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FDA, EFSA to review new aspartame study

By Lorraine Heller

6/27/2007- Regulatory bodies in the United States and Europe have said they will review a new study linking aspartame to an increased risk of cancer, but have reiterated that until an evaluation of the data is conducted they continue to support the safety of the sweetener.

The measured comments come in a climate of fierce debate ignited by the release of the second round of findings from the European Ramazzini Foundation of Oncology and Environmental Sciences (ERF) in Italy.

Published this month in the journal *Environmental Health Perspectives*, the new study with rats linked regular intake of the sweetener with increased risk of leukaemia, lymphomas and breast cancer. It also reported that when exposure to the sweetener starts during fetal life, the potential carcinogenic effects are increased.

In an e-mail to FoodNavigator-USA.com, the US Food and Drug Administration (FDA) stated: *"FDA is interested in reviewing the recently published study; however, to date FDA has not been provided the data from this new study. Until FDA conducts an evaluation of the study, it cannot comment on the findings."*

"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. Therefore, at this time, FDA finds no reason to alter its previous conclusion that aspartame is safe as a general purpose sweetener in food."

The European Food Safety Authority (EFSA) said it *"considers carefully"* any *"new evidence that was not available at the time an opinion is adopted."*

"EFSA was aware of the upcoming study of the Ramazzini Foundation on aspartame and had requested detailed information from them. The Ramazzini Foundation however would not consider giving EFSA the data before the peer reviewed study was published," it said.

"Now that the study has been published, EFSA will reiterate its request and will decide on the level of priority to review the data as soon as these become available."

The safety of aspartame was first called into question in 2005 when ERF published its first study on the sweetener's link to cancer. After reviewing the study data, both FDA and EFSA concluded last year that the findings did not provide sufficient evidence to call into question their classification of aspartame as safe for human consumption.

The new study, which was funded entirely by ERF, is said to support and expand on this initial study.

"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," concluded the researchers.

Consumer groups are also calling for immediate action. In the US, the Center for Science in the Public Interest (CSPI) together with a dozen toxicology and epidemiology experts on Monday wrote to FDA Commissioner Andrew von Eschenbach requesting the agency to review the study without further delay.

"Considering how widely aspartame is consumed by young children, as well as adults, in the United States and abroad, it is essential that this review be done as expeditiously as possible," they wrote.

Among those who signed the letter were former Occupational Safety and Health Administration officials John Froines (now at UCLA) and Peter F. Infante (now at George Washington University);

James Huff, current Associate Director for Chemical Carcinogenesis at the National Institute of Environmental Health Sciences (NIEHS); and Kamal M. Abdo, a toxicologist formerly at the National Toxicology Program of the NIEHS.

Industry groups, however, viciously supported the safety of the ingredient, citing numerous studies that have shown the ingredient is not a carcinogen.

The Calorie Control Council, which represents the low-calorie industry, said in a statement that *"it is difficult to accept a new claim of carcinogenesis in rats ingesting large amounts of the sweetener, particularly given the extensive database that already exists showing the absence of carcinogenic effects"*.

The International Sweeteners Association criticized the methodology used by ERF, claiming that the cancer incidence in the rats used in both Ramazzini studies were *"the result of variations in the high spontaneous rates of cancers in this animal colony"*.

"Replication of flawed data does not make that data any less flawed," it said.

The Grocery Manufacturers Association (GMA) made no mention to the new study other than to say it approaches it with *"significant skepticism"*. It reiterated its view that *"there is a plethora of scientific studies, reports, databases, and regulatory rulings indicating there is no evidence to support any notion that aspartame is carcinogenic"*.

Similarly, the manufacturer of leading aspartame product NutraSweet told FoodNavigator-USA.com that *"aspartame is safe. It has been tested for more than three decades, in more than 200 studies: Aspartame is safe for use"*.

"Aspartame has been reviewed and determined to be safe by the United States Food and Drug Administration, the Scientific Committee on Food of the European Union, Joint Expert Committee on Food Additives (JECFA) of the Food and Agricultural Organization/ World Health Organization, and the regulatory bodies of more than 100 countries," said NutraSweet chief executive officer Craig Petray.

Merisant, which sells the other leading aspartame brand Equal, did not respond in time for publication.

Kathryn Knowles, director of resource development at ERF told FoodNavigator-USA.com that *"the approach of industry and industry-sponsored lobbies is two-fold; first to raise doubts about the credibility of our institution and then about the design or conduct of our studies"*.

"The ERF has faced similar criticism by industry, lobbies and industry-sponsored scientists almost every time we have published new data on the carcinogenicity of a compound or agent in the last 35 years."

"Despite these criticisms, it must be noted that experimental data reported by the ERF have not been challenged by epidemiological evidence. It is also interesting that these criticisms are never applied to our carcinogenicity studies when the results are negative."

To view a copy of the latest ERF study, click [here](#).

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