Safety Assessment and Regulatory Authority to Use Flavors – Focus on E-Cigarettes and Flavored Tobacco Products

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The Use of Flavors in E-Cigarettes and Flavored Tobacco Products

Electronic cigarettes (e-cigarettes) are becoming increasingly popular. These products involve a delivery vehicle that may resemble a tobacco cigarette through which the user inhales vapor from a mixture of constituents typically including nicotine, flavor and other materials. The use of other flavored non-cigarette tobacco products like cigars, smokeless tobacco products and hookah products is also increasing. The 2009 Family Smoking Prevention and Tobacco Control Act prohibits the use of “characterizing flavors,” except for tobacco flavors and menthol, in combustible cigarettes but not in other tobacco products such as cigars and smokeless tobacco products or in hookah smoking products (“flavored tobacco products”). There are several important issues associated with the use of flavors in e-cigarettes and other flavored tobacco products.

1. There is no apparent direct regulatory authority in the United States to use flavors in e-cigarettes and flavored tobacco products. In this context, it is important to note that the “generally recognized as safe” (GRAS) provision in Section 201(s) of the Federal Food, Drug, and Cosmetic Act (FFDCA) applies only to food as defined in Section 201(f) of the Act.

2. None of the primary safety assessment programs for flavors, including the GRAS program sponsored by the Flavor and Extract Manufacturers Association of the United States (FEMA), evaluate flavor ingredients for use in products other than human food. FEMA GRAS™ status for the use of flavor ingredients in food does not provide regulatory authority to use flavor ingredients in e-cigarettes or any tobacco products in the U.S.

   • The manufacturers and marketers of e-cigarettes 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.
   • The manufacturers and marketers of e-cigarettes and all other flavored tobacco products should take appropriate action to assure the safety of flavor ingredients used in these products. FEMA GRAS™ status for the use of flavor ingredients in food does not mean that FEMA GRAS™ flavor ingredients are safe for use in e-cigarettes and flavored tobacco products.

3. The U.S. Food and Drug Administration (FDA) issued regulatory correspondence on e-cigarettes in 2010. In 2014, FDA published proposed regulations to deem e-cigarettes, 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 FFDCA thereby bringing them under regulation by the FDA. 80 Fed. Reg. 23142 (25 April 2014). Recognizing that many of these products
currently contain flavors, FDA is considering how it might regulate the use of flavors in these products.

The Regulation of Flavors in the United States

In the U.S., the vast majority of flavoring substances are added to food consistent with the GRAS provision in FFDCA Section 201(s). For the purposes of the FFDCA GRAS provision, food is defined in FFDCA Section 201(f) as “(1) articles used for food or drink for man or other animals, (2) chewing gum, (3) articles used as components for any such article.” The primary route to regulatory authority to use flavor ingredients in the U.S. is the FEMA GRAS™ program.

The FEMA Expert Panel

The FEMA Expert Panel evaluates the safety of flavoring substances only under their conditions of intended use in human food, including beverages and chewing gum. Therefore, the Expert Panel only evaluates flavor ingredients for exposure through ingestion. The Expert Panel does not evaluate flavor ingredients for use in e-cigarettes or any tobacco products, or other products that are not human food, or products that result in exposures other than by ingestion.

Other Safety Assessment and Regulatory Programs

There are a variety of programs in various countries and geographic regions to evaluate the safety of flavoring substances for use in food. All of these programs evaluate the safety of flavoring substances only under their conditions of intended use in human food meaning that they are evaluated only for safety upon ingestion. In Europe, flavoring substances are evaluated by the European Food Safety Authority solely for their use in human food. Also consistent with this principle is the global flavor safety evaluation program conducted by the Joint FAO/WHO Expert Committee on Food Additives that also evaluates the safety of flavoring substances solely for their use in human food.

Occupational Exposure Limits and E-Cigarettes

Occupational exposure limits (OELs) have been established for a small number of flavoring substances. OELs have no relevance to exposure to flavors from the use of e-cigarettes or other uses that do not constitute exposure in the workplace. OELs, such as permissible exposure limits (PELs) established by the Occupational Safety and Health Administration (OSHA), recommended exposure limits (RELs) established by the National Institute for Occupational Safety and Health and threshold limit values (TLVs) established by the American Conference of Government Industrial Hygienists, are intended to serve as regulatory limits in the case of OSHA PELs, or in the case of RELs and TLVs, as benchmarks for limiting exposure to substances in the workplace. It is improper to use OELs as indications of safe levels of exposure to flavoring substances from the use of electronic cigarettes and exposures that do not occur in the workplace.

For More Information
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