their children, especially ones with ADHD, from synthetic food dyes,” Jacobson added.

But color manufacturers and users are still very pleased that EFSA is revisiting the science and largely affirming their view that synthetic colors used appropriately do not pose safety concerns for consumers of brightly colored foods.

“There have been a lot of concerns raised about the safety of these colors,” Codrea said. “We’re pleased that, in reviewing new and existing information, they’ve either reinstated the pre-existing ADI or raised the ADI.”

In other words, EFSA is “not concerned about exposure,” said Codrea.

“It’s important to our members that [the colors] are considered safe,” she said, noting that color additives “have been so thoroughly studied.”