International Sweeteners Association

FACTSHEET

Safety and Regulation
of Low/no Calorie Sweeteners

Demand for tasty, healthy and convenient foods that are lower in sugars has grown in recent years. As part of a greater awareness of the benefits of healthier eating, consumers are also seeking reassurance about the safety of food ingredients.

Both international food standards and the laws and food regulations of individual countries ensure food and drink ingredients are safe.

All food additives have to undergo a thorough safety assessment before they are approved, and low/no calories sweeteners are no exception. In fact, low/no calorie sweeteners are among the most thoroughly researched ingredients. Regulatory food safety bodies around the world confirm their safety and allow their use.[1]

At international level low/no calorie sweeteners have gone through the safety assessments of the Joint Expert Scientific Committee on Food Additives (JEFCA).[2] JEFCA was created by the United Nations Food & Agriculture Organization (FAO) and the World Health Organization (WHO) in the mid-1950s. It is an independent committee that provides scientific advice to the Codex Alimentarius Commission and specifically to the Codex Committee on Food Additives (CCFA).

Committees of the Codex Commission, including CCFA, produce the international 'food guide' known as Codex Alimentarius, a collection of food standards, guidelines and codes of good practice.

Scientific consensus on safety

When conducting the safety assessment of sweeteners, JEFCA, as well as regional or national food safety authorities such as the European Food Safety Authority (EFSA) and the U.S. Food and Drug Administration (FDA), establish an Acceptable Daily Intake (ADI) for each low/no calorie sweetener.[2-4]

An ADI is the amount of a low/no calorie sweetener, or other food ingredient, that can be consumed daily over a lifetime without appreciable risk to health. It is based on the maximum amount that test animals can be given throughout their life without any noticeable harmful effects, divided by a safety factor of 100.

The 100-fold safety factor takes into account potential differences between animals and humans, as well as among different population groups ensuring the safety of the most vulnerable, including children and pregnant women.

Different low/no calorie sweeteners have different ADIs because the characteristics and components of each sweetener vary. All ADIs are measured in milligrams per kilo of bodyweight per day, so the amount of Acesulfame-K permitted in drinks, for example, will be different to the amount of Aspartame or Cyclamate, or other low/no calorie sweeteners.

Safe usage levels in food and drink are set to ensure that consumers do not reach ADI levels. Intake estimates based on international research and dietary surveys in different populations and countries consistently show that the global consumption of all approved low/no calorie sweeteners is below their respective ADIs for both adults and children, even among high consumers and people living with diabetes.[5]

Several health and nutrition organisations globally, including the British Dietetic Association (BDA), the British Nutrition Foundation, and Diabetes UK,[6] the American Diabetes Association (ADA),[7] the European Association for the Study of Diabetes,[8] and the Latin-American Association of Diabetes[9] recognise that:

Low/no calorie sweeteners are a safe way to replace sugars and help control weight and conditions such as diabetes when used to replace sugars and as part of a healthy diet and lifestyle.

Sweeteners' safety reaffirmed in recent re-evaluations

In Europe, EFSA's scientists have been called to re-assess the safety of all food additives permitted for use before 20 January 2009.[3] This process included most of the common low/no calorie sweeteners. **The re-evaluations of aspartame, thaumatin, neohesperidine DC, saccharin, acesulfame-K, neotame, and sucralose have now been completed, with EFSA re-affirming their safety.** EFSA experts also confirmed that consumption of these sweeteners remains well below their respective ADIs. These re evaluations also consider the published scientific literature, thereby evaluating emerging areas of scientific investigation.

The safety of aspartame was also re-evaluated at the global level by JECFA in 2023.[10] JECFA did a comprehensive risk assessment including a review of the hazard assessment conclusions by the International Agency for the Research on Cancer (IARC) that categorised aspartame as "possible carcinogenic to humans" based on limited evidence. **JECFA concluded that dietary exposure to aspartame does not pose a health concern and reaffirmed its Acceptable Daily Intake (ADI) of 40 mg/kg body weight/day.**

Hazard vs Risk

A hazard assessment identifies a substance's potential to cause harm, whereas a risk assessment evaluates the likelihood of harm occurring under real-world exposure conditions.

References:

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