



EUROPEAN COMMISSION

DIRECTORATE-GENERAL XXIV
CONSUMER POLICY AND CONSUMER HEALTH PROTECTION
Directorate B - Scientific opinions on health matters
Unit B3 - Management of scientific committees II

SCIENTIFIC COMMITTEE ON FOOD

CS/NF/STEV/3 Final
17 June 1999

Opinion on
Stevia Rebaudiana Bertoni plants and leaves
(adopted on 17/6/99)

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: BE232 - 6/37.
Telephone: direct line (+32-2) 295.81.10 / 296.48.70, exchange 299.11.11. Fax: (+32-2) 299.48.91
Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.
http://www.europa.eu.int/comm/dg24/health/sc/scf/index_en.html

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OPINION

ON *STEVIA REBAUDIANA* BERTONI PLANTS AND LEAVES

(expressed on 17 June 1999)

Terms of Reference

The Committee is asked to assess the safety from the consumer health point of view of the leaves of *Stevia Rebaudiana* Bertoni as Novel Food.

Background

A request for authorisation to market as a novel food under Regulation 258/97 (EC) concerning Novel Foods and Novel Food Ingredients (2) has been received in February 1998 for the plants and dried leaves of *Stevia Rebaudiana* Bertoni (SRB) (1). According to the Regulation, an initial assessment of the safety from the consumer health point of view is required before marketing may be authorised. Based on this initial assessment, public health concerns have been raised by Member States. An SCF and JECFA opinion on the safety of stevioside, the main sweet principle of SRB, is available (3,4).

Nature of the novel food

The genus *Stevia* belongs to the Asteraceae family, tribe *Eupatorieae*, and comprises some 150-300 species of perennial herbs and shrubs, growing mostly at altitudes of 500-3000 meters in semidry mountainous terrain. The species can also grow in grasslands, scrub forests and sub-alpine areas. SRB is entirely a New World genus, its distribution ranging from southern United States and northeastern Paraguay to southeastern Brazil through Mexico, Central America, the Southern American Andes and the Brazilian highlands. The plant yields a sweet aqueous extract containing various glycosides and has therefore been used for centuries by the indigenous Guarany natives as a traditional sweetener, added to herbal teas and other beverages. It is still cultivated today in Paraguay, Mexico, Central America, Japan, China, Malaysia, and South Korea. In Europe it is reported to be cultivated in Spain, Belgium and the UK. (1,5).

As the plant does not survive winter climate it is cultivated in Europe as a leaf crop under greenhouse conditions. It is propagated by outgrowths of axially buds and by cuttings and is harvested after 3-4 months growth by cutting. The parts of the plant used are the aboveground portions of the living plant and the dried and powdered leaves. The commercial dried leaf product may include small amounts of flowers, stems and seeds.

The leaves contain a complex mixture of natural sweet diterpene glycosides. These are stevioside (4-13% dry weight), steviolbioside (trace), the rebaudiosides A (2-4%), B (trace), C (1-2%), D (trace), E (trace) and dulcoside A (0.4-0.7%). The dry weight composition is given as protein ~6.2%, lipids ~5.6%, total carbohydrates ~52.8%, stevioside~15% (1) and about 42% water-soluble substances (5). The following non-sweet constituents have been identified: labdane diterpene, triterpenes, sterols, flavonoids, volatile oil constituents, pigments, gums and inorganic matter (5).

No information is given regarding the geographical location of the source material, the composition of the commercial dried leaf products, the species variety cultivated nor is a minimum lower limit for stevioside in the product specified. The composition of the commercial plant product is not standardised with regard to any of its components, especially stevioside, and no analytical data have been supplied. No inherent toxic components are described but again no analytical evidence for their absence has been supplied. No microbiological specification has been supplied

The plant is well identified botanically and a sample of the living plant cultivated in Belgium has been deposited with the Laboratory of Plant Physiology of KUL (Catholic University of Leuven) at Heverlee as well as with the National Plant Collection of Belgium. A sample of the dried plant and leaves of the Belgian cultivar has also been deposited in the Laboratory of Systematics of KUL at Heverlee. The dried and ground leaves can thus be identified microscopically. No detailed information is available on material of non-Belgian origin.

Technological information

The dried plant material is produced in Europe, Paraguay and Japan by traditional processes for vegetable crops, i.e. drying in warm air at 70°C for 3 hours to a moisture content of 5-8%. Under these conditions the stevioside is not decomposed. The dried material can be stored in the dark in airtight containers for up to 2 years (1).

Intakes

The dried leaves are about 30-45 times as sweet as sucrose. The leaves have not been widely consumed in Europe. Among those who do consume them, about 90 mg dry powder are used per cup of tea or coffee. The dried powder can be added to chocolate (1.2 g in 120 g, i.e. 1%) and to jam (9 g to 1 kg fruit). Fresh leaves can be used to sweeten vinegar (6-9 g fresh weight to 1 L). Fresh leaves can be added to salads. The claimed intake per person per day in Europe from these uses of the fresh and powdered leaves is 2.4 g dry powder equivalent to 400 mg stevioside. The

application suggests an acceptable daily intake of 5g/day but this figure is not based on the results of any toxicity studies (1).

In Paraguay a mixture of milled dried leaves, flowers and fine branchlets at a daily dose of up to 5 g in the form of a tea has been used for some 45 years in diabetic patients to reduce the blood sugar level with a maintenance dose of 1 g /day also as a tea. Small capsules containing dried leaves have also been used to relieve physical and emotional fatigue. No intake estimates have been submitted (5).

In Japan SRB was introduced as cultivar from Brazil and Paraguay about 1970. New varieties yielding 3-5% more of the sweet diterpeneglycosides are grown in the warm regions. In 1992 some 70 SRB-extracts were marketed in Japan for use in canned foods, pickles, sauces, baked goods, ice creams and soft drinks. Some SRB extracts high in rebaudioside A in combination with glycyrrhizin are available. The average intake is estimated at 4 mg/kg b.w./day/person (5).

Large quantities of SRB leaves are cultivated in China, mostly for export, but local use is limited to dried leaves packaged for use as tea. Intake estimates have not been supplied (5). In Brazil the dried leaves, sterilised with ethylene oxide, are used for the preparation of different flavoured teas (5). In the US only leaf extracts are marketed as dietary supplements (not regulated under the Food and Drug Regulations) but the same products are forbidden as sweeteners or food additives (5).

Nutritional implications

The fresh leaves are used in very small amounts and are therefore most unlikely to replace other vegetable foods to any significant extent. The dry powder is intended to replace some of the sucrose in drinks, jams and sweets to reduce the caloric intake. It may be used by diabetics and overweight individuals. No relevant studies have been submitted to show the physiological and pharmacological effects of this substitution on diabetic or obese individuals. No studies have been submitted showing the effect of the addition of the powdered material on the bioavailability of macro and micro-constituents of the normal diet.

Toxicological evaluation

Almost all the toxicological data submitted concern essentially crude or purified extracts or pure stevioside and have been summarised by the SCF and JECFA (3,4). As the studies do not enable determination of the precise specification and origin of the source material used for these extracts they are irrelevant for the assessment of the safety of the leaves and powdered leaf products. These studies are therefore not reviewed again in this opinion. The only reported study using the plant material is a feeding study in rats using 10% dried SRB leaves of unknown specification in a high carbohydrate diet investigating the effect on blood glucose level. No details of the study have been submitted but the results were reported as showing a continued significant decrease in liver glycogen after 2 weeks and a significant decrease in blood glucose levels after 4 weeks (6).

No investigations on the allergenic potential of the leaves and the powdered leaves have been submitted.

Conclusion

The information submitted on the plant products was insufficient with regard to specification and standardisation of the commercial product and contains no safety studies. There are no satisfactory data to support the safe use of these products as ingredients of food or as sucrose substitute for diabetics and obese individuals. The only toxicological data submitted are essentially concerned with the stevioside component of the plant product. No appropriate data were presented to enable the safety of the commercial plant product to be evaluated.

References

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