### FEMA 2014 - 2015

# Mission Statement and Critical Objectives



#### **Mission Statement:**

The Flavor and Extract Manufacturers Association furthers the business interests of its members through a sound scientific program designed to promote the safe use of flavors. Through effective representation of its members, FEMA fosters a global environment in which the flavor industry can create, innovate, and compete.

### **Critical Objectives:**

#### Science

- Achieve and maintain a consistent, scientifically valid approach to safety evaluation of flavor ingredients.
- Continue to support the ongoing role of the FEMA Expert Panel for independent evaluation of the safety-in-use of flavor ingredients.
- Assist FEMA members in having the safest workplace possible.
- Identify and address emerging issues.

### **Advocacy**

• Serve as an effective advocate for FEMA members by representing industry interests before domestic and global legislative, regulatory, and other bodies.

### Communication

- Provide a forum to identify and implement solutions to industry problems.
- Communicate our performance against critical objectives.
- Communicate the status of key ongoing programs.
- Communicate the benefits of FEMA membership.
- Regularly update members on activities of the Board and Committees.
- Ensure prompt responses to member requests.
- Measure effectiveness of education, training and communication.

### **Intellectual Property Protection**

 Promote and encourage the protection of intellectual property of FEMA members by actively responding to regulatory developments and by educating members.

### **FEMA Background**



### FEMA is the national association of the U.S. flavor industry.

Founded in 1909 by flavor industry leaders, FEMA's original principles continue to guide the Association today to:

- cooperate, promote, and protect the business interests of its membership;
- foster and promote good will among the membership; and
- assist in the enactment and enforcement of laws and regulations which protect the integrity of the flavor industry and the health and safety of consumers.

# FEMA today is as robust and relevant to the flavor industry as when it was founded.

In 2014, in addition to the mission of its founding fathers, FEMA furthers the business interest of its members through:

- A sound scientific program designed to promote the safe use of flavors and foster a global environment in which the flavor industry can create, innovate and compete.
- A close relationship with the FDA, USDA, OSHA, EPA, the Department of Transportation, and relevant committees of the U.S. House of Representatives where matters of concern continue to dominate FEMA's advocacy agenda.
- A volunteer leadership and committee structure which set Association priorities establishes policy decisions and determines forum topics.

# A century of advocacy has resulted in successes beneficial to the industry.

FEMA has been at the forefront of every issue concerning flavors and safety for the past 100 years. FEMA's service to its membership has included:

- formulation of industry standards;
- protection from unfair taxation;
- protection of the rights of the industry to maintain trade secrets; and
- development of worker safety notification protocols to protect workers without compromising proprietary information.

# FEMA's internationally respected scientific body has fifty years of GRAS experience.

For fifty years, FEMA and the FDA have developed a cooperative exchange of information and supported a mutual concern for safety which continues to flourish today.







### The FEMA GRASTM Program



The Expert Panel of the Flavor and Extract Manufacturers Association (FEMA) is the primary body for the safety evaluation of food flavorings for the flavor industry and the public through its "generally recognized as safe" (GRAS) assessment of flavoring substances. Flavoring substances are determined to be GRAS by the FEMA Expert Panel pursuant to the authority granted in Section 201(s) of the U.S. Federal Food, Drug, and Cosmetic Act, which is administered by the FDA.

The FEMA GRAS™ assessment program continually incorporates the latest scientific advances for evaluating the safety of flavoring substances. The Expert Panel's main goal is to ensure that flavoring substances added to foods are safe for their intended use. The conclusions of the Expert Panel on GRAS status apply only to the use of a flavoring substance in food. The Expert Panel is comprised of experts in the fields of chemistry, toxicology, pharmacology, medicine, pathology, and statistics; all are also specialists in flavor safety assessment.

A critical part of the FEMA GRAS<sup>TM</sup> assessment program is the dissemination of the Expert Panel's decisions. Since 1965, lists of flavoring substances that have been determined to be GRAS have been published in Food Technology. A comprehensive list of all the FEMA GRAS<sup>TM</sup> flavor ingredients and a list of the GRAS publications<sup>1</sup> are available from the FEMA office. A small number of other flavoring substances are also permitted for use in the U.S. under separate authority as provided for in the U.S. Code of Federal Regulations (CFR). The FEMA office can supply information on these substances as well as a comprehensive list of all flavor ingredients listed in the CFR. Please note that the vast majority of the substances listed in the CFR are FEMA GRAS<sup>TM</sup> substances.

A number of articles have been published on the FEMA GRAS<sup>TM</sup> program. These include descriptions of the legal and scientific bases for the program (Hallagan and Hall, 1995); the history and operations of the Expert Panel (Oser and Ford, 1991); and scientific criteria employed by the Expert Panel (Oser and Hall, 1977 and Woods and Doull, 1991; Smith et al., 2005).

In addition to evaluating new substances for GRAS status, the Expert Panel carries out comprehensive, periodic reviews of all FEMA GRAS™ flavoring substances to reaffirm GRAS status. Several safety evaluations on groups of structurally related flavoring substances have recently been published. Reviews of additional groups of substances will be published as the Expert Panel continues the GRAS reaffirmation program.

Based on the conclusions of the Expert Panel, FEMA GRAS<sup>TM</sup> flavoring substances are accepted as safe food ingredients in many countries around the world. A list of countries that accept FEMA GRAS<sup>TM</sup> flavoring substances is available from the FEMA office.

Additional information on the FEMA GRAS™ assessment program is available from Sean Taylor or Christie Harman in the FEMA office at 202-293-5800.

¹ There are a total of 24 FEMA GRAS™ publications referred to as "GRAS 3" through "GRAS 26." The "GRAS 1" and "GRAS 2" publications were notices that did not contain lists of GRAS substances or other relevant information. All FEMA GRAS™ publications are available from the FEMA office.

### Frequently Asked Questions



# How do consumers know that flavors used in their foods and beverages are safe?

Nothing is more important to flavor manufacturers than the safety of the ingredients in our food. Before any new flavors are used in consumer products, they are evaluated for their safety by an independent panel of experts that publishes its findings and shares the results with the United States Food and Drug Administration.

The great majority of the substances reviewed by the FEMA Expert Panel also have been evaluated by other scientific bodies, including the United Nations/ World Health Organization Joint Expert Committee on Food Additives (JECFA), the European Food Safety Authority, and the Japanese Ministry of Health, Labor and Welfare. In addition, the FEMA Expert Panel periodically and routinely re-evaluates the safety of flavorings, using the most up-to-date science.

### What is the FEMA Expert Panel?

The Expert Panel of the Flavor and Extract Manufacturers Association (FEMA) has served as the primary body for the safety evaluation of food flavorings for the flavor industry, and the public through its "generally recognized as safe" (GRAS) assessment of flavoring substances for over fifty years. Flavoring substances are determined to be GRAS by the FEMA Expert Panel pursuant to the authority granted in Section 201(s) of the U.S. Federal Food, Drug, and Cosmetic Act, which is administered by the FDA.

The FEMA GRAS<sup>TM</sup> assessment program continually incorporates the latest scientific advances for evaluating the safety of flavoring substances. The Expert Panel has operated continuously since it was first appointed in 1960. The Expert Panel's primary goal is to ensure that flavoring substances added to foods are safe for their intended use — the conclusions of the Expert Panel on GRAS status apply only to the use of a flavoring substance in food. The Expert Panel is comprised of experts in the fields of chemistry, toxicology, pharmacology, medicine, pathology, and statistics; all are also experts in flavor safety assessment.

The flavor industry takes great pains to ensure the independence of the panel's work. Panel members do not know the identity of companies seeking FEMA GRAS<sup>TM</sup> status for their flavorings. The Expert Panel determines its own agenda, develops its own safety standards, informs the Food and Drug Administration of its GRAS determinations, and publishes its findings.

### What is "GRAS"?

"GRAS" is an acronym for the phrase Generally Recognized As Safe. Under Section 201(s) of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. (From the FDA's definition of "GRAS").

## Frequently Asked Questions



### What is the FEMA GRAS™ Program?

The FEMA GRAS<sup>TM</sup> Program is the longest running and most admired industry GRAS program. Under authority granted by the United States Congress, the FEMA Expert Panel has been evaluating the safety of flavoring substances for more than 50 years under the auspices of the FEMA GRAS<sup>TM</sup> Program and has earned the respect of governmental agencies in the United States and around the world. Consumers should feel comfortable with the independence of the FEMA GRAS<sup>TM</sup> Program's findings, as they are not the only scientific safety evaluations that flavoring substances undergo. The vast majority of substances determined to be safe under conditions of intended use through the FEMA GRAS<sup>TM</sup> Program have also been submitted to other international regulatory bodies for review. Additionally, the FEMA Expert Panel periodically and routinely carries out re-evaluations of FEMA GRAS<sup>TM</sup> substances.

#### What Is A Natural Flavor?

Natural flavors are ingredients that come from natural sources such as a spice, fruit, or vegetable. They can even come from herbs, barks, roots, or similar plant materials. Natural flavors also come from meat, seafood, poultry, eggs, and dairy products. Flavors are only used to add taste to foods; they are not nutritional.

If something is labeled as "natural flavor" it must fit the definition of "natural flavor." Different countries define what it means for a flavor to be considered "natural." In the United States, both the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) have definitions of "natural flavor" in their regulations.

#### What Is An Artificial Flavor?

Quite simply, artificial flavors are flavorings that don't meet the definition of natural flavor.

There isn't much difference in the chemical compositions of natural and artificial flavorings. What is different is the source. For example, an artificial strawberry flavor may contain the same individual substances as a natural one, but the ingredients come from a source other than a strawberry.

Based on "What is the difference between artificial and natural flavors?" by Gary Reineccius, Professor, Department of Food Science and Nutrition at the University of Minnesota, in Scientific American (July 29, 2002).



## **Executive Biographies**



John H. Cox, JD Executive Director, FEMA jcox@vertosolutions.net

John Cox focuses his skills helping associations serve their members in effective and innovative ways. He has provided advocacy, communications, and legal counsel to the food and cosmetic ingredient industries since 2000. John is a lawyer, a communicator, and an association executive, bringing passion and expertise to all three roles.



As Executive Director of the Flavor and Extract Manufacturers Association (FEMA), John is responsible for the daily management of the organization and for ensuring all activities align with FEMA's mission and Critical Objectives.

John's experience includes overall financial management of associations with annual revenues exceeding \$5 million. His involvement with communications includes web site design, convention and educational program development, and marketing. The associations under John's management have seen increases in membership as a result of strategic and creative recruitment programs.

John's past experiences include serving on the staff in several Congressional offices on Capitol Hill, as well as positions at Booz Allen & Hamilton, the U.S. Federal Trade Commission, Occupational Safety & Health Review Commission, and the Environmental Protection Agency. John has a B.A. in English from Spring Hill College and a Juris Doctor from the University of Alabama School of Law. He is admitted to practice law in the District of Columbia and Georgia.

John blogs at: http://associationnavigator.com/



Mat Gulick Communications Director mgulick@vertosolutions.net

Mathew Gulick is Verto Solutions' Communications Director. In his role, he develops clear and effective communication strategies for each of Verto's clients and also manages the marketing of each client's programs.

Prior to joining Verto Solutions, Mat served for five years as the Policy and Communications Director at the Association of Nutrition Services Agencies, where he built an effective communications program to keep members,

partners, and other interested groups aware of the association's activities and successes. Earlier in his career, Mat was an Editor at SmartBrief, Inc., where he oversaw the creation and distribution of more than a dozen daily, weekly, and monthly electronic news publications targeting the healthcare and biotechnology industries.

Mat received his B.A. in Biology from St. Mary's College of Maryland.