SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 31 January 2018

doi: 10.2903/j.efsa.2018.5181

Safety in use of glucosylated steviol glycosides as a food additive in different food categories

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Abstract

The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) provides a scientific opinion on the safety of glucosylated steviol glycosides proposed for use as a new food additive in different food categories. According to the applicant, glucosylated steviol glycosides preparations consist of not less than 95% (on anhydrous basis) total steviol glycosides, made up of glucosylated steviol glycosides of different molecular weights as well as any remaining steviol glycosides. The applicant proposed that glucosylated steviol glycosides and parent steviol glycosides undergo a common metabolic process in pathway following ingestion and suggested that data from steviol glycosides can be used for read-across to glucosylated steviol glycosides. The limited evidence provided in the application dossier did not demonstrate the complete hydrolysis of the glucosylated steviol glycosides. No toxicological studies on glucosylated steviol glycoside preparations under evaluation have been provided for its assessment. The Panel concluded that the submitted data are insufficient to assess the safety of the glucosylated steviol glycoside preparations to be used as a new food additive.

Keywords: glucosylated steviol glycosides, steviol glycoside, food additive

Requestor: European Commission

Question number: EFSA-Q-2017-00247

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Acknowledgements: The Panel wishes to thank EFSA staff member: Fabiola Pizzo for the support provided to this scientific output. The ANS Panel wishes to acknowledge all European competent institutions, Member State bodies and other organisations that provided data for this scientific output.

Suggested citation: EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), Younes M, Aggett P, Aguilar F, Crebelli R, Dusemund B, Filipič M, Frutos MJ, Galtier P, Gundert-Remy U, Kuhnle GG, Lambré C, Leblanc J-C, Lillegaard IT, Moldeus P, Mortensen A, Oskarsson A, Stankovic I, Waalkens-Berendsen I, Woutersen RA, Wright M, Tobback P, Rincon AM, Smeraldi C and Gott D, 2018. Scientific opinion on the safety in use of glucosylated steviol glycosides as a food additive in different food categories. EFSA Journal 2018;16(2):5181, 11 pp. https://doi.org/10.2903/j.efsa.2018.5181

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

Following a request from the European Commission to the European Food Safety Authority (EFSA), the Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to provide a scientific opinion on the safety in use of glucosylated steviol glycosides as a food additive in different food categories, in accordance with Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

According to the applicant, glucosylated steviol glycosides preparations consist of not less than 95% (on anhydrous basis) total steviol glycosides, made up of glucosylated steviol glycosides of different molecular weights as well as any remaining steviol glycosides. The Panel noted that within the typical components of the glucosylated steviol glycosides and parent steviol glycosides some steviol glycosides – e.g. rebaudioside N, rebaudioside O – are not included within the current steviol glycosides listed for the food additive E 960.

The applicant proposed that glucosylated steviol glycosides and parent steviol glycosides undergo a common metabolic process in pathway following ingestion. Thus, the applicant suggested that data from steviol glycosides can be used for read-across to glucosylated steviol glycosides.

The limited evidence provided in the application dossier did not demonstrate the complete hydrolysis of the glucosylated steviol glycosides under what the Panel considered extreme hydrolysis conditions. No further information on hydrolysis under realistic conditions was provided.

The applicant provided the information on the GRAS Notice No 375 for 'glycosylated enzyme treated stevia'. Since the applicant was not able to provide the full data from the studies described in the GRAS Notice No 375, the Panel could not consider the information for the current assessment.

No toxicological studies on glucosylated steviol glycoside preparations under evaluation have been provided for its assessment.

Considering that the complete hydrolysis of the glucosylated steviol glycosides was not demonstrated, toxicological data on steviol glycosides cannot be used in a read-across approach to fully evaluate the safety of the glucosylated steviol glycoside preparations under evaluation. The Panel noted that in such circumstances a Tier 1 evaluation according to the Guidance on food additives is required with the material under evaluation.

The Panel further noted that the proposed glucosylated steviol glycosides preparations may contain up to 20 glucose moieties per molecule of steviol glycoside. The proposed permitted level for this new food additive is expressed on a steviol equivalent basis (as for the already authorised food additive steviol glycosides (E 960)). The Panel therefore considered that this could lead to an additional exposure to glucose from a sweetener which is proposed to have a technological function of replacing sugars in food.

Therefore, the Panel concluded that the submitted data are insufficient to assess the safety of the glucosylated steviol glycoside preparations to be used as a new food additive.

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1. Introduction

The present scientific opinion deals with the evaluation of the safety of glucosylated steviol glycosides proposed for use as a new food additive in different food categories.

1.1. Background and Terms of Reference as provided by the European Commission

1.1.1. Background

The use of food additives is regulated under the European Parliament and Council Regulation (EC) No 1333/2008 on food additives.[1] Only food additives that are included in the Union list, in particular in Annex II to that regulation, may be placed on the market and used in foods under the conditions of use specified therein.

An application has been introduced for the authorisation of the use of Glucosylated steviol glycosides as sweetener in several food categories. Glucosylated steviol glycosides are manufactured by adding glucose units (between 1 to 20 additional units) to steviol glycosides extracted from the leaves of *Stevia rebaudiana*. This is achieved using enzymes that transfer glucose units from a starch source to the steviol glycosides, and results in the production of a mixture of glucosylated steviol glycosides (~80 to 92%) and non-modified parent steviol glycosides (~5 to 15%).

The addition of glucose units to parent steviol glycosides improve the sensory characteristics of the glycosides by reducing bitterness and astringency. Glucosylated steviol glycosides preparations are approximately 167 times sweeter than sucrose.

1.1.2. Terms of Reference

In accordance with Article 29(1)(a) of Regulation (EC) No 178/2002[2], the European Commission (EC) asks the European Food Safety Authority (EFSA) to perform a risk assessment and to provide a scientific opinion on the safety in use of Glucosylated steviol glycosides as a food additive, in accordance with Regulation (EC) No 1331/2008[3] establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

1.1.3. Information on existing evaluations and authorisations

According to the applicant, a number of enzyme-modified steviol glycosides preparations are Generally Recognised as Safe (GRAS) in the US for use as flavouring agents and/or general purpose sweetener in foods.

Glucosylated Stevia Leaf Extract (GRAS notice 662) has been notified as to be GRAS (FDA, 2016a,b). An Expert Panel convened by PureCircle concluded that the available data demonstrated that glucosylated steviol glycosides are subject to the same metabolic fate as steviol glycosides, and therefore, the safety conclusions that have been drawn for steviol glycosides could be extended to PureCircle's Glucosylated Stevia Leaf Extract. This was the basis for the GRAS notification.

According to the applicant, α-Glucosyltransferase treated stevia is described as a substance composed mainly of α-glucosylsteviosides obtained from stevia extract which is approved by the Japanese Minister of Health, Labour and Welfare (MHLW) as a food additive (Japan Food Chemical Research Foundation, 2014).

The safety of steviol glycosides as a food additive was evaluated by EFSA in 2010 (EFSA ANS Panel, 2010). Following the EFSA assessment in 2015 (EFSA ANS Panel, 2015), rebaudioside M was included in the specifications for the food additive steviol glycosides (E 960) according to the Commission Regulation (EU) No 231/2012[4]. The latest evaluation of steviol glycosides by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) took place in 2016 (JECFA, 2016).

[1] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

[3] Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L 354, 31.12.2008, p. 1–6.

[4] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1–295.

2. Data and methodologies

2.1. Data

The present evaluation is based on the data on glucosylated steviol glycosides in a newly submitted dossier by the applicant (Documentation provided to EFSA n. 1) and additional information submitted by the applicant during the assessment process in response to a following request by EFSA (Documentation provided to EFSA n. 2).

2.2. Methodologies

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing Guidance from the EFSA Scientific Committee.

The current 'Guidance for submission for food additive evaluations' (EFSA ANS Panel, 2012) has been followed by the ANS Panel for the evaluation of the application for authorisation of the new food additive glucosylated steviol glycosides.

3. Assessment

3.1. Technical data

3.1.1. Identity of the substance

Glucosylated steviol glycosides preparations were described by the applicant as being a mixture of glucosylated steviol glycosides, containing 1–20 additional glucose units bound to the parent steviol glycoside (Figure 1).

The applicant stated that based on distribution analyses: the mono-, di- and tri-glucosylated are the predominant forms of the glucosylated steviol glycosides. From analytical data provided within the application dossier, it can be observed that the proportion of each glucosylated steviol glycoside (mono-, di-, tri-, poly-glucosylated) in the commercial preparation depends on the composition of steviol glycosides in the starting material (> 95%) consisting of either rebaudioside A, rebaudioside D or a mixture of steviol glycosides.

Glucosylated steviol glycosides preparations consist of not less than 95% (on anhydrous basis) total steviol glycosides, made up of glucosylated steviol glycosides of different molecular weights as well as any remaining steviol glycosides.

The glucosylated fraction of the total steviol glycosides is between 80% and 92% and the parent glycosides between 5% and 15%.

The parent steviol glycosides include rebaudioside N and rebaudioside O in addition to the steviol glycosides comprised in the current EU specifications for steviol glycosides (E 960).

According to the applicant, glucosylated steviol glycosides preparations are white to off-white powders that have a clean taste with a mild odour and are soluble in water. The Panel noted that the solubility in water varies between the different glucosylated steviol glycosides. According to the applicant, the glucosylation increased the solubility in comparison to the parent steviol glycoside.

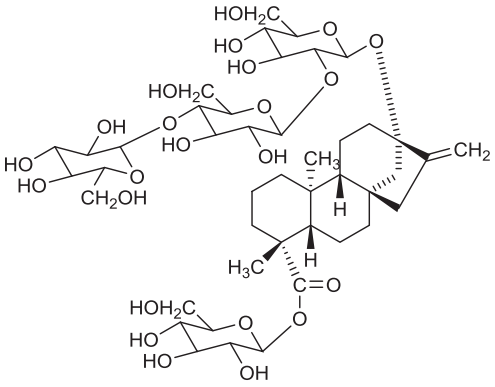

Figure 1: A representative structure of a glucosylated steviol glycoside

3.1.2. Proposed specifications

The specifications for glucosylated steviol glycosides preparations as proposed by the applicant are presented in Table 1 (Documentation provided to EFSA n.1).

Table 1: Specifications for glucosylated steviol glycosides preparations as proposed by the applicant (Documentation provided to EFSA n. 1)

GLUCOSYLATED STEVIOL GLYCOSIDES	
Synonyms	
Definition	The product is obtained by extracting and purifying steviol glycosides (E 960) from the dried leaves of *Stevia rebaudiana* Bertoni, then reacting these steviol glycosides with glucotransferase enzymes in the presence of glucose resulting in the addition of glucose moieties to the parent steviol glycosides. These glucosylated steviol glycosides are purified by employing adsorption and ion exchange chromatography, resulting in a final product comprising not less than 95% steviol glycosides, determined as the sum of the glucosylated and parent steviol glycosides.
Chemical name, molecular formula and molecular weight	Separate table for the chemical information for some example glucosylated steviol glycosides. Note: This list is not exhaustive.
Assay	Not less than 95% of total steviol glycosides, comprised of glucosylated and parent glycosides, on the dried basis.
Description	White to off-white powder, approximately 100–200 times sweeter than sucrose (at 5% sucrose equivalency).
Identification	
Solubility	Soluble in water
pH	Between 4.5 and 7.0 (1 in 100 solution)
Purity	
Total ash	Not more than 1%
Loss on drying	Not more than 6% (105°C, 2 h)
Residual solvents	Not more than 200 mg/kg methanol Not more than 3,000 mg/kg ethanol
Arsenic	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg

The applicant has provided certificates of analysis of five non-consecutive, independent batches (Documentation provided to EFSA n. 1).

The Panel noted that in the definition of glucosylated steviol glycosides the origin of glucose is not specified. However, according to the description of the manufacturing process, glucose source is liquefied tapioca starch.

The Panel noted that according to information provided in the application dossier the glucosylated fraction will be approximately 80–92% and this has not been defined in the proposed specifications.

The Panel considered that the analytical data provided are sufficient to demonstrate conformity with the proposed specifications.

No information was provided by the applicant on particle size, shape and distribution.

The Panel noted that neither microbiological parameters have been included nor limits for environmental contaminants as pesticides in the proposed specifications. The maximum levels proposed in the specifications for the solvents (methanol and ethanol) are much higher than the analytical data provided. Regarding toxic elements, only maximum limits are proposed for lead and arsenic whilst cadmium and mercury were also reported in the analysis provided. The maximum limits proposed for toxic elements are much higher compared to the values obtained in the five batches analysed (< 0.005 mg/kg for As, Cd and Hg and < 0.054 mg/kg for Pb). The Panel noted that these parameters should be added to the proposed specifications and that, based on the analytical results provided by the applicant, lower levels of the maximum limits for the heavy metals present as impurity, should be considered in the proposed specifications.

3.1.3. Manufacturing process

Glucosylated steviol glycosides preparations are prepared in two production stages.

In a first stage, steviol glycosides are extracted from dried leaves of *S. rebaudiana* using hot water (temperature of 50–60°C). The filtrate so obtained is separated, treated with a flocculant, filtered (plate-and-frame filter press) and deionised (ion-exchange resins). The extract is then submitted to a series of purification and concentration steps and finally spray-dried to yield a high-purity stevia extract in powder form with a total steviol glycoside content of not less than 95%.

In a second separate stage, tapioca starch is liquefied in a process, using natural cyclomaltodextrin glucanotransferase (CGTase) and/or α-amylase, to generate glucose units. The natural CGTase is derived from a non-genetically modified and a non-pathogenic strain of *Bacillus stearothermophilus;* the natural α-amylase is derived from a non-genetically modified and non-pathogenic strain of *Bacillus licheniformis.*

Next, the purified stevia extract powder, produced in the first stage, is added to the liquefied tapioca starch together with an additional portion of CGTase. The mixture is incubated at 60°C for 48 h. In this process, purified steviol glycosides are enzymatically modified with glucotransferase enzymes and the glucose moieties are conjugated to the parent steviol glycoside structure *via* α-(1–4) linkages by the use of a CGTase. In the process, a mixture of glucosylated steviol glycosides containing from 1 to 20 additional glucose units bound to the parent steviol glycoside is generated.

The enzymes are inactivated by heating 15 min at 100°C and removed by activated carbon. The reaction mixture undergoes further a series of purification and concentration steps. The refined solution is spray-dried and sifted to give the final glucosylated steviol glycosides powder that consists of not less than 95% total steviol glycosides and is made up of a mixture of glucosylated steviol glycosides of different molecular weights as well as the remaining parent steviol glycosides.

The Panel noted that *B. stearothermophilus* and *B. licheniformis* are included in the list of qualified presumption of safety (QPS)-recommended biological agents intentionally added to food or feed as notified to EFSA 5 (EFSA BIOHAZ Panel, 2017). However, no statement on the absence of toxigenic potential tested by a cytotoxicity assay and the general qualification of the absence of acquired antibiotic resistance were provided within the dossier.

3.1.4. Methods of analysis in food

No method of analysis of glucosylated steviol glycosides in foods was provided.

According to the applicant, total glucosylated steviol glycosides may be quantified by the assay for α-Glucosyltransferase Treated Stevia published by the MHLW in the Japan's Specifications and Standards for Food Additives (MHLW, 2009). This method consists on a two-stage process involving the analysis of parent steviol glycosides and glucose content separately. This is achieved by treating the glucosylated steviol glycoside sample with glucoamylase to cleave the α-glucosyl residues from the parent steviol glycosides. The concentration of D-glucose in the test solution is determined by the α-glucosyl residues content in the formula. The α-glucosyl residues are quantified against a D-glucose standard and the non-modified steviol glycoside content is measured according to JECFA method (JECFA, 2008). The sum of the percentage of measured α-glucosyl residues and non-modified steviol glycosides represents the total steviol glycoside content, comprised of the glucosylated and unreacted steviol glycosides.

3.1.5. Stability of the substance and reaction and fate in food

The submitted data demonstrated that the stability of glucosylated steviol glycoside preparations is temperature-, time- and pH-dependent.

The applicant states that the stability of glucosylated steviol glycosides to temperature in a range from 5 to 56°C and to pH from 2 to 8 over 8 weeks is equivalent to that of parent steviol glycosides. With the highest losses of glucosylated steviol glycosides when stored at low pHs (2 and 3) and high temperature (56°C). However, no information on the degradation products was submitted.

Information on the variation of the percentage of glucosylated steviol glycosides (e.g. mono-, di, tri, etc.) was provided when the preparation at pH 3 (26,42 mg/mL) was stored during 8 weeks at temperatures of 5, 25, 37 and 56°C and heated at 88°C for 30 s and at 138°C for 10 s (Documentation provided to EFSA n. 2). The Panel noted that the relevance of this last study was very limited to reach a conclusion due to the short heating period and the temperatures not being representative of the temperatures reached during baking processes.

3.2. Proposed uses and use levels

According to the applicant, the glucosylated steviol glycoside preparations are proposed for use as a high-intensity sweetener in the same manner as currently authorised for steviol glycosides (E 960) as defined in Annex II to Regulation (EC) No 1333/2008[5] (Documentation provided to EFSA n. 1).

3.3. Exposure estimate

The proposed permitted level for the new food additive glucosylated steviol glycosides are expressed on a steviol equivalent basis as those of the already authorised food additive steviol glycosides (E 960).

Because the proposed uses and use levels are the same as the already authorised food additive steviol glycosides (E 960), the applicant did not provide an exposure estimate for the new proposed food additive glucosylated steviol glycosides but made reference to the latest estimated exposure to E 960 (EFSA ANS Panel, 2015).

3.4. Biological and toxicological data

3.4.1. Absorption, distribution, metabolism and excretion

The microbial metabolism of two glucosylated steviol glycosides, α-monoglucosylated rebaudioside A and α-monoglucosylated stevioside, was investigated *in vitro* using human faecal homogenates (Koyama et al., 2003). The two glucosylated steviol glycosides were incubated with human faecal homogenates for 24 h at 37°C under anaerobic conditions and metabolites generated were analysed and identified by liquid chromatography–mass spectrometry (LC–MS). According to the authors, the glucosylated steviol glycosides were completely metabolised to steviol after 24 h. Furthermore, the authors also reported that a mixture of enzymatically modified stevia containing the primary components α-glucosylated rebaudioside A, α-glucosylated stevioside, α-glucosylated rebaudioside C and α-glucosylated dulcoside A was hydrolysed to steviol following a 24-h *in vitro* incubation with human faecal homogenates. The metabolic pathway proposed for α-glucosylated steviol glycosides starts with α-deglucosylation to the parent steviol glycoside, followed by hydrolysis to steviol, similar to that established for parent steviol glycosides. The Panel noted that there were no intermediate incubation times to provide information on the rate of degradation and that a considerable proportion (20%) of enzymatically modified stevia remained intact or partially degraded after 24 h incubation with faecal homogenates.

The applicant provided the publicly available information on the GRAS Notice No 375 for 'glycosylated enzyme treated stevia' describing two *in vitro* studies on the gastrointestinal degradation (FDA, 2016b). Since the applicant was not able to provide information on the characterisation of the test material in those studies to extrapolate the results to glucosylated steviol glycoside preparations under evaluation (Documentation provided to EFSA n.2), the Panel could not consider the information for the current assessment.

[5] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

3.4.2. Short-term and subchronic toxicity

The applicant provided the publicly available information on the GRAS Notice No 375 for 'glycosylated enzyme treated stevia' describing a 13-week study in rats (FDA, 2016b). Since the applicant was not able to provide the full data from this study including the characterisation of the test material (Documentation provided to EFSA n. 2), the Panel could not consider the information for the current assessment.

3.4.3. Genotoxicity

The applicant referred to the lack of *in vitro* and *in vivo* genotoxic activity reported in the GRAS Notice No 375 for 'glycosylated enzyme treated stevia' (FDA, 2016b). Since the applicant was not able to provide the full data from these studies including the characterisation of the test material (Documentation provided to EFSA n. 2), the Panel could not consider the information for the current assessment.

3.5. Discussion

The current assessment by the Panel is based on the information submitted in the application dossier (Documentation provided to EFSA n. 1) and the additional information provided by the applicant following a request by EFSA (Documentation provided to EFSA n. 2).

According to the applicant, glucosylated steviol glycosides preparations consist of not less than 95% (on anhydrous basis) total steviol glycosides, made up of glucosylated steviol glycosides of different molecular weights as well as any remaining steviol glycosides. The Panel noted that within the typical components of the glucosylated steviol glycosides and parent steviol glycosides some steviol glycosides – e.g. rebaudioside N, rebaudioside O – are not included in the current steviol glycosides listed for the food additive E 960.

The applicant proposed that glucosylated steviol glycosides and parent steviol glycosides undergo a common metabolic process in pathway following ingestion. Thus, the applicant suggested that data from steviol glycosides can be used for read-across to glucosylated steviol glycosides.

However, the evidence provided in the application dossier based on the study by Koyama et al. (2003) did not demonstrate complete hydrolysis of the glucosylated steviol glycosides under what the Panel considered extreme hydrolysis conditions. No further information on hydrolysis under realistic conditions was provided.

The applicant provided the information on the GRAS Notice No 375 for 'glycosylated enzyme treated stevia' (FDA, 2016b). Since the applicant was not able to provide the full data from the studies described in the GRAS Notice No 375, the Panel could not consider the information for the current assessment.

No toxicological studies on glucosylated steviol glycoside preparations under evaluation have been provided for its assessment.

Considering that the complete hydrolysis of the glucosylated steviol glycosides was not demonstrated, toxicological data on steviol glycosides cannot be used in a read-across approach to fully evaluate the safety of the glucosylated steviol glycoside preparations under evaluation.

The Panel noted that in such circumstances a Tier 1 evaluation according to the Guidance on food additives (EFSA ANS Panel, 2012) is required with the material under evaluation.

The Panel further noted that the proposed glucosylated steviol glycosides preparations may contain up to 20 glucose moieties per molecule of steviol glycoside. The proposed permitted level for this new food additive is expressed on a steviol equivalent basis (as for the already authorised food additive steviol glycosides (E 960)). The Panel therefore considered that this could lead to an additional exposure to glucose from a sweetener which is proposed to have a technological function of replacing sugars in food.

4. Conclusions

The Panel concluded that the submitted data are insufficient to assess the safety of the glucosylated steviol glycoside preparations to be used as a new food additive.

Documentation provided to EFSA

1) Dossier 'Application for authorisation of glucosylated steviol glycosides as a food additive in the European Union pursuant to Regulation (EC) No 1333/2008 of the European Parliament and the Council of 16 December 2008 on food additive'. Submission on 17 March 2017. Missing information submitted on 12 May 2017.
2) Additional information. 22 August 2017. Submitted by PureCircle in response to a request from EFSA.

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Abbreviations

ANS	EFSA Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
CAS	Chemical Abstracts Service
CGTase	cyclomaltodextrin glucanotransferase
FDA	Food and Drug Administration
GRAS	Generally Recognized as Safe
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LC–MS	liquid chromatography–mass spectrometry
MHLW	Minister of Health, Labour and Welfare
WHO	World Health Organization