UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition to add the names of all ingredients that contain excitotoxic glutamic acid to the Food Code, Annex 4, Table 2b, *Added Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures.*	)))))	Docket No. FDA-2021-P-0267

Petitioner: Adrienne Samuels, Ph.D.
Date: March 1, 2021

CITIZEN PETITION

Petitioner respectfully requests that the Commissioner of Food and Drugs (the Commissioner) add the names of all ingredients that contain excitotoxic glutamic acid to the Food Code, Annex 4, Table 2b, *Added Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures*.

Introduction

In the Food Code, Annex 4, Table 2b, "Added Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures," monosodium glutamate (MSG) is appropriately identified as an "Added Chemical Hazard." Monosodium glutamate (MSG) is a man-made product composed of sodium, moisture, and manufactured free glutamate (MfG): L-glutamic acid (L-glutamate), D-glutamic acid (D-glutamate), pyroglutamic acid, and other impurities (unwanted and unavoidable by-products of the manufacture of L-glutamate).

Glutamic acid (glutamate) is an acidic amino acid which when present in protein or released from protein in a regulated fashion (through routine digestion) is vital for normal body function. It is the principal neurotransmitter in humans, carrying nerve impulses from glutamate stimuli to glutamate receptors throughout the body. Yet, when present outside of protein in amounts that exceed what the healthy human body was designed to accommodate, glutamate becomes an excitotoxic neurotransmitter, firing repeatedly, damaging targeted glutamate-receptors and/or causing neuronal and non-neuronal death by over exciting those glutamate receptors until their host cells die (1,2).

The glutamate in MfG is, as its name indicates, made up of single manufactured amino acids, not amino acids bound with other amino acids in protein.

The excitotoxic amino acid glutamate becomes actively excitotoxic only when there is an accumulation of glutamate (or glutamate plus other excitotoxic amino acids) that exceeds what the human body requires for normal functioning. That is most likely to occur when there are a number of glutamate-containing foods eaten within a relatively short period of time – but short is undefined. Since the reformulation of MSG in 1957, there has been more than enough MfG available in processed food to cause excitotoxic cell death resulting in the significant increases of brain-related disorders such as Alzheimer's, obesity, infertility, and adverse reactions such as a-fib, tachycardia, asthma, fibromyalgia, and migraine headache that we have seen since 1957.

MfG is the excitotoxic chemical (amino acid) that makes MSG a chemical hazard.

All of the ingredients that contain MfG, most of which are relatively new, should be included in the Food Code, Annex 4, Table 2b, “Added Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures.”

Given Ajinomoto’s history of countering claims that MSG has toxic potential, it is to be expected that they will mount a vigorous campaign to defeat this petition. For that reason, it is appropriate to have the record show that:

1) All studies to which the glutamate industry refers as evidence of the safety of MSG have negative results which, statisticians will agree, may be interesting for the detail that they provide, but cannot be used as “proof” of anything (3-4).

2) The animal studies which were claimed replications of studies wherein MSG had been found to be toxic used methods and materials that differed from the originals, and were not replications (5).

3) The FDA has done no study of the safety/toxicity of MSG, and what might be referred to as extensive reviews were done at the suggestion of the glutamate industry, staffed by persons with conflicts of interest who did no independent reviews but were provided material to review by agents of the glutamate industry, with “final” reports found unacceptable by the glutamate industry and then rewritten for the FDA (6).

All of the human studies alleged to demonstrate that MSG is harmless were rigged to produce negative results. For example, the placebos used in the double-blind studies cited by Ajinomoto as demonstrating that MSG is harmless, contained excitotoxic amino acids including, but not limited to, the excitotoxic aspartic acid (in aspartame) and the excitotoxic glutamic acid in ingredients such as autolyzed yeast, maltodextrin, and hydrolyzed proteins (6-7).

Action Requested

Petitioner respectfully requests that the Commissioner shall add hydrolyzed protein, autolyzed yeast, maltodextrin and the names of all other ingredients that contain excitotoxic manufactured free glutamic acid to the Food Code, Annex 4, Table 2b, “Added Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures.”

The flavor enhancer monosodium glutamate is cited as a chemical hazard in the Food Code, Annex 4, Table 2b, “Added Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures.” (Exhibit A.) The names of all of the other ingredients that contain potentially excitotoxic manufactured free glutamate (MfG) should be added to that list.

The names of ingredients that always contain MfG follow. An assay of the free L-glutamate in each will verify its MfG content.

Names of ingredients that ***always*** contain MfG:

Glutamic acid (E 620)
Glutamate (E 620)

Monosodium glutamate (E 621)
Monopotassium glutamate (E 622)
Calcium glutamate (E 623)
Monoammonium glutamate (E 624)
Magnesium glutamate (E 625)
Natrium glutamate
Anything “hydrolyzed”
Any “hydrolyzed protein”
Calcium caseinate, Sodium caseinate
Yeast extract, Torula yeast
Yeast food, Yeast nutrient
Autolyzed yeast
Nutritional yeast
Gelatin
Textured protein
Whey protein
Whey protein concentrate
Any protein concentrate
Whey protein isolate
Soy protein
Soy protein concentrate
Soy protein isolate
Any protein isolate
Anything “protein”
Anything “protein fortified”
Zinc proteninate
Anything “proteninate”
Soy sauce
Soy sauce extract
Protease
Anything “enzyme modified”
Anything containing “enzymes”
Anything “fermented”
Vetsin
Ajinomoto

Statement of Grounds

Monosodium glutamate. Monosodium glutamate (MSG) is a man-made product composed of L-glutamic acid (L-glutamate), sodium, moisture, D-glutamic acid (D-glutamate), pyroglutamic acid, and other impurities (unwanted and unavoidable by-products of the manufacture of L-glutamate). MSG is manufactured in plants throughout the world. In the United States, MSG is produced in Ajinomoto’s factory in Eddyville, Iowa. Its principal ingredient is its excitotoxic – brain damaging -- L-glutamate.

For purposes of food labeling, monosodium glutamate is the common or usual name of the product that contains nothing in addition to glutamate, sodium, moisture and unwanted (but unavoidable) by-products of production.

All flavor-enhancers contain L-glutamate. The difference between MSG and flavor-enhancing ingredients identified by the FDA in CFR 101.22 (a)(3) as "natural flavor or natural flavoring" lies in the fact that the flavor-enhancing properties of MSG stem from relatively large quantities of glutamate, the essential ingredient in MSG, opening glutamate receptors in the mouth and on the tongue, producing the **perception** of a more robust taste than there would otherwise be. (Before there was a change in industry's basic propaganda, MSG was referred to as a "flavor enhancer," never an ingredient with a flavor of its own.) In contrast, the constituents of what the FDA calls "natural flavor or natural flavoring" are derived from spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products that start out with their own flavors, and are processed to the point that the small amounts of protein present will be broken down into their constituent amino acids. Their toxic properties will be virtually identical to those present in the glutamate component of MSG, but less concentrated.

Another category of flavor-enhancer is made up of glutamate-containing ingredients other than MSG that don't fit the FDA description of "natural flavors." Autolyzed yeast extract, maltodextrin and hydrolyzed protein products are examples. The glutamate in these ingredients is produced as each ingredient is processed. It is this category of flavor-enhancer that is, in part, the subject of this petition.

L-glutamate. Glutamate is the name given by scientists to the sodium salt of glutamic acid. It is found in most unadulterated foods that contain protein. It is also found in monosodium glutamate (MSG) and all other ingredients where protein content is fermented, hydrolyzed, autolyzed, or otherwise broken into free amino acids.

When present in protein or released from protein in a regulated fashion (through routine digestion), L-glutamate is vital to normal body function. It is the major neurotransmitter in humans, carrying nerve impulses from glutamate stimuli to glutamate receptors throughout the body. Yet, when present outside of protein in amounts that exceed what the healthy human body was designed to accommodate (which can vary widely from person to person), glutamate becomes an excitotoxic neurotransmitter, firing repeatedly, damaging targeted glutamate-receptors and/or causing neuronal and non-neuronal death by over exciting those glutamate receptors until their host cells die (1,2).

L-Glutamate occurs naturally in unadulterated fruits, grains, and vegetables, where it is a constituent of the protein in those fruits, grains, and vegetables. In **ingredients** such as hydrolyzed proteins, autolyzed yeast, hydrolyzed yeast, yeast extract, soy extracts, and protein isolates, glutamate is created when those ingredients are manufactured. The brain-damaging potential of those ingredients has been demonstrated (10). Glutamate is an essential and unavoidable part of each of those ingredients.

Metabolism. Although the claim is made by the FDA and the producers of MSG that the human body utilizes and metabolizes glutamate in the same way whether it comes from MSG or other dietary sources of glutamate, there are no studies to back that claim.

Alleged safety of MSG: the animal studies. The FDA maintains that MSG is a safe ingredient. But they offer no evidence. It would appear that they base their declarations of safety, in part, on **alleged** replications of animal studies of MSG-induced brain damage done for Ajinomoto by Filer, Stegink, Lemkey-Johnston, Boaz, Brummel, Reynolds, Pitkin, and Butler. When Olney and others demonstrated that both L-glutamate and MSG cause brain lesions and neuroendocrine disorders in maturing

animals fed L-glutamate-containing MSG as neonates and infants, glutamate industry researchers produced studies that they claimed were failed attempted replications -- but their procedures were different enough to guarantee that toxic doses had not been administered, or that all evidence that nerve cells had died would be obscured. Industry-sponsored researchers said they were replicating studies but did not do so. Instead, discussion was phrased to suggest that these studies were "replications," and the conclusions were based on what was said, not on what was done (5).

When it became undeniable that L-glutamate was toxic — when L-glutamate was being used by researchers to kill brain cells in laboratory animals in order to identify interventions for treating glutamate-related abnormalities — Ajinomoto decreed that animal studies did not represent the human condition and were therefore meaningless. The FDA did not comment.

L-glutamate-induced brain damage. In the 1960s and 1970s it was repeatedly demonstrated that animals fed L-glutamate as fetuses, or in the first 12 days of life suffered brain damage and neuroendocrine disturbances including obesity, stunting, abnormalities of the reproductive system, and underdevelopment of certain endocrine glands. In addition, researchers observed pathological changes in several brain regions associated with endocrine function in maturing mice that had been given L-glutamate as neonates. In those studies, Accent brand monosodium glutamate was used as the source of L-glutamate, because the L-glutamate in Accent brand monosodium glutamate had been found to be comparable to pharmaceutical-grade L-glutamate in its ability to cause brain damage, but was less expensive (11).

While much of the investigation into the toxicity of L-glutamate focused on MSG-induced toxicity, it was found that hydrolyzed proteins produced brain damage as well (10).

Alleged safety of MSG: the human studies. Those who turned out studies of the "safety" of MSG were paid by glutamate-industry interests to promote their product, MSG. Accordingly, it would not be in their best interests to mention toxic ingredients. So it must be understood that while the human MSG-safety studies are unavoidably studies of the safety of MSG's excitotoxic component, MfG, that is not spelled out in the literature.

Glutamate-industry agents made no attempt to examine MSG-induced brain damage in humans. Rather, in the 1980s human studies of adverse reactions as opposed to brain damage were offered to the FDA as evidence that MSG was a harmless food additive. These weren't alleged replications like the brain-damage studies were, but were creatively designed, each assured of producing negative results (i.e., no harm done by MSG). Negative results could be ensured if researchers considered the effects of glutamate on irrelevant variables, i.e., variables such as blood pressure and weight loss that have never been shown to be associated with glutamate-induced toxicity. Or if females exhibited MSG-induced reproductive disorders and males did not, males would be studied. A variation used was to study the effects on ingestion of glutamate on plasma glutamate levels. Elevated plasma glutamate is associated with production of brain lesions but has never been shown to be relevant to glutamate-induced adverse reactions. The logical fallacy in these studies comes when it is concluded that finding nothing while studying irrelevant variables proves that glutamate is safe.

Negative results were also reliably produced by a series of double-blind studies conducted by a variety of researchers from various universities and medical schools

who were given study protocols that would guarantee negative results, all supervised by Andrew G. Ebert, Ph.D., Ajinomoto's agent in charge of research at the time (without the involvement of Ajinomoto being disclosed). Although these studies had common elements, no two studies were identical. There was, however, one feature that was shared by all – use of placebos that contained excitotoxic amino acids that would trigger reactions identical to those caused by the MSG test material. According to a letter from Ebert to Sue Ann Anderson, Senior Staff Scientist with the Life Sciences Research Office at FASEB, this practice began in 1978 (12).

In a double-blind study, test material is given to a subject on one occasion, and on another occasion the subject is given a placebo. The placebo, if it's a true placebo, looks, tastes and smells like the test material, but it will not cause a reaction. If the subject reacts to the inert placebo, the researchers could conclude that the subject is not having a true reaction, but responding to the mere thought of consuming MSG, in other words, some kind of nut case who might react to anything.

To make sure that it appeared to be appropriate for researchers to conclude that MSG is harmless, glutamate-industry researchers guaranteed that subjects would react to placebos with MSG-type reactions by using aspartame in their placebos, for the aspartic acid in aspartame and the glutamic acid in MSG cause virtually identical reactions as well as identical brain damage (13-14) Having set that up, glutamate-industry researchers (and those who quote them) will say "These people aren't sensitive to MSG, they reacted to the 'placebo' too" (15).

Conclusions drawn from these industry-sponsored studies were based on negative results. The inferential statistics used ask the question of whether a difference between two groups of subjects or two sets of measurements could have occurred by chance. If statistical analysis determines that observed differences rarely would have occurred by chance, an investigator would describe those differences as statistically significant and would specify the probability with which differences of that magnitude would be expected to be reproduced if the experiment were replicated at another time. In statistical parlance, the investigator had tested the hypothesis that there would be no difference between two groups — the null hypothesis — and had rejected that hypothesis when he found that there was indeed a significant difference. The statistical model on which these statistics are based allows the investigator to conclude that it is highly likely — the probability used usually being 95 percent or 99 percent — that differences found were not due to chance. The statistical model does not allow the investigator to conclude that no difference exists between the two groups when a statistically significant difference is not found. The industry-sponsored studies invariably violated the assumptions of the statistical used.

The FDA has reviewed studies of the safety of MSG on multiple occasions, but has never done reviews of MSG toxicity.

The FDA has built and then reinforced its case for the "safety" of MSG on misleading and deceptive studies sponsored by the glutamate industry.

FDA regulations require that those who manufacture food additives must provide evidence demonstrating that they are "safe." The glutamate industry has, indeed, presented evidence, but they have falsified data -- not by changing test scores or research results, but by rigging the procedures used in conducting their studies so that only after careful scrutiny would one discern that their studies were flawed to the point of being fraudulent. Glutamate industry studies are generally methodologically

inadequate, statistically unsound, and/or irrelevant to the safety/toxicity of MSG. Researchers have gone so far as to use aspartame and/or MSG in placebos to cause subjects to respond to placebos just as they would respond to monosodium glutamate test material. In addition, industry's researchers have been known to draw conclusions that did not follow from the results of their studies.

Ajinomoto has focused on the safety of its product, monosodium glutamate, and ignored the toxic potential of L-glutamate and the toxic potential of manufactured free glutamate that does not relate directly to MSG. But what is known about the toxicity of MSG is also true of all other free-glutamate-containing ingredients (10).

A blind eye turned to relevant research. Over the course of the last 50 years, the FDA has summarily dismissed much of the research that clearly demonstrates that MSG places humans at risk. They don't counter it, they simply ignore it. Reports of adverse reactions to MSG collected by its own Adverse Reactions Monitoring System have been dismissed because "they could have been caused by something else."

The FDA has suppressed results of studies that might suggest that use of MSG places humans at risk. The FDA suppressed results of its own study that suggested that use of free glutamic acid in supplements is unsafe. In a July, 1992 report to the FDA, the Federation of American Societies for Experimental Biology (FASEB) had concluded, in part, that: "...it is prudent to avoid the use of dietary supplements of L-glutamic acid by pregnant women, infants, and children.... and...by women of childbearing age and individuals with affective disorders." (MSG is called L-glutamic acid when used in supplements.) Mention has not been made of those recommendations – not to the medical community or anywhere else.

Persons who have identified themselves as representing The Glutamate Association, an organization created and maintained by Ajinomoto, declared that both the FDA and regulators around the world have found monosodium glutamate to be safe. The FDA has parroted that statement. However, neither independent scientists nor independent regulators have deemed monosodium glutamate safe. FDA studies, which were actually reviews, have always been staffed by persons with ties to the glutamate industry. And the regulators and/or authoritative bodies referred to here did no research of their own; they were given copies of FDA opinions on MSG safety or were provided review information by Ajinomoto, its not-for-profit corporations, and/or its agents — the International Food Information Council (IFIC) and the International Life Sciences Institute (ILSI), for example.

Glutamic acid is one of a class of excitotoxic – brain damaging -- amino acids. When consumed in controlled quantities, it is essential to normal body function as neurotransmitters and building blocks of protein. But when consumed in quantities greater than needed for normal body function it becomes excitotoxic, firing repeatedly and killing their targeted glutamate receptors. John Olney coined the term "excitotoxin" in 1969 to describe the actions of glutamic acid and MSG (16).

At one time it would have been meaningful to note that the amount of excitotoxic material in a particular ingredient would not be sufficient to cause brain damage or adverse reactions. But since the 1957 change in method of MSG production, there are so many products that contain excitotoxins that it is easy for a consumer to ingest an excess of excitotoxic material during the course of a day (17-21).

Prior to 1957, the amount of free glutamate or other excitotoxic additives in the average U.S. diet had been unremarkable. During that year, however, the method of producing the free glutamate that makes up the excitotoxic portion of MSG changed from extraction of glutamate from a protein source, a slow and costly method, to a process of bacterial fermentation. This allowed virtually unlimited production of free glutamate and MSG.

It didn't take long for industry to add dozens more excitotoxic food additives to the American diet. Following MSG's surge in production and aggressive advertising, it was realized that profits could be significantly increased if companies produced their own flavor-enhancing additives. Since that time, the market has been flooded with flavor enhancers and protein substitutes that contain manufactured free glutamate (MfG) such as hydrolyzed proteins, yeast extracts, maltodextrin and soy protein isolate, as well as MSG. To that has been added the toxic load contributed by excitotoxic aspartic acid, approved by the FDA for use in aspartame, equal, and related products starting in 1974.

Soon after use of genetically modified bacteria in the production of MSG began, availability of MSG and other MfG-containing products increased to the point where there was more than sufficient MfG to become excitotoxic if a number of processed and ultra-processed foods were consumed during the course of a day.

Annex 4, Table 2b. Added Chemical Hazards at Retail, Along with Their Associated Foods and Control Measures

Added Chemical Hazards	Associated Foods	Control measures
Environmental contaminants: Pesticides, fungicides, fertilizers, insecticides, antibiotics, growth hormones	Any food may become contaminated.	Follow label instructions for use of environmental chemicals. Soil or water analysis may be used to verify safety.
PCBs	Fish	Comply with fish advisories.
Prohibited substances (21 CFR 189)	Numerous substances are prohibited from use in human food; no substance may be used in human food unless it meets all applicable requirements of the FD&C Act.	Do not use chemical substances that are not approved for use in human food.
Toxic elements/compounds Mercury	Fish exposed to organic mercury: shark, tilefish, king mackerel and swordfish. Grains treated with mercury based fungicides	Pregnant women/women of childbearing age/nursing mothers, and young children should not eat shark, swordfish, king mackerel or tilefish because they contain high levels of mercury. Do not use mercury containing fungicides on grains or animals.
Copper	High acid foods and beverages	Do not store high acid foods in copper utensils; use backflow prevention device on beverage vending machines.
Lead	High acid food and beverages	Do not use vessels containing lead.

Added Chemical Hazards	Associated Foods	Control measures
Preservatives and Food Additives: Sulfiting agents (sulfur dioxide, sodium and potassium bisulfite, sodium and potassium metabisulfite)	Fresh fruits and Vegetables Shrimp Lobster Wine	Sulfiting agents added to a product in a processing plant must be declared on labeling. Do not use on raw produce in food establishments.
Nitrites/nitrates Niacin	Cured meats, fish, any food exposed to accidental contamination, spinach Meat and other foods to which sodium nicotinate is added	Do not use more than the prescribed amount of curing compound according to labeling instructions. Sodium nicotinate (niacin) is not currently approved for use in meat or poultry with or without nitrates or nitrates.
Flavor enhancers Monosodium glutamate (MSG)	Asian or Latin American food	Avoid using excessive amounts
Chemicals used in retail establishments (e.g., lubricants, cleaners, sanitizers, cleaning compounds, and paints	Any food could become contaminated	Address through SOPs for proper labeling, storage, handling, and use of chemicals; retain Material Safety Data Sheets for all chemicals.

U.S. Food and Drug Administration 2017 Food Code

EXHIBIT A: FDA 2017 Food Code pages 563-564

Information known to the petitioner which representatives of industry will claim are unfavorable to the petition.

For more than 50 years, Ajinomoto has maintained that monosodium glutamate is a harmless, even beneficial, product. Illustrations of their deceptive and misleading activities including detail of the ways in which they rigged the research from which they concluded that MSG is a harmless food additive are included in the Statement of Grounds. Additional detail can be found in a 1999 peer reviewed published study (6). Ajinomoto's single most clearly documented unethical activity was the use of excitotoxic aspartic acid (in aspartame) in placebos used in double-blind studies proclaiming the safety of MSG.

Environmental Impact: none

Economic impact: Economic impact information will be submitted upon request of the commissioner.

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11. Studies demonstrating both glutamate and MSG-induced brain damage https://www.truthinlabeling.org/Data%20from%20the%201960s%20and%201970s%20demonstrate_2.html

12. The Ebert/Anderson letter: Andrew Ebert's letter to FASEB acknowledging that from 1978 forward, placebos used in International Glutamate Technical Committee (IGTC) studies of the safety of monosodium glutamate were laced with aspartame. https://www.truthinlabeling.org/assets/ebert_letter.pdf

13. FDA Adverse Reactions Monitoring System (ARMS) – Collected Reports of Adverse reactions to monosodium glutamate. https://www.truthinlabeling.org/assets/arms_msg.pdf

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Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Adrienne Samuels