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IACM Reaffirms Safety of Tartrazine

Washington, DC, June 12, 2018 – Ensuring the safety of color ingredients and maintaining the public’s confidence in that safety is the color industry’s primary goal. 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 synthetic colors.

In response to recent actions, IACM wants to reiterate that Tartrazine has been thoroughly tested, repeatedly evaluated, and concluded to be safe for use. Opinions to the contrary are simply not supported by the numerous safety studies and expert reviews that have been conducted.

Synthetic color additives are among the most tested food additives in the world. Through exhaustive testing and expert scientific review of those tests, Tartrazine has been approved as a food color additive internationally with INS number 102, in the United States by the Food and Drug Administration (FDA) as food color subject to batch certification “Food, Drug, and Cosmetic” (FD&C) Yellow No. 5, and in Europe as food color additive E number 102. Its safety for use in food in Europe was re-affirmed as recently as 2009.¹ Internationally, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) re-evaluated Tartrazine in 2016 and increased the previously established acceptable daily intake (ADI) from 0-7.5 to 0–10 mg/kg bw, based on the no-observed-adverse-effect-level (NOAEL) of 984 mg/kg bw/day in a chronic rat study.² It was also noted that, based on either reported industry use data or on regulatory agency analysis of products in the market, even the most conservative estimated dietary exposures to Tartrazine for children were well below the margin of safety and dietary exposure to the color does not present a health concern for any age group.

Tartrazine’s lack of carcinogenicity has been shown in numerous scientific studies. In addition, the presence of any contaminants derived from the manufacturing process is negligible and below any level of possible concern. In the US, the FDA analyzes and certifies as safe for use every batch of FD&C Yellow No. 5, and this testing is conducted before the batch can be used in any product sold in the US.

Additionally, IACM participates as a non-governmental observer at the Codex Alimentarius Commission, particularly at the Codex Committee on Food Additives (CCFA), which considers color uses and use levels for inclusion in the General Standard of Food Additives (GSFA). Inclusion of colors in the GSFA follows an 8-Step Process separate from the JECFA evaluation of the color safety and remains incomplete even for colors, such as Tartrazine, that have completed JECFA evaluations and are concluded to be safe. IACM appreciates and supports that many countries look to Codex standards for guidance. However, since the Codex process is very deliberate and the GSFA is still under development, all additives, including many colors that are approved for use in foods and beverages in countries such as the US, the EU, and many other markets throughout the world, have made it through the Codex Step Process for inclusion in the GSFA. Additionally, it was not the intent of the creators of the GSFA for it to be adopted as a positive list at this stage of development. Footnote 1 of the GSFA states,

Notwithstanding the provisions of this Section of the General Standard, the lack of reference to a particular additive or to a particular use of an additive in a food in the General Standard as currently drafted, does not imply that the additive is unsafe or unsuitable for use in food. The Commission shall review the necessity for maintaining this footnote on a regular basis, with a view to its deletion once the General Standard is substantially complete.³

¹ [EFSA \(2009\) Scientific Opinion](#) on the re-evaluation of Tartrazine (E 102) on request from the European Commission. EFSA Journal, 7(11), 1331, 52 pp.

² [JECFA \(Joint FAO/WHO Expert Committee on Food Additives\)](#) (2016) Evaluation of certain food additives (eighty-second report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report series, 1000.

³ CODEX STAN 192-1995

Tartrazine's current omission from most food categories in the GSFA is not due to safety concerns, but instead due to the considerable number of additives waiting for completion of the step process. To treat the tables of the GSFA (only adopted additives) as a positive list results in a ban on color additives, such as Tartrazine, that are widely approved and commonly used on a global basis.

The CCFA agreed at its 50th meeting in 2018 to begin consideration of draft color provisions, beginning with food categories 5.2 (Confectionery including hard and soft candy, nougats, etc. other than food categories 05.1, 05.3 and 05.4), 5.3 (Chewing gum) and 5.4 (Decorations (e.g. for fine bakery wares), toppings (non-fruit) and sweet sauces). It is anticipated that CCFA will work as quickly as possible through the additional draft color provisions in future meetings, which should provide additional assurance that there is no reason for a country to disallow the use of Tartrazine provisions currently pending at Step 7 (awaiting finalization) of the GSFA process.

IACM is confident in reassuring all parties that Tartrazine is a safe color additive. Our industry remains vigilant about the safety of our products through additional testing and close monitoring of new scientific developments related to color additive safety. We will continue to work closely with regulatory authorities around the world to ensure that food colors are safe.

Please contact IACM's Executive Director, Sarah Codrea (scodrea@iacmcolor.org) or Scientific Director, Dr. Maria Bastaki (mbastaki@iacmcolor.org), with any questions or concerns.