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Scientific Opinion on the re-evaluation of aspartame (E 951) as a food additive

EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)

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Abstract

The EFSA ANS Panel provides a scientific opinion on the safety of aspartame (E 951). Aspartame is a sweetener authorised as a food additive in the EU. In previous evaluations by JECFA and the SCF, an ADI of 40 mg/kg bw/day was established based on chronic toxicity in animals. Original reports, previous evaluations, additional literature and data made available following a public call were evaluated. Aspartame is rapidly and completely hydrolysed in the gastrointestinal tract to phenylalanine, aspartic acid and methanol. Chronic and developmental toxicities were relevant endpoints in the animal database. From chronic toxicity studies in animals, a NOAEL of 4000 mg/kg bw/day was identified. The possibility of developmental toxicity occurring at lower doses than 4000 mg/kg in animals could not be excluded. Based on MoA and weight-of-evidence analysis, the Panel concluded that developmental toxicity in animals was attributable to phenylalanine. Phenylalanine at high plasma levels is known to cause developmental toxicity in humans. The Panel concluded that human data on developmental toxicity were more appropriate for the risk assessment. Concentration-response modelling was used to determine the effects of aspartame administration on plasma phenylalanine using human data after phenylalanine administration