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PRESS RELEASE

EFSA assesses new aspartame study and reconfirms its safety

The AFC Panel¹ of the European Food Safety Authority (EFSA) has evaluated the new long-term study on the carcinogenicity of aspartame conducted by the European Ramazzini Foundation² in Bologna, Italy. In its opinion published today, the Panel concluded, on the basis of all the evidence currently available, that there is no need to further review the safety of aspartame nor to revise the previously established Acceptable Daily Intake (ADI) for aspartame (40 mg/kg body weight). The Panel also noted that intakes of aspartame in Europe, with levels up to 10 mg/kg body weight per day, are well below the ADI.

Aspartame, an intense sweetener, has been authorized for use in foods and as a table-top sweetener for more than 20 years in many countries throughout the world. Extensive investigations have been carried out on aspartame and its breakdown products through experimental animal and human studies, intake studies and post-marketing surveillance. In addition to a number of safety evaluations conducted in the past, the Scientific Committee on Food (SCF) carried out a review of all original and more recent studies on aspartame in 2002³ and reconfirmed that aspartame is safe for human consumption.

However, since it was introduced onto the market, the safety of aspartame has been a controversial issue. In 2005, the European Ramazzini Foundation published new findings of a long-term study on aspartame conducted in rats. The scientists from the European Ramazzini Foundation concluded that the results of their study indicate that aspartame can cause cancer and that the current guidelines on the use and consumption of the sweetener should be re-evaluated. EFSA immediately undertook the evaluation of the new findings and requested that the European Ramazzini Foundation provide all study details necessary for the assessment. The European Commission confirmed the need to assess the study and supported the high priority given to this work.

¹ Panel on food additives, flavourings, processing aids and materials in contact with food (AFC)

² European Foundation of Oncology and Environmental Sciences "B. Ramazzini"

³ http://europa.eu.int/comm/food/fs/sc/scf/out155_en.pdf

The Panel has evaluated extensive data from the new study on aspartame provided to EFSA by the European Ramazzini Foundation. The Panel noted that this lifetime study used more animals per dose group and a larger number of doses than conventional carcinogenicity studies. It therefore represented a substantial effort and had the potential to be more sensitive to low incidence effects. However, a number of major issues with the study were identified by the Panel which made interpretation of the findings difficult. Notably, a high background incidence of chronic inflammatory disease in the lung and other organs was observed in all the animal groups including controls which did not receive aspartame, as reported by the European Ramazzini Foundation. This was considered to be a major confounding factor.

In detail the Panel concluded the following:

- The slight increase in incidence of cancers known as lymphomas and leukemias in treated rats was considered to be unrelated to aspartame treatment and most likely attributed to the high background incidence of inflammatory changes in the lung. In addition, there was no dose-response relationship with respect to increasing doses of aspartame.
- The findings in the kidney, ureter and bladder, observed mainly in female rats, are not specific to aspartame and have been observed with a number of chemicals administered to rats at high dose levels. Such changes are normally the result of irritation or imbalances in calcium metabolism specific to rats and are of no relevance for humans.
- Concerning the malignant tumors of the peripheral nerves, the numbers of tumours were low with no clear dose- response relationship over a wide dose range. There is also uncertainty about the diagnosis of these tumours. The Panel indicated that this finding can only be fully evaluated by an independent peer-review of the relevant tissues.

Finally the Panel concluded that based on all the available data to date there is no reason to further review the previous scientific opinion on the safety of aspartame nor to revise the Acceptable Daily Intake (ADI) for aspartame of 40 mg/kg body weight. Commenting on the AFC Panel's risk assessment, Dr. Herman Koëter, EFSA Acting Executive Director, said: "EFSA considers that the results of this new study on aspartame do not provide a scientific basis for reconsidering its use in foods. If any new information would become available in the future, EFSA will review these as a matter of priority."

The full text of the opinion is available at:

http://www.efsa.eu.int/science/afc/afc_opinions/1471_en.html

For additional information, please see the related background documents (Frequently Asked Questions on aspartame) and links to previous press releases and risk assessments related to aspartame which are provided on the EFSA website at: http://www.efsa.eu.int/press_room/focus_on_the_issues/aspartame/catindex_en.html

Note to editors

The data from the new study on aspartame presented in the European Ramazzini Foundation's publications⁴ were insufficient for the AFC Panel to evaluate the study and its findings. Following discussions with the Foundation in June 2005, EFSA requested access to further scientific information required for the evaluation. In December 2005, EFSA received an extended dossier of the findings. An EFSA Working Group on aspartame consisting of independent scientific experts in the area was set up immediately after the receipt of the data at the end of 2005. However, some crucial information and data were still lacking. On request, the European Ramazzini Foundation provided EFSA on 19th April 2006 with further data. However on review, they did not contribute significantly to the evaluation of the findings.

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⁴ <http://www.ramazzini.it/fondazione/docs/AspartameGEO2005.pdf>
<http://www.ehponline.org/members/2005/8711/8711.html>