

**Partial Agreement
in the Social and Public Health Field
Accord Partiel
dans le domaine social et de la santé publique**



**GUIDELINES ON THE QUALITY, SAFETY AND MARKETING
OF PLANT-BASED FOOD SUPPLEMENTS**

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GUIDELINES ON THE QUALITY, SAFETY AND MARKETING OF PLANT-BASED FOOD SUPPLEMENTS

I. PREAMBLE

The market of plant-based food products is expanding strongly both in Europe and in other parts of the world. However, the way in which these products are presented to the public could frequently be improved. The rapid growth in consumption of these products and greater publicising of their potentially beneficial health effects must lead to the adoption of appropriate measures to reinforce consumer health protection and to make these products safer for health.

It is accordingly important to analyse the risks run by the consumer and to propose greater strictness in the area of scientific ethics so that such plant-based food supplements can be monitored. This is particularly important because they enjoy freedom of movement within the European Union area and are almost always available in various more or less specialised distribution sectors, by mail or over the Internet. The current situation poses a genuine public health problem and requires recommendations at European level capable of bringing order to this anarchy, which is mostly due to a lack of guidelines and the diversity of each state's legislation. In order to avoid accidents due to confusion between herbs and/or unsuspected molecular interactions, specific recommendations should be defined concerning safety and quality issues which imply a certain set of strict assessment.

The reasons for the increased consumption of food supplements appear to fall under two heads:

- socio-economic: people are living longer, are more highly educated, feel more responsible as individuals and are more active consumers who feel they are the managers of their health capital;
- behavioural: it has become a preference to use, where possible, only "natural" products in order to maintain a certain level of physical and intellectual health.

The consumer must therefore be offered products that:

- are safe;
- are perfectly defined and of properly controlled quality;
- offer a positive physiologic effect in a healthy person on the basis of convincing traditional usages and/or of strict scientific data,
- provide honest information for the consumer.

These guidelines thus constitute a scientific document whose purpose is to define the necessary level of requirements more accurately and to harmonise the conditions needed to maximise the consumer's safety and justify his or her interest in plant-based food supplements. Three fundamental criteria must be respected: safety, quality of the marketed product and transparency of information.

1. Which food supplements are covered by these guidelines?

1.1. Plants, whose chemical content has been shaped by thousands of years of evolution, produce two types of metabolites:

- primary metabolites: proteins, lipids, carbohydrates, vitamins, fibres, minerals;

the resulting products are generally intended with a nutritional aim and their use raises no serious problem;

- secondary metabolites: alkaloids, polyphenols, carotenoids, coumarins, quinones, terpenes, lignanes etc.; medicines containing them have been marketed and they are currently being increasingly used for physiological purposes; most such plants, which border on those used in herbal medicine, represent a genuine problem in that legislation concerning them in the area of plant-based food supplements varies widely from country to country or may even be non-existent.

These guidelines concern all plant-based food supplements, and special attention will be paid to the secondary metabolites of plants.

1.2. The products concerned by these guidelines are accordingly plant-based food supplements consumed for their nutritional and/or physiological properties. It should also be noted that plant-based food supplements sometimes also contain:¹

- vitamins and minerals, for which well-established scientific data exist and specific conditions of use in food supplements have been laid down at European Union level,²
- other substances, of animal or other origin, not covered by any specific provisions.

The diversity of the ingredients used can lead to interactions, with unpredictable consequences for consumer health. As a result, the safety requirements are all the more important as the product's complexity increases.

Consequently, these guidelines concern plant-based products consumed for a non-nutritional purpose, mostly derived from European herbal medicine and which differ significantly from vitamin and mineral-based food supplements.

These products are presented in a whole series of special forms, the content of which may employ all the constituents present in a given plant (powder) or a selection of certain groups of substances linked to the use of solvents of varying polarity; in such cases, by departing from traditional usage, this type of product may have a different impact on the organism and may endanger the consumer's safety.

¹A "nutritional or physiological" effect is mentioned in the European Union legislation, in article 2 of framework Directive n°2002/46/CE on the approximation of the laws of the Member States of the European Union relating to food supplements.

² Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States of the European Union relating to food supplements.

2. Important data and definitions

2.1. The European Union definition of "food supplement", which simultaneously covers products based on vitamins and mineral salts, certain animal products and certain plants, is set out in Article 2 of Framework Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, which states that food supplements are "foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquid and powders designed to be taken in measured small unit quantities".

2.2. The plant substances used are sometimes whole plants, usually parts of plants (roots, bark, flowery heads, leaves, flowers, fruit, seeds etc.), either whole or fragmented, but also juices removed by pressure or incision of the living plant (oleoresins, gums, latex etc) which have not undergone any specific treatment.

A plant-based food supplement will therefore be composed of plant substances or plant-based preparations and/or other nutrients, or of associations of several plant substances or plant-based preparations either combined with other ingredients or not.

2.3. Preparations may be obtained by treating plant substances, for example by extraction, distillation, expression, fractionation, purification, concentration or fragmentation. They include crushed or powdered plant substances, extracts, essential oils, juices obtained by pressure and treated exudates.

2.4. Physiology is the science that studies the generally normal functions, organ properties and tissues of living beings. Physiological activities in the context of a healthy individual are the normal functions in the body which keep it working. Contrary to medicines that concern disease, food supplements must therefore be designed with the beneficial aim in mind of ensuring the maintenance and metabolic and physiological functioning of an individual in good health. This is the principle of homeostasis. As a matter of fact, homeostasis is defined as the bodily situation of a healthy individual in whom his/her physiological activities are functioning between the limits considered as normal.

2.5. Knowledge of plant usage rests very largely on tradition, which varies from one country to another. In practice, tradition mainly concerns the methods of preparing the plant and the usual forms in which it is used, also including the question of dosage. The latter factor, together with the concept of 'history of use', provides information both about safety and about the desired physiological effect. If the plant is in longstanding use,³ in certain cases it will be less necessary to perform studies in man since it can be assumed to be effective as a result of long experience.

6. Risk assessment as regards health should make possible the identification of any potential danger involved in using the plant. It should be based on all the data

³ "Bibliographical or expert evidence to the effect that the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Community", article 16 quarter, c, from Directive 2004/24/EC, of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use

available in the latest scientific literature, should concern not only the plants themselves and the type of extract chosen but where appropriate also the individual chemical constituents present in the composition of the finished product, and should refer to pharmaco-toxicological and clinical data. Numerous parameters influencing the chemical profile of the consumption-oriented product as a result of the plants' distinctive properties may play an important role in the final quality and possibly in any risk to the consumer. Molecular interactions with other components or perhaps with medicines are also possible. The precautionary principle must be the rule in all cases to ensure health consumer protection.

II. GENERAL GUIDELINES

1. A plant-based food supplement is intended for a person with a normal physiological profile and is aimed at keeping that person in a state of homeostasis. In no case should it seek to deal with a pathological state, which belongs exclusively to the field of therapy.

The dividing line between "therapeutic effect" and "physiological effect", even if not always easy to pinpoint, must be kept constantly in mind because of the existence of an area of interface in which some constituents are present both in plants used for food and food supplement and in plants used as herbal medicine. These plants are called 'ambivalent herbs' as they can be used either in food supplements or in herbal medicines. Apart from the intended use and/or the claim made, also the dosage will be an important criterion to distinguish in between both application fields.⁴

2. There must be no reference to any preventive aim as food supplements are intended at most to reduce the risk factor of disease.

3. The scientific justification for the safety and purpose of the supplement must be based on all available data, including experimental studies, but should also refer to clinical and even epidemiological findings where they exist. In cases where the history of use in terms of duration and magnitude is substantial in Europe and where a longstanding traditional method of use is involved, some of the scientific proofs can be trimmed and the level of requirements reduced. It is particularly important to take account of tradition, which as a sort of popular wisdom has selected or eliminated certain types of preparations over the centuries on account of effects that are sometimes beneficial sometimes harmful. Therefore as soon as the product moves away from traditional usage, the level of scientific, toxicological and clinical requirements must be higher, as much for the safety in use, as for the physiological effect and consequently for the claim.

4. The basic criterion must be the product's safety. Each product must be prepared according to precise specifications covering all stages in the process, from description of the raw material to release of finished batches of the product. The description of the various stages must be sufficiently detailed to serve as a basis for industrial production and must be accompanied by a description of the in-house verifications that will be performed at each stage to enable the manufacturer to monitor and assess the product's quality.

⁴“(12) This Directive allows non-medicinal herbal products, fulfilling the criteria of food legislation, to be regulated under food legislation in the Community”, Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use;
Explanatory statement of the European Parliament on the directive 2004/24/EC

5. Public information and communication concerning these products must be fair, supported by scientific data or studies and make it possible to guarantee safety of use, so that the products' consumption is risk-free.

III. GUIDELINES ON SAFETY ASSESSMENT AND ON THE EVALUATION OF CLAIMS

1. Safety of use depends to a great extent on the quality of the finished product. However, it must also be assumed that the consumer possesses sufficient common sense to avoid, for example, the cumulative effects of ingesting similar products and to take note of the information supplied.

2. The level of safety must be as high as possible and be comparable in every case with that of other consumer products. The more the finished product departs from traditional food use (powders, extracts of varying degrees of selectivity), the more care must be taken to collect data that demonstrate its physiological value and the absence of risk. Where the preparation differs greatly from that in current usage, the manufacturer must prove the harmlessness of his product in a suitable argument presentation and pharmaco-toxicological file.

3. History of use may constitute one of the major criteria if the method of preparation is identical with, or as close as possible to, the traditional one.

4. Markers or tracers must be taken into account as these are essential tools able to provide proof of:

- quality: a tracer is a chemically-defined constituent of a plant useful for the performance of checks through its role in calculating the quantity of plant or preparation in the finished product;
- physiological effect: the biochemical nature of a marker allows an objective evaluation to be made of any influences on organic functions associated with the consumer's psychological and physical performance;
- absence of toxicity: this relevant indicator must be of a chemical, biological, clinical or epidemiological nature and explain with reasonable certainty the benefit to health, on which there must be general agreement in the scientific community.

5. The daily amount to be taken must be planned as precisely as possible since plant constituents, which may be highly concentrated in certain extracts, can sometimes reach intake levels causing pharmacological effects. The daily intake of plant substances used as such must take account of normal traditional usage. On the other hand, for special preparations, correlations must be established on the basis of the physiological markers present, but the more the manufacturing process leads to a chemically homogeneous group purified of its active constituents, the more the manufacturer will have to justify the recommended daily intake by both scientific and pharmaco-clinical explanation. However, it must be recognised that in some cases it will be difficult to assess the physiological effect with the aim of identifying the daily intake that can reasonably be recommended because it will be impossible to establish the existence of a daily intake-effect relationship and fix a minimum effective daily intake.

6. Although traditionally quite complex mixtures of plants are used, in the case of manifest deviation of traditional preparations, it is recommended to limit the number of different plants or plant preparations in the products in order to allow a correct chemical analysis.

7. Particular attention must be given to the characteristics of the potential differences between matrices, whose effect may alter digestive absorption and the bio-availability of the substances present as well as possible molecular interactions which may enhance risks.

8. Evaluation of the health claim must be consistent with the recognised physiological effect and the degree to which the claimed effect is demonstrated. However, the distinctive aspects of the use of plants are such that it should be possible to define a special level of health claims based *inter alia* on tradition, distinct from nutritional and other claims but akin to claims concerning functions that play a recognised role in maintaining the organism's normal physiological activities or in contributing to reduce risk's factor of disease. Finally, the degree to which any beneficial physiological effect is demonstrated varies according to the nature of the constituents present and the plant concerned.

9. The proofs required in support of claims:

- must be internally consistent;
- where based on tradition, must relay on generally recognised knowledge;
- must respect recognised scientific standards of statistical and biological significance;
- may be based on experiments *in vitro* and *in vivo*;
- may be obtained from several sources, including human intervention studies or even epidemiological studies, if available.

Claims must be compatible with the nature and extent of the proofs supplied. They must not imply that the product offered is the only means of helping to reduce a risk of disease.

10. In conclusion, a scientific assessment of the possible value of a given plant and of the risks of consuming it means that the fullest possible information must be available, for example in a monograph as outlined in outlined in Appendix 2.

IV. SPECIFIC GUIDELINES ON QUALITY CONTROL

1. A large number of parameters influence the chemical profile of the plant. In addition to the plant's variability, also transforming the plant into a raw extract, sometimes followed by selective extractions of particular components will result in preparations which are very different in terms of activity and risks.

2. Assessment of the physiological value and/or safety of a plant, its components and the finished product must allow for the distinctive characteristics of plants. The diversity of plants in terms of species, variety, ecotype and chemo type, and also those linked to agricultural practices (contaminants, pesticides etc.), means that there are plants available which can be very similar botanically but which present very

different compositions. Another important factor concerns the extraction stage. It seems clear that the type of solvent plays an essential role by selecting ranges of lipophile and/or hydrophile substances with consequently differing activities; as does also the control of various technological parameters (duration, temperature etc.). New extraction methods have appeared, such as those employing supercritical gases and leading to chemical profiles that deviate little by little from those produced by traditional extraction methods (water, alcohol etc.).

3. These effectiveness and risk factors associated with quality control of the finished product require the drawing up of specifications and the performance of strict checks at different stages. The required levels are indicated in Appendix 1 (guide to setting up the manufacturing file). These checks must include:

- strict identification of the plant raw material;
- determination of all relevant data concerning its past: origin, harvesting period, cultivation method, contaminants etc.;
- involvement of the supplier in order to ensure traceability;
- detailed description of the manufacturing process and of the checks performed at the various stages;
- specifications that can be linked to standard references;
- validation of standardisation criteria based on a judicious choice of markers and the resulting physico-chemical specifications;
- a stability study of the raw materials and of the finished product in its packaging;
- drawing up specifications concerning batches of finished product intended for the consumer;

These stages taken as a whole govern the quality of the finished product, bearing in mind that the qualitative and quantitative composition may be affected during the various operations.

V. GUIDELINES ON INFORMATION

1. In order to inform the public, the manufacturer must be able to answer the questions about the product concerning :

- its anticipated uses
- its purpose
- the existence of population at risk
- the information available on foreseeable consumption
- the geographic limitation of its use, when appropriate

It is possible to envisage a consumption monitoring programme aimed at reassessing, if necessary, the level of exposure to the product, so that any undesirable effects may be detected.

2. The conditions of use must require the consumer to be informed as clearly as possible when buying a product, and with the maximum transparency, about:

- the exact centesimal formula of the product;
- the exact nature (the most precise scientific denomination – variety, chemotic-part used) of the plants and/or the type of extracts present;
- the conditions of use with, *inter alia*, the population category at which the product is aimed: period of use, the maximum permitted daily amount, when possible the optimum amount to be consumed to obtain the desired effect, the use-by date and other user advice in terms understandable by the public, particularly persons for whom the use of such products is not recommended (infants, pregnant women, diabetics, hypertensive individuals etc.);
- possible interactions with certain medicines or food ;
- special features of the claims, which must in no case refer to the prevention, treatment or cure of a given pathology, or mention such properties.

3. In consequence, apart from labelling obligation, including conditions of use, information to the consumer can include further detailed instructions concerning the product in the packaging.

4. Such information:

- must be unambiguous and understandable by the average consumer and be not misleading to the consumer;
- must not encourage over-consumption of the product at the expense of other products;
- must include information about target groups or potentially vulnerable categories of the population;
- must provide information about the way to use the product;
- may refer to scientific and empirical or traditional data based on adequate and undisputed literature;
- may give the references of a website to which the consumer can go for a useful and constructive dialogue.

Finally, labelling and advertising must not be likely to create confusion in the consumer's mind. Therefore they must comply with the general guidelines on labelling and advertising.

VI. PERSPECTIVES AND RECOMMENDATIONS

These guidelines are a first step in the analysis of the quite particular subject of plant-based food supplements. They include practical general recommendations for manufacturers, aimed at protecting consumers' fundamental right to health and safety.

It is the vocation of the 46 member states Council of Europe to take an interest in public health, not only in a general interest ethical and social context, but at the individual human level.

A very large number of specific questions remain open, of course, which these guidelines do not address, and these will require further, in-depth consideration at different levels. Here, therefore, are a few ideas to which more thought may be given:

1. On a general conceptual level:

- the exact positioning of plant-based food supplements, proposing a more tangible approach to the interface between food and medication;
- listing particularly vulnerable population groups, who are at risk when consuming certain categories of plants or substances and to whom recommendations should be addressed;
- evaluation of acceptable claims made about specific plants, based on available information about their traditional uses, and on up-to-date scientific data;
- preparation of a communication tool for the industry, in order to keep advertising within bounds, and implementation of an information network including the emergence of a new discipline: “nutrivigilance” (monitoring of nutritional safety);
- the desirability of developing marketing and consumption monitoring, which necessitates careful consideration of the approach to be used and the prospects of success.

2. On a scientific and technical level:

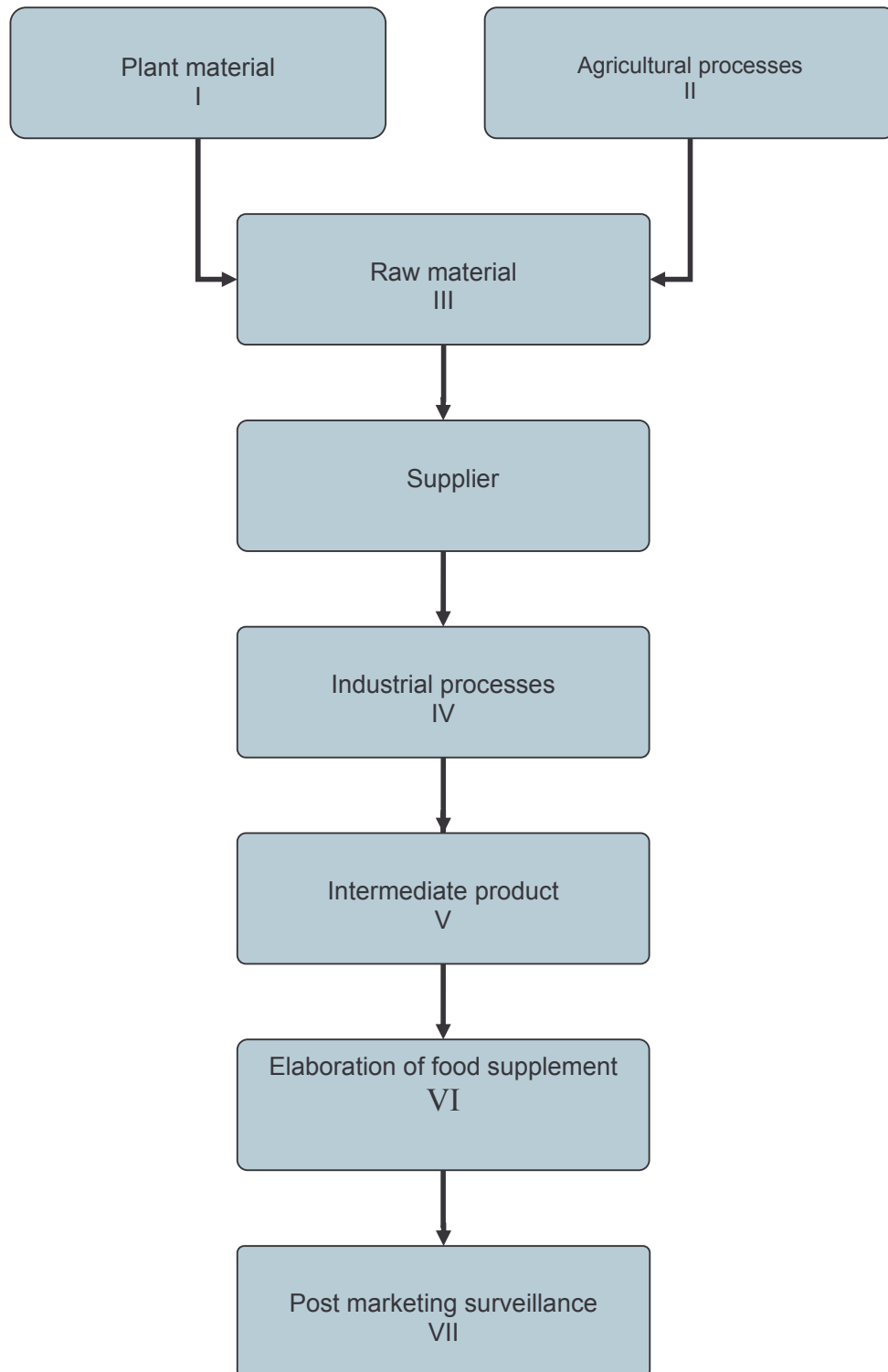
- Implementation of a product assessment methodology based on the desired physiological impact, highlighting the product’s safety and efficacy and stating what means should be used for each plant, particularly in respect of toxicological requirements.
- Two lists of plants should be drawn up:
 - a positive list containing plants whose usage is traditionally accepted for nutritional and/or physiological purposes and whose safety has been established by scientific risk assessment; this list should be prepared on the basis of data available to every expert and of a scientific plant-by-plant assessment which may result in the definition of specific conditions of use, in particular concerning forms of use and of extraction and maximum doses;
 - a list of plants which present risks to health and whose use must be banned for food supplements.

The content of these two lists is unlikely to be exhaustive and will almost certainly evolve as new scientific data become available.

- Recommendations should be made concerning certain categories of product, such as essential oils, which are receiving increasing media attention, and which could expose consumers to risks in the event of incorrect or prolonged use. The same applies to certain special or enriched extracts. Recommendations adapted to each individual case should also be issued concerning products available to consumers which contain special groups of molecules (bioflavonoids, sterols, coumarins, etc.). Finally, the requirements set for the finished products also need to be completed and made more detailed.

In conclusion, with pragmatism, common sense and scientific rigour it should be possible, in the interests of European public health and the consumer, to market increasingly reliable, risk-free plant-based food supplements.

**Specifications :
Important stages and quality-level requirements**



Content of the specification headings

These headings are for indication only, they can change according to the nature of the product.

- I - Scientific name (botanical family, genus, species, variety with author's name)
 - Common names
 - Possible chemotype
 - Part used
 - Geographical origin (continent, country, region)
 - Plant state (wild or cultivated)
 - Plant-health treatments
 - Good farming practices
 - Possible adulteration

- II When possible:
 - Place of harvesting, collection date, plant state
 - Drying, fermentation
 - Drying and fermentation conditions
 - Storage conditions
 - Plant-health or other treatments
 - Supplier's letter of engagement (traceability)

- III - Specifications according to standard reference (pharmacopoeias etc.) including
 - identification tests: botanical characteristics including morphological, anatomical, and/or organoleptic characteristics by means of ao. macroscopy, microscopy, micro-chemistry, *in vitro* method, chromatographic or spectroscopic tests such as HPLC/GC/TLC profiles etc
 - dosage:
 - * constituents responsible for beneficial effects or possible markers
 - * constituents responsible for undesirable effects (investigation of foreign toxic substances: alkaloids etc.)
 - analysis of purity: foreign elements, heavy metals, pesticides/herbicides, microbial contamination, radioactive materials etc.

- IV
 - Manufacturing process: principal stages, parameters and checks during manufacture, size of industrial batches
 - Stages of preparation: extraction processes, solvents, reagents etc.
 - Special precautions: light, temperature etc.
 - Specifications of material used
 - Validation of process
 - Analysis reports
 - Storage conditions
 - Packaging and labelling
 - Manufacturer's letter of engagement

- V**
- Standardisation criteria of the intermediate product and the finished product:
 - markers = physiologically active or toxic constituents, or selected other constituents
 - plant-extract ratio
 - Validated measurement dosage of active constituents or markers
 - Specifications: quantitative levels required for markers
 - Physico-chemical properties of important constituents (stability)
 - Purity criteria (microbiology, heavy metals, residual solvents, other contaminants)
 - Excipients: quantitative and qualitative aspects
 - Justification of formulation
 - Storage conditions
- VI**
- Defining the food matrix: stability, bio-availability etc.
 - Process impact on food matrix
 - In process and end product control
 - Specifications of product before release of batch
 - Drawing up of manufacturer's internal monograph
 - Nature of routine checks used
 - Microbiological test
 - Stability study of intermediate and finished product (real and/or accelerated time)
 - Interactions between container and content
 - Analysis of batches: date and place of manufacture, date of checks, size and use of batches, use-by date
 - Conservation conditions
- VII** Post marketing surveillance if possible

Outline of a monograph for assessment of the value and safety of a plant

1. Botanical data

State usage if there is a difference between food supplements and medicines

- complete scientific name and family
- synonym and common name
- part used
- geographical origin and production
- monographs available (Pharmacopoeias, ESCOP, WHO etc.)
- risks of adulteration by a toxic neighbouring species

2. Chemical constituents

State use if there is a difference between food supplements and medicines

- molecules present classified by groups and chemical affinities (eg. flavonoid, alkaloid etc.)
- quantitative incidence (methods?)
- possible influence of cultivation practices on composition

3. Pharmacology

WHERE POSSIBLE, INDICATE SOURCE REFERENCES

- human pharmaco-clinical: properties described, galenic forms used, method of administration, dosages
- experimental *in vivo* : properties described, animal species, galenic forms used, dosage, method of administration
- experimental *in vitro*: properties described on single organs and/or cellular impact etc., galenic forms used, dosages, solvents
- molecular: nature of tested molecule, molecular targets, experimental conditions and results
- pharmaco-kinetic data

4. Toxicology

WHERE POSSIBLE, INDICATE SOURCE REFERENCES

- symptomatology described, galenic forms and/or substances used, doses etc.
- available drug-monitoring data
- overdoses

5. Normal conditions of use

State usage if there is a difference between food supplements and medicines.

- galenic forms: powder, type of extract (totum and/or specific)
- indications and doses used in the form of medicines
- claims and doses proposed in the form of food supplements
- history of use and country of use

6. Identification of warning points

- Proven or potential toxicity of constituents (carcinogenicity, mutagenicity, teratogenicity, allergenicity etc.) or of molecular interactions
- Possible side-effects
- Possible counter-indications (pregnancy, breast-feeding, paediatric use, conduct of machines etc.)
- Risks connected with galenic forms (extracts)
- Interactions between medicines
- Questions concerning the claim

7. Bibliography

Bibliographical references

- 1) "Démarche d'évaluation de la sécurité, de l'intérêt et de l'allégation des denrées alimentaires, contenant des plantes, destinées à la consommation humaine"

(Framework for the evaluation of the safety, the effect and the claims of foodstuff made from plants for the human diet)

Publication AFSSA, 2003

- 2) Guidance for the safety assessment of botanicals and botanical preparations for use in food and food supplements, ILSI, August 2003

Appendix 4**Liste of ad hoc Group members on food supplements****BELGIUM/BELGIQUE**

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