European Food Safety Authority
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EFSA completes full risk assessment on aspartame and concludes it is safe at current levels of exposure [1]

Aspartame and its breakdown products are safe for human consumption at current levels of exposure, EFSA concludes in its first full risk assessment of this sweetener. To carry out its risk assessment, EFSA has undertaken a rigorous review of all available scientific research on aspartame and its breakdown products, including both animal and human studies.

"This opinion represents one of the most comprehensive risk assessments of aspartame ever undertaken. It's a step forward in strengthening consumer confidence in the scientific underpinning of the EU food safety system and the regulation of food additives", said the Chair of EFSA's Panel on Food Additives and Nutrient Sources Added to Foods (ANS Panel), Dr Alicja Mortensen.

Experts of ANS Panel have considered all available information and, following a detailed analysis, have concluded that the current Acceptable Daily Intake (ADI) of 40mg/kg bw/day is protective for the general population. However, in patients suffering from the medical condition phenylketonuria (PKU), the ADI is not applicable, as they require strict adherence to a diet low in phenylalanine (an amino acid found in proteins).

Following a thorough review of evidence provided both by animal and human studies, experts have ruled out a potential risk of aspartame causing damage to genes and inducing cancer. EFSA's experts also concluded that aspartame does not harm the brain, the nervous system or affect behaviour or cognitive function in children or adults. With respect to pregnancy, the Panel noted that there was no risk to the developing fetus from exposure to phenylalanine derived from aspartame at the current ADI (with the exception of women suffering from PKU).

The opinion makes clear that the breakdown products of aspartame (phenylalanine, methanol and aspartic acid) are also naturally present in other foods (for instance, methanol is found in fruit and vegetables). The contribution of breakdown products of aspartame to the overall dietary exposure to these substances is low.

The opinion describes the **criteria** used to identify the studies relevant for the risk assessment and standards applied to evaluate the scientific evidence. EFSA's experts examined all **uncertainties** related to the evaluation of aspartame. The opinion explains how these were addressed in the risk assessment to ensure that potential risks from aspartame were not underestimated.

The comprehensive review carried out by the ANS Panel was made possible following two public calls for data which made available a large body of scientific information, comprising both published and previously unpublished data and studies.

EFSA received over 200 comments during the public consultation on the draft opinion (that took place from 9 January 2013 to 15 February 2013) and all of these were considered. During the consultative phase EFSA also held a hearing with interested parties to discuss its draft opinion and the feedback received from the online public consultation. EFSA's dialogue with stakeholders revealed that there were important aspects of the draft opinion that needed to be clarified in the final output.

EFSA is also publishing today the comments on the draft opinion received during the public consultation, its responses to the comments received and a statement on two recent publications, one from the US Environmental Protection Agency and the other Gift *et al*., that were brought to EFSA's attention after the closure of the public consultation. Neither of these studies alters EFSA's conclusion on aspartame.

- Scientific Opinion on the re-evaluation of aspartame (E 951) as a food additive [2]
- Output of the public consultation on the draft EFSA scientific opinion on the re-evaluation of aspartame (E951) as a food additive [3]
- Statement on two reports published after the closing date of the public consultation of the draft Scientific Opinion on the re-evaluation of aspartame (E 951) as a food additive [4]

Notes to editors

Safety of the breakdown products of aspartame

As the breakdown of aspartame in the gut is very rapid and complete, any effect reported to occur in the body following ingestion of aspartame will be caused by one or more of the three constituents: aspartic acid, phenylalanine or methanol. EFSA's scientific opinion reviews possible risks associated with the three breakdown products and concludes that these do not pose a safety concern at current levels of exposure.

- **Phenylalanine** is an amino acid making up proteins found in many foods. It is known to be toxic at high intake levels, in particular to the developing fetus in women suffering from the medical condition phenylketonuria (PKU).
- **Methanol** is present in or can be released from foods such as fruits and vegetables and is also naturally produced by the body. It becomes toxic when exposure is extremely high, such as from consumption of some home-distilled alcoholic spirits. EFSA's experts concluded that methanol derived from aspartame is a small portion of total exposure to methanol from all sources.
- **Aspartic acid** is an amino acid found in proteins. The body may convert aspartic acid into the neurotransmitter glutamate which at very high levels can have harmful effects on the nervous system. However, EFSA's experts did not see any evidence of neurotoxicity associated with aspartame and concluded that aspartic acid derived from aspartame does not raise any safety concerns for consumers.

Useful background information

- A programme for the re-evaluation of all food additives approved before 2009 was set up by Commission Regulation (EU) No 257/2010.
- The re-evaluation of aspartame is part of the systematic re-evaluation. In May 2011, EFSA was asked by the European Commission to bring forward the full re-evaluation of the safety of aspartame (E 951), which was previously planned for completion by 2020, due to concerns raised regarding recent studies.

- While EFSA has reviewed new studies on aspartame in the past, this is the first full risk assessment of aspartame requested to EFSA and carried out by the Authority's ANS Panel.
- Studies reviewed in the risk assessment include the 112 original documents on aspartame that were submitted to support the request for authorisation of aspartame in the early 1980s. In the interest of transparency, EFSA published the full list of these studies and made available the previously unpublished data.