

New research data on the sweetener aspartame to be considered by EFSA's scientific experts

A scientific institute in Bologna* has carried out a new study on the sweetener aspartame. The first results of the study conducted in rats to assess the possible carcinogenicity of aspartame have been made public today at a press conference in Bologna. EFSA has already held initial discussions with the scientists concerned and will ask its Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC), as a matter of high priority, to review these results, in the context of the previous extensive safety data available on aspartame. The full data from this new study are not yet available to enable this process to start; therefore, several months are likely to be required before the Panel can come to a conclusion. EFSA has also informed its Advisory Forum regarding this study and requested that members share any new research or data for consideration by the Panel. EFSA does not currently have a basis for recommending any changes in consumers' diets in respect of aspartame.

Aspartame has been authorised for use in foods and as a table-top sweetener for a long time in many countries throughout the world, but it has a controversial history. Since its approval, the safety of aspartame has been discussed in the generalist press and among scientists, including not only the safety of aspartame itself but also that of its breakdown products: aspartic acid, phenylalanine and methanol. Aspartame has undergone extensive investigation through clinical and laboratory research, intake studies and post-marketing surveillance of reports of adverse health effects. Up to now aspartame has been considered as safe, based on the studies available.

In the European Union (EU), aspartame was first authorised for use by several Member States in the 1980s and European legislation harmonising its use in foodstuffs was introduced in 1994**, following thorough safety evaluations (in 1984, 1987, 1988) by the EC Scientific Committee for Food (SCF). A further review of all the original and more recent data on aspartame was carried out in 2002 by the SCF. Both published and unpublished data, including all the information on genotoxicity and carcinogenicity in animals and humans, were considered at that time and the SCF re-confirmed the previously established Acceptable Daily Intake (ADI) for aspartame.

Today the European Foundation of Oncology and Environmental Sciences "B.Ramazzini" in Bologna (Italy) presented new results to the public. An outline of the new findings was presented by the institute to a small group of EFSA staff and scientific experts in June. The AFC Panel will give high priority to the evaluation of the new data. As soon as all the data have been provided to EFSA by the institute in Bologna, including full pathology reports which are still in preparation, the Panel will start its evaluation. At the same time the experts will take into account the other studies and data available to date in the scientific literature on the sweetener aspartame. This will probably take several months.

EFSA does not consider it appropriate to suggest any change in consumers' diets relative to aspartame on the basis of the information it currently has. The issue will however be fully reconsidered in the risk assessment which will be undertaken and following EFSA's usual practice, the results will be communicated to the public and to risk managers.

^{*}The cancer research centre of the European Foundation of Oncology and Environmental sciences "B. Ramazzini",

Bologna (Italy)

**Further information regarding EU legislation on the use of sweeteners in foodstuffs is provided on the website of the European Commission Health and Consumer Protection Directorate General at https://ec.europa.eu/jrc/en/science-area/health-and-consumer-protection

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