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### IACM rejects new study's concerns about blue food coloring

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A new study that questions the safety of a blue food coloring approved for use in the U.S. since the 1920s is "misleading" and "unnecessarily alarming," the International Association of Color Manufacturers asserts.

Published in the November issue of the journal *Food and Chemical Toxicology*, the study, led by Marianna Lucova and a team of three researchers with the Slovak University of Technology, in Bratislava, Slovakia, suggests that children who spend any length of time sucking on lollipops that are colored with either Brilliant Blue (also known in the U.S. as FD&C Blue No. 1) or Patent Blue V (which is not approved for use in food in the U.S.) could suffer from refractory shock, metabolic acidosis or death. An abstract of the study is available at <http://1.usa.gov/SzPejG>.

The longer a dye is present on the skin, the more of it might seep into the bloodstream, Lucova and her team advise. So, in addition to examining how much dye was absorbed by shaved and unshaved skin, as shaved skin might be more permeable than unshaved skin, Lucova and her team exposed slices of pig tongue to the blue dyes for 20 minutes, to approximate the amount of time a child might spend licking a lollipop. They then examined how long the blue color remained on the tongue samples.

The team found 65% of the pig tongue cells exposed to Brilliant Blue retained the coloring after 20 minutes, and 27% remained on the cells after 24 hours. After 20 minutes, 72% of the cells exposed to Patent Blue retained the blue color, decreasing to 25% after 24 hours.

The researchers note that "relatively small portions of dyes reached viable layers [of the] deeper epithelium," but the amount of the dyes present in the tongues was within the average daily intake (ADI) limits approved by the European Food Safety Authority and the Joint FAO/WHO Expert Committee on Food Additives (JECFA), of 10 milligrams per kilogram of body weight daily (mg/kg bw/day). An ADI has not been established for Patent Blue by JECFA, but the EU approves its use in food at a weight of up to 15 mg/kg bw/day.

"Both dyes have the potential to enter the bloodstream from the saliva through the dorsum of the tongue," Lucova and her team say. "This finding is troubling, particularly with regard to the repeated licking of lollipops by children. Taken together, the results suggested that due to the possible adverse health effects of (Brilliant Blue and Patent Blue) for the people, both dyes should not be used in topical products, which are primarily intended for tongue and slightly damaged skin."

But IACM, a Washington, D.C.-based trade association representing color manufacturers, insists that FD&C Blue No. 1, as it is known in the U.S., is safe, and has been considered safe by the FDA since 1929.

"Brilliant Blue has been evaluated extensively for toxicity including life-long studies in laboratory animals in which no adverse effects were identified at doses exceeding 1,000 mg/kg bw/day," the group says in a two-page statement released Jan. 10. "Similar studies have established that Brilliant Blue is non-carcinogenic. In evaluating claims of potential toxicity, it is critical to note how the intake levels at which adverse effects are reported compared to the levels indicated in the published article by Lucova *et al.*"

The researchers admit only small amounts of the dye reached deeper layers of skin, and the dyes are excreted in the feces "because the gastrointestinal permeability in healthy subjects is limited; only less than 5% of these dyes is absorbed systemically and then excreted in bile or urine," IACM notes. "In essence, less than 0.1% of an applied dose of Brilliant Blue on the tongue was able to penetrate to a deeper than surface level and thus the absorption of Brilliant Blue during its brief presence in the mouth when used in certain foods makes a miniscule contribution to the overall typical consumer absorption."

"Even under the conservative exposure scenario presented in the article, the amount of dye that can possibly permeate the surface is negligible compared to the levels which have been

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consistently established as safe in a large number of scientific studies to date, and many orders of magnitude below the established and proposed ADI level," IACM says. -- A. Healy



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