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Aspartame

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Summary

Recent information broadcast on the internet, suggesting that there are health hazards associated with use of the artificial sweetener, aspartame, has precipitated constituent mail to congressional offices. Since it was first approved for use as a food additive in 1981, aspartame has been linked by its critics to a number of health problems. However, federal officials report that, after more than a decade of monitoring, there is no clinical evidence that this artificial sweetener poses a hazard to the average consumer. Individuals with phenylketonuria (PKU), a genetic metabolic disorder, should avoid aspartame because it contains phenylalanine which they can not metabolize. The Food and Drug Administration (FDA) has approved aspartame for use in all food and beverages, following one of the most rigorous testing programs and regulatory reviews in food additive history. Food labels are required to identify the presence of aspartame both on the ingredient label and the warning statement for individuals with PKU. Bills were introduced in the 98th and 99th Congresses to address maximum concentrations, labeling, and consumer education issues, but no final action was taken. In 1987, the Senate Committee on Labor and Human Resources (since renamed Health, Education, Labor and Pensions (HELP)) held the most recent aspartame hearing. This report provides background information and will not be updated.

Aspartame and Health Problems

Since aspartame was first approved for use as a food additive, there have been concerns raised about the health problems associated with this artificial sweetener. Its critics linked aspartame use with Alzheimer's disease, various birth defects, brain tumors, diabetes, Gulf War syndrome, lupus, multiple sclerosis and seizures. However, these assertions have not been borne out by clinical studies following accepted scientific methods.

To date, the only condition for which aspartame use has been recognized as a potential health problem is phenylketonuria (PKU). PKU occurs in individuals with a genetic metabolic disorder in which the amino acid phenylalanine is not metabolized. Aspartame is composed of two amino acids, aspartic acid and phenylalanine. If

phenylalanine builds up in the body, it can cause brain damage. Prenatal diagnosis is now possible in the majority of PKU families and their newborns are tested within 48 hours of birth. Individuals with this condition generally follow a fairly strict dietary regimen to minimize their intake of this amino acid, while otherwise maintaining a balanced diet. Phenylketonurics generally are advised by their health professionals on how to avoid food sources of phenylalanine, including aspartame.

Recent information broadcast on the internet has suggested that aspartame is converted to formaldehyde, then to formic acid, which in turn causes metabolic acidosis. As it is metabolized, aspartame is split into its respective parts, aspartic acid, phenylalanine and methanol. The internet report suggests that methanol toxicity results. However, there is no evidence in the scientific literature to support this contention. In the extensive literature on studies of aspartame metabolism, methanol blood levels were unchanged by normal consumption of this additive. Other commonly consumed foods (for example, tomato juice) result in significantly higher levels of methanol in the body, without any adverse effects.

Aspartame Regulation

The Food and Drug Administration (FDA) first approved aspartame for use as a food additive in 1981. Since 1996 it has been approved for use in all foods and beverages.[1] The sweetener has been approved by more than 90 countries. As a sweetener, it is 200 times sweeter than sugar, enhances fruit flavors, saves calories and does not contribute to tooth decay.

Prior to its approval, aspartame underwent one of the most extensive testing programs and regulatory reviews in food additive history. Tests were conducted in animals and humans, including normal adults and children, lactating women, and individuals with diabetes, obesity and special genetic problems. Aspartame was tested in amounts significantly higher than individuals could normally consume in their diets. This sweetener continues to be studied by scientists as is done for many other ingredients in the food supply. FDA also continues to monitor and evaluate all new research on this compound and other food ingredients.

There is no scientific evidence that aspartame is linked to adverse reactions in humans, with the exception of PKU as noted above. Since 1981 FDA has investigated all reported complaints and has reported a gradual decrease in reports of adverse reactions to aspartame received since the 1985 peak. Individuals who have concerns about possible adverse reactions from the consumption of aspartame are advised to contact their physician.

By regulation, if aspartame is present in a food product, it must be listed on the ingredient label of the product in which it is used. The following warning statement, **Phenylketonurics: Contains Phenylalanine,** is also required to appear on the product to advise consumers who have this genetic defect. This warning statement recognizes the potential health problem to phenylketonurics from the use of aspartame. Early in its use,

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[1] Department of Health and Human Services (HHS). Food and Drug Administration. FDA Statement on Aspartame. FDA Talk Paper. T96-75. November 18, 1996.

the company used the trademark symbol for aspartame on the front panel of product packages containing the sweetener. This trademark was not required by any regulation and seems to have been largely phased out.

It is relatively easy for consumers to avoid aspartame. First, if a product is not marked as "diet or sugar-free," it probably does not contain any artificial sweetener. Regardless of whether a product is marked as "diet or sugar-free," the ingredient listing can be checked to determine whether aspartame is present, because all food products are required to provide a complete list of all ingredients. There are other approved artificial sweeteners that may be used alone or in combination with aspartame to sweeten a product. The product can also be checked for the presence of the company trademark for aspartame on the label or the warning statement for phenylketonurics, if consumers wish to avoid this sweetener.

Congressional Attention

In the 98th Congress, H.R. 4112 was introduced by Congressman Gejdenson to require the Secretary of the Department of Health and Human Services (HHS) to establish a maximum concentration level for aspartame as a food additive. It was referred to the House Committee on Energy and Commerce's Subcommittee on Health and the Environment, but no further action was taken.

In the 99th Congress, Senator Metzenbaum introduced S. 1557 which would have provided for public information concerning the use of products containing aspartame and the conduct of studies to determine the health effects of using this sweetener in food products. Entitled the Aspartame Safety Act of 1985, this measure was referred to the Committee on Labor and Human Resources, but no further action was taken. Earlier in the session, Senator Metzenbaum also sponsored an amendment that would have required a soft drink containing aspartame to be labeled with a statement of the total number of milligrams of the sweetener contained in the drink. The amendment was defeated in the Senate in a recorded vote. Since then no other bills have been introduced on aspartame.

The most recent hearing on aspartame identified was held on November 3, 1987 by the Senate Committee on Labor and Human Resources, chaired by Senator Metzenbaum. The hearing, entitled **"Nutrasweet" — Health and Safety Concerns,** included testimony from consumers who believed that they had experienced severe reactions to aspartame, and a physician who reported having observed reactions in his patients. In addition, several scientists on both sides of the controversy and the FDA commissioner, a consumer attorney concerned about food safety in general, and the president of Nutrasweet (aspartame manufacturer) also testified.

No additional attention to this food additive has been identified since the 99th Congress. The outcome of the 1987 hearing seemed to be that the ongoing clinical studies and post-marketing surveillance reported at that time were sufficient to address the concerns that had been raised, with the understanding that FDA would continue to monitor whether there was evidence of any pattern of adverse effects from the use of aspartame.