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## Artificial Sweeteners

4.25 pm

**Mr. Roger Williams (Brecon and Radnorshire) (LD):** I am grateful for the opportunity to have this debate. For almost a year, I have been looking into the safety of the artificial sweetener, aspartame, and I was truly horrified by what I discovered. When I began my research, I was unconvinced by the off-the-wall internet conspiracy theories. I am a man of science, not of the internet. However, a number of eminent academics from the UK and further afield have persuaded me beyond doubt that aspartame represents a serious health problem.

There is strong scientific evidence that the components of aspartame and their metabolites can cause very serious toxic effects in humans. There is also a wealth of subjective evidence that suggests a range of adverse neurological reactions to aspartame. Most importantly, undoubted scientific evidence was published in a top peer-reviewed journal last month that showed that long-term aspartame use causes cancer in rodents. The World Health Organisation recognises such findings in rats as highly predictive of carcinogenic risk for humans.

The history of aspartame's approval is mired in controversy, not least because of the likes of Donald Rumsfeld "calling in his markers" to get it approved. The science that supported its approval was biased, inconclusive and incompetent. Aspartame is in a higher category of risk than Sudan 1, the UK's fastest recalled food substance. However, bad science, bad regulation and bad politics have left the bigger of those two threats in everyday products on our supermarket shelves.

Aspartame is consumed every day by an average of one in 15 people worldwide, most of whom are children. How many children in Britain do not consume Walker's prawn cocktail crisps, Orbit or Airwaves chewing gum, Robinson's fruit squash, Lucozade or Diet Coke? Aspartame is even found in Centrum Kidz multivitamins, Lemsip cold and flu sachets for children, and Nurofen Meltlets for children. Those are the very products that are designed to cure our children when they are sick.

The economic reality of a sweetening agent that costs one third of the price of sugar means that it is present in no fewer than 6,000 foods, drinks and pharmaceutical products in our supermarkets. The history of the approval of this ubiquitous product puts public health regulators and politicians to shame. Health regulators are set up to ensure that substances that reach our food shops are safe for human consumption. The average citizen does not—and should not have to—question the safety of every product on sale in a supermarket. Nor should the average citizen have to question the processes that lead to the licensing of a product. The public should be able to meet—and have trust in—the regulatory experts. However, in licensing aspartame for public consumption, UK and international health regulators did not perform the one task that they were set up for, namely to protect the public.

Crucial questions that have been largely repressed since the early '80s hang over aspartame's safety. When journalists attempted to tackle those questions, their

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newspapers were threatened with intimidating letters from the industry's lawyers. I am duty-bound by the immunity afforded to me under parliamentary privilege—and as a servant of the public—to initiate a debate that has been silenced for over two decades.

I believe that aspartame should never have been licensed for use as a low-calorie sweetener in foods and drinks, and that there is compelling and reliable evidence for this carcinogenic substance to be banned from the UK food and drinks market. I call on the Government to ban the use and sale of aspartame.

What is in aspartame that merits a ban? The chemical breakdown of aspartame reveals three basic components: a methyl ester and two amino acids; phenylalanine and aspartic acid. The sweetener industry will say that those three components occur naturally in fruit, eggs and alcohol. Those compounds are, they argue, harmless or even beneficial to humans. However, those simple truths hide the complex science that makes every one of those components, when found in aspartame, harmful to humans. Molecules that can be good or harmless to the human body are not always so. Factors such as the compounds that the molecules form, the substances with which they are ingested and the concentrations in which they are absorbed can make the difference between an innocuous substance and a toxic substance.

In their natural form, the first two components, phenylalanine and aspartic acid, help keep humans healthy. In foods like meat, fish, dairy products, vegetables and eggs, phenylalanine and aspartic acid are bound to other amino acids in long, complex chains of proteins. When proteins are broken down into their constituent parts during digestion, the protein's amino acids compete with each other for absorption into the human body. That dilutes the risk of a dramatic rise in one single substance in the blood stream, which is when damage is most liable to occur. However, when present in aspartame neither phenylalanine nor aspartic acid are bound to complex chains of amino acids. Enzymes in the gut can easily split them apart. When phenylalanine is released in its free form, it is metabolised into diketopiperazine or DKP, which is a suspected carcinogen.

A similar process occurs when aspartic acid enters the bloodstream. In its free form, aspartic acid becomes an excitotoxin, a toxic molecule that stimulates nerve cells to the point of damage or death. That can have an adverse effect from the twitching of a hand to a grand mal seizure. Studies by Meldrum attest to the damaging effect of free aspartic acid in the human body. If both of the amino acids in aspartame are potentially very harmful to humans, the third component—methyl ester—is the most harmful and potentially lethal component. As soon as it is ingested, the methyl ester is metabolised by the body into methanol. Methanol is a well-known poison.

In the United States, the Environmental Protection Agency defines safe consumption of methanol as no more than 7.8 mg per day. That means that anyone drinking three cans of a drink sweetened with aspartame is consuming about 56 mg of methanol, eight times the EPA limit. Like phenylalanine and aspartic acid, methanol is naturally present in a regular diet of fruit, vegetables and even alcohol. However, as with phenylalanine and aspartic acid, those everyday occurrences of methanol do not make it safe in

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aspartame. In those natural occurrences, the body is shielded from methanol's adverse effects by two protective substances, pectin and ethanol.

The human body lacks the enzyme required to cleave methanol from pectin in fruit and vegetables, so the methanol is never released into our bodies. Moreover, when consuming alcoholic drinks, which almost always contain methanol impurities, the body is protected by the preferential metabolism of ethanol. There is so much more ethanol than methanol in alcohol that the body does

not have time to metabolise the methanol before it is excreted naturally through breath and urine. A human being would need to drink 58 bottles of Jack Daniels in one go to reach potentially toxic levels of methanol through alcohol.

When we ingest aspartame, things are different. Humans do possess the enzyme required to separate methanol from the amino acids. The methanol is then released in its free form and absorbed into the body, according to Davoli's paper in 1986. During the digestion of aspartame, methanol is not coupled with the natural protection of ethanol or pectin, and that leaves us exposed to its toxic properties. However, then comes the alarming part: methanol is unstable in the human body and so gets converted into formaldehyde. Reference to that can be found in the papers of Kavet in 1990 and Trocho in 1998. Let us be clear that formaldehyde is a class A poison, which was used to prevent dead bodies from decaying.

Do we really want our children exposed to an embalming fluid? Some of the formaldehyde accumulated in the body will be converted into formic acid, a potent toxin, which can cause central nervous system depression and, in sufficient quantity, coma and death. Many human studies show the adverse effects from chronic, low-level formaldehyde exposure. Crucially, in 1998 Trocho demonstrated that, even when consuming small doses, severe problems occur from the gradual accumulation of formaldehyde in the body, which cannot be excreted.

Adverse effects include irreversible genetic damage from long-term, low-level exposure shown by Shaham in 1996, low birth weight shown by Marozziene's research in 2002 and cytogenic effects of blood lymphocytes, under Suruda's paper in 1993. The Suruda research that shows the degeneration of white blood cells is particularly relevant in light of the evidence from the World Health Organisation's International Agency for Research on Cancer. A working group looking into the toxicity of chemicals in humans found that exposure to formaldehyde induced leukaemia—a cancer of the white blood cells—and cancer of the nose and throat. Surely, if aspartame metabolites have been shown to cause cancer in humans, we should be more concerned about the safety of the entire product. How can the Government, faced with those facts, still hope to reassure regular consumers of diet cola and other products containing aspartame that they do not run a significantly higher risk of developing cancer as a result of drinking them?

Before considering the studies revealing the dangers of aspartame itself, it is worth reflecting on the magnitude of the risks of the product and its metabolites. Hon. Members will no doubt remember the

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scandal in February this year, when Sudan 1 dye found in food in the UK led to possibly the biggest and fastest ever food recall that this country has ever known. A human being would have had to consume 3 tonnes of Worcestershire sauce every day for two years for potentially harmful effects to occur from tiny doses of Sudan 1 in foods. Despite that minimal risk, however, it was removed immediately.

Sudan 1 was found to be carcinogenic in 1975, but despite that it was placed in the least dangerous of the three WHO categories of carcinogenic substances. Aspartame, which is found in 10 times more products is, on the basis of the ground-breaking Ramazzini study, in WHO category 2, which is potentially far more dangerous to humans.

The Ramazzini study, to which I will return in depth later, revealed a repeated incidence of malignant tumours in rats after moderate regular consumption. Will the Minister explain why the treatment of aspartame, which is still in 6,000 supermarket products today, has been so different from that of Sudan 1?

The toxicity of aspartame's individual components is surely sufficient for us to be alarmed about its widespread use in the products that we and our children consume every day. But consumers and scientists alike have shown there is cause for concern from the regular consumption of products containing aspartame. The US Food and Drug Administration website lists more than 9,000 aspartame-related health complaints, but this could be just the tip of the iceberg.

Health professionals are often unable to diagnose a case of aspartame toxicity when they see one—after all, doctors are not currently trained to recognise it—and a number of cases have been misdiagnosed. A number of independent studies have shown that aspartame toxicity mimics conditions such as multiple sclerosis, Parkinson's disease, Alzheimer's disease, arthritis, chronic fatigue syndrome, panic disorder, lupus, diabetes, lymphoma, depression and other psychological disorders. It is perhaps not so surprising therefore that, frustrated by repeated flawed diagnosis, some people have turned to support groups as a method of sharing case history and exchanging information, some of which even leans towards the hysterical.

The final nail in the coffin for aspartame must surely be the monumental Ramazzini study. The research by the independent European Ramazzini Foundation in Bologna was published online in the highly acclaimed and peer-reviewed *Environment Health Perspectives* journal last month. It should have set alarm bells ringing in health departments around the world.

The conclusions of the Ramazzini study deserve painstaking dissection. It was, without a doubt, the most large-scale, comprehensive study ever performed on aspartame. The study looked at the effects of aspartame on 1,800 male and female rats, using six different control doses. Most studies use only around 400 rats and three usage doses, so it is easy to see why the Ramazzini study is so much more statistically significant than anything done before.

The Italian study allowed the animals to live out their full life of about three years, rather than culling them after two years as sometimes happens. That is particularly crucial, as tumours both in animals and humans are much more prevalent in later life. This vast

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study demonstrated that aspartame administered at varying levels in feed causes a statistically significant increase of lymphomas and leukaemias, malignant tumours of the kidneys in female rats and malignant tumours of peripheral and cranial nerves in male rats. Such tumours occurred even in two of the doses that were well below the acceptable daily intake recommended by regulatory authorities in the EU and the US.

There has been a wealth of compelling and rigorous research showing aspartame to be harmful, which culminated in last month's comprehensive Ramazzini study. How has the industry responded to such an overwhelming volume of sound science? I met industry representatives in October and if they were not scientifically illiterate, they were certainly very misinformed as to the credentials of the Ramazzini study, which they presented as worthless, unpublished and un-peer-reviewed. Holland Sweetener, Ajinomoto and NutraSweet must think that they are very convincing when they claim that aspartame is the safest product on the market by virtue of the 500 studies attesting to its safety. One can test a product 4,000 times, but if the tests are badly conducted and planned in such a way as to yield the desired results, its safety will always be questionable. In reality, the contrast between the quality of the science in the Ramazzini study and the industry studies could not be more clear or more damaging to the industry.

Serious doubts have been raised that suggest links between the results of scientific research and the body responsible for funding it. Professor Ralph Walton, who is present today, demonstrated in 1996 that of the 166 studies conducted on aspartame's safety deemed relevant to humans, 74 were sponsored by the aspartame industry and 92 were independently funded. Of the 92 non-industry

sponsored studies, 92 per cent. identified one or more problems with aspartame's safety. The industry-sponsored studies, on the other hand, found unanimously in favour of aspartame's safety.

The industry has also suggested that aspartame is essential for helping diabetics. Although the American Diabetes Association, which incidentally receives considerable funding from the aspartame industry, claims that aspartame is useful in managing diabetes, there is plenty of evidence to the contrary. Diabetic management is much more complex than simply avoiding sugar. Total calorific intake is far more significant than whether or not a diabetic patient takes a small amount of sugar. Aspartame is known to interfere with the synthesis of serotonin, a neurotransmitter important in appetite regulation. Emerging evidence suggests that aspartame can lead to carbohydrate craving, a devastating situation for a diabetic. The stimulation of insulin release by a non-nutritive substance such as aspartame could potentially lead to hypoglycaemia. Animal studies by Sardesai and Dunbar conclude that aspartame may adversely affect the capacity to control glucose in a diabetic. Diabetic specialists, such as Roberts and Barua, have published extensively on problems of diabetic management caused by aspartame. So, even on diabetes, the industry's arguments have been shown to be highly contestable, at the very least.

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On the question of who to trust on the competing scientific tests—be they on diabetes or aspartame safety—the track record of the industry should leave us in no doubt. The history of aspartame's approval is one in which sound science and proper regulatory and political independence seem to be notable by their absence. Aspartame was first licensed in the United States in 1981. Searle, the chemical company that discovered it, submitted a host of tests to the FDA in the hope of getting it approved. It was granted a provisional licence in 1974. However, when flaws were revealed in the science behind another Searle product—Flagyl—later that year, aspartame's impending licence was brought into question.

The FDA set up a taskforce to investigate 15 of the key aspartame studies submitted by Searle. Dr. Bressler was commissioned to investigate three of those studies. Due to insufficient funds, the FDA submitted the other 12 studies to be analysed by a body called universities associated for research and evaluation in pathology, which was under contract with Searle and which unsurprisingly declared all 12 studies to be authentic. Aspartame was recommended for approval.

Meanwhile, Dr. Bressler reported to the FDA in early 1976. He found no less than 52 major discrepancies in Searle's clinical conduct of its toxicological studies. They included no clear record being kept of the doses fed to rats; antibiotics being given to animals showing symptoms but not being reported; tumours contracted by rats during the experiment being surgically removed before dissection and not reported; and, above all, no clear record of death. One record shows an animal was alive, then dead, then alive, then dead. Yet despite the 52 major discrepancies, FDA scientists were overruled by the FDA's administration, which seems to have been more concerned with safeguarding the institution's reputation after having been initially misled by unreliable data.

**Mr. Bill Olnier** (in the Chair): Order. The hon. Gentleman should be concluding his remarks, because I want to give the Minister at least 15 minutes to reply to the serious allegations that he is making.

**Mr. Williams** : I will quickly draw to a conclusion. I have agreed 10 minutes with the Minister.

**Mr. Bill Olnier** (in the Chair): You have been speaking for 20 minutes.

**Mr. Williams** : Thank you, Mr. Olnier.

Although no formal good laboratory practice protocols existed in the early '70s, it is quite clear that Searle's scientists breached even the most basic understanding of sound laboratory science. However, the real tragedy is that it was on those 15 deeply flawed studies that the final decision to approve aspartame in the US was made, and many other countries soon followed suit. Today, those same highly questionable studies still underpin the science attesting to aspartame's safety.

Aspartame's approval incorporates not just bad science but bad politics. On the political scene, Donald Rumsfeld was instrumental in securing its approval. As chief executive officer of Searle from 1977, he publicly

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pledged to call in his markers to get it approved. Despite a public board of inquiry reopening the case in 1979 and ruling unanimously against its approval, Rumsfeld appears to have honoured his pledge.

When Ronald Reagan was inaugurated as President in 1981, Donald Rumsfeld was on his transition team. President Reagan sealed the lid on the aspartame controversy. On the very day of his inauguration, Reagan personally wrote the executive order suspending the FDA commissioner's powers on aspartame. Reagan replaced the commissioner one month later with Arthur Hayes Jr., who granted the official licence for aspartame. The history of its approval is littered with examples showing that if key decision-makers found against its safety, they were discredited, ignored or replaced by industry sympathisers, who were in turn recompensed with lucrative jobs.

**Mr. Bill Olnier** (in the Chair): I must ask the hon. Gentleman now to conclude.

**Mr. Williams** : Thank you, Mr. Olnier.

I have raised some of the most important questions about aspartame's safety ever discussed in this place. There is solid evidence to suggest that its regular long-term use can cause cancer and a range of other health problems. Emergency action is now needed to remove the toxin from our own and our children's diets. Aspartame has caused concern among the public and the scientific community for more than 30 years. Better information or better product labelling simply is not enough at this point. Today, I am giving the Government a chance to set right what previous British, European and international health authorities have so dismally failed to do. A total ban is the only way to protect the British public.

4.46 pm

**The Parliamentary Under-Secretary of State for Health (Caroline Flint)** : I welcome the debate secured by the hon. Member for Brecon and Radnorshire (Mr. Williams). He obviously feels passionately about this issue. He cited a number of scientists and experts who have a particular view about aspartame. I will go through the procedures that we have in the European Union, which are outside whatever the United States does, for confirming and granting the status and use of additives in our foods, and I will discuss safety in the food chain in relation to the issue. This is not a status quo issue; as any new evidence comes forward, it is important that all these issues are examined afresh. I link to that the latest study to which the hon. Gentleman refers.

I will give an overview. We take the safe use of artificial sweeteners and all additives in food seriously. We are all aware that food additives may be added to food, usually at very low concentrations, for a variety of reasons. Those include restoring colours lost during processing, providing sweetness in low sugar products and preventing deterioration during storage. As the Minister with responsibility for public health, I am always advocating that people have a healthy diet,

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which I hope would include more of the fresh foodstuffs that are available in our stores. That is why we support the five-a-day programme.

The use of artificial sweeteners can be beneficial, particularly for those who seek a low calorie alternative to a certain food. That is especially true given our current debate on how we tackle the increasing problem of obesity in this country. Despite that, the important issue is consumer safety, regardless of whether the additive comes from a natural source or is man made. The question of safety is central to the decision as to whether or not an additive should be permitted in our food.

The use of food additives is strictly controlled by laws that are negotiated at European level, which list those additives that are approved for food use, the types of food in which the additives may be used and the maximum amounts that may be used. Before an additive is approved it must go through an extensive safety evaluation undertaken by independent experts. In the EU, that is now carried out by the independent scientific committees that advise the European Food Safety Authority. The manufacturer of the additive must submit a detailed dossier of research into the safety of that substance in order for it to be evaluated. That research must include toxicological tests to determine whether the substance is harmful. Such tests are designed to give information on any possible effects of exposure to the additive, including whether it may have any potential to cause cancer.

As far as I am advised, aspartame is not known to cause cancer in humans and the evidence does not indicate the potential for it to do so. Most studies in animals showed that it did not cause cancer. It is important for experts to examine the data to see why the Ramazzini study is different. I will come to that matter later and go into more detail.

I shall say something about the difference between aspartame and Sudan 1. Sudan 1 is an industrial dye that has never been approved for use in food and its presence in food is therefore illegal. When it became clear that the substance was being used in foodstuffs—Worcester sauce is one example—we had to act quickly to take those substances off the market. The data from the scientific literature suggests that Sudan 1 is genotoxic in that it damages DNA, but there is no suggestion that aspartame is genotoxic. I make that clear because Sudan 1 should never have been in food products.

The applicant has to justify the technological need for the additive; the process of evaluation can often take years before safety can be assured and even after approval it will be subject to continued monitoring. I am sure the Committee agrees that that is absolutely right.

We need to ensure that consumers can make choices about the foods they eat and European Community labelling regulations require the additive to appear clearly in the ingredient list on food labels. It must be identified by one of a number of category names specified in the regulations, such as sweetener or colour, followed either by the specific name of the additive or by its E number.

Aspartame has been used in soft drinks and other low-calorie or sugar-free foods throughout the world for more than 25 years. Questions have been asked

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about the safety of the product and I shall outline the conclusions that have been drawn from the large body of research investigating its safety.

In 2001, the Food Standards Agency pressed the European Commission to revisit its previous safety assessment of aspartame published in 1988. As a result of that request, the European Commission's independent Scientific Committee on Food reviewed more than 500 research papers published in the scientific literature between 1988 and 2001 on the safety of the product. The papers included studies

that considered the toxicity of the substance, and the research was conducted by independent researchers. The SCF also took into account the outcome of a review published in 2002 of the safety of aspartame, which was carried out by the French Agency for Food, Health and Safety. The review by that agency concluded that there was no evidence of a link between the consumption of aspartame and the development of brain tumours. Following that extensive exercise in December 2002, the SCF concluded that there was no evidence to suggest the need to revise the conclusion previously drawn by the committee that aspartame was safe for use in food.

More recently, in July this year, Worcester at the Ramazzini Foundation in Italy published the findings of new research on the safety of aspartame, suggesting that rats may develop tumours when given doses of aspartame equivalent to the acceptable daily intake amount for humans. However, I understand from the study that the full data has yet to be published and the UK's independent committee on the carcinogenicity of chemicals in foods has reviewed initial data from the study published in July. At this stage they are not convinced by the Worcester interpretation of the data.

However, the Committee agreed that the full data set should be reviewed, and that will be carried out by the European Food Safety Authority. Of course, the findings from the study will need to be considered in the light of the extensive body of existing data on the safety of aspartame. I hope that reassures the hon. Gentleman that we are also open to any new evidence that comes to light but it is important that the full evidence is explored and examined.

The researchers from the Italian institute have been asked to make available all the data from the study in order for the assessment to be carried out. When we

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have advice from the European Food Safety Authority, the Food Standards Agency and its independent scientific advisory committees will study EFSA's opinion carefully and consider whether it needs to revise its advice on consuming aspartame. The current advice from the Food Standards Agency remains in place, namely that aspartame is safe for use in food.

The hon. Gentleman mentioned methanol and formaldehyde. Those substances are naturally present in the body and, as far as I understand, studies have shown that they are not increased by aspartame. Those substances are toxic at high doses, but not at the levels released from aspartame.

I understand that the hon. Gentleman has asked the Food Standards Agency for information to assist him in his investigations. I hope that he agrees that the FSA and its officials have tried to respond in good faith and in a transparent way with the information that he has asked for. That includes information on how scientists and others developed the acceptable daily intake, or ADI, for aspartame.

As I understand it, the intakes are defined for both adults and children, and are set at a very conservative, low level to cover the maximum levels that people might consume. As part of that work, issues were explored, particularly to do with children, the sort of food and drink products that they might use, and the maximum amount of foods containing aspartame that they might consume in a day. That was cross-referenced with the levels of aspartame that children might acquire if they really went all out to consume as many products containing aspartame as possible. When that was done, the study showed that that was still below the accepted daily maximum level.

I recognise the concerns raised in this debate, and I hope that I have assured the hon. Gentleman that we take the issue seriously. Our procedure in the European Union is to continue to keep an open mind about any new evidence that comes forward. However, we should not lose sight of the fact that additives are approved only if they are of benefit to consumers and are shown to be safe at the levels used in foods.

*Question put and agreed to.*

Adjourned accordingly at three minutes to Five o'clock.

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