Myth vs. Fact on Red No. 3 and Titanium Dioxide

Myth: U.S. manufacturers can easily replace titanium dioxide and Red No. 3 in food products.

Facts: Due to the strict premarket review process for color additives in the U.S., the process to petition U.S. Food and Drug Administration (FDA) to approve a new color, complete all the required safety studies, and for FDA to issue a regulation approving its use takes at minimum five years from research and development to regulatory approval. This same process is required for any alternatives to existing FDA-approved color additives to be legally approved as a color additive in the U.S.

Currently, no FDA-approved alternative to titanium dioxide can provide similar pigment/opacity properties. Calcium carbonate is the only other white option currently legally approved for use as a food color in the U.S. Its uses are currently limited to dietary supplement tablets and capsules, soft and hard candies and mints, and inks used on the surface of chewing gum.

For Red No. 3, no other certified color provides the same pink shade. While some naturally derived replacement options exist, none can effectively replace Red No. 3 in products with long shelf life. Any replacement options must first be petitioned for FDA review and gain approval for use before being legally used as a color additive in the U.S.

Myth: Colors are generally recognized as safe (GRAS) and not reviewed for safety by FDA.

Facts: No GRAS exemption exists for using color additives, ensuring that no color additive is marketed before an extensive FDA safety evaluation.

Colors are safely used in a wide variety of consumer products, are among the most widely studied food ingredients, and are subject to strict global regulatory requirements.

FDA requires pre-approval of color additives before they can be used in food and other FDA-regulated products. To obtain approval for the use of a new color additive, an interested person must petition the FDA and submit data demonstrating its safety and await FDA's approval before marketing the color.

Myth: FDA has not reviewed titanium dioxide or FD&C Red No. 3 in more than 30 years.

Facts: FDA continuously monitors information relating to the safety of all color additives and maintains a Color Master File containing data on the safety of all color additives approved in the U.S., including FD&C Red No. 3 and Titanium Dioxide. FDA is currently conducting a comprehensive evaluation of both colors in response to Color Additive Petitions filed by the bill's advocates.

As stated on its website, "FDA scientists conduct a variety of activities to ensure the safety of color additives listed for use in FDA-regulated products." For example, FDA recently conducted its own internal review and provided a statement confirming that the agency continues to consider titanium dioxide safe for use as a color additive.

FDA has acknowledged that the agency reassesses safety studies on color additives available in its files and confirmed that all exposure estimates for FD&C color additives are well below the acceptable intake levels established by FDA.

FDA has specifically considered FD&C color additives and behavioral effects in children, most recently in 2019. Agency representatives also serve on the WHO/FAO Joint Expert Committee on Food Additives (JECFA), including the review team that re-evaluated Red 3 in 2018.

Myth: FDA banned FD&C Red No. 3 for cosmetic use since it can cause cancer.

Facts: In 1990, FDA denied a petition to expand authorized uses of FD&C Red No. 3 to cosmetics, dermal pharmaceutical applications, and lakes, citing the Delany Clause, which prohibits FDA from authorizing a food or color additive shown to be a carcinogen. When the Delaney Clause was introduced in the late 1950s, it was believed that even one molecule of a substance could cause cancer and pose a risk. However, science has advanced significantly in the past three decades, and it is now a well-accepted principle that test animals fed additives in high concentrations may produce increased incidences of tumors, but that does not necessarily indicate that the same effects will pertain to humans.

Myth: FD&C Red No. 3 is banned in Europe and many other countries.

Facts: It is incorrect to state that Red No. 3 (known globally as erythrosine) is banned in Europe and other countries. In Europe, the color is allowed for use in candied cherries, cosmetics, pharmaceuticals, and toothpaste.

In fact, no authoritative body, including FDA, JECFA, or EFSA, has identified any safety concerns with the continued use of Red 3 in food, with JECFA reconfirming its safe use in 2018 and EFSA in 2011. In its 1990 final rule on FD&C Red No. 3, the FDA concluded that it poses no threat to human health.

Myth: Titanium dioxide was banned in Europe due to the identification of safety concerns with its use in food.

Facts: There is no actual safety concern to justify a ban on titanium dioxide. Europe's 2021 opinion was based on safety data not representative of the material approved for use as a food color. Since then, highly regarded food agencies from the United States, United Kingdom, Canada, Australia, and New Zealand have reviewed Europe's data and confirmed its continued safe use as a food color.