

***Stevia rebaudiana* Bertoni plants
and
dried leaves
as Novel Food**

**Summary of the Application and Specifications of
the EUSTAS Quality Label**



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1. Evaluation and conclusion by the applicant

The *Stevia* plant as well as the dried and ground leaves and the crude extracts used as NF are completely safe and natural.

The NF has nothing to do with genetic manipulation and it is extensively used in countries such as eg. Brazil, Paraguay, Argentina, South Korea, Japan as well as in the USA (permitted as a dietary supplement). In these countries the dried leaves, leaf extracts as well as the pure stevioside are authorised. Even in the EU, *Stevia* and its extracts have already been consumed.

The NF of our proposal (*Stevia* plants, dried and ground leaves) is well defined and characterised. A voucher specimen of the plant and the dried leaves has been deposited in the Herbarium of the Laboratory of Systematics (LV). The NF has been specified and a quality label has been developed by EUSTAS to guarantee that only the best quality will be available on the European market.

The cultivation of the plants and the drying and processing of the leaves is similar to that of other herbs. No hazardous microorganisms are present in the samples that will be authorised in Europe.

The NF is not detrimental to human health as evidenced by extensive use in Paraguay for over 500 years and in Japan since 1970, and even in the USA since 1995. The yearly production of stevia leaves is estimated around 50,000 tons. This implies that about 93,000,000 people are daily exposed to the consumption of stevia leaves, extracts and purified steviol glycosides (not part of this NF).

Toxicological studies by oral intake of dried leaves, leaf extracts and/or pure stevioside have proven the safety of the NF. Moreover, the expected intake of the NF is very low due to the sweetness of the dried leaves. The expected intake, even in the worst case (4.4 g/day or about 75 mg/kg BW), is less than the ADI suggested (250 mg/kg BW).

The NF does not replace the sugar naturally present in various foods, but it reduces the use of added sugar to sweeten various foods, in a similar way as eg. oligofructanes and synthetic sweeteners. Therefore, our NF is beneficial to diabetics and to obese persons, and this way helps to prevent heart diseases and diabetes type 2. It is also safe for PKU patients.

The NF will be commercialised as whole *Stevia* plants, as dried leaves and leaf powders and as crude extracts too. To maintain optimal quality, the dry powder will be stored in air-tight sealed vials. The plants and the dried ground leaves will mostly be used directly by the end-user as in jams, choco, strawberry bavaois, stewed fruit, etc.. The NF will also be used in different teas.

The answers needed to the questions of the structured schemes I, II, III, IX, X, XI, XII and XIII were given and for each scheme sufficient information could be given.

Conclusion: The toxicological information given, together with the extensive use of *Stevia* in other countries for many years (more than 500 years in Paraguay, over 40 years in Japan, and even in Europe), is sufficient to conclude that *Stevia* and dried *Stevia* leaves (intact or ground) are a safe food for human consumption. It should be authorised as a Novel Food in the EU. *Stevia*, its dried leaves (intact or ground) should be put on the positive list of foods of the EU.

2. Summary by the applicant

Stevia rebaudiana Bertoni plants and dried leaves were proposed as a Novel Food, class 2.1, category e. Specimen of the plants and of the dried powdered leaves have been deposited in the Herbarium of the KULeuven, Kasteelpark 31, B-3001 Heverlee-Leuven (LV). The plant is a completely natural plant obtained without GM or other selection procedures.

In the proposal, it is emphasised that *Stevia* has been cultured and used in the UK and that dried leaves and extracts have been sold in the EU at least since 1989. Moreover, the Belgian Ministry of Human Health and Food Inspection has put *Stevia rebaudiana* on a positive list of admitted herbs (Enclosure 15) and had no objection to commercialising dried *Stevia* leaf extracts (Enclosure 10).

The cultivation of the plants and the drying of the leaves is described and is comparable to that of other herbs.

The use of *Stevia* in other countries is described, eg. in Paraguay, Brazil, Japan and in the USA, where *Stevia* and even stevioside are authorised as a dietary supplement since 1995.

A complete toxicological study is given, including absorption and metabolism studies, acute and sub-acute toxicity, genotoxicity, chronic toxicity and carcinogenicity, reproduction and developmental toxicity.

The estimated intake of dried *Stevia* leaves is very low. From the results of the scientific literature a daily intake of 5-15 g of dried *Stevia* leaves can be considered as completely safe. An ADI up to 250 mg dried leaves/kg body weight can be suggested.

Examples are given of the use of dried powdered leaves in tea as well as in recipes such as jam, choco, bavaois etc., and of fresh leaves in salads and in sweet vinegar.

The toxicological information given, together with the extensive use of *Stevia* in other countries for many years (more than 500 years in Paraguay, over 40 years in Japan), is sufficient to conclude that *Stevia* and dried powdered *Stevia* leaves are a safe food for human consumption. It should be approved as a food in the EU.

3. Specification of the NF

Stevia rebaudiana (Bertoni) Bertoni is a plant belonging to the Asteraceae family and contains sweet steviol glycosides, of which stevioside and rebaudioside A are the most abundant ones. Plants were grown in Paraguay and harvested by cutting about 10 cm above the soil just before the onset of flowering. After drying, the leaves are collected by mechanical shaking and packed in containers suited for food and stored in a dry place. No contamination by other plants is present.

The NF consists of *Stevia rebaudiana* Bertoni living plants and dried and/or ground leaves.

1) The dried leaves (intact or ground to a fine powder) consist of only the leaves of the plants, but may include small amounts of flowers, stems and seeds (less than 1%). Table 3 shows the specifications of the dried leaves and leaf powders of normally grown *Stevia* plants (Var. Criolla, NF1.1), of organically grown *Stevia* plants (Var. Criolla, NF1.2) and of var. Eireté[®]. EUSTAS stands for the European *Stevia* Association and this organisation developed a **Quality Label** for the *Stevia* plants and leaves for the European market (www.eustas.org). EUSTAS will also guarantee that there is a continuous quality control of the NF on the European market.

2) The living plants are complete plants still containing their roots and they are usually grown in peat. Eustas will control the quality on the market by taking samples. After drying, the leaves, being the parts to be consumed, should conform the EUSTAS Quality Label as given in Table 3.

The analysis of stevioside was done by the HPLC method as described by Kitada et al. (1989) as advised by the FDA and the Division of Field Science (Enclosure 1; HPLC-chromatogram).

Table 3 A: EUSTAS Quality label for *S. rebaudiana*, cv. Criolla. NF 1.1

Parameter	EUSTAS Quality Label 1.1 Criolla
Variety	Criolla
Aspect	Dry leaves or leaf powder
Colour	Green
Water content (%)	<12%
Proteins	± 16 %
Lipids	± 2.6%
Crude fiber	± 6.8%
Total steviol glycosides	Minimum 10 %
Stevioside	Minimum 6% of dry wt.
Rebaudioside A	Minimum 3% of dry wt.
Steviol	<10 µg/g dry wt
Ash content (550°C; %)	<8.5%
Visible Impurities	Absent
Nickel	<2 mg/kg dry wt.
Arsenic	<3 mg/kg dry wt.
Lead	<3 mg/kg dry wt.
Cadmium	<2 mg/kg dry wt.
<u>Micro-biological purity</u>	
- Aerobic mesophilic bacteria	Not more than 10 ⁷ /g dry wt.
- Enterobacteriaceae	Not more than 3x10 ⁴ /g dry wt.
- <i>Salmonella</i>	Absent in 25 g dry wt.
- <i>E. coli</i>	<10/g dry wt.
- Bacillus cereus	<10 ⁴ /g dry wt.
Residue Analysis	
Pesticides	< maximum levels of pesticides (EU regulation 396/2005)
Fungicides	< maximum levels of pesticides (EU regulation 396/2005)
Others	< maximum levels of pesticides (EU regulation 396/2005)

Table 3 B: EUSTAS Quality label for *S. rebaudiana*, cv. Criolla organic. NF 1.2

Parameter	EUSTAS Quality Label 1.2 Criolla organic
Variety	Criolla organic
Aspect	Dry leaves or leaf powder
Colour	Green
Water content (%)	<12%
Proteins	± 16 %
Lipids	± 2.6%
Crude fiber	± 6.8%
Total steviol glycosides	Minimum 10 %
Stevioside	Minimum 6% of dry wt.
Rebaudioside A	Minimum 3% of dry wt.
Steviol	<10 µg/g dry wt
Ash content (550°C; %)	<8.5%
Visible Impurities	Absent
Nickel	<2 mg/kg dry wt.
Arsenic	<3 mg/kg dry wt.
Lead	<3 mg/kg dry wt.
Cadmium	<2 mg/kg dry wt.
<u>Micro-biological purity</u>	
- Aerobic mesophilic bacteria	Not more than 10 ⁷ /g dry wt.
- Enterobacteriaceae	Not more than 3x10 ⁴ /g dry wt.
- <i>Salmonella</i>	Absent in 25 g dry wt.
- <i>E. coli</i>	<10/g dry wt.
- Bacillus cereus	<10 ⁴ /g dry wt.
Residue Analysis	
Pesticides	Guaranteed organic by IMO* (EU regulation 396/2005)
Fungicides	Guaranteed organic by IMO (EU regulation 396/2005)
Others	Guaranteed organic by IMO (EU regulation 396/2005)

*IMO: Institute for Market Ecology, Switzerland

Table 3 C: EUSTAS Quality label for *Stevia*. NF 1.3

Parameter	EUSTAS Quality Label 1.3 Eireté®
Variety	Eireté®
Aspect	Dry leaves or leaf powder
Colour	Green
Water content (%)	<12%
Proteins	± 16 %
Lipids	± 2.6%
Crude fiber	± 6.8%
Total steviol glycosides	Minimum 15 %
Stevioside	Minimum 5% of dry wt.
Rebaudioside A	Minimum 9% of dry wt.
Steviol	<10 µg/g dry wt
Ash content (550°C; %)	<8.5%
Visible Impurities	Absent
Nickel	<2 mg/kg dry wt.
Arsenic	<3 mg/kg dry wt.
Lead	<3 mg/kg dry wt.
Cadmium	<2 mg/kg dry wt.
<u>Micro-biological purity</u>	
- Aerobic mesophilic bacteria	Not more than 10 ⁷ /g dry wt.
- Enterobacteriaceae	Not more than 3x10 ⁴ /g dry wt.
- <i>Salmonella</i>	Absent in 25 g dry wt.
- <i>E. coli</i>	<10/g dry wt.
- Bacillus cereus	<10 ⁴ /g dry wt.
Residue Analysis	
Pesticides	< maximum levels of pesticides (EU regulation 396/2005)
Fungicides	< maximum levels of pesticides (EU regulation 396/2005)
Others	< maximum levels of pesticides (EU regulation 396/2005)