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IACM Finds Lucova Study Misleading and Unnecessarily Alarming

In response to a recently published study that asserts that the use of FD&C Blue No. 1 in candy could result in increased absorption of the dye (Lucova et al. 2013), the International Association of Color Manufacturers (IACM) reaffirms the safety of FDA-certified color additive FD&C Blue No. 1, also known as Brilliant Blue when not certified, and reassures consumers that all food color additives are safe and well-tested.

Brilliant Blue has a long history of safe use in the US, Europe and elsewhere. The color is approved for use in more than 50 countries throughout the world, and has been used in foods in the US since 1929. The US Food and Drug Administration (FDA) permanently listed FD&C Blue No. 1 in 1969 and numerous studies have continuously reaffirmed the safety of this color additive.

The acceptable daily intake (ADI) established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) since 1969 is 12 mg/kg bw/day, while in 2010 the European Food Safety Authority (EFSA) confirmed the safety of Brilliant Blue and established an ADI of 6 mg/kg bw/day. These values are consistent between jurisdictions, and have been considered satisfactorily protective of human health to date.

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. 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.

Based on scientific assessment of the data presented in the Lucova article, any amount absorbed from lollipops is at least 3,600 times below the ADI established by EFSA. Furthermore, by the authors' own admission, "relatively small portions of dyes reached viable layers [of the] deeper epithelium," and as the author's note, "after receiving a diet, the majority of BB [Brilliant Blue] and PB [Patent Blue] is 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."

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. Nonetheless, the authors did not hesitate to consider this amount of Brilliant Blue to be a "risk to human health" in their conclusions. This is an unfortunate incidence where the communication of novel scientific findings removes critical numerical

information and context from the content, which renders it misleading and unnecessarily alarming.

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 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.

The color industry takes its responsibility for consumer safety seriously. IACM members are vigilant about the safety of their products and will continue to work closely with regulatory authorities around the world to ensure that all food colors are safe.

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The International Association of Color Manufacturers (IACM) is the trade association that represents the manufacturers and end-users of coloring substances that are used in foods, including natural and artificial colors.