



Maisons-Alfort,

## OPINION

### of the French Food Safety Agency (Afssa) on the identification of populations concerned by particular nutritional uses and the assessment approach.

THE DIRECTOR GENERAL

The French Food Safety Agency (Afssa) initiated deliberations on particular nutritional uses through a self-request dated 23 August 2006.

Between 2000 and 2005, Afssa assessed some forty products presented as targeting a population. Eighteen of these products claimed to be foodstuffs intended for particular nutritional uses (PARNUT). The analysis of requests shows that only the population of adult men has never been targeted specifically.

Afssa's ongoing deliberations are part of a process to clarify the assessment of foodstuffs intended for certain categories of commonly targeted populations.

The assessment method was based on:

- an analysis of Afssa's opinions submitted on products positioned as intended for a group of individuals (normal consumption or PARNUT);
- methods concerning the fortification of ordinary foods with vitamins and minerals and the conditions for a satisfactory fortification for consumer nutrition and safety (Afssa, 2001), as well as the specifications for the selection of a Nutrient-Vector food pair (Afssa, 2004);
- an analysis of the scientific literature;
- consideration of the evolution of regulations on fortification<sup>1</sup>;
- the proposal of a definition of particular nutritional uses;
- the definition of populations concerned by particular nutritional uses;
- a proposal of an assessment approach for foods targeting groups of individuals.

After consulting the "Human Nutrition" Scientific Panel on 23 March, 20 April, 7 July and 19 December 2006, 25 January, 15 February, 29 March and 26 April 2007 and 21 February 2008, Afssa issues the following opinion:

#### 1. Regulations in force

##### 1.1. Current regulatory definition of particular nutritional uses

Article 1 of the decree of 29 August 1991<sup>2</sup> amended – which transposes Council Directive 89/398/EEC<sup>3</sup> - defines foodstuffs intended for particular nutritional uses (PARNUT) as follows:

"Foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.

A particular nutritional use must fulfil the particular nutritional requirements:

- of certain categories of persons whose digestive processes or metabolism are disturbed; or

<sup>1</sup> Decree 2006-1264 of 16 October 2006 on vitamins, minerals and other substances used in the manufacture of foodstuffs. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.

<sup>2</sup> Decree no. 91-287 of 29 August 1991 amended on foodstuffs intended for particular nutritional uses.

<sup>3</sup> Council Directive of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses.

- of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or
- of infants or young children in good health.”

Moreover, Annex I of the decree specifies the groups of foodstuffs for particular nutritional uses for which specific provisions will be laid down (European Directives and/or French Orders):

1. infant formulae and follow-on formulae;
2. processed cereal-based foods and baby foods for infants and young children;
3. foods intended for use in energy-restricted diets for weight reduction;
4. dietary foods for special medical purposes;
5. foods intended to meet the expenditure of intense muscular effort, especially for sportsmen;
6. foods for persons suffering from carbohydrate-metabolism disorders (diabetes)<sup>4</sup>.

This list is not exhaustive, it is possible to market PARNUTs which do not belong to one of the groups listed in Annex I. This opinion concerns such foodstuffs.

### **1.2. Addition of vitamins and minerals and of certain other substances to foodstuffs for normal consumption**

Decree no. 2006-1264 of 16 October 2006 aims to establish, at national level, a list of vitamins, minerals and other substances that can be used in the manufacture of foodstuffs.

Since the publication of Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods, the provisions concerning vitamins and minerals in this decree no longer apply. However, with regard to substances other than vitamins and minerals, pending a list established at European level, the provisions of Decree no. 2006-1264 of 16 October 2006 continue to apply.

The provisions of both these texts apply without prejudice to the specific provisions of Community and national law on PARNUTs.

## **2. Afssa’s opinion on the positioning of products in particular nutritional uses and in normal consumption**

The grounds on which PARNUTs can be distinguished from fortified foods for normal consumption need clarifying, with regard to the PARNUT regulatory definition.

**In this opinion, Afssa suggests the following definition for PARNUTs:**

**“Foodstuffs for particular nutritional uses are intended to meet the nutritional needs of a target population. They are not suitable for other populations.**

**Such foodstuffs must meet the following condition: they are suitable for a particular population for whom the vitamin, mineral and other substance levels of food for normal consumption do not cover nutritional requirements or pose a health risk.”**

By “normal consumption”, Afssa means a balanced, diversified diet covering the nutritional requirements of the general population.

Afssa defines “nutritional requirements” as follows: the requirements for a given nutrient (or energy) are defined as the level of this nutrient (or energy) required to ensure the upkeep (or maintenance) and metabolic and physiological functioning (homeostasis) of a healthy individual, including the needs linked to physical activity and thermoregulation, and additional needs required at certain stages of life such as during growth, gestation and lactation (Martin et al, 2001).

<sup>4</sup> In its opinion of 3 January 2007, Afssa suggested that foods intended for diabetics did not fall within the scope of Directive EEC 89/398 (Afssa opinion on the request for scientific and technical support in view of the modification of the role that nutrition plays for diabetics in Directive 89/398/EEC, on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses).

### 3. Afssa's opinion on PARNUTs which do not belong to one of the groups listed in Annex

#### 3.1. The elderly

Several definitions of ageing are given and there is no consensus over the definition of a typical elderly person (WHO, 2001; Hogan, 2003).

The recent observation (2005) by the French National Nutrition Council emerges as a pertinent introduction to deliberations:

“Ageing is the result of a genetic component specific to each person and of an acquired component depending on a person's lifestyle (diet, physical activity, etc.). Many parameters characterise the elderly person. These naturally include age, but also the state of physical and mental health, frailty, disability, loss of independence, social links or loneliness, living at home or in an establishment, income, physical mobility, ability to communicate and activity.

The profusion of these parameters explains [... that] age is not necessarily the most relevant criterion, apart from in very old people perhaps. There is consequently a wide variety of “elderly people”. Geriatricians and gerontologists tend to group elderly people into three categories: ageing people in good health, frail elderly people and sick elderly people nearing the end of their life. These people have very different dietary habits and needs and it may be dangerous to confuse the different situations by establishing undifferentiated recommendations.”

From a strict scientific viewpoint, it is impossible to define a specific age for characterising the population of elderly people. That said, as a management option, Afssa suggests a minimum age of 75 years to define elderly people. This corresponds to the age from which different vitamin and mineral requirements and therefore different French RDIs (ANCs) from those of younger adults have been defined (Cynober *et al.*, 2001).

Afssa recommends distinguishing between frail elderly people, healthy elderly people and sick elderly people. The latter present illnesses that are likely to place the vital prognosis under threat, including cardiovascular diseases, cancers, obstructive bronchopneumopathy and asthma (Newman, 2003). Sick elderly people can be included in point 4 of Annex I of Decree 91-287 of 29 August 1991 on dietary foods for special medical purposes.

#### a. Frail elderly people

There are several definitions of frailty. Frailty represents an intermediate state between physiological and pathological ageing.

According to Fried *et al.* (2004), frailty is a syndrome characterised by the reduction in resistance to attacks and physiological resources to deal with these. This manifests through weight loss, fatigue and weakness, reduced spontaneous physical activity, slowed motivity and balance and walking problems. A cognitive component may also exist. Frailty can increase the risk of morbidity, functional dependence, hospitalisation, admission into an establishment or death (Hogan, 2003).

This syndrome can be observed at different ages. This is because, at a given age, there is a *continuum* of situations ranging from normal health to evident illness and, conversely, a clinical situation can correspond to a population of different ages. For these reasons, this paragraph will deal with frail elderly people aged 75 years and over.

Ageing results in lower dietary intake due to quicker satiety (Morley, 2002; Ferry, 2007), appetite dysregulation and secondary nutritional problems from previous illnesses. The nutritional requirements of elderly people are defined by French RDIs (ANCs) (Cynober *et al.*, 2001). They are at least equal to those of younger adults in amount (per kg of body weight), except for energy, and in quality. Since spontaneous consumption in frail elderly people is reduced, foods intended for normal consumption are not sufficient to cover their requirements.

This consumption deficit is one of the key mechanisms of function and weight loss, and increases frailty.

**Afssa therefore believes that frail elderly people may be considered as a target population for PARNUTs.**

### b. Healthy elderly people

The nutritional requirements of healthy elderly people aged 75 and over can be met by foods for normal consumption. A balanced and diversified diet is suitable for healthy elderly people. Its composition is described by the French National Programme for Nutrition and Health (2003; 2006) and the French RDIs (ANCs) are defined by age group (Cynober *et al.*, 2001).

**As a result, healthy elderly people cannot be considered as a target population for PARNUTs.**

**To conclude**, there are therefore two types of elderly populations:

- healthy elderly people;
- frail elderly people.

PARNUTs intended for frail elderly people may not be suitable for healthy elderly people, and may pose a risk of unbalanced intake if the upper or lower limits for certain nutrients are exceeded: this justifies an appropriate labelling for PARNUTs intended for frail elderly people.

### 3.2 Other populations that have previously been put forward as targets by petitioners

The analysis of Afssa's opinions mentioned previously (on products presented as PARNUTs or otherwise) identifies several targeted populations in petitioner files:

- seniors;
- post-menopausal women;
- women concerned about following a balanced diet and wanting to keep their figure;
- "everyone watching their figure".
- pregnant and breastfeeding women;
- women of childbearing age;
- growing children and teenagers;
- women, particularly teenagers and post-menopausal women, for whom daily calcium intakes are globally clearly insufficient;
- people intolerant to lactose or gluten .

#### a. Seniors

There is no consensus on the definition of this term as it can refer to people over 65 years of age, 60, 55 and even over 45.

These populations belong to the group of adult populations, for whom normal consumption covers nutritional requirements (Cynober *et al.*, 2001).

**As a result, seniors cannot be considered as a target population for PARNUTs.**

#### b. Post-menopausal women

As knowledge currently stands, post-menopausal women are at risk of insufficient intake for both calcium and magnesium (Afssa, 2004). Calcium requirements are increased after menopause, and insufficient intakes reduce bone mineralisation, thereby increasing the risk of fracture (Dawson-Hugues, 1998; Flynn, 2003). Attention should therefore be paid to ensuring that calcium intakes in post-menopausal women are close to the recommended intakes for this population (Cynober *et al.*, 2001).

Furthermore, calcium supplements are not advised in women whose spontaneous calcium intakes are close to the recommended intakes. This is because these supplements have no benefit on the fracture risk of these women, and may increase the risk of renal lithiasis (Jackson *et al.*, 2006).

The nutritional requirements of post-menopausal women can be met by food for normal consumption.

**As a result, post-menopausal women cannot be considered as a target population for PARNUTs.**

**c. Women watching their figure**

The requirements of people watching their figure can be covered by food for normal consumption. These people do not have specific nutritional requirements.

Apart from people following energy-restricted diets for weight reduction, as defined in decree 91-287 of 29 August 1991 (point 3 of its Annex), **people (men or women) watching their figure cannot be considered as a target population for PARNUTs.**

**d. Pregnant or breastfeeding women**

The nutritional requirements of pregnant or breastfeeding women are covered by a balanced and varied diet, due to proven digestive and metabolic adaptations (Afssa, 2007a).

Current knowledge points to a risk of insufficient folate and vitamin D intakes and, in some cases, inadequate iron and iodine intakes, in pregnant or breastfeeding women. The requirements for each of these nutrients do not vary in the same way during pregnancy and then breastfeeding, however.

For each of these micronutrients, supplements for pregnant women, targeted depending on individual risk factors, are to be advised and followed up by a healthcare professional (doctor, midwife) (Afssa, 2007a; French National Programme for Nutrition and Health 2007).

**As a result, a PARNUT targeting all pregnant or breastfeeding women is not suitable for all situations and all different stages of pregnancy or breastfeeding.**

**Pregnant or breastfeeding women cannot therefore be considered as a target population for PARNUTs.**

**e. Women of childbearing age**

The nutritional requirements of women of childbearing age can be covered by food for normal consumption.

Folate deficiency is a risk factor for malformation of the embryo's neural tube during the first month of pregnancy. This risk can be reduced by an optimum intake of folate in the 8 weeks prior to conception and the first 4 weeks of pregnancy. This intake can be provided by food for normal consumption. It is preferable that intakes and their readjustment be monitored by a healthcare professional.

**As a result, women of childbearing age cannot be considered as a target population for PARNUTs.**

**f. Children and teenagers**

Over the age of 3 years, the nutritional requirements of children and teenagers can be met by food for normal consumption (Afssa, 2004).

Current knowledge points to a risk of insufficient intakes for calcium, magnesium and iron in children and teenagers depending on age and sex (Afssa, 2004). Calcium requirements are higher during growth (Beaufrère *et al.*, 2001), and insufficient intakes have known harmful effects on bone accretion (Flynn, 2003; Heaney, 2000).

Calcium supplements in children and teenagers with spontaneous calcium intakes close to the recommended intakes have no known benefit on bone health (Weinsier et Krumdieck, 2000; Lanou *et al.*, 2005).

The requirements of children and teenagers can be met by food for normal consumption once their diet is balanced and diversified.

**As a result, children and teenagers cannot be considered as a target population for PARNUTs.**

#### **g. People suffering from hypercholesterolaemia**

People suffering from hypercholesterolaemia do not form a particular population since they can correct the hypercholesterolaemia, at least partially, through a diet favouring certain ordinary foods. There are ordinary foods targeting this population, particularly products with a modified lipid profile, and products fortified with phytosterols or phytostanols.

Regarding products with modified lipid profile, the bibliographical data (Hu *et al.* 1997, Clarke *et al.* 1997; Chisholm *et al.* 1996; Cleghorn *et al.* 2003; Judd *et al.* 1998 and Seppanen-Laasko *et al.* 1992) show that substituting saturated fatty acids for a similar amount of monounsaturated fatty acids (MUFAs) and polyunsaturated fatty acids (PUFAs) reduces the LDL-cholesterol in the blood (Afssa, 2007b; Afssaps, 2005). What's more, consumption of these products increases the levels of MUFA and PUFA intakes in the general population (Afssa, 2007b) as recommended (RDI, 2001).

Plant sterol intake through the consumption of foods that naturally contain them is low, between 150 and 500 mg/d (EFSA, 2008). There are products with added phytosterols or phytostanols. Scientific data highlight the interest in consuming 1.5 to 3 g/d of phytosterols or phytostanols for reducing LDL-cholesterol in people suffering from hypercholesterolaemia (EFSA, 2008). There is no proof of additional benefits from consuming more than 3 g a day, which may induce adverse effects. As a result, daily intake should not exceed 3 g and the consumption of these products is not suitable for pregnant or breastfeeding women, nor for children who are not suffering from hypercholesterolaemia (SCF, 2002; EFSA, 2003; EFSA, 2005; Afssa, 2006). These products require specific labelling (Commission Regulation (EC) No 608/2004<sup>5</sup>).

**People suffering from hypercholesterolaemia are not a target population for PARNUTs.**

#### **h. Lactose or gluten intolerant people**

Lactose or gluten intolerant people can meet their requirements through food for normal consumption as long as suitable nutritional information is provided. According to Directive 2003/89/EC<sup>6</sup>, milk and gluten labelling is compulsory.

**As a result, lactose or gluten intolerant people cannot be considered as target populations for PARNUTs.**

### **4. Assessment of the nutritional interest of PARNUTs**

The nutritional interest of a product (nutrient, substance, fortification or reduction level and vector used) for the targeted population is assessed according to the method presented in Afssa's previous report "Specifications for the selection of a Nutrient-Vector Food Pair" (Afssa, 2004).

### **5. Assessment of risks for the targeted population and the general population.**

The assessment is carried out according to the method described in the Specifications for the selection of a Nutrient-Vector Food Pair (Afssa, 2004) and on the basis of possible toxicity data, upper limits, of Decree 2006-1264 of 16 October 2006 and Regulation (EC) No 1925/2006 and publications on possible interactions between nutrients, etc.

In practice: if the product is considered to be a PARNUT:

- the absence of risk for the target population must be demonstrated;

<sup>5</sup> Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters.

<sup>6</sup> Directive 2003/89/EC of 10 November 2003 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs.

- in the event of risk for a population that is not targeted by the product, Afssa recommends that this population be mentioned on the labelling.

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**Key words:**

Foodstuff intended for particular nutritional uses, elderly people, frail elderly people, seniors, post-menopausal women, people watching their figure, pregnant or breastfeeding women, women of childbearing age, children and teenagers, people suffering from hypercholesterolaemia, gluten intolerant people, lactose intolerant people.