



Maisons-Alfort, 31 March 2009

OPINION

of the French Food Safety Agency relating to a request to assess the risks related to the regular consumption of virgin flaxseed oil

THE DIRECTOR GENERAL

Reminder of the request:

On 10 December 2008 the French Food Safety Agency (Afssa) received a request from the Directorate-General for Competition, Consumer Affairs and Fraud Control (DGCCRF) to assess the risks related to the regular consumption of virgin flaxseed oil.

After consulting the scientific panel (CES) on "Human Nutrition", which met on 30 January 2009, Afssa issued the following opinion:

Context of the request

In December 2004 Afssa received a request to assess the use of flaxseed oil, alone or blended, in the normal diet. In response, Afssa recommended, in its opinion of 25 July 2006, an assessment prior to the use of virgin flaxseed oil, in order to be sure of conditions of stability (Afssa, 2006).

The DGCCRF points out that Article 28 of the Union Treaty does not allow the marketing of products legally sold within the European Union to be conditioned by the performance of a technical expert assessment. Virgin flaxseed oil is commonly used in the countries of the European Union and is actually traded, in particular, in France. Only a serious risk to the health and safety of users could justify banning the sale of virgin flaxseed oil, pure or blended. However, the points mentioned by Afssa in its opinion of 25 July 2006 are not sufficient to oppose the free circulation of this oil.

In view of this situation, the DGCCRF has asked Afssa:

- either to provide substantiated scientific arguments that would justify the banning of flaxseed oil;
- or to provide information allowing the marketing of this oil to be controlled.

Quality criteria for virgin oils

Virgin fats and oils are edible fats and oils obtained exclusively by mechanical procedures, for example expelling or pressing, and the application of heat (without altering the nature of the oil). They may only be purified by washing with water, settling, filtering and centrifuging (Codex STAN 19-1981, the standard relating to edible fats and oils not covered by individual standards). Under this standard, no additives are permitted in virgin oils. The addition of an antioxidant is therefore totally out of the question. The Codex STAN 19-1981 standard also puts forwards quality criteria for virgin oils, in particular in terms of odours, impurities or metal content.

Flaxseed oil meets these quality criteria when it is analysed immediately after pressing (Wiesenborn et al., 2005). However, in analyses carried out on samples of virgin oils taken from shops, these criteria are not always met, particularly in terms of the peroxide value and free fatty acid levels (de Panfilis et al., 1998).

Nutritional properties of virgin flaxseed oil

Flaxseed oil contains approximately 54 to 71% α -linolenic acid (ALA) (Manuel des Corps Gras, 1992) for which the current consumption recommendations are 2 g.d⁻¹ for an adult male (Legrand et al., 2001). There is no tolerable upper intake level for this fatty acid, in particular because of its high β -oxidation rate. An association has been suggested between a high consumption of ALA and an increase in the risk of prostate cancer, but was not confirmed in Afssa's opinion of 8 September 2008 (request 2007-SA-0231); in this opinion, it is concluded that "the majority of studies, and most of the cohort studies, do not reveal an increase in the risk of prostate cancer associated with the highest consumptions or blood levels of α -linolenic acid".

French consumption of α -linolenic acid varies, according to the studies, from 0.61 to 0.8 g.d⁻¹ in women and from 0.78 to 0.94 g.d⁻¹ in men (or approximately 0.3-0.4% of the total energy intake) (Combe & Boué, 2001; Astorg et al., 2004, Charrière et al., 2007). In all cases, these values are much lower than the ANC¹ (Legrand et al., 2001), which are of the same order of magnitude as the intakes recommended by other international bodies (1 to 3 g.d⁻¹).

In its opinion of 25 July 2006, Afssa indicated that no studies had been conducted on the nutritional interest and safety of the consumption of flaxseed oil in children under the age of three years. As a result, it concluded that flaxseed oil should not be used in the diet of children under the age of three, and that this point should be mentioned on the labelling (Afssa, 2006).

The antinutritional factors initially present in flax seeds, cyanogenic compounds (linamarin, linustatin, neolinustatin and lotaustralin) and linatine (antivitamin B6), are very water-soluble polar substances that do not pass into the oil. Thus, the only study that has, to our knowledge, analysed the levels of linustatin and neolinustatin (the two main cyanogenic compounds in flax seeds) and of linamarin in virgin flaxseed oil, did not detect any of these cyanogenic compounds (Cunnane et al., 1993).

Oxidation stability of virgin flaxseed oil

Due to its high ALA content, flaxseed oil is particularly sensitive to auto-oxidation. In fact, ALA (C18 :3 n-3) has three double bonds and its reactivity to auto-oxidation, measured by the oxygen absorption of the corresponding methyl esters at 37°C, is considered as approximately 2.4 times higher than that of linoleic acid (C18 :2 n-6), and 100 times higher than that of oleic acid (C18 :1 n-9) (Frankel, 2005).

The stability of oils depends on their fatty acid composition, but also on the presence of minor compounds that may act as natural antioxidants, such as for example the tocopherols or plastochromanol-8 present in flaxseed oil (Valasco & Goffman, 2000). The total tocopherol content of virgin flaxseed oil amounts to approximately 44 - 58 mg/100g of lipids (AOCS, 1996).

The study by proton magnetic resonance of the evolution of a flaxseed oil during accelerated ageing at 70°C in a ventilation oven (Guillen et al., 2005) shows that hydroperoxides, which are primary oxidation compounds and the aldehydes, which are secondary oxidation compounds, are present from the first day of ageing, unlike the other oils tested (rapeseed and walnut), where the aldehydes appear much later. It seems therefore that the hydroperoxides in flaxseed oil tend to degrade rapidly into secondary oxidation compounds, which explains why the peroxide value is not considered as a good oxidation marker for oils that are very rich in ALA (Kamal-Eldin, 2002).

Only a few authors have studied the stability of virgin flaxseed oil in non-accelerated conditions. A study carried out in 2004 by the French Institute for fats and oils (Institut des Corps Gras, ITERG), not published but presented at a conference in 2004

¹ "Apports nutritionnels conseillés" are the French equivalent of the Population Reference Intakes (PRI)

(Lechat et al., 2004), showed that a virgin flaxseed oil stored at room temperature and in the dark in its original packaging (closed bottle in a closed cardboard box) could be kept for 18 months without the quality parameters being significantly affected (table 1).

The same virgin flaxseed oil was also kept for 18 months in bottles that had been opened and begun, at room temperature and in the dark in order to replicate the storage conditions in the consumer's home. The specific oxidation markers had increased considerably after 18 months: peroxide value, absorbance at 232 nm (conjugated diene), anisidine value (secondary oxidation compounds), polar compounds and volatile aldehydes (propanal and hexanal).

Table 1: Result of the virgin flaxseed oil storage study (unpublished ITERG data)

Storage period	Method of storage	Peroxide value meq O ₂ /kg	Oleic acidity %	UV 232 nm	Total tocopherols mg/kg	Anisidine value	Polar compounds g/100g	Propanal mg/kg	Hexanal mg/kg	Triglyceride polymers g/100g
t=0		1,8	0,58	2,31	408	2,1	6,3	0	0	0
t= 18 months	Closed bottle	2,4	0,65	2,54	421	2,4	7,9	1,6	2,3	0,11
	Opened bottle	34,9	0,68	5,85	371	7,8	9,6	10,0	10,5	0,45

The sensory qualities of the oil stored in the closed bottles were nevertheless altered (appearance of a paint-like smell), which proves that the traditional physico-chemical criteria used to measure oxidation are not always relevant for detecting a sensory change in virgin flaxseed oil. Recent studies have shown that virgin flaxseed oil stored for 15 weeks at 4°C presented an increase in bitterness, whereas the peroxide value and the free fatty acid content (oleic acidity) changed little (Wiesenborn et al., 2005). It would seem that the formation of a cyclic peptide, cyclolinopeptide (CLE) is the cause of this bitter taste (Brühl et al., 2008).

These results prove that as soon as it is opened, virgin flaxseed oil becomes oxidised very quickly and that it is necessary to advise consumers to keep the oil in the refrigerator after opening.

Protection of fats during storage

As a general rule, good storage practices for vegetable oils consist of protecting the oil from the oxygen in the air, high temperatures and light. They take the form of opaque and non-permeable packaging, nitrogen inerting, and in some cases cold storage for very sensitive oils (such as fish oils).

In view of its degree of unsaturation, specific storage conditions are recommended for flaxseed oil. It is considered, generally speaking, that virgin flaxseed oil should not be kept for more than 3 to 6 months when it is stored in bottles or hermetic packaging (Brühl et al., 2008).

The recommendations published in 2003 regarding the packaging and use of flaxseed oil are as follows (Thompson & Cunnane, 2003):

"Flaxseed oil was until recently, shipped refrigerated in opaque bottles to prevent oxidation. Flaxseed oil is now shipped in opaque bottles, but does not require refrigeration as the space in the top of the bottles has been subjected to nitrogen flushing to replace the air. As soon as the bottle is opened, it must be refrigerated in order to delay oxidation. Flaxseed oil, like fish or soya oils, is subject to flavour reversion, which results in the appearance of a hay or straw-type flavour and is linked to the beginning of oxidation, preceding rancidity.... Flaxseed oil is recommended for cold uses, for seasoning salads or blended fruit juices. It can also be used as a cooking oil as long as the temperature does not exceed 150°C."

Conclusion and recommendations

Afssa considers that banning the sale of virgin flaxseed oil in France is not justified for several reasons.

Firstly, flaxseed oil has a nutritional interest in terms of alpha-linolenic acid content, secondly it is a product that has been on sale for a long time in many countries (Germany, Canada, China, etc.) without any adverse effects having been found.

It is necessary, however, that measures be taken concerning its packaging, storage and use that are more restrictive than the measures existing for more conventional oils, in order to limit oxidation of the product, namely:

- batch traceability, from the pressing of the seeds through to packaging, in order to optimise control over the shelf life (must not exceed one year, including consumption);
- a maximum package volume of 250 ml;
- nitrogen inerting before sealing the bottle;
- packaging in an opaque material;
- a best before period of less than 9 months.

Finally, Afssa recommends labelling with adequate information for the consumer:

- use only for seasoning;
- do not heat;
- store in a cool place before opening;
- refrigerate after opening;
- do not keep for more than 3 months after opening;
- not suitable for children under 3 years of age.

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