

FSA note on Stevia and stevioside

Stevioside is a high intensity sweetener, 250-300 times sweeter than sucrose. It is isolated and purified from the leaves of the Stevia plant (*Stevia rebaudiana* Bertoni), where it is present at levels up to 13%, and has been used for a number of years as a sweetener in South America, Asia, Japan and China.

As a result of the outcome of safety assessments which have been carried out **Stevia and stevioside are not permitted for sale as food or food ingredients in the UK or elsewhere within the EU.**

Safety Evaluations

Sweeteners and other food additives are tightly regulated within the European Union (EU) and may only be used once their safety has been rigorously assessed. The EC Scientific Committee on Food (SCF) is an independent committee which advises the European Commission on questions concerning consumer health and food safety, in particular relating to toxicology and food hygiene. The SCF identified safety problems with stevioside and recently rejected applications to market the plant and its products as sweeteners and as novel foods within the European Union.

Stevioside was first considered by the SCF for approval for use as a sweetener within the EU in 1985 and the review was updated in 1989. On both occasions the Committee raised several questions of concern and concluded that, based on the submitted documentation, it could not accept its use. Extracts from *Stevia rebaudiana* leaves were also considered as toxicologically not acceptable.

A further application for approval of stevioside was received by the European Commission in 1998 and again referred to the SCF. The data considered by the Committee indicated that the extract has the potential to produce adverse effects in the male reproductive system that could affect fertility and that a metabolite produced by the human gut microflora, steviol, is genotoxic (ie. damages DNA). The Committee concluded that stevioside was not acceptable as a sweetener.

In 1998 a request was made for Stevia (the plants and dried leaves of *Stevia rebaudiana* Bertoni) to be marketed as a novel food under the EU novel foods legislation (Regulation 258/97(EC)). The application was initially evaluated by the Belgian Authorities who

recommended that the product should not be approved. The product was then considered in the UK by the Advisory Committee on Novel Foods and Processes (ACNFP) as part of the approval process for novel foods. The ACNFP agreed with the opinion of the Belgian Authorities and recommended that the product should not be approved due to lack of information supporting its safety, a view that was shared by a number of other Member States. The application was subsequently referred to the SCF. The SCF concluded in June 1999 that the information submitted on the plant products was insufficient with regard to specification and standardisation of the commercial product and contained no safety studies. There was no satisfactory data to support the safe use of these products as ingredients in food or as sucrose substitutes.

In December 1999 the Joint MAFF/DH Food Safety and Standards Group wrote to various companies known to be trading in Stevia products, informing them of the SCF's opinion and stating that Stevia should not be offered for sale as a food or food ingredient in the UK.

Copies of the SCF's opinion on Stevia as a sweetener and its opinion on *Stevia rebaudiana* Bertoni plants and leaves are available on the internet via

http://www.europa.eu.int/comm/dg24/health/sc/scfindex_en.html

A letter setting out the ACNFP's views can be found at:

<http://www.foodstandards.gov.uk/maff/archive/food/novel/stevreb.htm>

Alternatively, copies can be obtained by post from the Food Standards Agency at the address below.

Background to relevant UK legislation

In the UK there are 3 areas of legislation potentially relevant to the sale of stevia and stevioside – these are the general provisions of the Food Safety Act, regulations relating to the sale of novel foods and those relating to the sale of sweeteners. Novel foods and sweeteners are both harmonised areas within the EU and the controls within the UK implement European legislation.

In the UK all food sold for consumption is subject to the general provisions of The Food Safety Act, 1990. Whilst this Act makes no specific reference to Stevia or any other vegetable or plant extracts, it makes it an offence to sell or possess for sale food which is injurious to health. This applies not only to retail sale but throughout the food chain. It would therefore be an offence to use extracts of Stevia or Stevia plants and leaves as food or food ingredients (or to offer them for sale) if it were to render the product injurious to health.

Any food products which were not used for human consumption to a significant degree within the European Community before 15 May 1997 are considered to be novel foods and are

therefore subject to approval under EC Directive 258/97 on Novel Foods and Novel Food Ingredients. An opinion of the SCF on Stevia plants and leaves has meant that approval under this Regulation has not been granted at the present time. Any new application to market Stevia or stevioside as a food or food ingredient would have to include safety studies that sufficiently addressed any concerns about the potential toxicological effects caused by them.

Any food additive used or intended to be used to impart a sweet taste to food is subject to the provisions of the Sweeteners in Food Regulations 1995. These regulations set out a list of permitted sweeteners. Again, following an opinion issued by the SCF neither Stevia (*Stevia rebaudiana* Bertoni), Stevia extracts or stevioside are permitted.

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