European Food Safety Authority

Introduction to the process of re-evaluation of aspartame by EFSA

Dr. Claudia Heppner, Head of FIP Unit, EFSA

Follow-up meeting on the web-based public consultation on aspartame
9 April 2013, Bruxelles

Aspartame: previous evaluations and current re-evaluation by EFSA

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- Is approved in the European Union as E951
  - Acceptable daily intake (ADI) of 40 mg aspartame per kg body weight per day

- Nearly 40 years of evaluations by …
  - FDA (1974, 1981)
  - SCF (1984, 1988, 2002)
  - JECFA (1975, 1976, 1978, 1980, 1981)
  - and national authorities (AFSSA, FSA, etc)
  - EFSA (2006, 2009, 2011)

- 2011: European Commission asked EFSA to anticipate the re-evaluation of the safety of aspartame from 2020 to May 2013 as the safety of aspartame has been challenged on several occasions.

Preparation of the re-evaluation of aspartame: Transparency and openness

- Public calls for data
  - Aspartame: 1 June - 30 September 2011 (>800 publications/studies received, including original study reports)
  - DKP (5-benzyl-3,6-dioxo-2-piperazine acetic acid, a degradation products from aspartame): 26 July – 30 September 2012
  - Publication of all data on EFSA webpage
- Continuous monitoring of publications on aspartame (ongoing since July 2011)
- Call for tender for preparation of an external scientific report
  - reviewing the existing literature on aspartame
  - reviewing 15 original study reports (independent quality check)

Preparation of the re-evaluation of aspartame: Transparency and openness

- Creation of Working Group (WG) 'Aspartame' by ANS Panel (December 2011)
  - Ten external experts in the areas of metabolism, general toxicity, carcinogenicity and exposure. Seven of the ten experts have not been involved in any previous assessment of aspartame.
  - Task: to prepare a draft opinion on the safety of aspartame. Meeting minutes and declaration of interests are published on website.

- Draft opinion prepared by ANS WG Aspartame and several times discussed during ANS Panel plenary meetings

- Endorsement of draft opinion by ANS Panel on 20 December 2012 and web-based public consultation on the draft opinion between 8 January-15 February 2013.

Today's follow up meeting of the public consultation: Transparency and openness

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Objective:

EFSA wants to ensure that all scientific views and information received during the public consultation process are fully understood and considered by the ANS Panel in order to feed into the final version of the opinion on the re-evaluation of aspartame as food additive before its adoption

Next steps: Finalisation of aspartame re-evaluation

- Discussions on the outcome of public consultation and follow-up meeting at 41st ANS Panel meeting (22-23 April 2013)
- Report on the outcome of the public consultation will be published in May 2013
- Adoption and publication of aspartame opinion expected in May 2013

Aspartame: key questions to be addressed by ANS Panel

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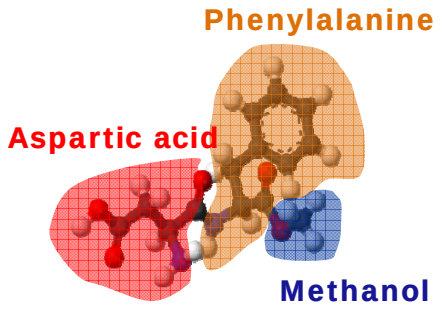
Terms of reference provided by the European Commission:

"..... to re-evaluate the safety of food additives already permitted in the Union before 2009 and to issue scientific opinions on these additives, taking especially into account the priorities, procedures and deadlines that are enshrined in the Regulation (EU) No 257/2010 ..."

This means:

- Re-evaluation of the stability of aspartame
- Re-evaluation of the toxicity studies on aspartame
- Re-evaluation of the metabolism of aspartame
- Refined exposure assessment for all age groups



Nutritional benefit of aspartame was outside the scope