FDA Removes 7 Synthetic Flavoring Substances from Food Additives List

Advocates petitioned to remove substances that cause cancer in lab animals, but FDA says they're safe.

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Constitutent Update

The FDA is amending its food additive regulations in response to two food additive petitions, to no longer allow for the use of a total of 7 synthetic flavoring substances and flavor enhancers (adjuvants). The FDA determined that the data presented in one of the petitions submitted to the FDA by Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Consumers Union, Environmental Defense Fund, Environmental Working Group, Improving Kids' Environment, Natural Resources Defense Council, WE ACT for Environmental Justice, and Mr. James Huff show that 6 of these synthetic substances

the studies. The seventh synthetic flavor is being de-listed because it is no longer used by industry.

The 6 flavoring substances include synthetically-derived benzophenone, ethyl acrylate, eugenyl methyl ether (methyl eugenol), myrcene, pulegone, and pyridine. These substances are being removed from the food additive regulations under the Delaney Clause of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (section 409(c)(3) of the FD&C Act). This clause, enacted in 1958, requires that the FDA cannot find as safe; i.e., cannot approve, the use of any food additive that has been found to induce cancer in humans or animals at any dose.

Although we are amending our food additive regulations for these synthetic flavoring substances in accordance with the Delaney Clause, the FDA's rigorous scientific analysis has determined that they do not pose a risk to public health under the conditions of their intended use. The synthetic flavoring substances that are the subject of this petition are typically used in foods available in the U.S. marketplace in very small amounts and their use results in very low levels of exposures and low risk. While the FDA's recent exposure assessment of these substances does not indicate that they pose a risk to public health under the conditions of their intended use, the petitioners provided evidence that these substances caused cancer in animals who were exposed to much higher doses. As such, the FDA is only revoking the listing of these six synthetic flavorings as a matter of law. The FDA has concluded that these substances are otherwise safe.

Each of these synthetic substances has a natural counterpart in food or in natural substances used to flavor foods. The FDA's revocation of the listings providing for the use of these synthetic flavoring substances and adjuvants does not affect the legal status of foods containing their natural counterparts or of flavoring substances extracted from such food, often labeled as "natural flavors."

Based on evidence presented by the petitioners that benzophenone causes cancer in animals, the FDA also is amending the food additive regulations to no longer provide for its use as a plasticizer in rubber articles intended for repeated use in contact with food.

In response to a separate food additive petition from the Styrene Information and Research Center, the FDA is granting the petition by amending its food additive regulations to no longer allow for the use of styrene as a synthetic flavoring substance and adjuvant because industry has abandoned this use. For the other 6 synthetic flavoring substances, the FDA will provide 24 months from the publication of the rule in the Federal Register for companies to identify suitable replacement ingredients and reformulate their food products.

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