AGENCE FRANÇAISE
DE SÉCURITÉ SANITAIRE
DES ALIMENTS

LA DIRECTRICE GENERALE

Afssa – Request no. 2008-SA-0321

Related requests no. 2006-SA-0231 and no. 2008-SA-0108

Maisons-Alfort, 16 December 2008

OPINION

of the French Food Safety Agency on a draft order concerning the use of steviol as an additive in food for human consumption

On 14 October 2008, the Directorate General for Competition, Consumer Affairs and Fraud Control requested the French Food Safety Agency (Afssa) to issue an opinion on a draft order concerning the use of steviol as an additive in food for human consumption.

This draft order plans to grant the authorisation to use steviol glycosides as a food additive (sweetener) in France for a limited period of two years, following Afssa's opinion of 11 September 2008.

Context

On 12 October 2007, Afssa issued an initial unfavourable opinion on a similar application to use steviol, extracts of *Stevia rebaudiana*, as a sweetener in food for human consumption. Additional information was provided by the petitioner in 2008.

In its opinion of 11 September 2008, Afssa stated that the examination of this new toxicological data did not enable an Acceptable Daily Intake (ADI) to be set for rebaudioside A. Afssa nevertheless held that, based on the assessment of the results of the most recent studies presented and predictive exposure calculations, estimated from a scientific publication and not from a precise list of claimed uses, the use of rebaudioside A, extract of *Stevia rebaudiana*, with a greater purity level than 97%, did not present a risk for consumers. This conclusion only concerned rebaudioside A, on which the latest studies supplied have focused.

Three other important remarks made in this opinion highlighted the importance of ensuring the chemical stability of rebaudioside A depending on the intended uses and the need to define the intended foodstuffs and the conditions of use and doses of use per foodstuff, to draw up chemical specifications for rebaudioside A and to define the production and control method guaranteeing a rebaudioside A purity level of over 97%. This purity level had been mentioned by the petitioner in his application.

Lastly, the information provided by the petitioner and transmitted with the draft order does not contain any new scientific findings on the other components of stevia.

After an internal analysis of the draft order subject to this request, Afssa issues the following considerations:

The draft order moves away from the scientific context for which Afssa's opinion of 11 September 2008 was issued, since the latter only concerns the use of rebaudioside A as a food additive. The draft order includes other steviol glycosides (stevioside, rebaudioside C and dulcoside A), which were not assessed by the aforementioned opinion.

Moreover, the list of intended foodstuffs referred to in Annex II of the draft order includes products which, to our knowledge, should undergo heat treatment during manufacture (e.g. sauces, bakery products, soups, jams), whereas the opinion highlights 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.

To conclude, for all these reasons, Afssa is unable to reserve a favourable opinion on this draft order as it moves away from the considerations expressed in its opinion of 11 September 2008.

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