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OPINION

of the French Food Safety Agency on the assessment of a draft decree on the use of nutritional and physiological substances and of botanicals and botanicals preparations in the manufacture of food supplements

DIRECTOR GENERAL

In a letter dated 30 July 2007 and received on 3 August 2007, the French Food Safety Agency (Afssa) was requested by the Directorate General for Competition, Consumer Affairs and Fraud Control to assess a draft decree on the use of nutritional and physiological substances and botanicals and botanicals preparations in the manufacture of food supplements.

After consulting the "Human Nutrition" specialist panel on 22 November 2007 and 13 December 2007 and in conjunction with Afssaps, Afssa issues the following opinion:

Decree 2006/352 of 20 March 2006 on food supplements, which applies Directive 2002/46/EC, contains an application decree listing the ingredients permitted from product marketing authorisations. This decree forms the subject of thie request 2007-SA-0231. Dgccrf is requesting Afssa to assess the risks of use of the ingredients listed in the decree: 32 substances, 230 plant materials, 40 fungi and 14 algae. In view of the specific features of each of these categories of ingredient, this opinion relates to annex II on botanicals and botanicals preparations which are permitted for use in food supplements, excluding fungi, algae and other substances which will form the subject of subsequent specific opinions.

The questions raised relate in particular to terminology (article 2 of the decree), botanical characterisation of the botanicals (Annex II A), the use of essential oils with a weight limit of 10%, the nature of the extracts and solvents and specific conditions for use (Annex II C lists undesirable substances to be kept at the lowest possible levels).

As stated in Afssa's report "assessment process on the safety, utility and claims of foods containing botanicals intended for human consumption" (Afssa, 2003)[1] and particularly in its opinions of 8 February 2005 (Afssa, 2005a), 6 September 2005 (Afssa, 2005b), 15 November 2005 (Afssa, 2005c) and 6 January 2006 (Afssa, 2006), Afssa still has reservations about the use of a positive list approach in view of the characteristics and specific features of the botanicals and their preparations. In particular:

- the chemical composition of the botanicals may vary depending on the part concerned and species;
- the different types of extraction usually lead to preparations with very different compositions (polar/nonpolar solvent, distillation process etc.);
- the extraction processes may concentrate some active or undesirable substances;
- the essential oils obtained by distillation may naturally contain within their composition compounds with specific toxicity (and listed to this effect in annex II part C as undesirable substances to be kept to the lowest possible levels): it would not appear possible to use such essential oils in food if these compounds are naturally present in high proportions.

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[1] Annex 1 restates the decision making tree of this 2003 report.

- hindsight of use from traditional therapeutic applications and information available can no longer be taken into account as a result when the uses and methods of preparation are different from those used traditionally, as illustrated regularly by the incidents reported by drug safety monitoring (Afssa, 2007).

Afssa also draws attention to the need for consistency between national and European considerations firstly on food supplements containing botanicals, and secondly on medicinal products containing botanicals, as a prior structured authorisation framework which is inextricably linked to therapeutic activity can only be envisaged for the latter.
Current consideration by the European Medicines Agency (Emea) about botanicals-based medicinal products is based on an approach incorporating a precise definition of the raw botanicals materials, production/extraction conditions, therapeutic indications and conditions for use. This integrated approach is very different to the approach used for food supplements which, for example, does not as yet envisage a concomitant assessment of the claims with one of the safety of use of the products (the claims for the list of botanicals submitted which are variably formulated and can be found on various communication media, particularly the Internet, have not been assessed by Afssa).
EFSA is also thinking about the specific features of botanicals-based preparations (drawing heavily from the Afssa report) and about establishing an initial list of botanicals used both in foods and as medicinal botanicals.

According to Directive 2004/27/EC of 31 March 2004 relating to medicinal products for human use, “in cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply”. This stipulation has not to date been illustrated by precise examples intended to interpret and explain its application.

Because of their constituents, several botanicals for example appear in the register of laxatives which falls within the field of medicines governed by strict precautions for use, particularly in terms of duration of treatment and non-use in children. Moreover, the wording “do not use without medical advice” does not appear to be consistent with the principle of the widespread consumption of food products such as food supplements.
Finally, the pharmacognosy specialists consulted were occasionally astounded by the use of some parts of botanicals which have never to this point been known to have been used as medicinal botanicals.

1) The review of the definitions proposed in the draft decree raises the following comments:

Afssa considers the terminology “botanicals materials” to be appropriate as the term “botanicals drugs” is classically used for raw materials for medicinal products.

Afssa suggests that the definition of botanicals preparations be supplemented: “Preparations obtained **by reducing botanicals materials to a powder or treating them with a solvent,** distillation, pressure, fractionation, purification, concentration or fermentation extraction process”. Afssa considers that this concept of botanicals preparation does not extend as far as the production of pure substances (which would fall within the scope of annex I), even if the pure substances may be of botanicals origin.

The definition of essential oils excludes aromatic fractions obtained by dissolution in a solvent (used in the perfume industry), which is preferable.

Afssa suggests that for the definition of solvent, the importance of the quality of solvent be stated: “any solvent **of appropriate quality** used in the extraction process in the treatment of raw materials, foodstuffs, constituents or ingredients of these products which is removed and which may cause the unintentional but technically inevitable presence of residues or derivatives in the foodstuff or ingredient”. The quality of solvent is important particularly for extraction using recycled solvents.

Beyond the few clarifications listed above, Afssa notes that none of these general definitions states the wide range of preparations liable to be obtained from botanicals drugs as stated, for example, in the pharmacopoeia, the definition of botanicals materials stops at botanicals organs structured as tissues without considering fractions such as exudates or mucilages.

2) The botanical characterisation of annex II A raises the following comments:

Non-defined species often group together a collection of species of chemical compositions which can vary considerably. Botanical species should therefore be expressed more precisely.

The following comments are made strictly on the botanical appearance.

According to list A of the French Pharmacopoiea of traditionally used medicinal botanicals:

- *Allium* spp. to be replaced by *Allium sativum* L.
- *Citrus* spp. to be replaced by *Citrus aurantium* L. or *Citrus sinensis* (L.) Pers.
- *Cucurbita* ssp. to be replaced by *Cucurbita pepo* L. or *Cucurbita maxima* Lam.
- *Cymbopogon* spp. to be replaced by *Cymbopogon* sp.
- *Eucalyptus* spp. to be replaced by *Eucalyptus globulus* Lapill.
- *Fragaria* spp. to be replaced by *Fragaria* vesca L.
- *Lavandula* spp to be replaced by *Lavandula angustifolia* Mill., *Lavandula stoechas* L., *Lavandula latifolia* (L. f.) Medik., *Lavandula intermedia* Emeric ex. Loisel.
- *Thymus spp.* to be replaced by *Thymus vulgaris, Thymus zygis* L.*, Thymus serpyllum* L. *sensu latiore*
- *Malus* ssp. to be replaced by *Malus sylvestris* Mill.
- *Prunus* spp. to be replaced by *Prunus domestica* L., *Prunus avium* (L.) L., *Prunus cerasus* L., *Prunus dulcis* (Mill.) D. Webb var. *dulcis*
- *Rosa* ssp. to be replaced by *Rosa centifolia*, *Rosa damascena* Mill., *Rosa gallica* L., *Rosa canina* L., *Rosa pendulina* L.
- *Rubus* spp. to be replaced by *Rubus* sp.
- *Tilia spp.* to be replaced by *Tilia platyphyllos* Scop.*, T. cordodata* Mill.
- *Triticum spp.* to be replaced by *Triticum aestivum* L. and cultivars
- *Vaccinium spp.* to be replaced by *Vaccinium myrtillus* L.
- *Viola spp.* to be replaced by *Viola arvensis* Murray, *Viola tricolor* L.

For the other species not listed in the Pharmacopoiea:

- *Annona* spp. to be replaced by *Annona* sp. as many species can be consumed (*Annona muricata* L., *Annona squamosa*, *Annona cherimolia* Miller, etc.).
- *Coffea* spp. to be replaced by *Coffea arabica* and *Coffea canephora* Pierre ex. Fröhner.
- *Dioscorea* ssp. to be replaced by *Dioscorea* sp.
- *Elaeis* spp. to be replaced by *Elaeis guineensis* Jacq. or *Elaeis oleifera* (Kunth) Cortès.
- *Lupinus* spp. to be replaced by *Lupinus albus.*
- *Musa* ssp. to be replaced by *Musa parasidiaca* L.

Some names are stated twice: “jujube tree”, “costmary”, “meadowsweet”, “linden and little leaf linden”.
Harmonisation of the fruit names is required (blueberry etc.) and tree names (banana tree, nutmeg tree etc.). It is incorrect for blueberry and moorberry to appear under the name “bilberry”.
The scientific name of the papaya tree is *Carica papaya* L. and scientific name of sesame is *Sesamum indicum* L.

Some vernacular names are little known or unknown: “common winter-cress”, “dulse” “mungo bean”, ”arrowroot”, “hon-shimeji”, “bearded tooth”, “conifer tuft”, “pecan tree”, “hen of the woods”, etc.
Other names should be reformulated: “greater galangal” could be replaced by “Siam ginger”, “lesser galangal” by “Chinese galanga”; and for the name “edible burdock” the use of this type of name should be avoided as it may cause confusion.

3) The use of essential oils in food supplements raises the following comments:

Essential oils formed from highly lipophilic substances with strong powers of persistence, which are often irritant or even pro-convulsant and of frequently poorly understood toxicity, and are fractions defined as having considerable **PER** (botanicals/extract ratios) and very limited history of traditional oral use, should not be included in this list.
The known mutagenic effects of molecules which are widely encountered in essential oils and at variable concentrations depending on the varieties and chemotypes of the species used are such that the use of these "extracts" should undergo a detailed investigation by toxicologists (deliberations on this subject are ongoing at Afssaps).
Whilst the general definition of essential oil can nevertheless be kept within this decree, the weight content of 10% essential oils, which is entirely arbitrary, has no scientific basis.

4) The nature of the extracts and solvents used in food supplements raises the following comments:

Two sorts of botanicals should be distinguished:

- Species for food purposes which have a *true history of traditional* consumption in nature and are mostly used for their *nutritional benefit,* or as spices or flavourings.
Once consumed, all of the constituents stored within their tissues can be absorbed although the matrix effect can, to a greater or lesser extent, delay their diffusion within the gastrointestinal tract. Ingestion of the botanicals in food supplements under conditions which are very far-removed from their traditional food use or of extracts of these botanicals defined by the PER[2] no longer necessarily carries a similar level of risk.
It would appear therefore that spices used at low doses intermittently to bring out the flavour of foods do not have specific toxicity. However, to give an example, possible risks from a food supplement containing 200 mg of spice per capsule at a dose of 3 capsules daily for 1 week require specific assessment.

- *Species used for physiological benefit*, but which only have a tradition of use in some forms of low concentration aqueous or aqueous-alcoholic extracts, with an alcohol content not exceeding 30°V/V (infusions, decoctions, etc.) only enabling the most polar constituents contained initially in the botanicals material to be extracted.
For these species, consumption of the botanicals, powder or extracts obtained with more lipophilic (or nonpolar) solvents is liable to result in the ingestion of some constituents which cannot be based on history of use (for example wild pansey).

5) As an illustration, the following comments are made from **an examination of the list of botanicals and botanicals preparations** from annex IIB proposed by this decree relating particularly to the conditions of use or restrictions for use in food supplements:

***Aesculus hippocastanum* L.: Indian chestnut**
The use of the extract must take account of the anti-coagulant risk as stated in the restrictions for use listed, even if coumarines are contained primarily in the bark. This type of preparation is deemed to be a medicinal product by function by Afssaps (vasoconstrictor, anti-inflammatory).

[2] The PER reflects the *maximum order of concentration by which any of the constituents* of the raw plant material (normal metabolite or impurity) *may be enriched* following extraction.

***Aloe ferox* and *Aloe vera* (L.) Burm. f.: aloes**
Gel and juice do not have the same composition: the gel represents mucilages (no aloin) whereas the juice is a dried aqueous extract with laxative properties as aloin is potentially present. The juice is considered to be a medicinal product by function by Afssaps.

***Alpinia galanga* (L.) Wild:**
The rhizomes are used as spices and contain terpene constituents including methyleugenol. The amounts consumed as a food supplement are *a priori* far greater than the amounts commonly used as spices: only the amounts ingested from consumption as a culinary spice are considered to be validated by tradition.

***Anethum graveolens* L.:**
The term "seed" is incorrect and must be replaced by "fruit". The description of use of the root is unrecognised. The leaves and fruits contain estragol.

***Angelica archangelica* L.:**
The fruit and root contain coumarin (2 ppm) and furocoumarin, compounds present in list C of undesirable substances to be kept to the lowest possible levels.

Annona spp. to be replaced by ***Annona sp.:***
Pseudo-parkinsonian syndromes associated with consumption of annonaceae have been reported but not clearly elucidated. It should be noted that the botanicals and particularly the leaf contains acetogenins and alkaloids.

***Apium graveolens* L.:**
The leaf, fruit and root contain furocoumarins, compounds present in list C of undesirable substances to be kept at the lowest possible levels.

***Artemisia dracunculus* L.:**
The flower tips and leaves contain estragol, compounds present in list C of undesirable substances to be kept at the lowest possible levels.

***Barbarea praetox*:**
Use of the leaf is not known.

***Betula pendula* Roth. and *Betula pubescens* Ehrh.: birch**
The restriction for use stating the absence of pyrrolizine alkaloids has no scientific basis even in the context of risk of confusion with other species.

***Camellia sinensis* (L.) Kuntze: green tea**
In terms of drug safety monitoring incidents, 14 cases of severe hepatic toxicity have been reported with preparations other than strict aqueous extracts.

***Capsicum frutescens* L.: Cayenne pepper**
Only the amounts consumed as a culinary spice are deemed to be validated by tradition. An extract obtained by super-critical C02 would lead to almost pure capsaicin, a compound which appears in list C of undesirable substances to be kept at the lowest possible levels. A limit of 0.05 ppm/day of capsaicin was cited in the initial EFSA works.

***Carum carvi* L.:**
The term "seed" is incorrect and must be replaced by "fruit".

***Cassia fistula* L.:**
The cassia fruit contains rhein derivatives (anthraquinones). These compounds give the preparations laxative properties which are subject to strict precautions when use as a medicinal product.

***Chamaemelum mobile* (L.) All.:**
There is no justification for considering Roman camomile and wild camomile (*Matricaria recutita L.*) differently in terms of preparations of extracts.

***Cinnamomum camphora* L.: Camphor tree**
The chemistry of the leaf is different to that of the wood and root. The essential oil contains a high proportion of camphor, a compound present in list C of undesirable substances to be kept at the lowest possible levels.

***Cinnamomum cassia* Blume: Chinese cinnamon**
The chemistry of the bark is different to that of the leaf and flower. The essential oil contains a high proportion of cinnamic aldehydes and estragol, compounds present in list C of undesirable substances to be kept at the lowest possible levels. It should be noted that in the context of European deliberations on flavouring agents, discussions are taking place on the ingestion of coumarins from the use of cinnamon.

***Cinnamomum verum* J.S. Presl.: Ceylon cinnamon tree**
The chemistry of the bark is different to that of the leaf and flower. The essential oil contains a high proportion of estragol and methyleugenol, compounds present in list C of the undesirable substances to be kept at the lowest possible levels. It should be noted that in the context of European deliberations on flavouring agents, discussions are taking place on the ingestion of coumarins from the use of cinnamon.

Citrus aurantium* L.*:
The use of the leaf as botanicals materials or botanicals preparations is problematic as it contains synephrine: occasionally serious adverse cardiovascular effects have been reported in drug safety monitoring and Afssaps distributed a warning in the July 2005 drug safety bulletin. The essential oil raises the problem of the concentration of synephrine. The limit of 20 mg/day of synephrine was cited in the initial EFSA works.

Citrus reticulata blanco:
The use of the leaf as botanicals materials or botanicals preparations is problematic as it contains synephrine: occasionally serious adverse cardiovascular effects have been reported from drug safety monitoring and Afssaps distributed a warning in the July 2005 drug safety bulletin. The essential oil raises a problem of the concentration of synephrine. The limit of 20 mg/day of synephrine was cited in the initial EFSA works.

Coffea spp. to be replaced by ***Coffea arabica* and *Coffea canephora* Pierre ex. Fröhner:**
The same restrictions listed for *Cola acuminata* should be restated.

***Crataegus laevigata* (Poir.) DC. and *Craetaegus monogyna* Jacq. (Lindm)**: **Hawthorn**
Extracts from the flower tip are deemed to be a medicinal product by function by Afssaps (cardiac effect).

Cucurbita pepo* L.*:
The term “fruit” should be replaced by “fruit pulp”.

***Curcuma longa* L. and *Curcuma xanthorrhiza* Roxb.:**
Preparations from the rhizome are deemed to be a medicinal product by function by Afssaps.

***Cynara scolymus* L.*:* artichoke**
There is no tradition of eating the leaves except as a hepatotropic medicinal product.

***Daucus carota* L.:**
The essential oil from the root contains methyleugenol, compounds present in list C of undesirable substances to be kept at the lowest possible levels.

Dioscorea spp.* to be replaced by *Dioscorea sp.:
The botanicals extract is rich in diosgenin, the properties of which cause poorly identified hormone interactions.

***Elettaria cardamum* (L.) Maton:**
The essential oil of the fruit contains up to 50% eucalyptol, a compound present in list C of undesirable substances to be kept at the lowest possible levels. The fatty oil obtained from the seed is subject to a specific authorisation procedure as a food oil.

Eucalyptus globulus
The essential oil contains 70% eucalyptol, a compound present in list C of undesirable substances to be kept at the lowest possible levels.

***Filipendula ulmaria* (L.) Maxim.: Meadowsweet**
This botanicals contains salicylate derivatives. It is subject to precautions for use because of salicylate allergies and its anti-coagulant activity.

***Foeniculum vulgare* Mill *var vulgare:* Bitter fennel**
Preparations from the leaves are deemed to be a medicinal product by function by Afssaps (hepatotoxicity). They contain 10 to 12% estragol, a compound present in list C of undesirable substances to be kept at the lowest possible levels.

Garcinia cambogia:
Preparations from the fruit are deemed to be a medicinal product by function by Afssaps. The high content of hydrocitric acid causes hypoglycaemic activity.

***Glycine max* (L.) Merr.: Soya**
This botanicals contains phyto-estrogens in the seeds: Afssa recommends a maximum limit of 1 mg of isoflavones per kg body weight per day and recommends the following labelling "Not recommended for children under 3 years old or for women with a past family or personal history of breast cancer" (Phyto-estrogens reports, Afssa 2005d).

***Glycyrrhiza glabra* L.: Liquorice**
Preparations from the underground parts are deemed to be a medicinal product by function by Afssaps (risk of hypertension as stated in the restrictions for use in the list submitted). Liquorice is also used as a flavouring.

***Hamamelis virginiana* L.*:* Virginia Witch hazel**
Preparations from the leaves are deemed to be a medicinal product by function by Afssaps.

***Harpagophytum procumbens* (Burch.) DC ex Meisn.: Harpagophyton**
Extracts from the secondary tuberised root are deemed to be a medicinal product by function by Afssaps (anti-rheumatismal). Many adverse effects (nausea, headaches) and 1 case of liver injury have been reported in drug safety monitoring by Afssaps. A calcium inhibiting effect is suspected with adverse cardiovascular effects. A monograph is currently being written at Emea.

***Humulus lupulus* L.*:* Hop**
Read "8-pr**e**nyl**n**aringenin": *typographical correction*. This botanicals contains phyto-estrogens: Afssa recommends a maximum limit of 1 mg of isoflavones per kg body weight per day and recommends the following labelling "Not recommended for children under 3 years old or for women with a past family or personal history of breast cancer" (Phyto-estrogens reports, Afssa 2005d).

***Juniperus communis* L.:**
The essential oil (female cone, leaf and wood) has renal toxicity and must not therefore be used.

***Laurus nobilis* L.:**

The essential oil of the leaf contains methyleugenol, a compound present in list C of undesirable substances to be kept at the lowest possible levels.

***Levisticum officinale* Koch.:**
The essential oil of the roots contain furocoumarins, compounds present in list C of undesirable substances to be kept at the lowest possible levels.

Linum usitatissimum* L.*:
The oil from the seed can be added to food supplements provided that the intake of alpha-linoleic acid per recommended daily dose does not exceed 1 g and that the proportion of *trans-fatty acids -typographical correction* - does not exceed 1% of total fatty acids (Afssa, 2005e).

Lupinus spp. to be replaced by ***Lupinus albus*:**
A risk of cross-allergy with peanut oil may occur with the seed. The botanicals preparations should not contain alkaloids.

***Melilotus officinalis* (L.) Pall. Lam.:**
Extracts from the flower tips are deemed to be a medicinal product by function by Afssaps. Coumarin, which is contained within the composition appears in list C of undesirable substances to be kept at the lowest possible levels.

***Myristica fragrans* Houtt.:**
The seed and seed coating contain myristicin and safrol, compounds present in list C of undesirable substances to be kept at the lowest possible levels.

Ocinum basilicum* L.*:
The essential leaf oil contains 80% estragol, a compound present in list C of undesirable substances to be kept at the lowest possible levels.

***Origanum majorana* L. and *Origanum vulgare* L.:**
The leaves and flower tips contain thymol and carvacrol, compounds present in list C of undesirable substances to be kept at the lowest possible levels.

***Passiflora incarnata* L.** to be replaced by ***Passiflora edulis*: passion fruit**
Extracts from the aerial parts are deemed to be a medicinal product by function by Afssaps.

***Pimpinella anisum* L.: green aniseed**
The essential oil of the fruit contains estragol and furocoumarins, compounds present in list C of undesirable substances to be kept at the lowest possible levels. It also contains anethol.

Prunus spp. to be replaced by ***Prunus domestica* L., *Prunus avium* (L.) L., *Prunus cerasus* L., *Prunus dulcis* (Mill.) D. Webb var. *dulcis*:**
The chemical substances are very different depending on the species.

***Ruscus aculeatus* L.*:* Butcher's broom**
Preparations from the roots are deemed to be a medicinal product by function by Afssaps (vaso-constrictor, anti-inflammatory etc.).

S*alvia lavandulifolia* Vahl., *Salvia scalarea* L. and ***Salvia fructicosa* Mill.: Sage**
Extreme caution is required as this probably contains cetones which are generally pro-convulsant, particularly as areas of sub-species and chemotypes exist with a degree of variability. In particular, thuyones, camphor and eucalyptol are compounds present in list C of undesirable substances to be kept to the lowest possible levels.

***Satureja hortensis* L. and *Satureja montana* L.: Savory**
The essential oils from these botanicals are relatively similar and very rich in phenols: carvacrol and thymol. Carvacrol and methyleugenol are present in list C of undesirable substances to be kept at the lowest possible levels.

Solanum tuberosum* L.*:

This is the tubercle and not the rhizome.

Thymus spp to be replaced by ***Thymus vulgaris*****:**
The essential oil of the flower tips contains phenols. In the column of restrictions for use, the term "dry herb" should be replaced by "dry botanicals" as this may lead to confusion.

Vicia faba L.:
Patients deficient in Glucose-6-Phosphate deshydrogenase (G-6-PD) must not consume this botanicals (Afssa, 2006b).

Viola tricolor (cf. opinion 2007-SA-0171): **Tricoloured viola, wild pansy**
Consumption of *Viola tricolor* in its traditional form of use (infusion) or with aqueous extracts containing doses less than an equivalent of 1500 mg of dry botanicals/day do not carry risks. Ingestion of *Viola tricolor* in powder or in extracts obtained from any solvent other than water is inadvisable.

Zingiber officinale Roscoe:
This botanicals contains methyleugenol.

6) The list of undesirable substances to be kept at the lowest possible levels raises the following comments:

"Myristin" should be replaced by "myristicin". Myristin is another name for trimyristin or glycerol trimyristate. It is a triglyceride which has no relationship to the constituents of the essential oil of *Myristica fragans,* which is rich in myristicin, which is also found in toxic illicium species.

The following substances should also appear in this indicative list of undesirable substances: fenchone, pinenes, pinocamphone.

In conclusion, Afssa recalls that the assessment of the safety of a botanicals or botanicals extracts used in a food supplement can only be conducted appropriately via an evidence-based dossier describing the conditions of production and use of the substance and its chemical composition.
Afssa considers as a result that beyond the comments made the list proposed in this draft decree does not in itself constitute a guarantee in terms of consumer food safety for the use of botanicals and their preparations in food supplements.

Bibliography:

Assessment process on the safety, utility and claims for foods containing botanicals intended for human consumption (Afssa, 2003).

Opinion 2005-SA-0015 on a draft decree on food supplements (Afssa, 2005a).

Opinion 2005-SA-0186 on the assessment of a new version of the draft decree on food supplements (Afssa, 2005b).

Opinion 2005-SA-0327 on the assessment of the draft decree applying article D. 4211-11 of the Public Health Code establishing the list of botanicals or parts of medicinal botanicals listed in the pharmacopoeia which may be sold to the public by people other than chemists (Afssa, 2005c).

Safety and benefit report of phyto-estrogens in food – Recommendations (Afssa, 2005d).

Health risks and benefits report on *trans* fatty acids contained in foods– Recommendations (Afssa, 2005e).

Opinion 2005-SA-0211 on a request for a draft decree on the establishment of dossiers for substances and botanicals which may be used in the manufacture of food supplements (Afssa, 2006a).

Opinion 2006-SA-0033 on the request to produce dietary recommendations for people suffering from Glucose -6-Phosphate dehydrogenase deficiency (Afssa, 2006b).

Opinion 2007-SA-0171 on the use of botanicals which have been the subject of drug safety monitoring reports in food supplements: *Hoodia gordonii*, *Cimicifuga racemosae, Viola tricolor*, *Desmodium*, *Echinacea,* or *Polygonum multiflorum* (Afssa 2007).

List of medicinal botanicals from the French Pharmacopoiea X edition (2007).

Key words:
draft decree, food supplements, botanicals, substances with nutritional or physiological purpose

Director General of the French
Food Safety Agency

Pascale BRIAND

Annex 1: extract from the report "Assessment process on the safety, utility and claims for foods containing botanicals intended for human consumption "

USE OF BOTANICALS IN HUMAN FOODS FOR A PHYSIOLOGICAL PURPOSE

ASSESSMENT DECISION MAKING TREE