Calorie Control Council
HEALTHY EATING & EXERCISE FOR LIFE®

REGULATORY HANDBOOK

An Overview of the Safety and Regulatory Status of Low- and No-Calorie Sweeteners, Reduced-Calorie Sweeteners, and Rare Sugars

Note: This document is updated periodically and contains information current as of August 1, 2024. We do our best to ensure accuracy but recognize there could be outdated information. Please notify info@caloriecontrol.org to provide any necessary corrections.

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I. Introduction

Low- and reduced- calorie foods and beverages provide consumers with many benefits, both psychological and physiological. Products with reduced added sugars content and/or reduced calories are made possible by formulations that include three distinct categories of sweeteners: low- and no-calorie sweeteners (LNCS), reduced-calorie sweeteners which are more commonly known as sugar alcohols or polyols, and rare sugars.

LNCS, reduced-calorie sweeteners, and rare sugars allow consumers to enjoy sweet tasting foods and beverages without added sugars or calories. Replacing added sugars with LNCS, reduced-calorie sweeteners, and rare sugars can help consumers reach dietary recommendations to limit added sugars consumption to no more than 10% of their daily caloric intake and presents consumers with a tool that – along with other interventions – can help them manage their calorie and added sugars intake, body weight, and diet-related diseases such as obesity and diabetes.

Reduced-calorie sweeteners, rare sugars, and in particular LNCS, are some of the most studied ingredients in the food supply and their safety has been reviewed and upheld by numerous international scientific and regulatory authorities, including the Joint Food and Agriculture Organization and World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA), the European Food Safety Authority (EFSA), the U.S. Food and Drug Administration (FDA), Food Standards Australia and New Zealand (FSANZ), Health Canada, and others (see Chapter 3). As the demand for reduced-sugar and reduced-calorie products continues to grow, LNCS in particular have been reviewed and studied more extensively, further enhancing their safety profile.

Global efforts are in place to prevent and control unhealthy weight gain and the development of diet-related chronic diseases, including obesity. In 2015, to reduce the risk of non-communicable diseases (particularly unhealthy weight gain and tooth decay), the World Health Organization (WHO) issued guidance recommending that adults and children consume less than 10% of their total calories from free sugars. WHO further suggested that free sugars be less than 5% of total calorie intake for additional benefit. Using LNCS, reduced-calorie sweeteners, and rare sugars to replace added sugars can help food and beverage manufacturers formulate products to help consumers around the globe achieve the WHO recommendations for sugar reduction.

Finally, LNCS, reduced-calorie sweeteners, and rare sugars can be beneficial for those with diabetes. The 2024 American Diabetes Association Standards of Medical Care in Diabetes state that, “Counsel people with prediabetes and diabetes that water is recommended over nutritive and nonnutritive sweetened beverages. However, the use of nonnutritive sweeteners as a replacement for sugar-sweetened products in moderation is acceptable if it reduces overall calorie and carbohydrate intake.”

This handbook serves as a global overview on the current use, safety assessments, regulatory status, and state of the science for LNCS, reduced-calorie sweeteners, and rare sugars. The content of this handbook focuses on the following ingredients:

- **LNCS:** acesulfame-potassium (ace-K), advantame, alitame, aspartame, aspartame-acesulfame salt, cyclamate, monk fruit extract (also known as Luo Han Guo), neotame, saccharin, steviol glycosides, sucralose, and thaumatin.
- **Sugar Alcohols:** erythritol, hydrogenated starch hydrolysates (polyglycitol syrup), isomalt, maltitol, maltitol syrup, mannitol, sorbitol, sorbitol syrup, and xylitol.
- **Rare Sugars:** allulose, isomaltulose, and tagatose.

II. Sweetener Profiles

To understand why LNCS, sugar alcohols, and rare sugars are used, one must understand their sweetness profiles as compared to sucrose. LNCS, for example, provide very intense sweetness in comparison to sucrose while contributing no or negligible amounts of calories to a product. The following table outlines the sweetness profiles of each class of sweetener and describes their functional use in foods and beverages.

Table 1. Low and No Calorie Sweetener Profiles

LNCS	Year Discovered	Sweetness (Compared to sucrose)	Caloric Value (kcal/mg)	Common Uses in Food
Acesulfame-Potassium (Ace-K)	1967	130 – 200x	0	Flavor enhancer, Sweetener
Advantame	2008	20,000x	0	Flavor enhancer, Sweetener
Alitame	1980	2000x	0	Sweetener
Aspartame	1965	200x	0	Flavor enhancer, Sweetener
Aspartame-Acesulfame Salt	1995	350x		Sweetener
Cyclamate	1937	30x	0	Sweetener
Neotame	1992	7,000 – 13,000x	0	Sweetener
Monk Fruit Extract	*Monk fruit has been consumed for hundreds of years*	100 – 250x	0	Sweetener
Saccharin	1879	300 – 500x	0	Sweetener
Steviol Glycoside (Stevia extract, Steviol Glycosides)	*The stevia plant has been used for over 200 years, 2009 (Codex approval)*	200 – 300x	0	Sweetener
Sucralose	1976	600x	0	Flavor enhancer, Sweetener
Thaumatin	1970s	3,000 – 11,000x	0	Flavor enhancer, Sweetener

Table 2. Sugar Alcohol Profiles

Sugar Alcohol	Year Discovered	Sweetness (Compared to sucrose)	Caloric Value (kcal/g)	Common Uses in Food
Erythritol	1848	0.70x	0 (US)	Flavor enhancer, Humectant, Sweetener
Isomalt	1960s	0.55x	2.0 (US)	Anticaking agent, Bulking agent, Flavor enhancer, Glazing agent, Stabilizer, Sweetener, Thickener
Hydrogenated Starch Hydrolysates (Polyglycitol syrup)	1960s	0.40 to 0.90x	3.0 (US)	Sweetener
Lactitol	1920	0.40x	2.0 (US)	Emulsifier, Sweetener, Thickener
Maltitol	1891	0.90x	2.1 (US)	Bulking agent, Emulsifier, Humectant, Stabilizer, Sweetener, Thickener
Maltitol Syrup		0.25 to 0.50x	2.1 (US)	Bulking agent, Emulsifier, Humectant, Stabilizer, Sweetener, Thickener
Mannitol	1806	0.60x	1.6 (US)	Anticaking agent, Bulking agent, Humectant, Stabilizer, Sweetener, Thickener
Sorbitol	1872	0.60x	2.6 (US)	Bulking agent, Humectant, Sequestrant, Stabilizer, Sweetener, Thickener
Sorbitol Syrup	1872	0.25 to 0.50x	2.6 (US)	Bulking agent, Humectant, Sequestrant, Stabilizer, Sweetener, Thickener
Xylitol	1891	Equal	2.4 (US)	Emulsifier, Humectant, Stabilizer, Sweetener, Thickener

Table 3. Rare Sugars Profiles

Rare Sugars	Year Discovered	Sweetness (Compared to sucrose)	Caloric Value (kcal/g)	Common Uses in Food
Allulose	1940s	0.70x	0.4	Sweetener
Isomaltulose	1954	0.50x	4.0	Sweetener
Tagatose	1988	0.90x	1.5	Sweetener

III. Global Regulatory Status of Sweeteners

Based on a wealth of scientific information, food safety and regulatory authorities from around the world – including the Joint Food and Agriculture Organization (FAO) / World Health Organization (WHO) Expert Committee on Food Additives (JECFA), the U.S. Food and Drug Administration (FDA), and the European Food Safety Authority (EFSA) – have consistently confirmed the safety of all LNCS, reduced-calorie sweeteners, and rare sugars permitted for use in food. The following is a review of the key safety and regulatory agencies that have studied LNCS, reduced-calorie sweeteners, and rare sugars as well as links to their determinations on individual sweeteners.

International Organizations

Joint Food and Agriculture Organization / World Health Organization Expert Committee on Food Additives (JECFA)

JECFA is an international expert scientific committee originally established in 1956 to evaluate the safety of food additives. JECFA is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).

Following are JECFA's four key areas of work:

- Risk assessment/safety evaluation of:
    - Food additives (intentionally added) (e.g., sweeteners)
    - Processing aids (considered food additives)
    - Flavoring agents (by functional groups)
    - Residues of veterinary drugs in animal products
    - Contaminants
    - Natural toxins
- Exposure assessments
- Specifications and analytical methods, residue definition, MRL proposals (veterinary drugs)
- Development of general principles

Requests for risk assessments/safety evaluations from JECFA are primarily channeled through the Codex Alimentarius Commission (CAC) in their work to develop international food standards and guidelines.

For more Information: http://www.fao.org/fao-who-codexalimentarius/about-codex/science/en/ and https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/.

Codex Committee on Food Additives (CCFA) and JECFA Reviews of Sweeteners

The Codex Alimentarius (Codex) is a collection of standards, guidelines, and codes of practice adopted by the CAC. Codex was established by FAO and WHO to protect consumer health and promote fair practices in food trade. The Codex Committee on Food Additives (CCFA) is one of ten "General Subject" Committees established by the Codex Alimentarius. CCFA's mandate is to:

- Establish and endorse permitted maximum levels for individual food additives.
- Prioritize food additives to undergo risk assessment by JECFA.
- Assign functional classes to individual food additives.
- Recommend specifications of identity and purity for food additives for adoption by the CAC.
- Consider methods of analysis for the determination of additives in food.
- Consider and elaborate standards or codes for related subjects such as the labelling of food additives when sold as such.

CCFA completes its work through electronic Working Groups (eWG), physical Working Groups (pWG), and an annual plenary session. All work endorsed by CCFA is referred to the CAC for adoption.

The "Codex General Standard for Food Additives" (GSFA) is an international standard which sets forth the conditions under which permitted food additives may be used in foods, whether they have previously been standardized by Codex. The GSFA is a key output of the CAC and is referenced/used by many countries in the development of their own regulations and standards.

The GSFA is updated and administered by CCFA. The GSFA consists of 16 main food categories with several criteria mandatory for food additives to be added to the GSFA. For a food additive to be entered into the GSFA, it must have been reviewed by JECFA and assigned an Acceptable Daily Intake level (ADI). It must also have an entry in the International Numbering System (INS), which is a harmonized naming system for food additives. Furthermore, it must present a technological justification and be assigned to a food category and have been reviewed by relevant electronic working groups. Once proposed provisions have adequate information, they are included in an 8-step review process before being formally adopted into the GSFA.

The following are ranges of the allowable maximum use levels for sweeteners across various food categories according to the GSFA database:

- **Acesulfame potassium (Ace-K):** 110 – 5,000 mg/kg (except for use at GMP as a tabletop sweetener)
- **Advantame:** 6 – 400 mg/kg
- **Alitame:** 40 mg/kg – 300 mg/kg (except for use at GMP as a tabletop sweetener)
- **Aspartame:** 399 – 10,000 mg/kg (except for use at GMP as a tabletop sweetener)
- **Aspartame-acesulfame salt:** 200 mg/kg – 2,000 mg/kg (except for use at GMP as a tabletop sweetener)
- **Cyclamate:** 250 – 3,000 mg/kg (except for use at GMP as a tabletop sweetener)
- **Neotame:** 10 – 1,000 mg/kg (except for use at GMP as a tabletop sweetener)
- **Saccharin:** 80 – 2,500 mg/kg (except for use at GMP as a tabletop sweetener)
- **Steviol glycosides:** 30 – 3,500 mg/kg (except for use at GMP as a tabletop sweetener)
- **Sucralose:** 120 – 5,000 mg/kg (except for use at GMP as a tabletop sweetener)
- **Thaumatin:** GMP unless otherwise specified

JECFA Reviews of LNCS

- **Ace-K:** ADI 0-15 mg/kg body weight (bw); Toxicological Monograph
- **Advantame:** ADI 0-5 mg/kg bw; Full evaluation (p.11-18); Toxicological Monograph
- **Aspartame:** ADI 0-40 mg/kg bw; Toxicological Monograph
- **Cyclamate:** ADI 0-11 mg/kg bw; Toxicological Monograph
- **Neotame:** ADI of 2 mg/kg bw; Toxicological Monograph
- **Saccharin:** ADI 0-5 mg/kg bw Full evaluation (p.17-19); Toxicological Monograph
- **Steviol Glycosides:** ADI 0-4 mg/kg bw; Full evaluation (2016) (2008); Toxicological Monograph (2016); Toxicological Monograph (2008); JECFA Framework for Steviol Glycosides Monograph 31 (2023) encompassing the four technologies (extraction, fermentation, enzymatically produced steviol glycosides, glucosylated steviol glycosides)
- **Sucralose:** ADI 0-15 mg/kg bw

JECFA Reviews of Polyols

- **Erythritol:** ADI not specified; Toxicological Monograph
- **Isomalt (Hydrogenated Isomaltulose):** ADI not specified; Toxicological Monograph
- **Lactitol:** ADI not specified; Toxicological Monograph
- **Maltitol:** ADI not specified; Toxicological Monograph
- **Maltitol Syrup:** ADI not specified; Toxicological Monograph
- **Mannitol:** ADI not specified; Toxicological Monograph
- **Polyglycitol Syrup:** ADI not specified; Toxicological Monograph
- **Sorbitol:** ADI not specified; Toxicological Monograph
- **Sorbitol Syrup:** ADI not specified
- **Xylitol:** ADI not specified; Toxicological Monograph

WHO Reviews of Aspartame

In 2023, two WHO agencies, JECFA and the International Agency for Research on Cancer (IARC), conducted separate reviews of the sweetener aspartame. JECFA, the WHO agency charged with evaluating the safety of food additives, conducted a full risk assessment which included evaluating biochemical, toxicological and epidemiology studies on aspartame, its metabolites and degradation products, as well as assessing dietary exposure estimates. JECFA concluded there are no concerns regarding aspartame consumption at current levels and re-affirmed the ADI of 0-40 mg/kg bodyweight/day. IARC conducted a hazard assessment and labeled aspartame as “possibly carcinogenic to humans” based on limited evidence in humans, animals, and mechanistic studies. “Possibly carcinogenic” is the second lowest rating in the IARC carcinogen classification system. Other chemicals characterized as “possibly carcinogenic” by IARC include aloe vera and pickled vegetables.

Following the JECFA and IARC reviews, dozens of health and regulatory agencies around the world issued statements acknowledging the outcomes, supporting JECFA’s conclusions and reaffirming the safety of aspartame. These include:

- Food and Agriculture Organization of the United Nations (FAO)
- Codex Alimentarius (Codex)
- Pan American Health Organization (PAHO)
- U.S. Food and Drug Administration (FDA)
- Food Standards Australia New Zealand (FSANZ)
- Health Canada
- China National Center for Food Safety Risk Assessment (CFSA)

- Food Safety Commission of Japan (FSCJ)
- German Federal Institute for Risk Assessment (BfR)
- UK Food Standards Agency (UK FSA)
- Korea Ministry of Food and Drug Safety (MFDS)
- Agência Nacional de Vigilância Sanitária (ANVISA)
- Food Safety Authority of Ireland (FSAI)
- Indonesia Agency for Drug and Food Control (BPOM)
- Saudi Food and Drug Authority (SFDA)
- New Zealand Ministry of Private Industries (MPI)
- Taiwan Food and Drug Administration (TFDA)
- Thailand Food and Drug Administration (TFDA)
- Austrian Agency for Health and Food Safety (AGES)
- Swedish Food Agency (Livsmedelsverket)
- Nigeria National Agency for Food and Drug Administration and Control (NAFDAC)
- Oman Food Safety and Quality Center (FSQC)
- Belgium Federal Public Service (FPS) Health, Food Chain Safety and Environment
- Jordan Food and Drug Administration (JFDA)

North America

U.S. Food and Drug Administration (FDA)

The FDA regulates approximately 80% of the U.S. food supply, with the U.S. Department of Agriculture regulating the rest. Within FDA, the Center for Food Safety and Applied Nutrition's (CFSAN) Office of Food Additive Safety is responsible for reviewing safety information for food ingredients and food packaging. In contrast to other global authoritative systems, such as those in the EU, the U.S. FDA serves as both the risk assessor and the risk manager.

The 1938 Food, Drug, and Cosmetic Act established three types of food standards: 1) Standards (definitions) of identity; 2) Standards of quality; and 3) Standards regulating the fill of container. This set of laws gave FDA authority to oversee the safety of food, drugs, medical devices, and cosmetics. In 1958, Congress enacted the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (FD&C Act), which along with other supporting legislative documents defined the term "food additive," established the required premarket approval for new uses of food additives, established the standard of review ("fair evaluation of the data..."), standard of safety, and the formal rulemaking procedures for food additives.

FDA Safety Evaluation Process

FDA CFSAN uses risk analysis to inform regulatory decisions about food and food ingredients. When evaluating the safety of a petitioned food additive, FDA considers: 1) the composition and properties of the substance; 2) the amount that would typically be consumed; 3) immediate and long-term health effects; and 4) various safety factors. The evaluation determines an appropriate level of use that allows for uncertainty about the levels of consumption that are expected to be harmless. This ensures that approved levels of use are much lower than what would be expected to have any adverse effect.

In the 1958 FD&C Act, Congress further stated that "substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety as having been adequately shown . . . to be safe under the conditions of their intended use," are excluded from the definition (of food additive)." This means that all food ingredients on the market in the U.S. are either approved food additives or GRAS (Generally Recognized as Safe) substances.

Petitioned food additives are reviewed by FDA and subject to the rulemaking process, which includes the opportunity for public review and comment before issuing a rule. GRAS substances are exempt from FDA pre-market review based on common knowledge among qualified scientific experts that they are safe under the intended conditions of use. Firms may also choose to notify FDA of their GRAS determination, which would result in a "no questions" letter if there are no safety concerns. The data to support the safety of a GRAS substance must be the same in quantity and quality as an approved food additive. The primary difference between a GRAS determination and a premarket approval is that the pivotal safety data to support a GRAS substance must be publicly available. For a food additive, the pivotal safety data may be privately held and does not need to be in the public domain.

For more information:

- Overview of Food Ingredients, Additives & Colors
- How U.S. FDA's GRAS Notification Program Works

U.S. Regulatory Status of LNCS

- **Acesulfame Potassium (Ace-K):** Food Additives Permitted for Direct Addition to Food for Human Consumption: Acesulfame Potassium (21 CFR 172.800); ADI of 15 mg/kg bw/day*
- **Advantame:** Food Additives Permitted for Direct Addition to Food for Human Consumption: Advantame (21 CFR 172.803); ADI of 32.8 mg/kg bw/day*
- **Aspartame:** Food Additives Permitted for Direct Addition to Food for Human Consumption; A; Aspartame (21 CFR 172.804) FDA Food Additive Approval Process for Aspartame; Carcinogenicity (1981); ADI of 50 mg/kg bw/day*
- **Monk Fruit Extract (Luo Han Guo):** Luo Han Guo (Monk Fruit) GRAS Notification List
- **Neotame:** Food Additives Permitted for Direct Addition to Food for Human Consumption; Neotame (21 CFR 172.829); ADI 0.3 mg/kg bw/day*
- **Saccharin:** Food Additives Permitted In Food Or In Contact With Food On An Interim Basis Pending Additional Study; Saccharin (21 CFR 180.37; ADI 15 mg/kg bw/day*
- **Steviol Glycosides:** Steviol Glycosides GRAS Notices; ADI of 0-4 mg/kg bw/day*
- **Sucralose:** Food Additives Permitted for Direct Addition to Food for Human Consumption: Sucralose (21 CFR 172.831); ADI of 0-15 mg/kg bw/day*
- **Thaumatin:** Thaumatin GRAS Notices

*FDA ADI Reference values and Additional Information about High-Intensity Sweeteners Permitted for Use in Food in the United States.

U.S. Regulatory Status of Sugar Alcohols

- **Erythritol:** Erythritol GRAS Notices
- **Isomalt:** GRAS
- **Hydrogenated Starch Hydrolysates:** GRAS
- **Lactitol:** GRAS
- **Maltitol:** GRAS
- **Mannitol:** Approved as a food additive
- **Sorbitol:** Affirmed as GRAS
- **Xylitol:** Approved as a food additive

U.S. Regulatory Status of Rare Sugars

- **Allulose (D-Psicose):** GRAS Notice; D-psicose GRAS Notices
- **Isomaltulose:** GRAS Notice
- **Tagatose:** GRAS Notices

Canada – Health Canada and Canadian Food Inspection Agency (CFIA)

Health and Welfare Canada was a federal department established in 1944. In 1993, the department was split into two departments: Health Canada and Human Resources and Labor Canada (now Human Resources Development Canada). Today, Health Canada oversees numerous federal health-related agencies, such as the Canadian Food Inspection Agency and the Public Health Agency of Canada.

Substances that are permitted for use as additives in or on foods marketed in Canada can be found in one of Health Canada's 15 Lists of Permitted Food Additives, such as the List of Permitted Sweeteners, that serve as Health Canada's official repository for approved food additives. Each list is incorporated by reference into a Marketing Authorization (MA), which sets out the conditions and legal foundation for the use of the lists.

Upon completion of a scientific assessment by Health Canada's Food Directorate, if the science supports the submission, Health Canada will notify the public of its intent to modify the Lists of Permitted Food Additives via a "Notice of Proposal" that will be posted on the Health Canada website for public consideration. Interested parties may provide comments on the proposal and, if new scientific or safety evidence is raised, revisions may be made. A "Notice of Modification" will be posted on the website once the proposal has been formally incorporated into the lists.

Health Canada Regulatory References for LNCS

Regulatory permissions for the use of LNCS, including permitted food categories and maximum use levels, are contained in the List of Permitted Sweeteners. Following are the LNCS permitted for use in Canada.

- **Acesulfame potassium:** Update to the Lists of Permitted Food Additives to Increase the Permitted Maximum Levels of Acesulfame Potassium and Sucralose in Chewing Gum and Breath Freshener Products Regulated as Food (2013)
- **Advantame:** Notice of Modification to the List of Permitted Sweeteners to Enable the Use of Advantame as a Sweetener in Certain Unstandardized Foods Including Certain Beverages (2017)
- **Aspartame:** Health Canada Comments on the Recent Study Relating to the Safety of Aspartame (2005); ADI 40 mg/kg bw
- **Monk Fruit Extract:** Notice of Modification to the List of Permitted Sweeteners to Enable the Use of Monk Fruit Extract (Luo Han Guo) as a Sweetener in Table-Top Sweeteners (2013)
- **Neotame:** List of Permitted Sweeteners
- **Saccharin** (including calcium saccharin, potassium saccharin, and sodium saccharin)**:** Notice of Proposal to Enable the Use of Saccharin, Calcium Saccharin, Potassium Saccharin and Sodium Saccharin as Sweeteners in Various Unstandardized Foods (2014); https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/modification-list-permitted-sweeteners-use-saccharin-calcium-potassium-sodium-sweeteners-table-top-0072.html (2016)
- **Steviol Glycosides:** Notice of Modification to the Lists of Permitted Food Additives to Enable the Use of Steviol Glycosides as a Table-Top Sweetener and as a Sweetener in Certain Food Categories
- **Sucralose:** Update to the Lists of Permitted Food Additives to Increase the Permitted Maximum Levels of Acesulfame Potassium and Sucralose in Chewing Gum and Breath Freshener Products Regulated as Food (2013)
- **Thaumatin:** List of Permitted Sweeteners

Health Canada Regulatory References for Sugar Alcohols (Polyols)

Regulatory permissions for the use of sugar alcohols, including permitted food categories and maximum use levels, are contained in the List of Permitted Sweeteners. The following sugar alcohols are permitted for use in Canada:

- **Erythritol**
- **Hydrogenated Starch Hydrolysates**
- **Isomalt**
- **Lactitol**
- **Maltitol**
- **Maltitol Syrup**
- **Mannitol**
- **Sorbitol**
- **Sorbitol Syrup**
- **Xylitol**

Health Canada Regulatory References for Rare Sugars

Health Canada assesses the safety of all novel foods proposed for sale or advertising in Canada. After completing an assessment for a novel food and finding it to be safe for human consumption, the Food Directorate includes the novel food in a database. For the following rare sugars, the assessment has been completed:

- Isomaltulose (2012)
- D-tagatose (2021)

European Union

European Commission and European Food Safety Authority (EFSA)

EFSA is the scientific agency in the European Union (EU) that provides independent recommendations to the European Commission and communicates existing and emerging risks associated with food and ingredients. Prior to the establishment of EFSA, the Scientific Committee on Food (SCF) was the Committee that provided the European Commission with scientific advice on food safety. The SCF, which was established in November 1947, was composed of independent scientists and its role transferred to the EFSA in May 2003.

EFSA operates independently of the EU legislative and executive institutions as well as EU Member States who are responsible for making their own decisions and developing policy. However, EFSA produces scientific opinions and advice that form the basis for European policies and legislation.

In 2002, the European Parliament and the Council adopted Regulation (EC) No 178/2002 laying down the general principles and requirements of food law (General Food Law Regulation). It also enacted EFSA as the independent agency responsible for scientific advice and support. Unlike in the U.S., for example, in the European Union (EU) food safety system, the responsibility for risk assessment (science) and for risk management (policy) are kept separate. EFSA's scope includes food and feed safety, nutrition, animal health and welfare, plant protection, and plant health.

EFSA's scientific work is conducted in accordance with three main stages: request, assessment, and adoption.

- First, EFSA receives a request for scientific advice from the European Commission, the European Parliament, or other National food safety bodies. EFSA may also undertake work on its own in fields such as emerging risks.
- Once accepted by EFSA, requests become mandates which are then assigned to one or more scientific panels of experts or the Scientific Committee depending on the subject matter.
- The scientific Panel on Food Additives and Flavourings (FAF) deals with questions of safety in the use of food additives and other substances deliberately added to food. The Panel on Nutrition, Novel Foods and Food Allergens (NDA) deals with nutrient sources (e.g. sources of vitamins and minerals).
- The Panel or the Scientific Committee sets up a Working Group of experts to carry out the risk assessment or assigns the task to an existing Working Group.
- The Working Group experts then do the detailed scientific work, and if there is a need for further data, EFSA may draw on its data collection networks or launch an open call for data. The Working Group develops a draft opinion, submits it to the Panel for discussion and possible adoption, and EFSA often holds additional public consultations on its draft opinions.
- The Scientific Committee or Panel reviews the feedback received to draft the final opinion.
- Finally, the Scientific Committee or Panel adopts the opinion by consensus.
- EFSA then sends the final opinion to the original requesters for use in their policy-making and legislative decisions on food and feed safety.

Note, all food additives approved before 2009 were required to be re-evaluated by 2020. Risk managers (Commission, Council (Member States), Parliament) prioritize which food additives (e.g., sweeteners) should be re-evaluated first. EFSA then carries out a thorough risk assessment of each food additive, including an exposure assessment.

The General Food Law Regulation is the foundation of food and feed law. It sets out an overarching and coherent framework for the development of food and feed legislation both at European Union and national levels. It lays down general principles, requirements and procedures that underpin decision making in matters of food and feed safety, covering all stages of food and feed production and distribution.

For more information:

- About EFSA
- General Food Law

EFSA Reviews of LNCS

- **Ace-K:** Safety of the proposed extension of use of acesulfame K (E 950) in foods for special medical purposes in young children; EFSA's Scientific Panel on Food Additives and Flavorings (FAF Panel) is currently re-evaluating Ace-K (outcome pending).
- **Advantame:** Scientific Opinion on the safety of advantame for the proposed uses as a food additive).
- **Aspartame:** Scientific Opinion on the re-evaluation of aspartame (E 951) as a food additive (2013).
- **Cyclamate:** Revised Opinion on Cyclamic Acid and Its Sodium/Calcium Salts; EFSA's FAF Panel is currently re-evaluating calcium cyclamate and is currently re-evaluating sodium cyclamate (outcome pending).
- **Neotame:** Scientific Opinion of the Panel on Food Additives, Flavorings, Processing Aids and Materials in Contact with Food; EFSA's FAF Panel is currently re-evaluating neotame (outcome pending).
- **Monk Fruit Extract:** Safety of use of Monk fruit extract as a food additive in different food categories (2019).
- **Saccharin:** Call for technical and toxicological data on sweeteners authorized as food additives in the EU (outcome pending); EFSA's FAF Panel is currently re-evaluating saccharin (outcome pending).
- **Steviol Glycosides:** Scientific Opinion on the safety of steviol glycosides for the proposed uses as a food additive (2010); Revised exposure assessment for steviol glycosides for the proposed uses as a food additive; Safety of the proposed amendment of the specifications of the food additive steviol glycosides (E 960); other Scientific Opinions pertaining to Steviol Glycosides.
- **Sucralose:** Statement on the validity of the conclusions of a mouse carcinogenicity study on sucralose (E 955) performed by the Ramazzini Institute (2017); according to Commission Regulation (EU) No 257/2010, EFSA's FAF Panel is currently re-evaluating sucralose (outcome pending).
- **Thaumatin:** Re-evaluation of thaumatin (E 957) as food additive - - 2021 - EFSA Journal - Wiley Online Library.

For more information: Call for technical and toxicological data on sweeteners authorized as food additives in the EU.
Additional reference: https://www.efsa.europa.eu/en/topics/topic/sweeteners.

EFSA Reviews of Polyols

As part of its re-evaluation of the safety of all food additives, EFSA is re-evaluating the safety of polyols. Data has been submitted in response to calls for technical and toxicological data and usage level data. EFSA's re-evaluation is expected to be completed in 2024-2025.

- **Erythritol:** Re-evaluation of erythritol (E 968) as a food additive - - 2023 - EFSA Journal - Wiley Online Library
- **Isomalt** (EFSA is currently re-evaluating isomalt)
- **Lactitol** (EFSA is currently re-evaluating lactitol)
- **Maltitol** (EFSA is currently re-evaluating maltitol)
- **Maltitol Syrup** (EFSA is currently re-evaluating maltitol syrup)
- **Mannitol** (EFSA is currently re-evaluating mannitol)
- **Sorbitol** (EFSA is currently re-evaluating sorbitol)
- **Sorbitol Syrup** (EFSA is currently re-evaluating sorbitol syrup)
- **Xylitol** (EFSA is currently re-evaluating xylitol)

United Kingdom (UK) Committee on Toxicity (COT)

The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) is an independent scientific committee that provides advice to the Food Standards Agency, the Department of Health and other Government Departments and Agencies in the United Kingdom (UK) on matters concerning the toxicity of substances, including those that are used or proposed to be used as food additives. Following the UK's withdrawal from the European Union, the responsibility for assessment of the safety of food additives, including sweeteners, in England, Wales, and Scotland lies with the Food Standards Agency and Food Standards Scotland, and the COT provides scientific advice to the FSA/FSS on matters related to the toxicity of substances in food. For the time being Northern Ireland continues to follow EU legislation on food additives.

The COT may be asked for advice on the risks associated with different risk management options, in order to support the Agency's decisions. The COT also conducts risk assessment of food additives. Note, the UK's Food Standards Agency makes decisions on risk management for food additives, not the COT.

The COT's risk assessment process consists of four linking steps. These are:

- hazard identification
- hazard characterization
- exposure assessment
- risk characterization

The last step, risk characterization, compares the exposure with the safety guideline or the doses found by the hazard characterization to have effects. The COT considers whether harm could result at the estimated exposure levels and how serious any effects might be. This risk characterization step provides the basis for making decisions on whether there is a need to manage the risk by reducing exposure. If the risk assessment indicates a need to reduce the risk associated with a chemical in food, then the Food Standards Agency will consider risk management. Risk management options include regulatory measures to limit the use of a particular food additive or limits on the amount allowed to be present in different types of food.

For more information: https://cot.food.gov.uk/risk-analysis-framework.

COT Reviews of LNCS

- **Aspartame:** Carcinogenicity (1992; 12-15); Response to EFSA consultation on a draft scientific opinion (pgs. 13-14)
- **Cyclamate:** Safety Review/carcinogenic effects (1995; pg. 6-8); ADI 0-6 mg/kg bw/day
- **Sucralose:** No observed effect level at 350 mg/kg (2000; pg. 23-24); ADI 0-15 mg/kg bw/day

European Union Regulatory References for Rare Sugars

The European Union's Novel Foods Regulation applies to foods and food ingredients if they have not been used for human consumption in a significant degree within the European Community before May 15, 1997. The EU Novel Foods Regulation states that novel foods falling within this scope must not present a danger to consumers, mislead consumers, or differ from foods or food ingredients for which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for a consumer. Each novel food and ingredient in the European Union are required to undergo pre-market authorization and if the novel food is liable to have an effect on human health, the Commission will request the EFSA carry out a risk assessment.

The following rare sugars are approved Novel Foods in the EU (Reg. (EU) 2017/2470):

- Isomaltulose (2005)
- D-tagatose (2005)

Asia-Pacific

Food Standards Australia New Zealand (FSANZ)

Food Standards of Australia New Zealand (FSANZ) is the legal authority in the Australian Government Health portfolio and was established by the Food Standards Australia New Zealand Act 1991. FSANZ, along with other government agencies in Australia and New Zealand, monitors the food supply to ensure it is safe.

FSANZ carries out safety assessments on food additives by following an internationally accepted (Codex Alimentarius) model involving a hazard (safety) assessment of the chemical and dietary exposure (consumption levels) assessment. FSANZ checks whether: (1) The food additive is safe (at the use levels being proposed), and (2) there is a good technological reason for using the additive. Extensive testing of food additives is required, including animal studies. They are typically conducted using extremely high concentrations in the diet—far greater than the level people are likely to consume if the substance was present in food. Exposure assessments predict the likely amount of the additive that would be consumed if it were permitted. This estimate is then compared with the ADI. FSANZ recommends a maximum level of the food additive, providing the estimate based on this level is well within the range of the ADI based on this comparison. The permitted level also takes account of the level of use that is required for the additive to perform its function.

FSANZ routinely conducts targeted surveys and Australian Total Diet Studies to collect analytical data on the levels of chemicals, microbiological contaminants, and nutrients in food. FSANZ is also constantly monitoring the scientific literature relevant to the safety of food additives. If any new information becomes available that is likely to affect the ADI value, FSANZ will evaluate the data and amend permissions as required.

The Australia New Zealand Joint Food Standards Code outlines the food standards developed and managed by FSANZ which dictate the use of ingredients, processing aids, colorings, additives, and vitamins and minerals. The Food Standards Code also covers the composition of some foods (e.g., dairy, meat and beverages) as well as foods developed using innovative technologies, such as genetically modified foods. The Code includes labelling requirements for packaged and unpackaged food (e.g., mandatory warnings or advisory labels). Note, some standards apply to Australia only. The Food Standards Code can be changed through a proposal. Proposals are prepared by FSANZ, and all applications and proposals are subject to public consultation. Permitted food additives are listed in Standard 1.3.1 of the Food Standards Code.

Section 1.3.1 of the Food Standards Code addresses food additives. Section 1.3.1—5 addresses limitations on the use of high intensity sweeteners and states: Unless Schedule 15 expressly provides otherwise, a substance that may be used as a food additive to perform the technological purpose of an intense sweetener may be added to food only:

(a) As a flavor enhancer; or
(b) In an amount necessary to replace, either wholly or partially, the sweetness normally provided by sugars.

FSANZ Reviews of LNCS

- **Ace-K:** ADI of 15 mg/kg bw/day; Final Assessment Report (2003)
- **Advantame:** ADI of 5 mg/kg bw/day; Assessment Report
- **Aspartame:** ADI of 0-40 mg/kg bw/day; Final Assessment Report (2003); Aspartame Safety Statement (2017)
- **Cyclamate:** ADI of 0-11 mg/kg bw/day; Final Assessment Report (2007)
- **Monk Fruit Extract:** no ADI set; Approval Report (2018)
- **Neotame:** ADI of 0-2 mg/kg bw/day; Safety Assessment Report
- **Saccharin:** ADI of 0-5 mg/kg bw/day; Final Assessment Report (2005)
- **Steviol Glycosides:** ADI of 0-4 mg/kg bw/day; FSANZ information on Steviol Glycosides approval
- **Sucralose:** ADI of 0-15 mg/kg bw/day
- **Thaumatin:** ADI not specified

FSANZ Reviews of Polyols

- **Erythritol**
- **Isomalt**
- **Maltitol**
- **Maltitol Syrup**
- **Mannitol**
- **Sorbitol**
- **Sorbitol Syrup**
- **Xylitol**

FSANZ Reviews of Rare Sugars

In Australia and New Zealand, novel foods and novel food ingredients are regulated under Standards 1.1.1 and 1.5.1 in the Australia New Zealand Food Standards Code.

- **Isomaltulose:** Final Assessment Report (2007)
- **D-tagatose:** Final Assessment Report (2004)

Asia

Food Safety and Standards Authority of India (FSSAI)

FSSAI is the agency responsible for determining the safety of foods and food ingredients in India. Food additives, including sweeteners, are regulated through the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

FSSAI Regulatory References for LNCS

The following are the LNCS permitted for use in India along with ranges of maximum use levels:

- **Ace-K** (300 – 5,000 ppm)
- **Aspartame** (200 – 10,000 ppm)
- **Neotame** (33 ppm)
- **Sodium Saccharin** (100 – 8,000 ppm)
- **Sucralose** (150 – 1,250 ppm)
- **Steviol glycosides** (by extraction) (200-3500 ppm); Compendium on Food Additives Regulations (2020)

FSSAI Regulatory References for Polyols

The following are the polyols permitted for use as sweeteners in India, which are allowed at GMP:

- **Erythritol**
- **Isomalt**
- **Maltitol**
- **Maltitol syrup**

Africa

Republic of South Africa

The National Department of Health of the Republic of South Africa is responsible for ensuring the safety of food and food ingredients. The Department of Health has developed a List of Permissible Sweeteners referred to in Regulation 4 of the Regulations Relating to the Use of Sweeteners in Foodstuffs. South Africa aligns its regulations with Codex and stipulates the maximum permitted levels for sweeteners must follow the Codex GSFA.

South Africa References for LNCS

The following LNCS are permitted for use in food in South Africa:

- **Ace-K**
- **Alitame**
- **Aspartame**
- **Aspartame-acesulfame salt**
- **Cyclamate** (including calcium cyclamate and sodium cyclamate)
- **Neotame**
- **Saccharin** (including calcium saccharin and sodium saccharin)
- **Steviol glycosides**; Regulations relating to the use of sweeteners in foodstuffs (2011)
- **Sucralose**
- **Thaumatin**

South Africa References for Polyols

The following polyols are permitted for use in food in South Africa:

- **Erythritol**
- **Isomalt**
- **Lactitol**
- **Maltitol**
- **Maltitol Syrup**
- **Mannitol**
- **Polyglycitol Syrup**
- **Sorbitol**
- **Sorbitol Syrup**
- **Xylitol**

Latin and South America

Mexico Secretary of Health

The Secretariat of Health is responsible for determining the safety of food and food ingredients in Mexico. Mexico's food additive regulations contain sections relating to permitted LNCS and polyols.

Mexico Regulatory References for LNCS

Annex VII relates to Sweeteners with an established ADI. Below are the permitted LNCS with ranges of allowable maximum use levels:

- **Ace-K** (110 – 2,000 mg/kg)
- **Advantame** (3 – 400 mg/kg)
- **Alitame** (40 – 300 mg/kg (including 40 mg/L in non-alcoholic drinks))
- **Aspartame** (300 – 10,000 mg/kg)
- **Aspartame-acesulfame salt** (200 – 1,000 mg/kg)
- **Cyclamates** (including its calcium, potassium, and sodium salts) (100 – 3,000 mg/kg)
- **Neotame** (10 – 1,000 mg/kg)
- **Neohesperine DC** (10 – 400 mg/kg)
- **Saccharins** (including its calcium, potassium, and sodium salts) (20 – 2,500 mg/kg)
- **Steviol glycosides** (40 – 3,500 mg/kg)
- **Sucralose** (250 – 5,000 mg/kg)

Mexico Regulatory References for Polyols and Thaumatin

Annex VIII refers to sweeteners that can be used in accordance with GMPs and contains the following:

- **D-Tagatose**
- **Erythritol**
- **Isomalt**
- **Lactitol**
- **Maltitol**
- **Maltitol syrup**
- **Mannitol**
- **Monk Fruit (Luo Han Guo)**
- **Polyglycitol syrup**
- **Sorbitol**
- **Sorbitol Syrup**
- **Thaumatin**
- **Xylitol**

Chile Ministry of Health

The Chilean Ministry of Health regulates food and food ingredients. The Health Regulations for Food contains lists of permitted LNCS and polyols in Chile.

Chile Regulatory References for LNCS

Article 146 of notes the following LNCS are permitted for use in foods in Chile:

- **Ace-K**
- **Alitame**
- **Aspartame**
- **Cyclamate and its salts (Na, K, Ca)**
- **Neotame**
- **Saccharin and its salts (Na, K, Ca)**
- **Steviol glycosides** (by extraction)
- **Sucralose**

Chile Regulatory References for Polyols

Article 151 of notes the following LNCS are permitted for use in foods in Chile:

- **Erythritol**
- **Isomalt**
- **Lactitol**
- **Maltitol**
- **Mannitol**
- **Sorbitol**
- **Xylitol**

IV. Tables Containing Global Permissions for Sweeteners

Following are tables outlining global regulatory permissions for sweeteners. Tables are separated in to LNCS, reduced-calorie sweeteners, and rare sugars.

Table 4. Global Regulatory Permissions for LNCS

Legend
√ = Permitted
T = Tabletop only
P = Pharmaceuticals only
# = Regulations in development
* = Regulations not available
X = Not permitted

	Acesulfame-potassium	Advantame	Alitame	Aspartame	Aspartame-acesulfame salt	Cyclamate	Monk Fruit (Luo Han Guo)	Neotame	Saccharin	Steviol glycosides[1]	Sucralose	Thaumatin
CODEX	√	#	√	√	√	√	*	√	√	√	√	√
Albania	*	*	*	*	*	√	*	*	*	√	√	*
Angola	√	*	√	√	√	√	√	√	√	√	√	*
Antigua	√	*	√	√	√	√	*	√	√	√	√	√
Argentina	√	*	√	√	√	√	*	√	√	√	√	√
Armenia	*	*	*	√	*	√	*	*	*	*	*	*
Australia	√	√	√	√	√	√	√	√	√	√	√	√
Austria	√	√	*	√	√	√	*	√	√	√	√	√
Azerbaijan	*	*	*	*	*	√	*	*	*	*	*	*
Bahamas	√	*	√	√	√	√	*	√	√	√	√	√
Bahrain	*	*	*	√	*	√	*	*	*	√	*	*
Belarus	*	*	*	*	*	√	*	*	*	*	*	*
Belgium	√	√	*	√	√	√	*	√	√	√	√	√
Bolivia	√	*	√	√	√	√	*	√	√	√	√	√
Bosnia and Herzegovina	*	*	*	√	*	√	*	*	*	√	*	*
Botswana	*	*	*	√	*	√	*	*	*	*	*	*
Brazil	√	√	*	√	*	√	*	√	√	√	√	√

[1] Steviol glycosides additional information:

- Australia: For extraction, bioconversion, and fermentation technologies.
- Canada: Only extraction, bioconversion, and fermentation are currently approved.
- Egypt: NFSA Decree No. 5, National Gazette issue no 18, 2024.
- FSANZ: Only extraction, bioconversion, and fermentation technologies are currently approved.
- Ghana: Some countries adopt the JECFA framework for steviol glycosides automatically and fully, such as Ghana.
- Indonesia: Extraction and bioconversion technologies approved.
- Mexico: Adopted the JECFA framework for steviol glycosides in 2022.
- New Zealand: For extraction, bioconversion, and fermentation technologies.
- South Korea: Approved only for certain manufacturing methods. Fermentation and enzymatic conversion methods are not allowed.
- Venezuela reference: https://sigbs.sencamer.gob.ve/cgi-bin/koha/opac-retrieve-file.pl?id=f72c53922b4cc9cede98b55fadaffd7a

	Acesulfame-potassium	Advantame	Alitame	Aspartame	Aspartame-acesulfame salt	Cyclamate	Monk Fruit (Luo Han Guo)	Neotame	Saccharin	Steviol glycosides	Sucralose	Thaumatin
Brunei	*	*	*	√	*	√	*	*	√	*	√	*
Bulgaria	√	√	*	√	√	√	*	√	√	√	√	√
Canada	√	√	*	√	*	√ (T)	√ (T)	√	√	√	√	√
Chile	√	*	√	√	*	√	*	√	*	√	√	*
China	√	√	√	√	*	√	√	*	√	√	√	*
Colombia	√	√	√	√	√	√	*	√	√	√	√	√
Comoros	*	*	*	*	*	√	*	*	*	*	*	*
Costa Rica	√	*	√	√	√	√	*	√	√	√	√	√
Croatia	√	√	*	√	√	√	*	√	√	√	√	√
Cyprus	√	√	*	√	√	√	*	√	√	√	√	√
Czechia	√	√	*	√	√	√	*	√	√	√	√	√
Denmark	√	√	*	√	√	√	*	√	√	√	√	√
Djibouti	*	*	*	*	*	√	*	*	*	*	*	*
Dominica	√	*	√	√	√	√	*	√	√	√	√	√
Dominican Republic	√	*	√	√	√	√	*	√	√	√	√	√
Ecuador	√	*	√	√	√	√ (T)	*	√	√	√	√	√
El Salvador	√	*	√	√	√	√	*	√	√	√	√	√
Estonia	√	√	*	√	√	√	*	√	√	√	√	√
Finland	√	√	*	√	√	√	*	√	√	√	√	√
France	√	√	*	√	√	√	*	√	√	√	√	√
French-Guyana	√	*	√	√	√	√	*	√	√	√	√	√
Germany	√	√	*	√	√	√	*	√	√	√	√	√
Georgia	*	√	*	√	*	√	*	*	*	√	*	*
Ghana	*	*	*	√	*	*	*	*	*	√	*	√
Greece	√	√	*	√	√	√	*	√	√	√	√	*
Grenada	√	*	√	√	√	√	*	√	√	√	√	√
Guadeloupe	√	*	√	√	√	√	*	√	√	√	√	√
Guatemala	√	*	√	√	√	√	*	√	√	√	√	√
Guyana	√	*	√	√	√	√	*	√	√	√	√	√
Haiti	√	*	√	√	√	√	*	√	√	√	√	√
Honduras	√	*	√	√	√	√	*	√	√	√	√	√
Hong Kong	√	*	*	√	*	√	*	*	√	√	√	√
Hungary	√	√	*	√	√	√	*	√	√	√	√	*
Iceland	*	√	*	√	*	√	*	*	*	√	*	*
India	√	*	*	√	*	√	*	*	√	√	√	*
Indonesia	√	*	√	√	*	√	*	*	√	√	√	*
Iran	*	*	*	√	*	√	*	*	*	*	*	*
Iraq	*	*	*	*	*	√	*	*	*	*	*	√
Ireland	√	√	*	√	√	√	*	√	√	√	√	*
Israel	*	√	*	√	*	√	*	*	*	√	*	√
Italy	√	√	*	√	√	√	*	√	√	√	√	*
Jamaica	√	*	√	√	√	√	*	√	√	√	√	√
Japan	√	√	*	√	*	X	√	√	√	√	√	*
Jordan	*	*	*	√	*	√ (P)	*	*	*	*	*	*
Kazakhstan	*	*	*	*	*	√	*	*	*	√	*	*
Kenya	*	*	*	√	*	√	*	*	*	*	*	*
Kyrgyzstan	*	*	*	*	*	√	*	*	*	*	*	*

	Acesulfame-potassium	Advantame	Alitame	Aspartame	Aspartame-acesulfame salt	Cyclamate	Monk Fruit (Luo Han Guo)	Neotame	Saccharin	Steviol glycosides	Sucralose	Thaumatin
Kuwait	*	*	*	√	*	√ (T)	*	*	*	√	*	√
Latvia	√	√	*	√	√	√	*	√	√	√	√	*
Lesotho	*	*	*	*	*	√	*	*	*	*	*	√
Lithuania	√	√	*	√	√	√	*	√	√	√	√	√
Luxembourg	√	√	*	√	√	√	*	√	√	√	√	*
Macau	*	*	*	*	*	√	*	*	*	*	*	*
Macedonia	*	√	*	√	*	√	*	*	*	√	*	*
Madagascar	*	*	*	*	*	√	*	*	*	*	*	*
Malawi	*	*	*	*	*	√	*	*	*	*	*	*
Malaysia	√	*	*	√	*	√	*	*	√	√	√	√
Malta	√	√	*	√	√	√	*	√	√	√	√	*
Martinique	√	*	√	√	√	√	*	√	√	√	√	√
Mauritius	*	*	*	√	*	√	*	*	*	*	*	*
Mayotte	*	*	*	*	*	√	*	*	*	*	*	√
Mexico	√	√	√	√	√	√	*	√	√	√	√	*
Moldova	*	*	*	*	*	√	*	*	*	√	*	*
Mongolia	*	*	*	*	*	√	*	*	*	√	*	*
Montenegro	*	*	*	*	*	√	*	*	*	√	*	*
Montserrat	*	*	*	*	*	√	*	*	*	*	*	*
Morocco	*	*	*	√	*	√	*	*	*	*	*	*
Mozambique	*	*	*	*	*	√	*	*	*	*	*	*
Namibia	*	*	*	*	*	√	*	*	*	*	*	√
Netherlands	√	√	*	√	√	√	*	√	√	√	√	√
New Zealand	√	√	√	√	√	√	√	√	√	√	√	√
Nicaragua	√	*	√	√	√	√	*	√	√	√	√	√
Norway	*	√	*	√	*	√	*	*	*	√	*	*
Oman	*	*	*	√	*	√	*	*	*	√	*	*
Pakistan	*	*	*	√	*	√	*	*	*	*	*	√
Panama	√	*	√	√	√	√	*	√	√	√	√	√
Papua New Guinea	*	*	*	*	*	√	*	*	*	*	*	*
Paraguay	√	*	√	√	√	√	*	√	√	√	√	√
Peru	√	*	√	√	√	√	*	√	√	√	√	*
Philippines	√	*	*	√	*	√	*	*	√	√	√	√
Poland	√	√	*	√	√	√	*	√	√	√	√	√
Portugal	√	√	*	√	√	√	*	√	√	√	√	*
Qatar	*	*	*	√	*	√	*	*	*	√	*	√
Romania	√	√	*	√	√	√	*	√	√	√	√	*
Russia	*	*	*	√	*	√	*	*	*	√	√	*
Rwanda	*	*	*	*	*	√	*	*	*	*	*	*
St. Helena	*	*	*	*	*	√	*	*	*	*	*	*
St. Kitts and Nevis	√	*	√	√	√	√	*	√	√	√	√	√
St. Lucia	√	*	√	√	√	√	*	√	√	√	√	√
St. Vincent	√	*	√	√	√	√	*	√	√	√	√	√
Saudi Arabia	*	*	*	√	*	√	*	*	*	√	*	*
Serbia	*	√	*	√	*	√	*	*	*	√	*	*
Seychelles	*	*	*	*	*	√	*	*	*	*	*	*
Sierra Leone	*	*	*	*	*	√	*	*	*	*	*	*
Singapore	√	√	*	√	*	√	*	*	√	√	√	√

	Acesulfame-potassium	Advantame	Alitame	Aspartame	Aspartame-acesulfame salt	Cyclamate	Monk Fruit (Luo Han Guo)[2]	Neotame	Saccharin[3]	Steviol glycosides	Sucralose	Thaumatin
Slovakia	√	√	*	√	√	√	*	√	√	√	√	√
Slovenia	√	√	*	√	√	√	*	√	√	√	√	*
South Africa	√	*	*	√	*	√	*	*	√	√	√	*
South Korea	√	*	*	√	*	*	√	√	√	√	√	√
Spain	√	√	*	√	√	√	*	√	√	√	√	*
Sri Lanka	*	*	*	√	*	√ (T)	*	*	*	*	*	*
Suriname	*	*	*	*	*	√	*	*	*	*	*	*
Swaziland	*	*	*	√	*	√	*	*	*	*	*	√
Sweden	√	√	*	√	√	√	*	√	√	√	√	*
Switzerland	*	√	*	√	*	√	*	*	*	√	*	*
Taiwan	*	*	*	√	*	√	*	*	*	√	*	*
Tajikistan	*	*	*	*	*	√	*	*	*	*	*	*
Tanzania	*	*	*	√	*	√	*	*	*	*	*	*
Thailand	√	*	*	√	*	√	*	√	√	√	√	√
Trinidad and Tobago	√	*	√	√	√	√	*	√	√	√	√	√
Tunisia	*	*	*	√	*	√	*	*	*	*	*	*
Turkey	*	√	*	√	*	√	*	*	*	√	*	*
Turkmenistan	*	*	*	*	*	√	*	*	*	*	*	*
Turks and Caicos	√	*	√	√	√	√	*	√	√	√	√	√
Ukraine	*	*	*	√	*	√	*	*	*	√	*	*
United Arab Emirates	*	*	*	√	*	√ (T)	*	*	*	√	*	√
United Kingdom	√	√	*	√	√	√	*	√	√	√	√	√
United States of America	√	√	*	√	*	X	√	√	√	√	√	√
Uruguay	√	*	*	√	√	√	*	√	√	√	√	*
Uzbekistan	*	*	*	√	*	√	*	*	*	√	*	*
Venezuela	*	*	*	√	*	√	*	*	*	*	*	*
Vietnam	√	*	*	√	*	√	*	*	√	√	√	*
West Bank	*	*	*	*	*	√	*	*	*	*	*	*
Zambia	*	*	*	*	*	√	*	*	*	*	*	*
Zimbabwe	*	*	*	√	*	√	*	*	*	√	*	*

[2] Monk Fruit (Luo Han Guo) additional information:

- South Korea: Only the fruit and leaves can be used.

[3] Saccharin additional information:

- South Korea: Sodium saccharin is listed in the Food Code defined by the Ministry of Food and Drug Safety. Reference: https://www.foodsafetykorea.go.kr/foodcode/04_03.jsp?idx=820.

Table 5. Global Regulatory Permissions for Sugar Alcohols

Legend

√ = Permitted

= Regulations in development

* = Regulations not available

	Erythritol	Hydrogenated Starch Hydrolysates	Isomalt	Lactitol	Maltitol	Maltitol syrup	Mannitol	Polyglycitol Syrup	Sorbitols	Xylitol
CODEX	√	*	√	√	√	√	√	√	√	√
Albania	*	*	*	*	*	*	*	√	*	*
Angola	*	*	*	*	*	*	*	*	*	*
Antigua	√	*	√	√	√	√	√	√	√	√
Argentina	√	*	√	√	√	√	√	*	√	√
Armenia	*	*	*	*	*	*	*	*	*	*
Australia	√	*	√	√	√	√	√	*	√	√
Austria	√	*	√	√	√	√	√	√	√	√
Azerbaijan	*	*	*	*	*	*	*	*	*	*
Bahamas	√	*	√	√	√	√	√	√	√	√
Bahrain	*	*	√	*	*	*	*	*	*	*
Belarus	*	*	√	*	*	*	*	*	*	*
Belgium	√	*	√	√	√	√	√	√	√	√
Bolivia	√	*	√	√	√	√	√	√	√	√
Bosnia and Herzegovina	*	*	*	*	*	*	*	*	*	*
Botswana	*	*	*	*	*	*	*	*	*	*
Brazil	√	*	√	√	√	√	√	√	√	√
Brunei	*	*	*	*	*	*	*	*	*	*
Bulgaria	√	*	√	√	√	√	√	√	√	√
Canada	√	√	√	√	√	√	√	*	√	√
Chile	√	*	√	√	√	*	√	*	√	√
China	*	*	√	*	*	*	*	*	*	*
Colombia	√	*	√	√	√	√	√	√	√	√
Comoros	*	*	*	*	*	*	*	*	*	*
Costa Rica	√	*	√	√	√	√	√	√	√	√
Croatia	√	*	√	√	√	√	√	√	√	√
Cyprus	√	*	√	√	√	√	√	√	√	√
Czechia	√	*	√	√	√	√	√	√	√	√
Denmark	√	*	√	√	√	√	√	√	√	√
Djibouti	*	*	*	*	*	*	*	*	*	*
Dominica	√	*	√	√	√	√	√	√	√	√
Dominican Republic	√	*	√	√	√	√	√	√	√	√
Ecuador	√	*	√	√	√	√	√	√	√	√
El Salvador	√	*	√	√	√	√	√	√	√	√
Estonia	√	*	√	√	√	√	√	√	√	√
Finland	√	*	√	√	√	√	√	√	√	√
France	√	*	√	√	√	√	√	√	√	√

	Erythritol	Hydrogenated Starch Hydrolysates	Isomalt	Lactitol	Maltitol	Maltitol syrup	Mannitol	Polyglycitol Syrup	Sorbitols	Xylitol
French-Guyana	√	*	√	√	√	√	√	√	√	√
Germany	√	*	√	√	√	√	√	√	√	√
Georgia	*	*	*	*	*	*	*	*	*	*
Greece	√	*	√	√	√	√	√	√	√	√
Grenada	√	*	√	√	√	√	√	√	√	√
Guadeloupe	√	*	√	√	√	√	√	√	√	√
Guatemala	√	*	√	√	√	√	√	√	√	√
Guyana	√	*	√	√	√	√	√	√	√	√
Haiti	√	*	√	√	√	√	√	√	√	√
Honduras	√	*	√	√	√	√	√	√	√	√
Hong Kong	*	*	√	*	*	*	*	*	*	*
Hungary	√	*	√	√	√	√	√	√	√	√
Iceland	*	*	√	*	*	*	*	*	*	*
India	*	*	√	*	*	*	*	*	*	*
Indonesia	*	*	√	*	*	*	*	*	*	*
Iran	*	*	*	*	*	*	*	*	*	*
Iraq	*	*	*	*	*	*	*	*	*	*
Ireland	√	*	√	√	√	√	√	√	√	√
Israel	*	*	√	*	*	*	*	*	*	*
Italy	√	*	√	√	√	√	√	√	√	√
Jamaica	√	*	√	√	√	√	√	√	√	√
Japan	*	*	√	*	*	*	*	*	*	*
Jordan	*	*	*	*	*	*	*	*	*	*
Kazakhstan	*	*	*	*	*	*	*	*	*	*
Kenya	*	*	*	*	*	*	*	*	*	*
Kyrgyzstan	*	*	√	*	*	*	*	*	*	*
Kuwait	*	*	√	*	*	*	*	*	*	*
Latvia	√	*	√	√	√	√	√	√	√	√
Lesotho	*	*	*	*	*	*	*	*	*	*
Lithuania	√	*	√	√	√	√	√	√	√	√
Luxembourg	√	*	√	√	√	√	√	√	√	√
Macau	*	*	*	*	*	*	*	*	*	*
Macedonia	*	*	*	*	*	*	*	*	*	*
Madagascar	*	*	*	*	*	*	*	*	*	*
Malawi	*	*	*	*	*	*	*	*	*	*
Malaysia	*	*	√	*	*	*	*	*	*	*
Malta	√	*	√	√	√	√	√	√	√	√
Martinique	√	*	√	√	√	√	√	√	√	√
Mauritius	*	*	*	*	*	*	*	*	*	*
Mayotte	*	*	*	*	*	*	*	*	*	*
Mexico	√	*	√	√	√	√	√	√	√	√
Moldova	*	*	*	*	*	*	*	*	*	*
Mongolia	*	*	*	*	*	*	*	*	*	*
Montenegro	*	*	*	*	*	*	*	*	*	*
Montserrat	*	*	*	*	*	*	*	*	*	*
Morocco	*	*	*	*	*	*	*	*	*	*
Mozambique	*	*	*	*	*	*	*	*	*	*

	Erythritol	Hydrogenated Starch Hydrolysates	Isomalt	Lactitol	Maltitol	Maltitol syrup	Mannitol	Polyglycitol Syrup	Sorbitols	Xylitol
Namibia	*	*	*	*	*	*	*	*	*	*
Netherlands	√	*	√	√	√	√	√	√	√	√
New Zealand	√	*	√	√	√	√	√	*	√	√
Nicaragua	√	*	√	√	√	√	√	√	√	√
Norway	*	*	√	*	*	*	*	*	*	*
Oman	*	*	√	*	*	*	*	*	*	*
Pakistan	*	*	√	*	*	*	*	*	*	*
Panama	√	*	√	√	√	√	√	√	√	√
Papua New Guinea	*	*	*	*	*	*	*	*	*	*
Paraguay	*	*	√	*	*	*	*	*	*	*
Peru	√	*	√	√	√	√	√	√	√	√
Philippines	*	*	√	*	*	*	*	*	*	*
Poland	√	*	√	√	√	√	√	√	√	√
Portugal	√	*	√	√	√	√	√	√	√	√
Qatar	*	*	√	*	*	*	*	*	*	*
Romania	√	*	√	√	√	√	√	√	√	√
Russia	*	*	√	*	*	*	*	*	*	*
Rwanda	*	*	*	*	*	*	*	*	*	*
St. Helena	*	*	*	*	*	*	*	*	*	*
St. Kitts and Nevis	√	*	√	√	√	√	√	√	√	√
St. Lucia	√	*	√	√	√	√	√	√	√	√
St. Vincent	√	*	√	√	√	√	√	√	√	√
Saudi Arabia	*	*	√	*	*	*	*	*	*	*
Serbia	*	*	√	*	*	*	*	*	*	*
Seychelles	*	*	*	*	*	*	*	*	*	*
Sierra Leone	*	*	*	*	*	*	*	*	*	*
Singapore	*	*	√	*	*	*	*	*	*	*
Slovakia	√	*	√	√	√	√	√	√	√	√
Slovenia	√	*	√	√	√	√	√	√	√	√
South Africa	*	*	√	*	*	*	*	*	*	*
South Korea	√	√	√	√	√	√	√	√	√	√
Spain	√	*	√	√	√	√	√	√	√	√
Sri Lanka	*	*	√	*	*	*	*	*	*	*
Suriname	*	*	*	*	*	*	*	*	*	*
Swaziland	*	*	*	*	*	*	*	*	*	*
Sweden	√	*	√	√	√	√	√	√	√	√
Switzerland	*	*	√	*	*	*	*	*	*	*
Taiwan	*	*	√	*	*	*	*	*	*	*
Tajikistan	*	*	*	*	*	*	*	*	*	*
Tanzania	*	*	*	*	*	*	*	*	*	*
Thailand	*	*	√	*	*	*	*	*	*	*
Trinidad and Tobago	√	*	√	√	√	√	√	√	√	√
Tunisia	*	*	*	*	*	*	*	*	*	*
Turkey	*	*	√	*	*	*	*	*	*	*
Turkmenistan	*	*	*	*	*	*	*	*	*	*
Turks and Caicos	√	*	√	√	√	√	√	√	√	√
Ukraine	*	*	√	*	*	*	*	*	*	*

	Erythritol	Hydrogenated Starch Hydrolysates	Isomalt	Lactitol	Maltitol	Maltitol syrup	Mannitol	Polyglycitol Syrup	Sorbitols	Xylitol
United Arab Emirates	*	*	√	*	*	*	*	*	*	*
United Kingdom	√	*	√	√	√	√	√	√	√	√
United States of America	√	√	√	√	√	√	√	*	√	√
Uruguay	√	*	√	*	√	√	√	√	√	√
Uzbekistan	*	*	*	*	*	*	*	*	*	*
Venezuela	*	*	√	*	*	*	*	*	*	*
Vietnam	*	*	√	*	*	*	*	*	*	*
West Bank	*	*	*	*	*	*	*	*	*	*
Zambia	*	*	*	*	*	*	*	*	*	*
Zimbabwe	*	*	*	*	*	*	*	*	*	*

Table 6. Global Regulatory Permissions for Rare Sugars

Legend

√ = Permitted

= Regulations in development

* = Regulations not available

	Allulose	Isomaltulose	Tagatose
Albania	*	*	*
Angola	*	*	*
Antigua	*	*	*
Argentina	*	√	*
Armenia	*	√	*
Australia	*	√	√
Austria	*	√	*
Azerbaijan	*	*	*
Bahamas	*	*	*
Bahrain	*	*	*
Belarus	*	√	*
Belgium	*	√	*
Bolivia	*	*	*
Bosnia and Herzegovina	*	*	*
Botswana	*	*	*
Brazil	*	√	*
Brunei	*	*	*
Bulgaria	*	√	*
Canada	*	√	√
Chile	√	*	*
China	*	√	*
Colombia	√	√	*
Comoros	*	*	*
Costa Rica	*	√	*
Croatia	*	√	*
Cyprus	*	√	*
Czechia	*	√	*
Denmark	*	√	*
Djibouti	*	*	*
Dominica	*	*	*
Dominican Republic	*	*	*
Ecuador	*	*	*
El Salvador	*	*	*
Estonia	*	√	*
Finland	*	√	*
France	*	√	*
French-Guyana	*	*	*
Germany	*	√	*
Georgia	*	*	*
Ghana	*	*	*
Greece	*	√	*
Grenada	*	*	*
Guadeloupe	*	*	*
Guatemala	*	*	*
Guyana	*	*	*

	Allulose	Isomaltulose	Tagatose
Haiti	*	*	*
Honduras	*	*	*
Hong Kong	√	*	*
Hungary	*	√	*
Iceland	*	√	*
India	√	*	*
Indonesia	√	√	*
Iran	*	*	*
Iraq	*	*	*
Ireland	*	√	*
Israel	*	√	*
Italy	*	√	*
Jamaica	*	*	*
Japan	*	√	#
Jordan	*	*	*
Kazakhstan	*	√	*
Kenya	*	*	*
Kyrgyzstan	*	√	*
Kuwait	*	*	*
Latvia	*	√	*
Lesotho	*	*	*
Lithuania	*	√	*
Luxembourg	*	√	*
Macau	*	*	*
Macedonia	*	*	*
Madagascar	*	*	*
Malawi	*	*	*
Malaysia	*	√	*
Malta	*	√	*
Martinique	*	*	*
Mauritius	*	*	*
Mayotte	*	*	*
Mexico	√	√	√
Moldova	*	*	*
Mongolia	*	*	*
Montenegro	*	*	*
Montserrat	*	*	*
Morocco	*	*	*
Mozambique	*	*	*
Namibia	*	*	*
Netherlands	*	√	*
New Zealand	*	√	√
Nicaragua	*	*	*
Norway	*	√	*
Oman	*	*	*
Pakistan	*	*	*
Panama	*	*	*
Papua New Guinea	*	*	*
Paraguay	*	*	*
Peru	√	*	*
Philippines	√	√	*
Poland	*	√	*

	Allulose	Isomaltulose[4]	Tagatose
Portugal	*	√	*
Qatar	*	*	*
Romania	*	√	*
Russia	*	√	*
Rwanda	*	*	*
St. Helena	*	*	*
St. Kitts and Nevis	*	*	*
St. Lucia	*	*	*
St. Vincent	*	*	*
Saudi Arabia	*	*	*
Serbia	*	√	*
Seychelles	*	*	*
Sierra Leone	*	*	*
Singapore	√	√	*
Slovakia	*	√	*
Slovenia	*	√	*
South Africa	*	√	*
South Korea	√	√	√
Spain	*	√	*
Sri Lanka	*	*	*
Suriname	*	*	*
Swaziland	*	*	*
Sweden	*	√	*
Switzerland	*	√	*
Taiwan	*	√	*
Tajikistan	*	*	*
Tanzania	*	*	*
Thailand	*	√	*
Trinidad and Tobago	*	*	*
Tunisia	*	*	*
Turkey	*	*	*
Turkmenistan	*	*	*
Turks and Caicos	*	*	*
Ukraine	*	*	*
United Arab Emirates	*	*	*
United Kingdom	*	√	*
United States of America	√	√	√
Uruguay	*	*	*
Uzbekistan	*	*	*
Venezuela	*	*	*
Vietnam	*	√	*
West Bank	*	*	*
Zambia	*	*	*
Zimbabwe	*	*	*

[4] Isomaltulose additional information:

- South Korea: Isomaltulose is listed in the Food Code under the synonym palatinose.