ADDITIVES 1

U. S. Department of Health and Human Services U. S. Food and Drug Administration FDA Backgrounder August 31, 1995

# FDA and Monosodium Glutamate (MSG)

# Monosodium Glutamate (MSG)

Monosodium glutamate (MSG) is used as a flavor enhancer in a variety of foods prepared at home, in restaurants, and by food processors. Its use has become controversial in the past 30 years because of reports of adverse reactions in people who've eaten foods that contain MSG. Research on the role of glutamate—a group of chemicals that includes MSG—in the nervous system also has raised questions about the chemical's safety.

Studies have shown that the body uses glutamate, an amino acid, as a nerve impulse transmitter in the brain and that there are glutamate-responsive tissues in other parts of the body, as well. Abnormal function of glutamate receptors has been linked with certain neurological diseases, such as Alzheimer's disease and Huntington's chorea. Injections of glutamate in laboratory animals have resulted in damage to nerve cells in the brain. Consumption of glutamate in food, however, does not cause this effect. While people normally consume dietary glutamate in large amounts and the body can make and metabolize glutamate efficiently, the results of animal studies conducted in the 1980s raised a significant question: Can MSG and possibly some other glutamates harm the nervous system?

A 1995 report from the Federation of American Societies for Experimental Biology (FASEB), an independent body of scientists, helps put these safety concerns into perspective and reaffirms the Food and Drug Administration's belief that MSG and related substances are safe food ingredients for most people when eaten at customary levels.

The FASEB report identifies two groups of people who may develop a condition the report refers to as "MSG symptom complex." One group is those who may be intolerant to MSG when eaten in a large quantity. The second is a group of people with severe, poorly controlled asthma. These people, in addition to being prone to MSG symptom complex, may suffer temporary worsening of asthmatic symptoms after consuming MSG. The MSG dosage that produced reactions in these people ranged from 0.5 grams to 2.5 grams.

Although FDA has not fully analyzed the FASEB report, the agency believes that the report provides the basis to require glutamate labeling. FDA will propose that foods containing significant amounts of free glutamate (not bound in protein along with other amino acids) declare glutamate on the label. This would allow consumers to distinguish between foods with insignificant free glutamate levels and those that might contribute to a reaction.

#### What Is MSG?

MSG is the sodium salt of the amino acid glutamic acid and a form of glutamate. It is sold as a fine white crystal substance, similar in appearance to salt or sugar. It does not have a distinct taste of its own,

and how it adds flavor to other foods is not fully understood. Many scientists believe that MSG stimulates glutamate receptors in the tongue to augment meat-like flavors.

Asians originally used a seaweed broth to obtain the flavor- enhancing effects of MSG, but today MSG is made by a fermenting process using starch, sugar beets, sugar cane, or molasses.

Glutamate itself is in many living things: It is found naturally in our bodies and in protein-containing foods, such as cheese, milk, meat, peas, and mushrooms.

Some glutamate is in foods in a "free" form. It is only in this free form that glutamate can enhance a food's flavor. Part of the flavor-enhancing effect of tomatoes, certain cheeses, and fermented or hydrolyzed protein products (such as soy sauce) is due to the presence of free glutamate.

Hydrolyzed proteins, or protein hydrolysates, are acid-treated or enzymatically treated proteins from certain foods. They contain salts of free amino acids, such as glutamate, at levels of 5 to 20 percent. Hydrolyzed proteins are used in the same manner as MSG in many foods, such as canned vegetables, soups, and processed meats.

#### Scientific Review

In 1959, FDA classified MSG as a "generally recognized as safe," or GRAS, substance, along with many other common food ingredients, such as salt, vinegar, and baking powder. This action stemmed from the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act, which required premarket approval for new food additives and led FDA to promulgate regulations listing substances, such as MSG, which have a history of safe use or are otherwise GRAS.

Since 1970, FDA has sponsored extensive reviews on the safety of MSG, other glutamates and hydrolyzed proteins, as part of an ongoing review of safety data on GRAS substances used in processed foods.

One such review was by the FASEB Select Committee on GRAS Substances. In 1980, the committee concluded that MSG was safe at current levels of use but recommended additional evaluation to determine MSG's safety at significantly higher levels of consumption. Additional reports attempted to look at this.

In 1986, FDA's Advisory Committee on Hypersensitivity to Food Constituents concluded that MSG poses no threat to the general public but that reactions of brief duration might occur in some people.

Other reports gave similar findings. A 1991 report by the European Communities' (EC) Scientific Committee for Foods reaffirmed MSG's safety and classified its "acceptable daily intake" as "not specified," the most favorable designation for a food ingredient. In addition, the EC Committee said, "Infants, including prematures, have been shown to metabolize glutamate as efficiently as adults and therefore do not display any special susceptibility to elevated oral intakes of glutamate."

A 1992 report from the Council on Scientific Affairs of the American Medical Association stated that glutamate in any form has not been shown to be a "significant health hazard."

Also, the 1987 Joint Expert Committee on Food Additives of the United Nations Food and Agriculture Organization and the World Health Organization have placed MSG in the safest category of food ingredients.

Scientific knowledge about how the body metabolizes glutamate developed rapidly during the 1980s. Studies showed that glutamate in the body plays an important role in normal functioning of the nervous system. Questions then arose on the role glutamate in food plays in these functions and whether or not glutamate in food contributes to certain neurological diseases.

#### **Anecdotal Evidence**

Many of these safety assessments were prompted by unconfirmed reports of MSG-related adverse reactions. Between 1980 and 1994, the Adverse Reaction Monitoring System in FDA's Center for Food Safety and Applied Nutrition received 622 reports of complaints about MSG. Headache was the most frequently reported symptom. No severe reactions were documented, but some reports indicated that people with asthma got worse after they consumed MSG. In some of those cases, the asthma didn't get worse until many hours later.

Also, several books and a TV news show have reported widespread and sometimes life-threatening adverse reactions to MSG, claiming that even small amounts of manufactured glutamates may cause adverse reactions.

A problem with these unconfirmed reports is that it is difficult to link the reactions specifically to MSG. Most are cases in which people have had reactions after, but not necessarily because of, eating certain foods containing MSG.

While such reports are helpful in raising issues of concern, they do not provide the kind of information necessary to describe who is most likely to be affected, under what conditions they'll be affected, and with what amounts of MSG. They are not controlled studies done in a scientifically credible manner.

## 1995 FASEB Report

Prompted by continuing public interest and a flurry of glutamate-related studies in the late 1980s, FDA contracted with FASEB in 1992 to review the available scientific data. The agency asked FASEB to address 18 questions dealing with:

- the possible role of MSG in eliciting MSG symptom complex
- the possible role of dietary glutamates in forming brain lesions and damaging nerve cells in humans
- underlying conditions that may predispose a person to adverse effects from MSG
- the amount consumed and other factors that may affect a person's response to MSG
- the quality of scientific data and previous safety reviews.

FASEB held a two-day meeting and convened an expert panel that thoroughly reviewed all the available scientific literature on this issue.

FASEB completed the final report, over 350 pages long, and delivered it to FDA on July 31, 1995. While not a new study, the report offers a new safety assessment based on the most comprehensive existing evaluation to date of glutamate safety.

Among the report's key findings:

• An unknown percentage of the population may react to MSG and develop MSG symptom complex, a condition characterized by one or more of the following symptoms:

- burning sensation in the back of the neck, forearms and chest
- numbness in the back of the neck, radiating to the arms and back
- tingling, warmth and weakness in the face, temples, upper back, neck and arms
- facial pressure or tightness
- chest pain
- headache
- nausea
- rapid heartbeat
- bronchospasm (difficulty breathing) in MSG-intolerant people with asthma
- drowsiness
- weakness.
- In otherwise healthy MSG-intolerant people, the MSG symptom complex tends to occur within one hour after eating 3 grams or more of MSG on an empty stomach or without other food. A typical serving of glutamate-treated food contains less than 0.5 grams of MSG. A reaction is most likely if the MSG is eaten in a large quantity or in a liquid, such as a clear soup.
- Severe, poorly controlled asthma may be a predisposing medical condition for MSG symptom complex.
- No evidence exists to suggest that dietary MSG or glutamate contributes to Alzheimer's disease, Huntington's chorea, amyotrophic lateral sclerosis, AIDS dementia complex, or any other longterm or chronic diseases.
- No evidence exists to suggest that dietary MSG causes brain lesions or damages nerve cells in humans.
- The level of vitamin B6 in a person's body plays a role in glutamate metabolism, and the possible impact of marginal B6 intake should be considered in future research.
- There is no scientific evidence that the levels of glutamate in hydrolyzed proteins causes adverse effects or that other manufactured glutamate has effects different from glutamate normally found in foods.

### **Ingredient Listing**

Under current FDA regulations, when MSG is added to a food, it must be identified as "monosodium glutamate" in the label's ingredient list. Each ingredient used to make a food must be declared by its name in this list.

While technically MSG is only one of several forms of free glutamate used in foods, consumers frequently use the term MSG to mean all free glutamate. For this reason, FDA considers foods whose labels say "No MSG" or "No Added MSG" to be misleading if the food contains ingredients that are sources of free glutamates, such as hydrolyzed protein.

In 1993, FDA proposed adding the phrase "(contains glutamate)" to the common or usual names of certain protein hydrolysates that contain substantial amounts of glutamate. For example, if the proposal were adopted, hydrolyzed soy protein would have to be declared on food labels as "hydrolyzed soy protein (contains glutamate)." However, if FDA issues a new proposal, it would probably supersede this 1993 one.

In 1994, FDA received a citizen's petition requesting changes in labeling requirements for foods that contain MSG or related substances. The petition asks for mandatory listing of MSG as an ingredient on labels of manufactured and processed foods that contain manufactured free glutamic acid. It further asks that the amount of free glutamic acid or MSG in such products be stated on the label, along with a warning that MSG may be harmful to certain groups of people. FDA has not yet taken action on the petition.

Copies of the 1995 FASEB report are available for \$50 each by writing to FASEB at 9650 Rockville Pike, Bethesda, MD 20814.

References: Federal Register, Dec. 4, 1992 (FR 57467) and Federal Register, Jan. 6, 1993 (FR 2950); FDA Consumer, December 1993, "Food Allergies: When Eating is Risky."

BG 95-16

This is a mirror of the page formerly at <a href="http://www.fda.gov/opacom/backgrounders/msg.html">http://www.fda.gov/opacom/backgrounders/msg.html</a>

#### Food Ingredients and Packaging

Foods Home | FDA Home | HHS Home | Search/Subject Index | Disclaimers & Privacy Policy | Accessibility/Help