German Federal Institute for Risk Assessment

Sweeteners in food – Selected questions and answers

BfR FAQ, 14 July 2023

Sweeteners are food additives. They are used in many processed foods, such as soft drinks, confectionery and dairy products, as calorie-free or calorie-reduced alternatives to sugar. As food additives, sweeteners are subject to an authorisation procedure within the European Union (EU) according to Regulation (EC) No 1333/2008. One requirement for authorisation is that they do not present any health risk. They must also generally be declared in the list of ingredients on the packaging of foodstuffs. 19 sweeteners are currently authorised in the EU. The German Federal Institute for Risk Assessment (BfR) has summarised below questions and answers on the subject.

Which sweeteners are currently authorised in Europe?

There are currently 19 sweeteners authorised in the EU according Regulation (EC) No 1333/2008, with specifications and purity criteria set out in Regulation (EU) No 231/2012. Of the authorised sweeteners, 11 are often also referred to as non-nutritive or intense sweeteners, namely acesulfame K (E 950), aspartame (E 951), cyclamic acid and its Na and Ca salts (cyclamate) (E 952), saccharin and its Na, K and Ca salts (E 954), sucralose (E 955), thaumatin (E 957), neohesperidin DC (E 959), steviol glycosides (E 960), neotame (E 961), aspartame-acesulfame salt (E 962) and advantame (E 969).

Eight of the currently approved sweeteners are sugar substitutes: sorbitol (E 420), mannitol (E 421), isomalt (E 953), polyglycitol syrup (E 964), maltitol (E 965), lactitol (E 966), xylitol (E 967) and erythritol (E 968). In chemical terms, these substances are sugar alcohols (polyols).

What is the difference between sugar substitutes and non-nutritive sweeteners?

In Regulation (EC) No 1333/2008, the seven sugar alcohols sorbitol, mannitol, isomalt, maltitol, lactitol, xylitol and erythritol are grouped together as “Group IV: polyols”. Polyols are part of the group of sugar substitutes. This also includes polyglycitol syrup (E 964). The other sweeteners mentioned in Regulation (EC) No 1333/2008 are commonly referred to as non-nutritive sweeteners. The terms “sugar substitutes” and “non-nutritive sweeteners” are not defined in this Regulation. Sugar substitutes are sugar-like substances, usually with lower sweetening power and calorific value (expressed in calories or joules) than sugar, which cause little or no caries. Conversely, non-nutritive sweeteners include very different chemical substances that have no or only an insignificant calorific value and taste significantly sweeter than sugar. Some non-nutritive sweeteners, such as steviol glycosides, are extracted from the leaves of the stevia plant.

How is the health safety of sweeteners ensured?

There are currently 19 sweeteners authorised in the EU for different food categories under Regulation (EC) No 1333/2008. All sweeteners – like all other food additives – have undergone a health assessment by an international panel of experts prior to their authorisation. Until 2003, these assessments were carried out by the European Commission’s Scientific Committee on Food (SCF). Since then, food additives have been assessed by the European Food Safety Authority (EFSA).

Will the health risk assessments of sweeteners be updated?

Since some of the assessments on the authorised food additives by international panels of experts were carried out some time ago, a programme for the re-evaluation of all food additives was established in the EU with Article 32 of Regulation (EC) No 1333/2008 and Regulation (EU) No 257/2010. Sweeteners are currently being re-evaluated by EFSA as part of this programme. This includes a review of the acceptable daily intake (ADI), some of which were derived by the SCF or EFSA more than 20 years ago. An acceptable daily intake can be consumed every day for a lifetime without any adverse health effects being expected.

However, the approximately 300 authorised food additives cannot all be re-evaluated at the same time. Priorities have therefore been set. Sweeteners were given a low priority and were to be re-evaluated by the end of 2020 according to Regulation (EU) No 257/2010 (however, EFSA has now been granted longer deadlines for this by the European Commission). This did not apply to aspartame, which was already re-evaluated by EFSA by the end of 2013 at the request of the European Commission (http://www.efsa.europa.eu/en/topics/topic/aspartame.htm).

How much sweetener is added to soft drinks?

The product monitoring of the Max Rubner Institute (MRI) from 2022 shows that the number of soft drinks sweetened exclusively with sweeteners has slightly increased. The BfR's MEAL Study (Meals for Exposure Estimation and Analysis of Food), investigated the concentrations of sweeteners in soft drinks. For this purpose, the concentrations of nine sweeteners, including aspartame, cyclamate and steviol glycosides, were analysed in 92 calorie-reduced or sugar-free market-relevant soft drinks. The result: The measured concentrations of the sweeteners showed large ranges in parts. In total, 87 of the 92 soft drinks analysed contained more than one sweetener. More information on this can be found in the corresponding BfR opinion 006/2023.

Do mixtures of several sweeteners lead to health risks for humans?

Mixtures of sweeteners are often found in non-alcoholic soft drinks, for example. One reason for this is that some sweeteners can cause a bitter, metallic aftertaste in higher concentrations. To avoid this, they are combined with other sweeteners. Reliable data from animal experiments regarding the potential effects of sweetener mixtures is not yet available. Therefore, this aspect has not yet been considered in the toxicological assessment by international expert panels as part of the EU authorisation as food additives. The BfR has investigated whether the available data, especially from animal studies, indicate health risks from the combined use of relevant sweeteners. This was carried out using sweetener combinations, as they are used in non-alcoholic soft drinks. The model calculation shows that combination effects could theoretically occur as adverse effects in the kidneys and urinary tract. The extent to which the findings can be transferred to humans cannot be assessed at present due to the limited data available on combination effects of sweeteners. More information on this can be found in the corresponding BfR opinion 005/2023.

Does an overall increase in the consumption of sweeteners pose health risks?

The BfR has assessed whether a possible increase in the use of sweeteners poses a health risk to the population. For this purpose, the institute assessed the data on the five most commonly used sweeteners – sucralose, acesulfame K, saccharin, aspartame and cyclamate. It particularly looked at how an increased use of sweeteners could affect the risk of obesity and metabolic diseases. Furthermore, it was investigated whether there are sensitive groups, such as pregnant women or children, who should avoid or limit the intake of sweeteners. The

BfR came to the conclusion that the data situation is inconsistent and very limited for some population groups considered (e.g. children and pregnant women) and for certain health aspects. It is clear that there is a need for further research to be able to derive substantiated conclusions, especially on long-term effects of sweeteners for different population groups. More information on this can be found in the corresponding BfR opinion 004/2023 (in German).

How is the sweetener aspartame assessed by various international expert panels?

In the past, various parties have repeatedly expressed the suspicion that aspartame (E 951) could be carcinogenic. Therefore, aspartame is one of the best-studied sweeteners and has been repeatedly assessed by various international expert panels. Scientific reviews by the relevant panels of EFSA and other institutions have not confirmed this suspicion thus far. So far, the scientific panels have concluded that there are no health concerns provided that the acceptable daily intake (ADI) of 40 mg/kg body weight per day is not exceeded. Foods containing aspartame (according to Point 2.3 of Annex III to Regulation (EU) No 1166/2011) must be labelled with the statement “contains a source of phenylalanine” to inform patients suffering from the hereditary metabolic disorder phenylketonuria that require a low-phenylalanine diet.

In its comprehensive assessment from 2013, EFSA concluded that there is no reason to change the previously derived acceptable daily intake of 40 mg of aspartame per kg body weight per day. This amount can be consumed every day for a lifetime without expecting any adverse effects. EFSA is currently assessing two similar sweeteners, the aspartame-acesulfame salt (E 962) and neotame (E 961). Aspartame-acesulfame salt (E 962) is made from aspartame (E 951) and acesulfame K (E 950), while neotame (E 961) is a chemically related substance made from aspartame. EFSA has emphasised that it will take into account all new evidence and studies, including the recent opinion of the International Agency for Research on Cancer (IARC), an agency of the World Health Organization (WHO), and the risk assessment of aspartame by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

How is the sweetener aspartame assessed by WHO expert panels?
In 2021, the International Council of Beverages Associations (ICBA) proposed a risk assessment of aspartame by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). This took place at the JECFA meeting from 27 June to 6 July 2023. The risk assessment also took into account the opinion of the IARC on aspartame.

The International Agency for Research on Cancer (IARC) classifies aspartame as “possibly carcinogenic to humans” (category 2B). However, the agency points out that the positive findings in the epidemiological studies evaluated are not clearly attributed to aspartame, but could also be attributed to other influencing factors: “*[…] chance, bias or confounding could not be ruled out as an explanation for the positive findings […]*. The agency also considers animal studies to be insufficiently reliable “[…] *based on concerns over the study design, interpretation and reporting of data, the working group concluded that the evidence for cancer in experimental animals was limited […]”*.

The Joint FAO/WHO Expert Committee on Food Additives, JECFA, comes to the conclusion in its risk assessment that the animal experimental data considered and the human data evaluated do not give an indication that aspartame is carcinogenic. The Expert Committee noted limitations in the method for determining aspartame exposure in the epidemiological studies and also points out that aspartame as such does not pass into the blood but is metabolised in the gastrointestinal tract to aspartic acid and phenylalanine as well as methanol.

These metabolites are also ingested when eating common foods. Therefore, the Expert Committee confirms the acceptable daily intake (ADI) of 40 mg/kg body weight per day already derived in an earlier opinion.

The WHO material on the topic of aspartame is available here.

A list of substances classified as possibly carcinogenic by the IARC can be found here.

The questions and answers from the WHO and IARC on aspartame are also helpful in this context.

The complete opinions of both institutions have not yet been published; they are expected in the near future.

Are there aspects that should be considered when using certain sweeteners?

If the sweetener sucralose (E955), which is approved and regarded as harmless to health, is heated above 120 °C, chlorinated compounds with harmful and carcinogenic potential might form. Temperatures between 120 °C and 150 °C are possible in the industrial production and processing of food and can also be reached in private households when preparing food (e.g. baking, frying) that contain sucralose.

Chlorinated organic compounds, such as polychlorinated dibenzodioxins (PCDD) or dibenzofurans (PCDF) or chloropropanols, can be formed. Data is currently still lacking for a conclusive assessment of potential health risks. Until then, the BfR recommends that foods containing sucralose should not be heated to temperatures that occur during baking, frying and roasting, or that sucralose should only be added after heating. This applies to consumers as well as to commercial food manufacturers. The BfR recommends that this aspect be given special consideration in the re-evaluation of sucralose as a food additive. More information on this can be found in the corresponding BfR opinion 012/2019.