

## Safety and Regulatory Authority to Use Flavors: Focus on Vaping Products

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### The Use of Flavors in Vaping Products

In the United States, the vast majority of flavoring substances are added to food consistent with the requirements of the GRAS (“generally recognized as safe”) provision in the statute that governs the safety and labeling of foods, the Federal Food, Drug, and Cosmetic Act (“FFDCA”). The primary route to regulatory authority to use flavor ingredients in the U.S. is the FEMA GRAS program for flavor ingredients with GRAS determinations made by the independent FEMA Expert Panel.

A variety of vaping products are available to consumers including “electronic nicotine delivery systems” (ENDS), “electronic cigarettes” (“e-cigarettes”), and other devices that provide the means by which the user inhales vapor from a mixture of constituents that may include nicotine, flavorings, cannabis derivatives, and other materials. The FEMA Expert Panel evaluates the safety of flavor ingredients only under their conditions of intended use in food and does not evaluate flavor ingredients for use in vaping products, or any other uses that are intended for inhalation. FEMA does not support the use of flavors in vaping products in the absence of rigorous safety assessments performed by vaping product manufacturers and marketers that demonstrate safety for this use.

There are several important issues associated with the use of flavors in vaping products. First, there is no current direct regulatory authority in the United States to use flavors in vaping products. In this context, it is important to note that the GRAS provision in FFDCA Section 201(s) applies only to food as defined in Section 201(f) of the Act. Furthermore, none of the primary safety assessment programs for flavors, including the FEMA GRAS program, evaluate flavor ingredients for use in products other than food. FEMA GRAS status for the use of flavor ingredients in food does not provide regulatory authority to use flavor ingredients in vaping products in the U.S.

The manufacturers and marketers of vaping products, and all other flavored tobacco products, and flavor manufacturers and marketers, should not represent or suggest that the flavor ingredients used in these products are safe because they have FEMA GRAS status for use in food because such statements are false and misleading.

### Vaping-Associated Lung Injuries

The U.S. Centers for Disease Control and Prevention (CDC) reported that more than 1,600 people in the United States have developed significant lung injuries from the use of vaping products, and more than 30 people have died (Moritz et al., 2019). These lung injuries are referred to as “electronic-cigarette, or vaping product-use associated lung injury” (EVALI). A significant majority of people suffering from EVALI consumed vaping liquids that contained tetrahydrocannabinol (THC), the psychoactive compound in marijuana. The CDC stated:

To date (28 October 2019), no single compound or ingredient has emerged as the cause of EVALI, and there might be more than one cause. Because most patients report using THC-containing products before the onset of symptoms, CDC recommends that persons should not use e-cigarette, or vaping, products that contain THC. Persons should not buy any type of e-cigarette, or vaping, products, particularly those containing THC, off the street and should not modify or add any substances to e-cigarette, or vaping, products that are not intended by the manufacturer ... (B)ecause the specific compound or ingredient causing lung injury is not yet known ... persons should consider refraining from use of all e-cigarette, or vaping, products (Moritz et al., 2019).

While CDC has not yet established the causative agent or agents for EVALI, it noted that analyses of vaping product samples have identified potentially harmful constituents such as vitamin E acetate, medium chain triglyceride oil, and other lipids. CDC identified vitamin E acetate in the lungs of 29/29 patients diagnosed with EVALI and stated, “Until the relationship of vitamin E acetate and lung health is better characterized, it is important that vitamin E acetate not be added to e-cigarette or vaping products” (Blount et al., 2019).

## FDA Activity

In 2010 FDA issued [regulatory correspondence on e-cigarettes](#). In 2014, FDA published regulations to deem vaping products, cigars, hookah tobacco, pipe tobacco, and certain other products as tobacco products subject to the regulatory authority of the 2009 Family Smoking Prevention and Tobacco Control Act amendments to the Federal Food, Drug, and Cosmetic Act thereby bringing them under regulation by the FDA. [81 Fed. Reg. 28974. 10 May 2016](#). Although the final deeming rule did not prohibit the use of flavors in these products, FDA designated flavors as “components” of vaping products and explained that the agency intended to consider a proposed tobacco product standard that would prohibit characterizing flavors in deemed tobacco products, including vaping products.

In March 2018, FDA took its first step toward regulatory action by publishing an Advanced Notice of Proposed Rulemaking (ANPR) seeking information from stakeholders on the role flavors play in tobacco products. [83 Fed. Reg. 12294. 21 Mar. 2018](#). FDA's ANPR reflects the agency's primary concern about the increase in the use of flavored tobacco products, including vaping products, among American youth. [FEMA submitted comments on FDA's ANPR](#) reiterating its long-standing positions that FEMA GRAS status for flavor ingredients does not apply to flavors used in vaping products and that there is no existing regulatory authority to use flavors in deemed tobacco products. In September 2018, [FDA Commissioner Gottlieb issued an extensive statement](#) on the direction of FDA's policies on regulating e-cigarettes noting that the agency has also issued a series of [warning letters](#) to the manufacturers of e-cigarettes and their components. As part of the agency's initiative to exercise its authority under the deeming rule, [FDA requested information](#) on nineteen potentially harmful constituents in vaping products (84 Fed. Reg. 38032, 5 August 2019). A number of the constituents may be used as flavoring substances. FEMA provided [comments](#) to the agency reiterating FEMA's long-standing positions.

In September 2019, the [Trump administration announced](#) that the FDA will develop and enforce a modified compliance policy for all flavored vaping products other than tobacco-flavored e-cigarettes. Once the policy is finalized, FDA plans to prioritize enforcement actions with the objective of flavored vaping products exiting the market until manufacturers demonstrate in product applications to the agency that each specific product is “appropriate for the protection of public health.”

## Recent Publications of Interest

Blount et al. Evaluation of bronchoalveolar lavage fluid from patients in an outbreak of e-cigarette, or vaping, product-use-associated lung injury. MMWR. Vol. 68. 8 November 2019

Davidson et al. Outbreak of electronic cigarette- associated acute lipoid pneumonia – North Carolina, July/August 2019. MMWR. Vol. 68. 6 September 2019.

Larcombe A.N. Early-life exposure to electronic cigarettes: cause for concern. Lancet Respiratory Medicine. 7, 985. 2019.

Layden et al. Pulmonary illness related to e-cigarette use in Illinois and Wisconsin – Preliminary report. New England Journal of Medicine. 6 September 2019.

Moritz E.D. et al. Update: Characteristics of patients in a national outbreak of e-cigarette, or vaping, product use-associated lung injuries – United States, October 2019. MMWR. Vol. 68. 1 November 2019.

National Academies of Sciences, Engineering and Medicine. Public health consequences of e-cigarettes. The National Academies Press. Available at <http://nap.edu/24952>. 2018.

Schier et al. Severe pulmonary disease associated with electronic cigarette product use – interim guidance. MMWR. Vol. 68. 6 September 2019.

Sommerfeld, C.G. et al. Hypersensitivity pneumonitis and acute respiratory distress syndrome from e-cigarette use. Pediatrics. 141, 6. 2018.

Staudt M.R. et al. Altered lung biology of healthy never smokers following acute inhalation of e-cigarettes. Respiratory Research. 19, 78. 2018.

## For More Information

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