



Coalition Brings Suit Over Food Additives

LITIGATION, US FDA

By ROGER PEARSON, June 12, 2018

A coalition of health, consumer, and environmental groups has filed a petition with the Ninth Circuit Court of Appeals in San Francisco asking that court to **order the U.S. Food and Drug Administration (FDA) to act¹⁾ order the U.S. Food and Drug Administration (FDA) to act¹⁾** on an earlier petition filed by the coalition members. That earlier petition asked FDA to overturn a decades old ruling holding that seven additives can be safely added to foods, because numerous studies since that approval have determined that the additives are carcinogenic.

A section of the Federal Food, Drug, and Cosmetic Act, known as the Delaney Clause, prohibits the use in food of additives, which have not been tested to establish their safety. The Act further provides that no additive may be deemed to be safe if it is found to induce cancer in man or animals. The petitioners note that this prohibition applies irrespective of the level of the additive. Thus once an additive is found to be carcinogenic there is no safe level at which it can be added to food.

This lawsuit involves seven chemicals that were approved as safe to be added to foods largely for flavoring purposes. 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. The FDA approved the addition of first six of these chemicals in 1964 (along with dozens of other synthetic flavors) and it approved the addition of styrene in 1967. In both cases the FDA determined that the use of the additives was safe.

Since that approval, according to the petitioners, there have been numerous studies determining that the chemicals induce cancer in humans or animals. In particular the National Toxicology Program (NTP) has determined that each of the seven flavors cause cancer in animals. The NTP, note the petitioners, was specifically created to provide information about chemicals to health and regulatory agencies like the FDA. Despite the conclusion of the NTP and other authoritative bodies that the seven additives are carcinogenic they continue to be added to foods based on the FDA's original approval.

Proposition 65 lists all of the chemicals as causing cancer.

The presence of these chemicals is particularly pernicious, argue the petitioners, because food manufacturers do not have to disclose their individual presence on food labels. Instead the manufacturers can simply lump all such additives together collectively as "artificial flavors" or "natural flavors."

The Act provides that an interested party may file a petition with the FDA seeking the amendment or rescission of any regulation that authorized the addition of an additive that is no longer considered safe. The FDA has a maximum of 180 days to respond to the petition by either granting the relief requested or rejecting it. The petitioners filed their petition asking the agency to revoke its approval of the seven additives effective as of February 10, 2016. The 180 day period for FDA's response expired on August 8, 2016.

The petitioners are asking the Ninth Circuit to order FDA to act on the petition within 30 days from the date of filing of the petition with the court (May 2). A direct filing with the Ninth Circuit is permitted under the Act.

The petitioners include the Environmental Defense Fund, the Natural Resources Defense Council, the Environmental Working Group, and five other organizations. They are collectively represented by attorneys from EarthJustice, the NRDC, and the Sacramento-based Center for Food Safety.

Resources for this article

1. order the U.S. Food and Drug Administration (FDA) to act
<https://prop65clearinghouse.com/documents/26782>