



## European Food Safety Authority

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Roma, 5 May 2006

### **EVALUATION OF THE NEW STUDY OF ASPARTAME CARRIED OUT BY THE RAMAZZINI FOUNDATION**

#### **Statements to the Press by the Acting Executive Director of EFSA, Dr. Herman B.W.M. Koëter**

- EFSA was established as Europe's food and feed watchdog: it assesses the risks, or the safety, of our food, beverages, including plants and animals that are part of the food chain. It so is key to ensuring that the food we eat is safe.
- EFSA's role is limited to science: EFSA is not responsible for risk management decisions but it provides the high quality science in a transparent and impartial manner, involving Europe's best scientists in the process.
- When EFSA was informed in May 2005 that a new, life span study was completed with aspartame by the Italian research institute of the Ramazzini Foundation, it immediately invited the authors of the study to share with EFSA detailed information of the study to allow an independent European evaluation of the results.
- Considering the wide use of aspartame in food and beverages by consumers of all age groups and geographical spread and to safeguard the European consumer's best protection, EFSA gave highest priority to conduct a comprehensive scientific evaluation of the new study once the requested data would be received. EFSA also arranged to closely inform all national food safety authorities in Europe through its Advisory Forum of all details of the study and the evaluation process.
- The Ramazzini Foundation and its Director, Professor Soffritti, have been very cooperative and following publication of abstracts of the new study's outcome in various journals and at technical meetings, EFSA received, as promised, extensive details of the study on 19 December 2005. These data were essential for the comprehensive scientific evaluation of the study's reported outcome.
- The evaluation started immediately following receipt of the data and was carried out by EFSA's Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel) and an *ad hoc* Working Group of the Panel comprising additional European experts on carcinogenicity, toxicological pathology and statistical analysis.

- All experts have been selected from Europe's best food scientists applying very strict selection criteria which included the number of years of professional experience with risk assessment and proven high levels of scientific expertise. The experts involved came from 12 European Member States.
- The strength of EFSA's risk assessment of aspartame in light of the new study and resulting opinion are determined not only by the high scientific level of the experts involved but also by their independence. While independence refers to total impartiality with respect to the outcome of the assessment this, unfortunately, is often confused with the notion that experts should never have had any dealings with the subject in the past. However, the required knowledge of the subject almost inevitably means having dealt with it scientifically before.
- The misunderstanding that previous involvement equals an interest in a particular outcome has unfortunately resulted in statements in the press that certain members of EFSA's AFC Panel might have had a conflict of interest. Therefore I would like to make it very clear that all EFSA's AFC Panel and Working Group experts were fully impartial as to the assessment of the new aspartame study; they had no interest whatsoever in the outcome of the assessment and were in no way dependent of any parties which may have an interest in the outcome of the assessment. Their respective published declarations of interest support this.
- In the evaluation of the new study, the Panel and Working Group have taken into account well established international agreements on preferred hazard and risk assessment approaches including study designs as defined by the Organisation for Economic Cooperation and Development (OECD) and WHO/FAO.
- EFSA has been on close contact with the Food and Drug Administration (FDA) in the USA, the Japanese Food Safety Commission (FSC) and the Ministry of Health in Canada and has kept these authorities informed of the assessment process and, on 2<sup>nd</sup> May, its outcome.
- EFSA is fully aware of the importance of its assessment of the risks of aspartame in light of the new study and of possible consequences of its scientific opinion. Separating risk assessment from risk management was the founding principle of EFSA establishment and in the best interest of European consumers. This opinion clearly reflects that principle: a purely scientific advice without any political or economical bias.
- EFSA is grateful to the Ramazzini Foundation and its Director, Professor Soffritti, for cooperating by sharing important details of the collected study data and I look forward to further cooperation in the future.

**For media enquires, please contact**

E-mail: [Press@efsa.eu.int](mailto:Press@efsa.eu.int)

Carola Sondermann, Senior Press Officer

Tel: +39 0521 036 294