



AGENCE FRANÇAISE  
DE SÉCURITÉ SANITAIRE  
DES ALIMENTS

THE DIRECTOR GENERAL

**Afssa – Request no. 2009-SA-0012**

**Associated requests nos 2006-SA-0231, 2008-SA-0108  
and 2008-SA-0321**

Maisons-Alfort, 30 of march 2009

## OPINION

### **of the French Food Safety Agency on a new draft order on the use of rebaudioside A, an extract of *Stevia rebaudiana*, as a food additive**

On 12 January 2009, the Directorate General for Competition, Consumer Affairs and Fraud Control requested the French Food Safety Agency (Afssa) to issue an opinion on a new draft order concerning the use of rebaudioside A, an extract of *Stevia rebaudiana*, as a food additive.

#### Context

Following Afssa's opinion of 11 September 2008, an initial version of the order authorising the use of steviol as an additive in food for human consumption was assessed by Afssa<sup>1</sup>. Afssa considered that this version of the draft order did not deal closely enough with the scientific context for which Afssa had issued its opinion: the opinion only concerned the use of rebaudioside A, whereas the draft order included other steviol glycosides.

It is also indicated that the list of intended foodstuffs referred to in Annex II of the draft order included products which should undergo heat treatment during manufacture (e.g. sauces, bakery products, soups, jams). Whereas Afssa's opinion of 11 September 2008 highlighted the need to document the intended use of rebaudioside A with regard to its chemical stability, particularly for products that are cooked or stabilised at temperatures exceeding 100°C.

The draft order referred to in this opinion plans to grant the authorisation to use rebaudioside A, an extract of *Stevia rebaudiana*, as a food additive for a limited period of two years.

After consulting the "Additives, Flavourings and Processing Aids" Scientific Panel, which met on 12 February and 12 March 2009, Afssa issues the following opinion.

#### Assessment of the draft order

The new draft order submitted for opinion takes account of the comments Afssa made in the opinion of 16 December 2008.

The chemical specifications adopted only concern rebaudioside A, presenting a purity over 97%, extracted from *Stevia rebaudiana*.

It is nevertheless noted that checks should be made with manufacturers that production of the following categories, provided for in the draft order: breakfast cereals, cones and wafers with no added sugar for ice cream and dry, salted appetizers made from starch or walnuts and hazelnuts, does not subject rebaudioside A to a higher temperature than 100°C, to avoid its possible thermal degradation.

#### Exposure to rebaudioside A

<sup>1</sup> Opinion of the French Food Safety Agency on a draft order on the use of steviol as an additive in food for human consumption. 16 December 2008.

The maximalist exposure calculations made by Afssa from the foods corresponding to the categories defined in the new draft order show that exposure remains below the human toxicity value identified in human studies and stipulated in Afssa's opinion of 11 September 2008.

According to these calculations, the adult population would be exposed to 0.16 mg/kg bw/day on average and to 0.93 mg/kg bw/day at the 97.5th percentile. In adult consumers only, average intake would be 0.36 mg/kg bw/day and 0.45 mg/kg bw/d at the 97.5<sup>th</sup> percentile. The human toxicity value used for comparison is 14.5 mg/kg bw/day for this population<sup>2</sup>.

In 3-17 year-old children, exposure would be 0.09 mg/kg bw/day on average and 0.72 mg/kg bw/day at the 97.5<sup>th</sup> percentile. In these consumers only, average intake would be 0.18 mg/kg bw/day and 0.88 mg/kg bw/d at the 97.5<sup>th</sup> percentile. The human toxicity value used for comparison is 23.5 mg/kg bw/day.

In 2-20 year-old diabetics, exposure would be 0.36 mg/kg bw/day on average and 1.66 mg/kg bw/day at the 97.5<sup>th</sup> percentile, overall. In consumers only (80% of diabetic patients are consumers), average intake would be 0.45 mg/kg bw/d and 1.70 mg/kg bw/day at the 97.5th percentile. The human toxicity value used for comparison is 23.5 mg/kg bw/day.

#### Conclusion

Afssa issues a favourable opinion on the new draft order, subject to the prior verification of conditions for use of this sweetener for certain food categories, given the thermal degradation of rebaudioside A at a temperature exceeding 100°C. These food categories are: breakfast cereals, cones and wafers with no added sugar for ice cream, dry, salted appetizers made from starch, or walnuts and hazelnuts.

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**Key words: draft order, sweeteners, extract, *Stevia rebaudiane*, rebaudioside A**

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<sup>2</sup> value obtained from the dose of 1,000 mg/day that has not demonstrated any adverse effects on blood pressure in people with normal or low-normal blood pressure, or in type 2 diabetics; divided by the mean body weight of each age group considered (Afssa opinion of 16 December 2008).