



# Safety evaluation of low/no calorie sweeteners

## HIGHLIGHTS

Low/no calorie sweeteners are amongst the most thoroughly researched ingredients worldwide. All approved low/no calorie sweeteners have undergone a stringent safety assessment by food safety agencies around the world who have consistently confirmed their safety.

Global research confirms that the intakes of all approved low/no calorie sweeteners are well below their respective Acceptable Daily Intake (ADI) values set by regulatory authorities as the amount of a sweetener that can be consumed daily in the diet, over a lifetime, without appreciable health risk.



## Who is responsible for the safety evaluation of low/no calorie sweeteners?

Before being approved for use on the market, all approved low/no calorie sweeteners have undergone a thorough and very strict safety evaluation by the competent food safety authority. Throughout the world, nations rely on regional or international governing food safety bodies and expert scientific committees, such as Joint Expert Scientific Committee on Food Additives (JECFA) of the United Nations Food & Agriculture Organization (FAO) and the World Health Organization (WHO), to evaluate the safety of food additives, or have their own regulatory bodies for food safety oversight. These regulatory bodies have consistently confirmed the safety of approved low/no calorie sweeteners at current levels of use.<sup>1-3</sup>

The safety of approved low/no calorie sweeteners has been consistently confirmed by numerous regulatory bodies around the world, including:

<b>At an international level</b>	Joint Expert Scientific Committee on Food Additives (JECFA) of the United Nations' Food and Agriculture Organization (FAO) & World Health Organization (WHO)
<b>In Europe</b>	European Food Safety Authority (EFSA)
<b>In the USA &amp; Canada</b>	U.S. Food & Drug Administration (FDA) Health Canada
<b>In Latin America</b>	Based on JECFA's safety assessment and the Codex Alimentarius provisions
<b>In Australia &amp; New Zealand</b>	Food Standards Australia New Zealand (FSANZ)

## What evidence is assessed during the safety evaluation process?

To determine the safety of low/no calorie sweeteners, the authorities thoroughly review and assess all available data on the chemistry, kinetics and metabolism of the substance, the proposed uses, exposure assessment, extensive toxicological studies, as well as data from observational research and controlled clinical trials in a weight of evidence (WoE) approach.<sup>4,5</sup> **Only when there is strong evidence of no safety concern is a food additive permitted for use in foods.**

## What is the Acceptable Daily Intake (ADI)?

In the approval process, the risk assessment experts of the food safety agencies establish an Acceptable Daily Intake (ADI) for each approved low/no calorie sweetener.

The ADI is defined as the amount of an approved food additive that can be consumed daily in the diet, over a lifetime, without appreciable health risk, and is expressed on a body weight basis: in milligrams (mg) per kilogram (kg) of body weight (bw) per day.<sup>6</sup>

### Acceptable Daily Intake (ADI) for low/no calorie sweeteners, as established by FAO/WHO JECFA

Low/no calorie sweetener	Acceptable Daily Intake (ADI) (mg/ kg BW/ day)
Acesulfame-K (INS 950)	0-15 mg/kg
Aspartame (INS 951)	0-40 mg/kg
Cyclamate (INS 952)	0-11 mg/kg
Saccharin (INS 954)	0-5 mg/kg
Sucralose (INS 955)	0-15 mg/kg
Thaumatococin (INS 957)	Not specified (An ADI of "not specified" means that thaumatococin can be used according to Good Manufacturing Practice (GMP))
Steviol glycosides (INS 960)	0-4 mg/kg (expressed as Steviol)
Neotame (INS 961)	0-2 mg/kg
Advantame (INS 969)	0-5 mg/kg

**Note:** The 'INS' reference for each additive refers to the International Numbering System of the Codex Alimentarius.

**Source:** WHO. Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Update of November 2023 (Accessed 14 March 2024). Available at: <https://apps.who.int/food-additives-contaminants-jecfa-database/>

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## Consumption of low/no calorie sweeteners is well below the ADI

Research from around the world confirms that the intake of approved low/no calorie sweeteners is well below the respective ADI levels. Numerous studies conducted across all continents including in Europe, North and Latin America, Asia and Middle East, **confirm that global levels of exposure are within the ADI limits for the individual sweeteners, and for all population groups including children.**<sup>7-20</sup>

In addition, updated safety evaluations of sweeteners by food safety bodies include consideration of all intake research and regulations to ensure that actual consumption of any low/no calorie sweetener remains within the set ADI.<sup>4</sup>

## Re-evaluation of sweeteners in Europe and around the world

Following their initial safety assessment and market approval, the regulatory food safety bodies globally continue to monitor and evaluate the latest science available on low/no calorie sweeteners. For example, FDA scientists reassess the science about the exposure and safety of a sweetener each time the agency files a food additive petition or a GRAS [generally recognized as safe] notice for that sweetener.<sup>21</sup> Another example is the recent re-evaluation of aspartame by FAO/WHO JECFA who re-affirmed the safety of aspartame and re-confirmed the ADI of 40 mg/kg body weight.<sup>22</sup>

In Europe, at the request of the European Commission, EFSA has been re-evaluating the safety of all food additives, including sweeteners, which were already approved on the EU market before 20th January 2009. Aspartame is the first sweetener to have undergone this thorough re-evaluation process by EFSA, which reconfirmed its safety.<sup>23</sup> The re-evaluations of thaumatococin<sup>24</sup> and neohesperidine DC<sup>25</sup> have also been completed, with EFSA affirming the safety of both sweeteners.