

Maisons-Alfort, 20 April 2005

DIRECTOR-GENERAL

## OPINION

***This opinion incorporates the amendments made in the erratum of 17 August 2005 correcting the number and identifier of the related requests shown in the upper-right inset of this opinion.***

**of the French Food Safety Agency (AFSSA)  
regarding the assessment of additional information on the stability of vitamin D  
and the phytoestrogen content of soy milk.**

On 25 October 2004, the Directorate General for Competition, Consumer Affairs and Fraud Control (DGCCRF) requested, in letter dated 19 October 2004, that the French Food Safety Agency (AFSSA) assess additional information on the stability of vitamin D and the content of phytoestrogens in soy milk.

In its opinions issued on 13 and 15 July 2004 (Request Nos. 2004-SA-0114 and 2004-SA-0100), AFSSA would like the petitioner to specify:

- The analysis data confirming the stability of vitamin D up through the Best Before Date (BBD),
- The phytoestrogen content in soy milk (tonyu).

After consulting the “Human Nutrition” Scientific Panel, which met on 27 January 2005, AFSSA is issuing the following opinion:

Considering that the doses of vitamin D in soy milk show no excessive degradation of vitamin D content up through the BBD;

Considering that phytoestrogen content was analysed by the petitioner in five different batches using seeds from the 2003 crop year; that these analyses were performed on various isoflavone compounds (daidzin, genistin, glycitin, acetyl and malonyl compounds) using the HPLC separation technique; that the concentration of total isoflavones varied among batches from 22.61 to 36.86 mg/100 g, with an average of  $27.07 \pm 5.92$  mg/100 g, or an aglycone equivalent of 15.38 mg/100 g; that the intake recommended by the petitioner (200 ml of beverage) can be estimated at 30.76 mg aglycone isoflavones; that the total individual intake can be further increased by the consumption of soy-based foods and exceed 1 mg/kg body weight per day;

Considering that the isoflavone content in tonyu sold on the market varies greatly, ranging from 0.2 mg to 2.3 mg/100 g of aglycone equivalent (averaging approximately 7 mg/100 g); that the average intake of aglycone isoflavones (genistein and daidzein) outside of soy-based foods has been estimated<sup>1</sup> at 26 µg per day for adults and 18 µg per day for children according to estimates based on the CIQUAL (French Information Centre on Food Quality) table and the INCA 99 study (intake slightly underestimated due to the limited data available on nutritional composition); that the tonyu content of the petitioner is thus high;

Considering that safety studies conducted on animals show undesirable effects in young animals (concerning the maturation of sex organs and fertility, in particular) and thus calls for utmost caution in humans during this period of life; that soy-protein preparations rich in isoflavones can increase the need for thyroxin in children with hypothyroidism; that the absence of risk is not carefully documented above an intake of 1 mg/kg of body weight per day in aglycone isoflavones;

<sup>1</sup> “Sécurité et bénéfices des phyto-estrogènes – Recommandations” [Safety and Benefits of Phytoestrogens – Recommendations] report



AFSSA considers that:

- the information regarding the stability of vitamin D up through the BBD is satisfactory and shows that the vitamin D content in soy milk is stable;
- the phytoestrogen content in tonyu is too high for children aged 3 to 15;
- the presence and content of aglycone isoflavones should be mentioned on recommended labelling for soy-based foods, i.e.: “contains X mg of isoflavones (phytoestrogen family). Consume with moderation (limit daily consumption to 1 mg/kg of body weight). Not recommended for children under the age of 3”;

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**Pascale Briand**