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Safety of artificial sweetener called into question by MP

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In 1977 Donald Rumsfeld, now George Bush's defence secretary but then chief executive of the pharmaceutical company GD Searle, publicly stated that he would "call in his markers" to win a licence for **aspartame**, the sweetener that had been discovered by chance in Searle's laboratories, according to Roger Williams in the Commons yesterday.

Mr Williams, MP for Brecon and Radnorshire, said in an adjournment debate that there was much controversy about **aspartame's** safety at the time but "Rumsfeld appears to have honoured his pledge". In fact, "the history of the approval of **aspartame** puts public health regulators and politicians to shame".

The sweetener is now used in 6,000 products, from crisps such as Walkers prawn cocktail, to soft drinks including Diet Coke and Robinson's fruit squash, chewing gums such as Orbit, and vitamins pills and medicines. Yet the science on which it was given approval was "biased, inconclusive, and incompetent". "There is compelling and reliable evidence for this carcinogenic substance to be banned from the UK food and drinks market."

On the day of his inauguration as president in 1981, with Mr Rumsfeld on his transition team, Ronald Reagan personally wrote an executive order suspending the head of the US Food and Drug Administration's powers on **aspartame**, Mr Williams further claimed. One month later Mr Reagan appointed a new head of the regulatory authority, Arthur Hayes, who granted a licence for the sweetener.

"The history of **aspartame's** approval is littered with examples showing that if key decision makers found against **aspartame's** safety, they were discredited or replaced by industry sympathisers, who were recompensed with lucrative jobs."

The MP said he was using his parliamentary privilege to highlight "the strong scientific evidence" that the components of **aspartame** and their metabolites can cause very serious toxic effects on humans, and that long-term **aspartame** use can cause cancer.

Searle had originally submitted a host of studies to the FDA in 1970s in the hope of getting **aspartame** approved. But when flaws were revealed in the science behind another Searle product, Flagyl, the FDA set up a taskforce to investigate 15 of the key studies submitted by Searle on **aspartame**. Dr **Jerome Bressler** was commissioned by the FDA to investigate three of these studies. He had found 52 major discrepancies in Searle's clinical conduct of the studies, Mr Williams told the Commons. Tumours contracted by rats were removed before dissection but not reported; one record shows an animal in the experiment was alive, then dead, then alive again, then dead again.

MPs were told that because it lacked funds, the FDA submitted 12 other studies to be analysed by a research body that

was under contract to Searle at the time. It declared all 12 studies authentic.

Doubts about **aspartame** among FDA scientists were overruled by the FDA's administration and it was given approval. Many other countries soon followed suit and approved **aspartame** on the basis of the same flawed studies, Mr Williams said. In 1996 a review of **aspartame** research found that every single industry-funded study found **aspartame** safe. But 92% of independent studies identified one or more problems with its safety.

Mr Williams outlined to MPs the evidence that the breakdown products of **aspartame** include suspected carcinogens and toxic molecules that damage nerve cells. But the final nail in the coffin for the sweetener, he said, was a new, "monumental" peer-reviewed study, that should have "set alarm bells ringing in health departments around the world".

This vast study, conducted by the Italian-based European Ramazzini Foundation, demonstrated that **aspartame** caused a significant increase in lymphomas and leukaemias, malignant tumours of the kidneys in female rats and malignant tumours of peripheral and cranial nerves in male rats. These tumours occurred at doses that were well below the acceptable daily intake recommended by the regulatory authorities in the EU and US.

The public health minister, Caroline Flint, responding for the government, said it took the issue very seriously and would look at any new evidence. But she added that the use of food additives was very strictly controlled at EU level. The safety of **aspartame** had been very extensively reviewed many times and the current advice remained that it does not cause cancer and is safe.

Artificial sweeteners help in the control of obesity, she said. Acceptable daily intakes were set at a very conservative level. Moreover, the UK's expert committee on toxicity had reviewed the initial data from the Ramazzini Foundation and had not been convinced by its interpretations, but the European Food Safety Authority would conduct a review when it had the full data.

The trade associations for confectionery, snack, soft drink and pill manufacturers and the sweetener industry's **Aspartame** Information Service said **aspartame** had been used safely for many years and evidence for its safety had been reviewed and approved many times by regulators around the world, including by the WHO, the FDA, the UN expert committee on food additives and the EU scientific committee for food.

They pointed out that the European Food Safety Authority has said that "based on current evidence, it does not recommend that consumers who wish to choose foods containing **aspartame** make any changes to their dietary habits".

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The compounds

Aspartame breaks down into three components - a methyl ester and two amino acids: phenylalanine and aspartic acid, according to Roger Williams during the parliamentary debate.

The sweetener industry repeatedly pointed out that these compounds occur naturally in food and drink, yet that statement hid the complex science that makes each one harmful to humans when found in **aspartame**, he added. In food, phenylalanine and aspartic acid are bound to other amino acids in long, complex chains of proteins so that they are not absorbed in a way that could cause damage. But in **aspartame** they are not, and enzymes in the gut can easily split them apart.

Once phenylalanine is released in its free form, it is metabolised into diketopiperazine, a suspected carcinogen. Aspartic acid in its free form becomes an excitotoxin, a toxic molecule that stimulates nerve cells to the point of damage or death.

The third component of **aspartame**, methyl ester, was the most harmful, Mr Williams said. It is metabolised by the

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body into methanol, a well-known poison. In the US, the environmental protection agency defines safe consumption of methanol as no more than 7.8mg a day. Anyone drinking three cans of a drink sweetened with **aspartame** a day was consuming about 56mg of methanol, the MP said.

The public health minister, Caroline Flint, responded by saying that studies had shown methanol levels were not increased by the ingestion of **aspartame**.

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