

Translation from French

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Afssa
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SECURITE SANITAIRE
DES ALIMENTS
[French Food Safety
Agency]

Afssaps
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Press Release

Safety and Benefits of Phytoestrogens in Food

The Afssa, in collaboration with the Afssaps, has assessed the safety and health benefits of phytoestrogens. The term "phytoestrogens" includes several molecules from the plant world with different structures, but all of which show similarities to the structure of oestradiol (one of the major sex hormones). As far as is known, this structural similarity gives them the ability to carry out an oestrogenic effect on target tissues. At the moment, phytoestrogens suffer from a mixed reputation, linked as much to research on their harmful effects (particularly in that they belong to the large group of "endocrine disruptors") as their beneficial effects (particularly from analytical epidemiological research carried out in Asia). This expert report has been carried out based on scientific literature and in response to requests from experts and businesses from the areas concerned. As such, more than 1,500 published and recognised scientific studies have been analysed.

Identification of these molecules depends on their capacity to show oestrogen-type effects in animals by means of binding to oestradiol receptors. However, the characteristics of this bond and its effects show some differences to oestradiol.

Phytoestrogens are present in a range of foods: they are naturally present in some soy protein based foods designed for infants and young children, and in soy-based food products (tofu, "Tonyu" or soy "juice", soy-based desserts). Manufacturers also add them in concentrate to dietary supplements aimed at post-menopausal women. In addition to the common presence of phytoestrogens, each of these food categories has its own set of problems: soy is an interesting food from a nutritional point of view even without the problems of phytoestrogens, while dietary supplements must be considered in the light of their borderline status between food and medicine.

Six families of molecules that fit the description of "phytoestrogens" have been identified in food. This identification does not prejudice the effects of any of these phytoestrogens on particular physiopathological states. In fact, most of the information in the literature relates to only one of these families, the isoflavones, molecules that are present in large quantities in soy. In a traditional Western diet, which does not include soy, the average daily intake of isoflavones known as "aglycones" is very low; less than 1mg/day. Measured introduction of soy-based foods into a Western diet increases the intake by 1,000 to 10,000 times, which is still lower than that of Asians. If dietary supplements are being taken, the intake can be as high as it is in Asia, and could tend towards being higher.

The consumption of phytoestrogens cannot *a priori* be considered safe, because they interfere with the hormonal system, and as such merit examination. On the basis of safety studies, it is considered that:

- an intake of 1mg/kg of body weight per day of aglycone isoflavones (that is, 60 mg for a person weighing 60 kg) presents no risk for the general population,
- some consumers need to take special precautions:
 - for infants and young children taking soy protein-based formula, it is recommended that phytoestrogen intake be limited to 1mg/l of formula. In the same way, *in utero* and neo-natal exposure needs to be limited
 - people with breast cancer or a personal or family history of breast cancer should limit their intake of phytoestrogens.

In addition, as has been shown in children, phytoestrogen consumption can increase thyroid hormone requirements in patients being treated for hypothyroidism.

As compared with effects associated with hormone replacement therapy for menopause (HRT):

- **Studies on phytoestrogens have not yet established the effect of phytoestrogens on hot flushes.**
- **Isoflavones may have a limited effect on osteoporosis and the loss of cognitive function. However, these effects need to be confirmed by well-managed clinical studies.**
- **The data available at present show that phytoestrogens are not associated with an increased risk of breast cancer in women. In Asian people, there is a decreased risk. However, the significant differences between Asian and Western people exclude the possibility of transposing the effects.**

In the light of this information, other studies with adequate methodology need to be performed in order to complete the available information, and the place of phytoestrogens in prevention or management of problems linked to menopause requires rigorous proof.

Finally, in the cardiovascular area, soy aglycone isoflavones have a beneficial effect on blood vessel tone (vasotonia) at levels from 45mg/day, but negative effects may be produced from 73mg/day.

Recommendations for research, public health and consumer information are being issued.

The "*Sécurité et bénéfices des phyto-estrogènes apportés par l'alimentation – Recommendations*" [Safety and Benefits of Phytoestrogens in Food – Recommendations] report is being made public on 9 March 2005. The conclusions, as developed in conjunction with the Afssaps, will be presented at that time, and discussed at the Afssa at 2pm, during a discussion and information meeting which will be attended by Dr. Mariette Gerber, president of the working group and an expert member of the group.

The complete report and a summary of it can be downloaded from www.afssa.fr

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