

Aspartame

1. Background

Aspartame (E951) has been used as a sweetener in foods and as a table-top sweetener for more than 20 years in many countries throughout the world. Aspartame is the methyl ester of the dipeptide of two amino acids, phenylalanine and aspartic acid. It is an odourless, white crystalline powder which has a clean, sweet taste. It is referred to as an intense (or artificial) sweetener and is used to replace sugar in a wide range of sugar-free and low-calorie foods. It has the same calorific value as sugar, but is about 200 times sweeter than sugar and so only a small amount is needed to sweeten products. Aspartame is sometimes referred to under its original trade name of "NutraSweet".

2. Legislation on sweeteners and assessment of their safety¹

Sweeteners such as aspartame are classified as food additives, and their use in food is strictly controlled by European Union (EU) legislation which requires that only authorised additives may be used in the manufacture or preparation of foodstuffs. A new additive which requires authorisation in the EU must go through an exhaustive safety assessment by the European Food Safety Authority (EFSA). Prior to the establishment of EFSA in 2002, this function was carried out by the EU Scientific Committee on Food (SCF).

The manufacturer of any potential new additive must not only produce evidence that there is a real need for the substance, but must also commission research into that substance. The research must include toxicological tests (tests to determine whether a substance is harmful) including tests to assess the genotoxic potential of the compound, that is the ability to interfere with genetic material in the body which could lead to the development of cancer or adverse effects in future generations. Following evaluation of a particular additive, it is placed on the EU 'positive list' of approved additives. If there were any doubts about the safety of an additive, then that substance would not be approved.

Aspartame has therefore only been authorised for use and included on the EU 'positive list' of approved additives after a rigorous safety assessment. It was evaluated by the SCF in 1984², 1988³ and 2002⁴, and more recently, in 2006 and 2009, EFSA issued opinions on two new carcinogenicity studies on aspartame^{5,6} carried out by the European Ramazzini Foundation (ERF), Bologna, Italy. The content of the EFSA opinions are outlined in more detail in section 5 of this document, "recent reviews of the safety of aspartame". Aspartame has also been evaluated by other regulatory bodies such as the Joint FAO/WHO Expert Committee on Food Additives⁷, the UK Food Standards Agency and the United States Food and Drug Administration (FDA).

¹ http://www.fsai.ie/legislation/food/legislation_foodadditives.asp

² http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_16.pdf

³ http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_21.pdf

⁴ http://ec.europa.eu/food/fs/sc/scf/out155_en.pdf

⁵ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620765743.htm

⁶ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902454309.htm

⁷ <http://www.inchem.org/documents/jecfa/jecmono/v16je03.htm>

The maximum levels at which additives such as aspartame may be used, and also the specific foodstuffs in which they may be used, are also established by the EU (and corresponding Irish) legislation. These levels are set at values which ensure that a person consuming a typical diet would not exceed the Acceptable Daily Intake (ADI⁸) established for the additive in question. In the case of sweeteners such as aspartame, the levels are set at values which will protect particularly vulnerable populations such as diabetics, who must avoid sugar-containing food and drinks, and children who are known to consume larger quantities of beverages such as fizzy drinks and squashes that may be sweetened using aspartame.

In Ireland, the use of sweeteners in foodstuffs is controlled by the European Communities (Additives, Colours and Sweeteners in Foodstuffs) Regulations, S.I. No. 437 of 2000⁹ and the European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) Regulations, 2005 (S.I. No. 61 of 2005)¹⁰. These Regulations implement European Council Directive 94/35/EC¹¹ and its amending Directives 96/83/EC and 2003/115/EC which harmonise controls on the use of sweeteners throughout the European Community. Dietary intake of food additives in Ireland has been evaluated in 2000¹² and has shown that the general population does not exceed the Acceptable Daily Intake (ADI) for sweeteners.

3. Labelling warning for phenylketonuria sufferers

A small group of people cannot safely consume aspartame. These are the sufferers of the inherited disease phenylketonuria (PKU), who are unable to metabolise the amino acid phenylalanine effectively, leading to the accumulation of potentially harmful levels of certain breakdown products. PKU is a serious metabolic disorder which is normally diagnosed shortly after birth by a routine blood test. Since aspartame is also a source of phenylalanine, all food products containing aspartame should be clearly labelled with the words "contains a source of phenylalanine", so that those people who suffer from PKU can avoid consuming these products.

4. Surveillance of additives in foods available on the Irish market

The Food Safety Authority of Ireland (FSAI), among its activities, coordinates the collation of food safety surveillance information from laboratories run by its official agents. The FSAI also conducts targeted food safety surveillance in areas where potential safety issues have been identified. The FSAI has recently carried out a targeted surveillance study on levels of artificial sweeteners including aspartame in foods available on the Irish market. The results of this survey were very reassuring, in that, of over 300 samples analysed, all were found to contain levels of aspartame below the maximum level permitted by the legislation, and only four products contained aspartame that was not declared on the label.

⁸ ADI – If an additive is deemed acceptable for food use, an Acceptable Daily Intake (ADI) is normally set. The concept of the ADI was established by the Joint Expert Committee on Food Additives (JECFA) and is defined as "an estimate of the amount of food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk."

⁹ <http://www.irishstatutebook.ie/2000/en/si/0437.html>

¹⁰ http://www.fsai.ie/legislation/food/eu_docs/Food_additives/Sweeteners/SI_61_2005.pdf

¹¹ http://www.fsai.ie/legislation/food/eu_docs/Food_additives/Dir94.35.pdf

¹² Food additive intake and patterns of food additive usage in Ireland. A report prepared for FSAI by the Irish Universities Nutrition Alliance in April 2000

5. Reviews of the safety of aspartame

All approvals of food additives are kept under review by the regulatory authorities as and when scientific and medical information becomes available on possible adverse effects, not previously recognised or reported. In relation to aspartame, a number of reports in recent years have indicated a possible link with epilepsy and brain tumours, headaches, allergies, and behavioural changes and/or changes in cognitive function. Concerns have also been raised about the possibility of toxicity from methanol, one of the breakdown products of aspartame (the methyl ester of the dipeptide formed from phenylalanine and aspartic acid) in the body. Additionally, it has been suggested that consumption of aspartame can be linked to development of serious disorders such as multiple sclerosis, lupus erythematosus, Gulf War Syndrome, chronic fatigue syndrome, and diabetes mellitus. However, most of the data to substantiate these claims are anecdotal and no reliable scientific evidence is available to show that aspartame might be responsible for these conditions. In relation to the formation of methanol, the amounts derived from aspartame are less than those found naturally in other foods and are not considered to pose a risk.

Because of the reports of possible adverse health effects associated with the consumption of aspartame, the EU Scientific Committee on Food in December 2002 published an updated opinion on the safety of aspartame¹³, taking into consideration more than 500 recent research reports. In particular, they took into account additional endpoints requiring evaluation or effects reported to occur at lower doses than those considered in their previous evaluations in 1984 and 1988. The Committee concluded on the basis of its review of all the data available to date that there was no need to revise its earlier risk assessment, which concluded that aspartame is safe and that the previously established ADI calculation for aspartame of 40 milligrams per kilogram of body weight per day (40mg/kg bw/day) still applied.

In 2005, the European Ramazzini Foundation (ERF), Bologna, Italy, a scientific institute involved in research into cancer, published the results of a new animal carcinogenicity study carried out by the ERF on the artificial sweetener aspartame. The authors of the ERF study considered, on the basis of their results that aspartame had carcinogenic potential, since rats fed aspartame for a lifetime developed cancers at various sites, including tumours of the blood cells, kidney and peripheral nerves. At the request of the European Commission, in 2006, the European Food Safety Authority (EFSA) assessed the published reports on this study, together with extensive data on the study provided to EFSA by the ERF, other recent studies and previous evaluations of the safety of aspartame. EFSA, in carefully examining this information, concluded that there were underlying explanations for the occurrence of the tumours seen in the study and that the study did not cause concerns about possible health effects for consumers of aspartame. EFSA concluded, on the basis of the information available from the ERF study, that there was no reason to further review the safety of aspartame at this time, or to revise the current ADI of 40 mg/kg body weight established by the SCF. EFSA also stated that consumer intake of aspartame in a number of European countries (up to 10 mg/kg body weight), is well below this figure, even in high consumers.

¹³ http://ec.europa.eu/food/fs/sc/scf/out155_en.pdf

¹⁴ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902454309.htm

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In 2007, the Ramazzini Foundation published the results of a further study that, in the opinion of the authors of the study, confirmed their previous observation that aspartame is a carcinogenic compound. This study has also been reviewed by EFSA¹⁴, who have again concluded that on the basis of all the evidence currently available including the last published ERF study that there is no indication of any genotoxic or carcinogenic potential of aspartame and, as in 2007, that there is no reason to revise the previously established ADI for aspartame of 40 mg/kg bw/day.

In addition, a group of European experts on the safety aspects of aspartame, including experts from Ireland, will meet on several occasions in 2009 to consider any new information on the toxicity of aspartame. The outcomes of their discussions will be reported to the European Commission and to EFSA. It will then be decided whether a further safety evaluation is needed from EFSA or whether any regulatory actions should be taken in relation to the use of aspartame.

Aspartame has also been reviewed in the recent past by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the US FDA and by the UK Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC). The FDA has reviewed all complaints alleging adverse reactions to products containing aspartame since 1985 but have failed to determine any consistent pattern of symptoms that can be attributed to the use of aspartame. The FDA has also stated that analysis of the National Cancer Institute database on cancer incidence in the USA does not support an association between the use of aspartame and increased incidence of brain tumours, a conclusion restated by the SCF.

6. Conclusion

The safety of aspartame has been extensively studied over the years and experts worldwide agree that aspartame is safe for use. This has been restated by the EU Scientific Committee for Food in 2002 and by EFSA in 2007 and 2009. In terms of the types of studies and the amounts given to human subjects in controlled studies, aspartame is one of the most thoroughly tested food additives. The approval of aspartame will continue to be kept under review by bodies such as the European Commission and EFSA as new scientific information becomes available. If this information shows that the conclusion that aspartame is safe for use is no longer valid, action will be taken immediately to review its authorisation.