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SPOTLIGHT

IARC Releases Monograph Classifying Aspartame "Possibly Carcinogenic"

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The International Agency for Research on Cancer (IARC) released a report in which it classifies a common artificial sweetener—aspartame—as a Group 2B carcinogen. The Food and Drug Administration first approved aspartame for use in 1974.

For several decades, IARC has been classifying various chemicals and compounds into four categories:

- Group 1: Carcinogenic to humans
- Group 2A: Probably carcinogenic to humans
- Group 2B: Possibly carcinogenic to humans
- Group 3: Not classifiable as to its carcinogenicity as to humans

In defining aspartame as a Group 2B carcinogen, IARC is saying that based on its review of human epidemiology, animal studies and mechanistic data, it believes aspartame is possibly carcinogenic to humans. According to IARC, "a classification of Group 2B means that there is convincing evidence that the agent causes cancer in experimental animals but little or no information about whether it causes cancer in humans. This category can also be used when there is some evidence that the agent could cause cancer in humans and in experimental animals but neither the evidence in humans nor the evidence in experimental animals is convincing enough to permit a definite conclusion to be drawn. There may also be consistent mechanistic evidence, showing that

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the agent exhibits one or more of the recognized key characteristics of human carcinogens." By its own definition, a Group 2B classification also means that IARC could not rule out chance, bias or confounding in its review of human epidemiology.

IARC has classified multiple everyday compounds as Group 2B carcinogens—including aloe vera, pickled vegetables, carrageenan, melamine, titanium dioxide and nickel—as well as common activities such as using cell phones and occupational exposures to dry cleaning, textile manufacturing, printing, carpentry and road paving.

Some of IARC's classifications have resulted in mass tort litigation, such as litigation targeting glyphosate-based herbicides, talc, gasoline and diesel fuel. IARC's classification of aspartame may trigger similar lawsuits alleging injury as a result of its consumption via food and beverage products. Experienced counsel can provide guidance on assessing exposure and preparing for any anticipated litigation.

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LEGISLATION, REGULATIONS & STANDARDS

Schumer Calls for Investigation of PRIME Beverages

Senate Majority Leader Chuck Schumer is calling on the U.S. Food and Drug Administration (FDA) to investigate PRIME Energy Drink for its caffeine content and marketing to children.

In a letter Schumer sent FDA Commissioner Robert Califf, he notes that at 200 mg for 12 ounces, PRIME's Energy Drink has more caffeine than a cup of coffee or a Red Bull. He said it could endanger the health of children as its demand skyrockets.

"PRIME is so new that most parents haven't a clue about it, but it is born from the reels of social media and the enigmatic world of influencers," Schumer said in a statement. "Kids see it on their phones or as they scroll, and they actually need it and the problem here is that this product has so much caffeine in it that it puts Red Bull to shame, but unlike Red Bull, this product has one true target market: children under the age of 18, and that is why I am sounding the alarm and asking the FDA to investigate PRIME."

PRIME comes both in both energy and hydration forms. While the bottled hydration version has no caffeine, the canned version is caffeinated, according to a release from Schumer's office.

ABOUT SHOOK

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

LITIGATION

Consumers Sue Dole for Health Claims on Snack Packaging

A California woman and New York man have filed a proposed class action against Dole Packaged Foods, LLC, alleging the company markets and labels its packaged snacks as healthy while containing added sugars. *Broussard v. Dole Packaged Foods, LLC*, No. 23-3320 (N.D. Cal., filed July 3, 2023).

The plaintiffs allege that Dole sells certain snacks, including parfaits, gels and juice products, with labels designed to convince consumers they are generally healthy or good for you, and are also specifically beneficial to immune system function. Meanwhile, the plaintiffs allege, the products contain at least 29% and up to 96% of their calories from added or free sugar. They assert that excessive sugar intake is associated with a higher risk of cardiovascular disease, diabetes, liver disease and other chronic diseases, and impairs the immune system.

“Because loading these products with FA Sugar and marketing them as good for you is directly contrary to the science, Dole’s claims are false or at least highly misleading,” they said in their complaint. “For example, Dole packs its popular gel snack products, which are marketed towards children as ‘good nutrition,’ with up to 20 grams of added sugar. This is 166% more added sugar than the [American Heart Association’s] recommended daily limit for children 4-8 years old.”

The plaintiffs are alleging violations of California's Unfair Competition Law, False Advertising Law and Consumers Legal Remedies Act; and violations of Sections 349 and 350 of the New York General Business Law. They seek class certification, disgorgement, restitution, damages, and attorney's fees and costs.