Aspartame

Aspartame is a low-calorie, intense artificial sweetener. It is a white, odourless powder, approximately 200 times sweeter than sugar. In Europe, it is authorised to be used as a food additive in foodstuffs such as drinks, desserts, sweets, dairy, chewing gums, energy-reducing and weight control products and as a table-top sweetener.

The sweetener aspartame and its breakdown products have been a matter of extensive investigation for more than 30 years including experimental animal studies, clinical research, intake and epidemiological studies and post-marketing surveillance. It has been found to be safe and authorised for human consumption for many years and in many countries following thorough safety assessments.

In the European Union (EU) the label on foodstuffs containing aspartame must state its presence, indicating either its name or its E number (E 951).

Activities Role EU framework FAQ Completed work

Since 2002, EFSA has kept the safety of aspartame under regular review and its Scientific Panels have issued several opinions on studies related to this sweetener. Currently, this work is carried out by the Panel on Food Additives and Nutrient Sources Added to Food (ANS).

Latest activities

In December 2013 EFSA published its first full risk assessment of aspartame. The opinion concludes that aspartame and its breakdown products are safe for general population (including infants, children and pregnant women).

The current Acceptable Daily Intake (ADI) of 40mg/kg bw/day is considered protective for the general population and consumer exposure to aspartame is well below this ADI. 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 making up proteins found in many foods).

The comments on the draft opinion received during the public consultation and EFSA's responses to the comments received have also been published.

- EFSA explains the Safety of Aspartame

Previous milestones

From 8 January to 15 February 2013, EFSA held an online public consultation on its draft scientific opinion on the safety of aspartame. All stakeholders and interested parties were invited to comment on the draft opinion. As part of this important process and the Authority's commitment to actively engaging with its stakeholders, EFSA also held a meeting with interested parties to discuss its draft opinion and the feedback received from the online public consultation. EFSA received over 200 comments for consideration during its online

public consultation as well as key learning from a wide-ranging and constructive exchange with stakeholders at the follow-up meeting. This process has ensured that no stone has been left unturned and that the widest possible range of scientific views and information have been considered before the finalisation of the opinion.

- EFSA wraps up aspartame consultation with public meeting

In May 2013, EFSA and the European Commission agreed to extend the timeframe for the Authority's full re-evaluation of aspartame to allow sufficient time to consider and address the feedback, including new information, resulting from the public consultation on its draft opinion.

- Aspartame opinion rescheduled until November 2013

In May 2011, EFSA was asked by the European Commission to bring forward the full re-evaluation of the safety of aspartame (E 951). Previously planned for completion by 2020, the review of this sweetener is part of the systematic re-evaluation of all food additives authorised in the EU prior to 20 January 2009, as anticipated under Regulation EU 257/2010.

- Request by the European Commission for a full re-evaluation of aspartame

EFSA accepted this mandate and launched a public call for scientific data as well as a thorough literature review. EFSA received access to a large number of both published and unpublished scientific studies and datasets following the call for data, which closed on 30 September 2011. Reaffirming its commitment to openness and transparency, the Authority published the full list of these scientific studies and also made publicly available previously unpublished scientific data including the 112 original documents on aspartame which were submitted to support the request for authorisation of aspartame in Europe in the early 1980s.

- Results of the Call for scientific data on aspartame – lists of published and unpublished studies and data files available for download

The ANS Panel started its risk assessment of aspartame in early 2012. In the course of its scientific deliberations, the Panel found that there were too little data available on 5-benzyl-3,6-dioxo-2-piperazine acetic acid (DKP) and other potential degradation products that can be formed from aspartame in food and beverages when stored under certain conditions. EFSA therefore launched an additional call for data on DKP and other degradation products of aspartame.

- Call for data on DKP and other potential degradation products of aspartame

In 2006, the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) assessed a long-term carcinogenicity study on aspartame performed by the European Ramazzini Foundation (ERF) in Bologna, Italy and published by Soffritti et al. in 2005 and 2006. Based on all the evidence available from the ERF study and other

recent studies and previous evaluations, the AFC Panel concluded that there was no reason to revise the previously established ADI for aspartame of 40 mg/kg bw/day.

In 2009, the ANS Panel adopted an opinion on the findings of an ERF study on the carcinogenicity of aspartame in rats published by Soffritti et al. in 2007. EFSA requested the data related to this study in 2007 and 2008. The opinion was subsequently updated, taking into consideration additional data submitted by ERF in February 2009. The Panel concluded that on the basis of all the then available evidence, including the ERF study published in 2007, there is no indication of any genotoxic or carcinogenic potential of aspartame and no reason to revise the previously established ADI for aspartame of 40 mg/kg bw/day.

In 2010, two studies on possible health risks related to the consumption of artificial sweeteners were published, namely a carcinogenicity study in mice exposed to aspartame through feed conducted by the ERF (Soffritti et al. 2010), and an epidemiological study on the association between intakes of artificially sweetened soft drinks and increased incidence of preterm delivery (Halldorsson et al.). In a February 2011 statement, EFSA concluded that the two studies do not give reason to reconsider previous safety assessments of aspartame or of other sweeteners currently authorised in the EU. EFSA's review of these studies was carried out in co-operation with France's Agency for Food, Environment and Occupational Health Safety (ANSES) which also undertakes work in this area.

Cooperation with EU Member States

In 2007, recognising that public concern about aspartame continues despite the risk assessments that have been undertaken, the Advisory Forum of EFSA, composed of the national food safety authorities, agreed to hold a series of meetings of national experts with relevant scientific knowledge in relation to aspartame, nominated by their Member States. They looked at all the published literature and took into consideration additional evidence and literature that EFSA had gathered through a call for data in 2008. In 2010, a report of these meetings was presented along with comments from stakeholders received through a public consultation.

- Report of the meetings on aspartame with national experts
- Summary of Responses from Stakeholders (282.91 KB)

The national experts concluded that no new evidence was identified to suggest that the previous opinions of EFSA and the SCF needed to be reconsidered, but also recognised that the public concern relating to aspartame remains high. Much of the concern expressed relates to the anecdotal reports of adverse effects. Whilst EFSA and the national experts have made considerable efforts and invested time and resources to assess the anecdotal information, this information has proved to have severe limitations preventing effective analysis.