

## Breaking News on Food & Beverage Development - North America

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### New study reignites aspartame cancer concerns

By Stephen Daniells

6/26/2007- **Concerns over the safety of aspartame could be reignited after a new study with rats linked regular intake of the sweetener with increased risk of leukaemia, lymphomas and breast cancer.**

The study, by the European Ramazzini Foundation of Oncology and Environmental Sciences in Italy, also reports that when exposure to the sweetener starts during foetal life, the potential carcinogenic effects are increased.

This has led some consumer groups, particularly in the US, to call for a review of the safety data on aspartame and for consumers to avoid products that contain the ingredient.

However, food regulatory bodies on both sides of the Atlantic appear unmoved by the new science. The Food and Drug Administration (FDA) has stated that it is currently reviewing the news, but notes that the research is at odds with its own studies.

Indeed, FDA spokesman Michael Herndon told Reuters: *"At this time, FDA finds no reason to alter its previous conclusion that aspartame is safe as a general purpose sweetener in food."*

The safety of aspartame was first called into question in 2005 when Ramazzini researchers claimed that aspartame consumption by rats leads to increase in lymphomas and leukaemias in females at dose levels *"very near those to which humans can be exposed"*.

The new study, published in the journal *Environmental Health Perspectives*, is said to support and expand on this initial study.

*"The results of this carcinogenicity bioassay not only confirm, but also reinforce the first experimental demonstration of APM's multipotential carcinogenicity at a dose level close to the acceptable daily intake (ADI) for humans. Furthermore, the study demonstrates that when lifespan exposure to APM begins during foetal life, its carcinogenic effects are increased,"* wrote lead author Morando Soffritti.

In terms of world consumption, the artificial sweetener represents 62 per cent of the value of the intense sweetener market, and is believed to be found in around 6,000 products worldwide, including carbonated and powdered soft drinks, hot chocolate, chewing gum, candy, desserts, yogurt, tabletop sweeteners, and some pharmaceutical products, such as vitamins and sugar-free cough drops.

For the new study, the researchers added aspartame (greater than 98.7 per cent purity, less than 0.3 per cent diketopiperazine, and less than 0.5 per cent L-phenylalanine) at concentrations of 2000, 400, or 0 ppm, which simulated an assumed daily aspartame intake of 100, 20, or 0 mg/kg bw.

Groups containing up to 95 male and female Sprague-Dawley rats, a strain of rat with cancer susceptibility reportedly similar to that of humans, were fed the diets, starting at the 12<sup>th</sup> day of foetal life.

*"The results of the study show: a) a significant dose-related increase of malignant tumor-bearing animals in males, in particular in the group treated at 2000 ppm; b) a significant increase of the incidence in lymphomas/leukemias in males treated at 2000 ppm and a significant dose-related increase of the incidence of lymphomas/leukemias in females, in particular in the group treated at 2000 ppm; c) a significant dose-related increase of the incidence of mammary cancer in females, in particular in the group treated at 2000 ppm,"* stated the researchers.

*"On the basis of the present findings, we believe that a review of the current regulations governing the use of aspartame cannot be delayed. This review is particularly urgent with regard to aspartame-containing beverages, heavily consumed by children,"* they concluded.

No one from EFSA was available for comment prior to publication, but after evaluating the first Ramazzini study in May 2006 the authority issued its opinion that there was no need for a further safety review of aspartame nor a revision of the acceptable daily intake (40 mg/kg body weight).

In the US, consumer group the Center for Science in the Public Interest (CSPI) called on the FDA to immediately review the study.

*"Because aspartame is so widely consumed, it is urgent that the FDA evaluate whether aspartame still poses a 'reasonable certainty of no harm,' the standard used for gauging the safety of food additives,"* said CSPI executive director Michael Jacobson.

But, according to Reuters, FDA spokesman Michael Herndon said the agency had not yet reviewed the study.

*"However, the conclusions from this second European Ramazzini Foundation are not consistent with those from the large number of studies on aspartame that have been evaluated by FDA, including five previously conducted negative chronic carcinogenicity studies,"* Herndon said in an e-mail to the news agency.

An epidemiological study in Italy concluded that there was no indication of an association between sweetener consumption and cancer risk (*The Annals of Oncology*, doi:10.1093/annonc/mdl346).

Moreover, a US study sponsored by the National Cancer Institute involving 340,045 men and 226,945 women, ages 50 to 69, found no statistically significant link between aspartame consumption and leukaemia, lymphomas or brain tumours.

Source: *Environmental Health Perspectives*

Available on-line 13 June 2007, doi: 10.1289/ehp.10271

*"Lifespan Exposure to Low Doses of Aspartame Beginning During Prenatal Life Increases Cancer Effects in Rats"*

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