FLAVOR AND EXTRACT MANUFACTURERS ASSOCIATION OF THE UNITED STATES
1101 17th Street, NW • Suite 700 • Washington, DC 20036
Phone: (202) 293-5800 www.femaflavor.org

The Safety Assessment and Regulatory Authority to Use Flavors – Focus on E-Cigarettes

Revised March 3, 2015

The Use of Flavors in E-Cigarettes

"E-cigarettes" ("electronic 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. There are several important issues associated with the use of flavors in e-cigarettes.

1. There is no apparent direct regulatory authority in the United States to use flavors in e-cigarettes. 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 a flavor ingredient in food does not provide regulatory authority to use the flavor ingredient in e-cigarettes in the U.S.

- E-cigarette and flavor manufacturers and marketers should not represent or suggest that the flavor ingredients used in e-cigarettes are safe because they have FEMA GRAS™ status for use in food because such statements are false and misleading.
- E-cigarette manufacturers and marketers should take appropriate action to assure the safety of flavor ingredients used in e-cigarettes. 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.

3. The U.S. Food and Drug Administration issued regulatory correspondence on e-cigarettes in 2010. In 2014, FDA published proposed regulations to deem e-cigarettes 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 Food and Drug Administration (FDA). 80 *Fed. Reg.* 23142 (25 April 2014).

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 tobacco products and e-cigarettes 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 (JECFA) 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. 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 (NIOSH) and threshold limit values (TLVs) established by the American Conference of Government Industrial Hygienists (ACGIH), 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.

For More Information

Please contact John Hallagan, FEMA Senior Advisor and General Counsel (Hondobear@aol.com; 202.331.2333).