UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

Petition requesting replacement of inaccurate information related to MSG toxicity	)))	Docket No. FDA-2021-P-0301 Petitioner: Adrienne Samuels, Ph.D Date: March 18, 2021

CITIZEN PETITION

The undersigned submits this petition under 21 CFR 10.30 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs remove misleading and incorrect information presently displayed on the FDA website in a post titled "Questions and Answers on Monosodium Glutamate," and replace it with accurate information about monosodium glutamate (MSG) toxicity.

Information issued by the FDA should be held to a high standard of accuracy. Consumers, the media and medical professionals are likely to take FDA statements as being truthful and reproduce them accordingly.

The FDA page: "Questions and Answers on Monosodium Glutamate," which has been displayed on the FDA website since 2012 is filled with inaccuracies and distortions of truth, starkly reminiscent of sales literature produced by or for Ajinomoto, a major manufacturer of monosodium glutamate (MSG).

Petitioner respectfully requests that the Commissioner replace that page with accurate, scientifically correct information about MSG.

Action Requested

Replace the FDA webpage post titled "Questions and Answers on Monosodium Glutamate" with accurate information about the additive, including its toxic potential.

Exact wording of the existing "Questions and Answers on Monosodium Glutamate"

What is MSG?

Monosodium glutamate (MSG) is the sodium salt of the common amino acid glutamic acid. Glutamic acid is naturally present in our bodies, and in many foods and food additives.

How is it made?

MSG occurs naturally in many foods, such as tomatoes and cheeses. People around the world have eaten glutamate-rich foods throughout history. For example, a historical dish in the Asian community is a glutamate-rich seaweed broth. In 1908, a Japanese professor named Kikunae Ikeda was able to extract glutamate from this broth and determined that glutamate provided the savory taste to the soup. Professor Ikeda then filed a patent to produce MSG and commercial production started the following year.

Today, instead of extracting and crystallizing MSG from seaweed broth, MSG is produced by the fermentation of starch, sugar beets, sugar cane or molasses. This fermentation process is similar to that used to make yogurt, vinegar and wine.

Is MSG safe to eat?

FDA considers the addition of MSG to foods to be “generally recognized as safe” (GRAS). Although many people identify themselves as sensitive to MSG, in studies with such individuals given MSG or a placebo, scientists have not been able to consistently trigger reactions.

Does “glutamate” in a product mean it contains gluten?

No—glutamate or glutamic acid have nothing to do with gluten. A person with Celiac disease may react to the wheat that may be present in soy sauce, but not to the MSG in the product.

What’s the difference between MSG and glutamate in food?

The glutamate in MSG is chemically indistinguishable from glutamate present in food proteins. Our bodies ultimately metabolize both sources of glutamate in the same way. An average adult consumes approximately 13 grams of glutamate each day from the protein in food, while intake of added MSG is estimates at around 0.55 grams per day.

How can I know if there is MSG in my food?

FDA requires that foods containing added MSG list it in the ingredient panel on the packaging as monosodium glutamate. However, MSG occurs naturally in ingredients such as hydrolyzed vegetable protein, autolyzed yeast, hydrolyzed yeast, yeast extract, soy extracts, and protein isolate, as well as in tomatoes and cheeses. While FDA requires that these products be listed on the ingredient panel, the agency does not require the label to also specify that they naturally contain MSG. However, foods with any ingredient that naturally contains MSG cannot claim “No MSG” or “No added MSG” on their packaging. MSG also cannot be listed as “spices and flavoring.”

Has FDA received any adverse event reports associated with MSG?

Over the years, FDA has received reports of symptoms such as headache and nausea after eating foods containing MSG. However, we were never able to confirm that the MSG caused the reported effects.

These adverse event reports helped trigger FDA to ask the independent scientific group Federation of American Societies for Experimental Biology (FASEB) to examine the safety of MSG in the 1990s. FASEB's report concluded that MSG is safe. The FASEB report identified some short-term, transient, and generally mild symptoms, such as headache, numbness, flushing, tingling, palpitations, and drowsiness that may occur in some sensitive individuals who consume 3 grams or more of MSG without food. However, a typical serving of a food with added MSG contains less than 0.5 grams of MSG. Consuming more than 3 grams of MSG without food at one time is unlikely.

Exact wording to be used for amending "Questions and Answers on Monosodium Glutamate"

What is MSG? Monosodium glutamate is a man-made product composed of L-glutamic acid (L-glutamate), impurities which include D-glutamic acid (D-glutamate) and pyroglutamic acid, sodium and moisture. Its essential ingredient is L-glutamate, an excitotoxic -- brain damaging – amino acid. When present in protein or released from protein in a regulated fashion (through routine digestion), 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 (as it is in MSG) 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).

How is it made? In 1957, the method used to produce the free L-glutamate that makes up the excitotoxic -- brain-damaging -- portion of MSG was changed from extraction of glutamate from a protein source, a slow and costly method, to a process of bacterial fermentation wherein carefully selected genetically engineered bacteria fed on various carbohydrate media secrete glutamic acid through their cell walls (3). This allowed virtually unlimited production of free L-glutamate and MSG.

Is MSG safe to eat? The FDA has maintained that MSG is a safe ingredient. That, however, is not based on evidence but, at least 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 MSG causes brain lesions and causes neuroendocrine disorders in maturing animals fed 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 studies were "replications," and conclusions were based on what was said, not on what was done.

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 less expensive (4).

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 earlier brain-damage studies were, but were skillfully designed, each apparently calculated to produce negative results (i.e., no harm done by MSG). Negative results are ensured when 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 that ingestion of glutamate had 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. All used 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 (5).

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 reacting to the test material, but is responding to the **thought** of consuming MSG. In other words, the subject would be portrayed as some kind of nut case who might react to anything, and reactions to MSG test material would be discounted.

To make sure that it appeared appropriate for researchers to conclude that MSG is harmless, glutamate-industry researchers guaranteed that subjects would react to placebos 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 (6,7). 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" (8).

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 statistics used.

Does “glutamate” in a product mean it contains gluten?

No—glutamate or glutamic acid have nothing to do with gluten.

What’s the difference between MSG and glutamate in food?

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). The glutamate in MSG is always free.

Glutamate in unadulterated/unprocessed food is almost always bound in protein with other amino acids as opposed to being free. There are none of the impurities that are produced when L-glutamate is manufactured. And when glutamate is freed from protein during normal digestion of unadulterated/unprocessed food, there are no impurities produced. Moreover, bound glutamate does not contribute to L-glutamate-induced adverse reactions or brain damage. The only glutamate that contributes to L-glutamate-induced adverse reactions and brain damage following ingestion of glutamate is manmade free L-glutamic acid. Glutamate in unadulterated/unprocessed food does not cause brain damage or adverse reactions.

How can I know if there is MSG in my food?

FDA requires that foods containing the ingredient identified as monosodium glutamate list it in the ingredient panel on its packaging as monosodium glutamate.

There are, however, other ingredients that contain excitotoxic L-glutamate such as hydrolyzed vegetable protein, autolyzed yeast, hydrolyzed yeast, yeast extract, soy extracts, and protein isolates that can trigger MSG-type reactions. While FDA requires that the names of these products be listed in ingredient panels, the agency does not require labels to also specify that they contain manufactured free L-glutamate.

However, foods with any ingredient that contains manufactured free glutamate cannot legally claim “No MSG” or “No added MSG” on their packaging.

Also worth noting is the fact that MSG cannot legally be listed as “spices and flavoring.” But according to an Ajinomoto 10/10/2020 advertisement in FoodDrive.com (https://www.fooddive.com/spons/glutamates-the-key-to-plant-based-success/586747/) L-glutamic acid can be labeled as a natural flavor.

Has FDA received any adverse event reports associated with MSG?

Over the years, FDA has received reports of symptoms ranging from skin rash to difficulty breathing, difficulty swallowing, a-fib, nausea and vomiting, fatigue, and weakness after eating foods containing MSG. But until pressure was put on the FDA amid growing consumer concern that MSG is toxic, no records were kept. And since a lawsuit against the FDA for failure to label the glutamate in processed food has been dismissed, and pressure has dissipated, reports are being taken of reactions to some commodities, of drug and therapeutic biologic products for example, but not of reactions to MSG.

The FDA Adverse Reactions Monitoring System collected unsolicited reports on reactions to MSG between 1980 and 1996 (6).

The claim is made by the FDA as well as by glutamate-industry interests that the FDA was never able to confirm that the MSG caused any reported effects. Although FDA regulations specify that reports of adverse events are to be investigated, the only reports of investigations of which the Truth in Labeling Campaign is aware were two that were both falsified in order to have them conclude that the subjects were not sensitive to MSG.

In the 1990s, adverse event reports combined with threat of a lawsuit helped trigger the FDA to ask the allegedly independent scientific group the Federation of American Societies for Experimental Biology (FASEB) to examine the safety of MSG. FASEB’s review, (which was staffed in part by persons with conflicts of interest), concluded that MSG is safe. The FASEB study considered reports of short-term, transient, and generally mild symptoms, such as headache, numbness, flushing, tingling, palpitations, and drowsiness, and ignored the potentially debilitating and left-threatening reports of such things as anaphylaxis, a-fib, tachycardia, asthma, and seizures. When industry objected to the 1994 report created for the FDA by FASEB, the FDA rejected the report of that allegedly independent body and had FASEB rewrite its report to include the flagrantly false information that reactions are limited to sensitive individuals who consume 3 grams or more of MSG without food, and the bold-faced lie that consuming more than 3 grams of MSG without food at one time is highly unlikely.

Statement of Grounds

L-glutamate. L-glutamate is the L enantiomer of glutamic acid (glutamate), 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 (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).

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.

Evidence of MSG toxicity. There are three lines of evidence pointing to the toxic potential of monosodium glutamate.

I. The first study to address the possibility that glutamate from exogenous sources (eating for example) might cause brain damage followed by obesity and reproductive dysfunction was published in 1969. At the time, researchers were administering glutamate to laboratory animals subcutaneously using Accent brand MSG because it had been observed that MSG was as effective for inflicting brain damage as more expensive pharmaceutical grade L-glutamate (9).

In the decade that followed, research confirmed that glutamate induces hypothalamic damage when given to immature animals after either subcutaneous or oral doses (4).

II. In the 1980s, researchers focused on identifying and understanding abnormalities associated with glutamate, often for the purpose of finding drugs that would mitigate glutamate's adverse effects. Researchers had found that glutamate was an excitotoxic amino acid. When consumed in controlled quantities, it is essential to normal body function as neurotransmitters and building blocks of protein. But when accumulated in interstitial tissue in quantities greater than needed for normal body function (in excess) it becomes excitotoxic, firing repeatedly and killing brain cells.

It is well documented that L-glutamate is implicated in kidney and liver disorders, neurodegenerative disease, and more. By1980, glutamate-associated disorders such as headaches, asthma, diabetes, muscle pain, atrial fibrillation, ischemia, trauma, seizures, stroke, Alzheimer's disease, amyotrophic lateral sclerosis (ALS), Huntington's disease, Parkinson's disease, depression, multiple sclerosis, schizophrenia, obsessive-compulsive disorder (OCD), epilepsy, addiction, attention-deficit/hyperactivity disorder (ADHD), frontotemporal dementia and autism were on the rise, and evidence of the toxic effects of glutamate were generally accepted by the scientific community. A November 15, 2020 search of the National Library of Medicine using PubMed.gov returned 3872 citations for "glutamate-induced."

By and large, the glutamate in question was, and still is, glutamate from endogenous sources. The possible toxicity of glutamate from exogenous sources such as glutamate-containing flavor enhancers has generally not been considered. But Olney and a few others have suggested that ingestion of free glutamate might play a role in producing

the excess amounts of glutamate needed for endogenous glutamate to become excitotoxic.

III. The third line of evidence comes from studies undertaken by the producer of MSG to convince the public that MSG is a harmless food additive.

To counter data that demonstrated that L-glutamate and MSG cause brain damage, researchers pretended to replicate toxicity studies but did not do so (10).

There is a certain sameness to these studies. They are generally methodologically inadequate, statistically unsound, and/or irrelevant to the safety/toxicity of MSG. In human double-blind studies, researchers have gone so far as to use excitotoxic aspartic acid (in aspartame) and/or various non-MSG sources of excitotoxic manufactured free glutamate, in placebos to cause subjects to respond to placebos just as they would respond to monosodium glutamate test material (8).

Metabolism. Although the claim is made by 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 MSG causes brain lesions and causes neuroendocrine disorders in maturing animals fed 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 studies were "replications," and the conclusions were based on what was said, not on what was done (10).

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 and MSG-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 less expensive (4).

Alleged safety of MSG: the human studies. 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 apparently calculated to produce negative results (i.e., no harm done by MSG). Negative results were ensured when 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 of 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 (5).

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 reacting to the test material, but is responding to the **thought** of consuming MSG. In other words, the subject would be portrayed as some kind of nut case who might react to anything, and reactions to MSG test material would be discounted.

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 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 (6,7). 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" (8).

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 statistics 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. In addition, industry's researchers have been known to draw conclusions that do not follow from the results of their studies (8).

Turning a blind eye 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. 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 its targeted glutamate receptors. John Olney coined the term “excitotoxin” in 1969 to describe the actions of glutamic acid and MSG.

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 (11-15).

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 (3). 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.

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, The Toxicity/Safety of Processed Free Glutamic Acid (MSG): A Study in Suppression of Information (16). Ajinomoto’s single most clearly documented unethical activity has been use of excitotoxic aspartic acid (in aspartame) in placebos used in double-blind studies proclaiming the safety of MSG.

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Environmental Impact: none

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

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.

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Adrienne Samuels