



INTERNATIONAL
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ASSOCIATION
ASSOCIATION
INTERNATIONALE
POUR LES EDULCORANTS
INTERNATIONALER
SÜBSTOFF-VERBAND

Avenue des Gaulois 9
B-1040 Brussels, Belgium
Tel. +32 2 736 53 54
Fax +32 2 732 34 27
e-mail : isa@ecco-eu.com
website : www.sweeteners.org

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Overwhelming Scientific Evidence Affirms Safety of Aspartame: No Link to Cancer

International Sweeteners Association (ISA) statement

Aspartame is a low-calorie sweetener, which is used to impart a sweet taste to foodstuffs and as a table-top sweetener. It is one of the most tested food ingredients ever and all evaluations undertaken by independent safety authorities at international, European and national level have concluded that aspartame is a safe foodstuff. In its December 2002 report the Scientific Committee on Food of the European Commission (SCF) - now the European Food Safety Authority (EFSA) - stated: "Aspartame is unique among the intense sweeteners in that the intake of its component parts can be compared with intakes of the same substances from natural foods". And concluded:- "The Committee concluded that on the basis of its review of all the data in animals and humans available to date, there is no evidence to suggest that there is a need to revise the outcome of the earlier risk assessment or the ADI previously established for aspartame."-Four long-term carcinogenicity studies on aspartame conducted in accordance with international standards have found no relationship between aspartame and any form of cancer. Aspartame has been used by hundreds of millions of consumers around the world for over 20 years. With billions of man-years of safe use, there is no indication of an association between aspartame and cancer in humans.

Aspartame, approved for use in Europe in 1983 and the US Food and Drug Administration (FDA) in 1981, is one of the most thoroughly studied food ingredients with more than 200 scientific studies confirming its safety.

In addition to SCF and FDA, the Joint Expert Committee on Food Additives (JECFA) of the World Health Organization (WHO) and the Food and Agriculture Organization (FAO), and regulatory agencies in more than 100 countries have reviewed aspartame and found it to be safe for use.

By providing sweetness without calories, aspartame can make a useful contribution to weight control. For example, a soft drink sweetened with aspartame can have as little as one calorie per serving. At a time when governments and the medical profession are increasingly concerned about overweight and obesity, it is unhelpful to raise ill-founded fears about a popular choice which helps people to control calorie intake. In Europe alone, obesity is estimated to cause 70,000 new cancer cases every year.

A study from Ramazzini researchers published in *Environmental Health Perspectives*, a publication of the National Institute of Environmental and Health Sciences (NIEHS), alleging that aspartame may be related to an increased risk of leukaemia and lymphoma in rats, is entirely inconsistent with the extensive scientific research and regulatory reviews conducted on aspartame by numerous national and international food safety authorities. Moreover, there is no association between the prevalence of aspartame in the marketplace and the incidence of leukaemia or lymphoma.

The researchers at Ramazzini have not followed the internationally established protocol for evaluation of animal carcinogenicity study findings. The U.S National Toxicology Program (NTP) has established guidelines for pathology peer review in order to provide scientific consensus that study conclusions are valid. An independent peer review of the pathology slides from this study has not been carried out.

The amounts of aspartame fed to the rats were in most cases significantly higher than those consumed by even the heaviest users of aspartame containing products and in some cases the doses of aspartame provided were even a hundred times greater than the Acceptable Daily Intake (ADI), established by SCF, now EFSA.

Importantly, regulatory agencies have reviewed studies conducted by the same researchers reporting the recent study. Findings by researchers at the same institution and using a similar protocol have been reviewed by the FDA Cancer Assessment Committee which concluded that the data reported were "unreliable" due to "a lack of critical detail ... questionable histopathological conclusions, and the use of unusual nomenclature to describe the tumours." According to Dr. James Swenberg, of the University of North Carolina at Chapel Hill, this study should undergo peer-review and most previous studies conducted at the Ramazzini Foundation have not undergone such review.

Consequently acceptance and reporting of such findings should be withheld until the pathology data has been peer reviewed by independent pathologists and more importantly, until the raw data from this study has been evaluated by the relevant food safety authorities.

In light of anecdotal reports and allegations about aspartame, several regulatory agencies and expert scientific committees, including Health Canada, SCF, the United Kingdom's Food Standards Agency (FSA) and the French Food Safety Agency (AFSSA) decided to conduct thorough reviews of aspartame's safety and the latest research findings. In these recent re-reviews, all concluded that aspartame is safe. (For more information about these re-confirmations of safety, please visit http://www.aspartame.org/aspartame_latest.html)

On 19th December 2005, EFSA announced that they had received the data on aspartame from the Ramazzini Foundation and that they would begin their evaluation as a matter of high priority, which could take three to five months. EFSA also pointed out that it would "consider the data from the new study in the context of the previous extensive safety data available" - http://www.efsa.eu.int/press_room/press_release/1272/pr_afc_aspartamedata_en3.pdf.

In the meantime, EFSA, AFSSA, Health Canada, the FSA and the FDA have all confirmed that **currently there is no basis for recommending any changes in consumers' diets in respect of aspartame**. The International Sweeteners Association (ISA) welcomes these comments and is confident that the safety of aspartame will once again be reconfirmed.