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Advocates sue FDA to force decision on cancer-causing chemicals in popular foods

FDA failed to act on petition to prohibit toxic chemicals used to flavor baked goods, candy, ice cream, and other foods

SAN FRANCISCO — Today a coalition of health, consumer and environmental advocacy organizations filed a lawsuit in the U.S. Court of Appeals for the Ninth Circuit aimed at forcing the U.S. Food and Drug Administration (FDA) to decide whether to prohibit seven cancercausing artificial chemicals from use in food as flavors. These chemicals have been used in beverages, baked goods, candy, chewing gum, and ice cream.

Earthjustice is representing the petitioners—Breast Cancer Prevention Partners, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Environmental Defense Fund, Environmental Working Group, Natural Resources Defense Council, and WE ACT for Environmental Justice—with Natural Resources Defense Council and Center for Food Safety serving as co-counsel for their respective organizations.

The seven chemicals at issue are: benzophenone (also known as diphenylketone), ethyl acrylate, eugenyl methyl ether (also known as 4-allylveratrole or methyl eugenol), myrcene (also known as 7-methyl-3-methylene-1,6-octadiene), pulegone (also known as p-menth-4(8)-en-3-one), pyridine, and styrene.

Though these seven chemicals are used to flavor a wide variety of processed foods, they are likely unfamiliar to consumers because, under food labeling rules, they would all appear only as "artificial flavor" on food ingredient lists. Though unidentifiable by name, the flavors themselves are certainly familiar. For example, some of the chemicals add floral, cinnamon, or mint flavor to baked goods, beverages, candy, chewing gum, and ice cream. Another is <u>described</u> as adding a "picnic-inspired . . . citrus, fruity mango note" or a "sweet woody note" to beer and other beverages. Yet another is <u>advertised</u> for its "irritating brown ethereal character reminiscent of ripe pineapple, rum and whiskey, roasted onion and garlic"--flavors that, according to one chemical manufacturer, could enhance beverages, butterscotch, and savory dishes.

The Federal Food, Drug, and Cosmetics Act prohibits the use of any food additive found to induce cancer in humans or animals. After the FDA approved the seven chemicals at issue for

use in food, multiple U.S. and international agencies—including the U.S. Department of Health and Human Services' National Toxicology Program—established that each of these chemicals induces cancer in humans or animals. Accordingly, the flavors cannot be deemed safe under the law and cannot lawfully be approved for use in food.

Even though FDA has known for years that these chemicals cause cancer, it nonetheless has failed to take legally required action on a petition by citizen organizations presenting this evidence and reminding FDA of its duty to prohibit carcinogenic substances in food. FDA has not decided the organizations' petition, and it has not prevented these chemicals from being used in food.

After accepting an earlier petition for consideration on the same topic, FDA formally accepted a revised and expanded petition filed by the Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Environmental Working Group, and Natural Resources Defense Council in February 2016. The document presented extensive scientific evidence and highlighted the dangers of these chemicals. Breast Cancer Prevention Partners, Environmental Defense Fund, and WE ACT for Environmental Justice later joined the effort. By statute, the FDA's final decision on this petition was due in August 2016, but the agency has so far failed to act. FDA's unlawful delay defies a congressional mandate requiring prompt action in assessing the safety of chemicals added to food and puts public health and welfare at risk.

"The federal agency charged with studying toxics found that these chemicals cause cancer. Congress clearly told FDA that known carcinogens cannot be used as food additives. What more does FDA need? It is time for FDA to take seriously its responsibility to keep cancercausing chemicals out of food," said **Earthjustice senior attorney Peter Lehner**. "Consumers cannot identify every ingredient in processed food and they shouldn't have to; we need FDA to do its job and protect our health and welfare."

"It's patently obvious that whether it's cinnamon or peppermint, citrus or floral; allowing cancercausing chemicals to be used as artificial flavors in chewing gum, ice cream, candy, beverages or baked goods is no treat for consumers!" said Nancy Buermeyer, Senior Policy Strategist at Breast Cancer Prevention Partners. "Chemicals linked to breast cancer, like benzophenone and styrene, should not be hiding in the foods we feed our children. It's time for the FDA to protect the public health by immediately banning the use of carcinogens masquerading as 'flavors' in our food."

"Cancer causing additives should not be used in our food," said **Caroline Cox, Research Director at Center for Environmental Health.** "The FDA needs to fulfill its promise to protect public health and ban the use of these chemicals immediately."

"These seven synthetic flavorings have been found to cause cancer, yet FDA sits on this information and takes no action, while these harmful chemicals continue to be widely used in

our food," said **Sylvia Wu, senior attorney at the Center for Food Safety**. "It is high time that FDA abide by the law and do its job to ensure our food is safe."

"Consumers have no clue that the unspecified 'natural or artificial flavors' on ingredients lists can actually include carcinogenic substances like benzophenone or myrcene," said **Center for Science in the Public Interest senior scientist Lisa Lefferts**. "The FDA can give consumers greater confidence in the safety of our food supply by eliminating these unnecessary chemicals from food altogether. And if manufacturers find they need to add notes of mango or citrus or some other flavor to a packaged food, how about they add mango or citrus itself, rather than some additive shown to cause cancer."

"The use of these carcinogens in food is not only contrary to the law – it is entirely unnecessary. There are thousands of other flavor chemicals available on the market that can be used to add similar flavors," said **Environmental Defense Fund chemicals policy director Tom Neltner**. "FDA should take immediate action to prohibit intentional use of these carcinogens and better protect consumers."

"Consumers want to know what's in their food and to feel confident that the FDA is protecting them from harmful chemicals," said **Melanie Benesh**, **Legislative Attorney with the Environmental Working Group**. "The FDA should not allow cancer-causing chemicals to lurk in our foods under the guise of 'natural' or 'artificial' flavorings."

"No one wants hidden carcinogens lurking in the food they feed their families," said **Erik Olson**, **Senior Director, Health and Food, Natural Resource Defense Council**. "It's disgraceful that FDA has allowed food companies to knowingly and secretively add cancer-causing additives to our food for years. FDA needs to put a stop to this once and for all, and ban them immediately."

"Synthetic ingredients are often used in mass-produced, low-cost, and packaged foods. People of color living in food insecure areas and/or low-income communities are sometimes forced to shop at dollar stores and similar places, based on price and convenience," said **WE ACT for Environmental Justice director of federal policy Dr. Adrienne Hollis**. "They are more likely to be exposed to foods that contain artificial flavors - some of which cause cancer. This legal action will ensure that vulnerable communities know what products they are consuming so they can avoid exposure to these products that may cause adverse health effects."

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<u>Breast Cancer Prevention Partners</u> (BCPP) is the leading science-based policy and advocacy organization working to prevent breast cancer by eliminating our exposure to toxic chemicals and radiation.

<u>Center for Environmental Health</u> (CEH) is a national nonprofit committed to ending health threats from toxic chemicals in our air, water, food and in products we use every day. We protect children and families

from harmful chemicals by working with communities, consumers, workers, and government to demand and support safer business practices. We also work with major industries and leaders in green business to promote healthier alternatives to toxic products and practices.

<u>Center for Food Safety</u>'s mission is to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture. Through groundbreaking legal, scientific, and grassroots action, we protect and promote your right to safe food and the environment.

<u>Center for Science in the Public Interest</u> is a nonprofit health-advocacy group based in Washington, D.C., that focuses on nutrition and food safety. CSPI is supported largely by subscribers to its Nutrition Action Healthletter and by foundation grants.

Earthjustice, the nation's premier nonprofit environmental law organization, wields the power of law and the strength of partnership to protect people's health, to preserve magnificent places and wildlife, to advance clean energy and to combat climate change. Because the earth needs a good lawyer.

<u>Environmental Defense Fund</u>, a leading international nonprofit organization, creates transformational solutions to the most serious environmental problems. EDF links science, economics, law and innovative private-sector partnerships.

<u>Environmental Working Group</u> is a non-profit, non-partisan organization dedicated to educating and inspiring people, businesses, and governments to make better decisions and to take action to protect health and the environment.

<u>Natural Resources Defense Council</u> (NRDC) is an international nonprofit environmental organization with more than 3 million members and online activists. Since 1970, our lawyers, scientists, and other environmental specialists have worked to protect the world's natural resources, public health, and the environment. NRDC has offices in New York City, Washington, D.C., Los Angeles, San Francisco, Chicago, Bozeman, MT, and Beijing.

<u>WE ACT for Environmental Justice</u> is a Northern Manhattan membership-based organization whose mission is to build healthy communities by ensuring that people of color and/or low income residents participate meaningfully in the creation of sound and fair environmental health and protection policies and practices. WE ACT has offices in Harlem, NYC and Washington, DC.