

Sweetener manufacturer disputes validity of new health research

- Study links aspartame with cancers
- Ingredient used in more than 6,000 products

Felicity Lawrence
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Aspartame, the artificial sweetener used in more than 6,000 food and drink products around the world, is the subject of renewed controversy this week after the results of the latest research into whether it can cause cancer.

Scientists at the independent European Ramazzini Foundation for cancer research in Bologna presented new results from its long-term, large-scale study of the effect of aspartame on 1,800 rats, at its international conference on cancer and environmental sciences in Italy last week.

The research centre said analysis of its latest results showed aspartame caused cancer of the kidney, and of the peripheral nerves, mainly in the head. Earlier data from the same study published in July linked aspartame to an increased risk of leukaemias and lymphomas in female lab rats "at doses very close to the acceptable daily intake for humans".

Manufacturers of the sweetener have challenged the validity of the study. They say the research is "in total conflict with hundreds of credible studies that have been thoroughly reviewed by the regulatory authorities around the world" and that "the allegations are inconsistent with human epidemiological data". They question the record of the institute and say it is "criminal" for it to present its data publicly before it had made it all available to the regulatory authorities and before it had been fully reviewed.

Aspartame is roughly 200 times sweeter than sugar. It is regularly consumed by more than 350 million people worldwide, and is estimated to account for 62% of the market in sweetening agents. It is commonly found in the UK in diet colas and other low-calorie drinks, juices, sweets, chewing gum, cereals, yoghurts, other desserts, snack foods such as crisps, medicines and vitamin supplements, including those for children.

The European Food Safety Authority is not at present recommending any change in consumers' diets. "Up to now aspartame has been considered safe, based on the studies available," it said. It would review the research "as a matter of high priority, in the context of previous extensive safety data available on aspartame".

Aspartame has been authorised for use in foods for a long time but has a "controversial history", according to EFSA. Because it is widely consumed, particularly by young children and pregnant women, the European Ramazzini Foundation decided to carry out an unusually large study of feeding aspartame to laboratory rats, according to its director, Dr Morando Soffritti.

The rats were studied for nearly three years, until the end of their natural lifespan; most studies last about two years. Six different dose levels were tested against a control group not given aspartame. The National Toxicology Programme of the US National Institutes of Health convened a pathology working group to provide a second opinion on the interpretation of some of the cancerous lesions observed by the Ramazzini researchers, and helped with the statistical evaluation of data.

The Italian scientists concluded that aspartame is a "multipotential carcinogen", causing a dose-related increase in leukaemias and lymphomas in female rats, and a dose-related increase in incidence of cancer and its precursors in the kidney (renal pelvis and ureter) as well as tumours in the peripheral nerves, in particular in cranial nerves.

Aspartame is metabolised into aspartic acid, phenylalanine and methanol. Methanol is in turn metabolised to formaldehyde. Previous large-scale experiments by the Ramazzini Foundation have linked both methanol and formaldehyde to a significant increase of leukaemias and lymphomas, the researchers say. However, they point out that the other sorts of cancer they observed in their aspartame study did not show up in studies on methanol and formaldehyde, suggesting an urgent need to study whether aspartic acid or phenylalanine were also potential carcinogens.

The researchers also found that while rats fed aspartame ate less food, there was no difference in weight between treated and untreated animals. The first results have been published in the foundation's journal, the *European Journal of Oncology*, and have been peer-reviewed by seven international experts, according to the journal's editorial board. The second results have not yet been peer-reviewed.

The foundation is now planning to enlarge its study to embryonic rats and mice - work that will take several years to complete. Meanwhile, one of the authors of the study, Fiorella Belpoggi said: "In our opinion, the results of our first experiment on aspartame call for urgent reconsideration of the rules governing its use as an artificial sweetener."

One of the largest manufacturers of aspartame, Ajinomoto, the Japanese multinational which also makes monosodium glutamate, has challenged the research. Its senior scientists said they did not agree with the interpretation of results, nor did they believe that the study's protocols met internationally approved standards. They said the results were not statistically significant, that numerous studies had shown aspartame was safe, and that regulatory bodies around the world had concluded it was safe.

"Aspartame has a record of 25 years of safe use. Aspartame is made from amino acids and is broken down into common dietary components. Aspartame itself therefore brings nothing new to the diet," a spokesman said. "Raising ill-founded fears about an ingredient which helps people to control calorie intake is not benign."

The International Sweeteners Association said last week: "Aspartame is one of the most tested food ingredients ever and all evaluations undertaken by independent risk assessors at international, European, and national level have concluded that aspartame is a safe foodstuff ... Aspartame can make a useful contribution to weight control. With billions of man-years of safe use, there is no indication of an association between aspartame and cancer in humans."

Aspartame was approved for use by the US Food and Drug Administration in 1981, and for use in soft drinks a couple of years later. The FDA looked at four previous studies conducted for the industry on whether aspartame causes cancer.

One had reported an increase in brain tumours in rats, although the FDA ruled that parts of the study were flawed. Three others concluded it was not carcinogenic. When the FDA reviewed all the data, it concluded that there was no evidence of a carcinogenic effect on the brains of animals. A review of all the data on aspartame was carried out in 2002 by the European commission's scientific committee on food. It concluded that it was safe and reconfirmed the previously established acceptable daily intake of the additive.

Speaking on behalf of Ajinomoto, Ewan Currie, of the Aspartame Information Service, said: "We are confident that when it has been scrutinised by third parties, aspartame will be exonerated."

Footnotes

Peripheral nerves: Parts of motor and sensory nerves, branch from the brain and spinal cord

Leukaemias and lymphomas: Malignant diseases of the blood and lymphatic system. Lymphomas are tumours arising from lymphoid tissue

Acceptable daily intake: The amount of an additive the regulatory authorities calculate a person may eat/drink each day without causing any known harm to health. The UK ADI for aspartame is 0-40mg per kg of body weight

Epidemiological data: The pattern of disease in the population as a whole