

Maisons-Alfort, 6 May 2008

OPINION

of the French Food Safety Agency (Afssa)
on assessing evidence of the exceeding of acceptable maximum intakes (set
in the order of 9 May 2006) of iron (30mg instead of 14mg) contained in food
supplements for pregnant women

LA DIRECTRICE GÉNÉRALE

By letter dated 4 January 2008, the French Food Safety Agency (Afssa) was solicited on 2 January 2008 by the Directorate General for Competition, Consumer Affairs and Fraud Control (Dgccrf) to assess evidence of the exceeding of acceptable maximum intakes (order of 9 May 2006) of iron (30mg instead of 14mg) contained in food supplements for pregnant women.

Generally, Afssa considers that "the nutritional needs of pregnant women are covered by a varied, balanced diet, due to well-proven digestive and metabolic adaptations, and that food supplements for pregnant women, necessary in specific situations, should be advised and followed up by a healthcare professional (doctor, midwife) on the basis of individual risk factors." (Opinion of 12 February 2007 on request no. 2005-SA-0331).

In particular, in its opinions of 5 February 2007 (on request no. 2006-SA-0276) and 12 February 2007 (on request no. 2005-SA-0331), Afssa indicates that:

- "there is no justification for the systematic iron supplementation of pregnant women" (National College of French Gynaecologists and Obstetricians (CNGOF), 1997, French National Authority for Health (HAS), 2005);
- "it is only in the case of iron-deficient anaemia that medical iron supplements are recommended for pregnant women".
- "only a biological analysis and its interpretation enable healthcare professionals to determine if a woman is iron-deficient anaemic";
- "high iron supplementation when iron-deficient anaemia is not present can pose a risk, namely an oxidative effect of iron and foetal hypotrophy should haemoglobin levels exceed 14 g/dL";
- "iron supplements increase the risk of excess in sensitive populations (women with a risk of gestational diabetes, preeclampsia or with an aggravated risk linked to oxidative stress exposure, such as if they smoke) (Nutrition Committee of the French Paediatrics Society, 1995, Favier et Hininger-Favier, 2004)."

Afssa consequently considers that the exceeding of acceptable maximum intakes of iron (30mg instead of 14mg) in food supplements for pregnant women is not justified and poses a risk of excess iron consumption which may cause a pro-oxidative effect or foetal hypotrophy, especially in sensitive populations.

Bibliographical references:

Nutrition Committee of the French Paediatrics Society (1995) Fer et grossesse. *Arch Pédiatr*, 2, pp. 1209-18.

Favier, M. et Hininger-Favier, I. (2004) Faut-il supplémenter en fer les femmes enceintes? *Gynécol Obstét Fertil*, 32, pp. 245-50.

<u>Key words:</u> food supplement, pregnant women, iron, oxidative stress

The Director General

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