



## BOTANICAL PREPARATIONS QUESTIONNAIRE

### IDENTIFICATION

- Manufacturer:  
[ ..... ]
- Distributor/Sales representative:  
[ ..... ]
- Botanical preparation commercial name:  
[ ..... ]

### 1. INFORMATION RELATING TO THE PLANT

#### 1.1. Plant name

- 1.1.1. Scientific name (Latin name, family, genus).  
Variety and chemotype where necessary:

[ ..... ]

Common (vernacular) name:

[ ..... ]

- 1.1.2. Risk of adulteration:

☐ No

☐ Yes

*[ Specify if a risk of adulteration exist with other species of the same genus or other genus of the same family or other plants containing for instance similar active constituents or other plant parts (for instance use of the leaf, partially or completely, instead of the root )*

- 1.1.3. Cultivated or wild variety:

☐ Cultivated

☐ Wild

#### 1.2. Place of harvesting / collection

- 1.2.1. Country / Region (Specify country and if possible region):

[ ..... ]

- 1.2.2. Specific authorisations (e.g. licences, official authorisations, etc):

[ ..... ]

- 1.2.3. Where applicable, information relating Regulation 338/97 on the protection of species of wild fauna and flora (or to the Convention on International Trades in Endangered Species of Wild Flora and Fauna (CITES)):

☐ Not applicable



☐ Applicable

*[ Specify: ..... ]*

**1.3. Method of harvesting / collection:**

☐ Manual

☐ Mechanical

**1.4. Period of harvesting / collection:**

*[ Specify the month or months during which harvesting /collection took place]*

**1.5. Stage of harvesting / collection:**

*[ indicate the stage of plant growth at the time of harvesting / collection]*

**1.6. Process used for drying:**

*[ Specify: (e.g. external, internal, open air, drying with gas, fuel, wood, etc ...) ]*

**1.7. Treatments (e.g. phytosanitary) applied:**

- Before harvesting / collection:

☐ No

☐ Yes

*[ Specify: ..... ]*

- After harvesting / collection:

☐ No

☐ Yes

*[ Specify: ..... ]*

**GACP form (Good Agricultural and Collection Practice - For example: EUROPAM Batch Document):**

☐ Not available

☐ Available

**(Attach the document)**

**2. PLANT PART OR PRODUCT USED**

☐ Aerial part

☐ Fruit

☐ Flower

☐ Seed

☐ Leaf

☐ Bark

☐ Exudate

☐ Other

*[ Specify: ..... (e.g. flowering tops, juice, buds, etc) ]*

☐ Underground part

☐ Root

☐ Rhizome

☐ Bulb

☐ Other

*[ Specify: ..... ]*

☐ Complete plant (including both aerial and underground parts)

*[ Specify: ..... (if relevant) ]*

### 3. BOTANICAL PREPARATION<sup>1</sup>

#### 3.1. Preparation type

- ☐ Comminuted or dried herb   ☐ Powder
- ☐ Liquid extract   ☐ Tincture   ☐ Macerate
- ☐ Soft extract   ☐ Oleoresin   ☐ Essential Oil
- ☐ Dry extract   ☐ Other

*[ Specify: ..... ]*

#### 3.2. Manufacturing process:

- ☐ Cutting/Comminuting/Grinding
- ☐ Pressing
- ☐ Distillation
- ☐ Extraction

Process:

*[ Specify the extraction process (dry/liquid: maceration, percolation, etc.) ]*

Solvents used:

*[ Specify: ..... ]*

- ☐ Purification Process:

*[ Specify process of purification (liquid/liquid, chromatographic, etc...) ]*

Solvents used:

*[ Specify: ..... ]*

- ☐ Other process(es):

*[ Specify the process used (e.g. biotechnological, culture cellular, etc...) ]*

#### 3.3. Ratios:

- Ratio dried plant / native extract<sup>2</sup>:

<sup>1</sup> Definition of Botanical preparation: All preparations obtained from botanicals by various processes (e.g. pressing, squeezing, extraction, fractionation, distillation, concentration, drying up and fermentation). These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.



[ Specify: ..... ]

- Ratio dried plant / final extract<sup>3</sup>:

[ Specify: ..... ]

**Attach a flow chart describing the ingredients manufacturing process, including In Process Controls (IPC)<sup>4</sup>**

**3.4. Country / Region:**

*[ Specify the country, region or manufacturing plant where the manufacturing or extraction took place (and not the location where the product was repacked, diluted or labelled). ]*

*Where relevant, attach a certificate of origin ]*

**3.5. Full composition<sup>5</sup> of the preparation (including additives<sup>6</sup> and other food ingredients)**

Ingredient	Theoretical %	Type and function
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....

<sup>2</sup> The native extract ratio corresponds to the ration between the quantity of the plant and the extract yield from the extraction / transformation (before addition of any compounds, such as technological additives, carriers or dilution matrix)

<sup>3</sup> The final extract ratio corresponds to the ratio between the plant and the extract as commercialised (with technological additives and other food ingredients added)

<sup>4</sup> The Flow Chart must enable

- to visualise the raw materials used plant, solvents, additives or other substances), the main steps in the manufacturing and the controls that are implemented during manufacturing to verify that the process is applied in a correct way.
- to verify the conformity of the solvents used (Directive 2009/32, and where appropriate European pharmacopeia 2.4.24 (Method) or 5.4 (Limits))
- to verify the conformity of the described processes (purification steps or elimination of hazardous compounds or use of non traditional extraction techniques). The processes and extraction solvents considered as traditional are usually included in Pharmacopeia monographs. These include for example maceration, infusion, lixiviation, percolation, decoction, etc.

<sup>5</sup> Specify the full composition (quantity of native extract, additives, bulking agents, etc), the levels in the product as well as their function. The product specifications file must indicate the composition.

<sup>6</sup> Additives in the sense of food law includes carriers





.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....

Contaminants and residues of the preparation <sup>7</sup>		Control				Level / Limit	Reference, method of analysis, Accreditation (external/internal)
		Plant		Preparation			
		Lot	Plan	Lot	Plan		
Residual Solvent <sup>8</sup>	....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	....	....
	....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	....	....
	....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	....	....
Heavy metals <sup>9</sup>	Pb	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	....	....
	Cd	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	....	....
	Hg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	....	....
	Others (e.g As)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	....	....
robiol	Total plate count	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	....	....

<sup>7</sup> Specify where applicable if control is performed on the plant or on the preparation and if control is applied on lot basis or according to a control plan.

Where applicable, as a result of analysis of the botanical raw material used for production and in view of the production process, tests for microbiological quality, contaminants and residues in the botanical preparation may / may not/ be necessary.

It is not needed to tick a box if it is not applicable.

When certain residues or contaminants are subject to a periodic monitoring, the control plan must be attached.

<sup>8</sup> Solvent residues (except for aqueous extracts) in accordance with Directive 2009/32 and, where appropriate, European Pharmacopeia 2.4.24 (Methods) – 5.4 (limits).

<sup>9</sup> Reference texts: Regulation 1881/2006 and Regulation 629/2008 and European Pharmacopeia: 2. 4. 27 (methods) + monograph 1433 « herbal drugs » (limits).

In addition to Lead, Cadmium and Mercury, other compounds usually tested (iodine, arsenic, ...) can also be indicated, where relevant or legally required.

<sup>10</sup> Reference texts: European Pharmacopeia 5.1.8 B and C (limits) – European Pharmacopeia 2.6.12 and 2.6.31 (methods).

Indicate the specifications and the methods of analysis. If internal methods are used, specify if the methods are validated.

Yeasts and moulds	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....
Enterobacteriaceae (Bile-tolerant gram-negative bacteria)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....
<i>Escherichia coli</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....
<i>Salmonella</i> spp	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....
Others (e.g. <i>Staphylococcus aureus</i> , <i>Pseudomonas aeruginosa</i> , ...)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....
Pesticides <sup>11</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....
Mycotoxins (e.g. Aflatoxins B1, B2, G1, G2, Ochratoxin A) <sup>12</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....
Polycyclic Aromatic Hydrocarbons (PAHs) <sup>13</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....
3-MCPD (3-monochloropropanol-1,2-diol) <sup>14</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....
Nitrate <sup>15</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....
Dioxins and PCBs (Polychlorobiphenyls) <sup>16</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....
Melamine and other structural analogues <sup>17</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....
Radioactivity (if relevant)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	.....	.....

Attach the control plan where appropriate

### 3.6. Genetical modification

<sup>11</sup> Reference texts: European Commission database + Regulation 396/2005 for Maximum Residue Limits (MRL) ([http://ec.europa.eu/sanco\\_pesticides/public/index.cfm](http://ec.europa.eu/sanco_pesticides/public/index.cfm)) or where relevant: European Pharmacopeia 2.8.13. Specify Under “ Type “ the reference applied (Regulation 396/2005, Ph. Eur., etc.) and under “ accreditation “ if the laboratory performing the analysis is accredited.

<sup>12</sup> Reference texts : Regulation 1881/2006, specifying maximum limits for aflatoxine B1, total aflatoxins, ochratoxin A, patulin, zearalenone, fumonisins and toxins for a number of food. These limits take into consideration the level of contamination generally observed. European Pharmacopeia 2.8.18 (aflatoxine B1) and 2.8.22 (ochratoxine A).

<sup>13</sup> PAH/benzopyrene. Reference text: Regulation 1881/2006.

<sup>14</sup> Reference text: Regulation 1881/2006

<sup>15</sup> Reference text: Regulation 1881/2006

<sup>16</sup> Reference text: Regulation 1881/2006

<sup>17</sup> Reference text: Regulation 1881/2006 + the EFSA opinion on melamine in food and feed. EFSA Journal 2010; 8(4):1573, <http://www.efsa.europa.eu/de/efsajournal/doc/1573.pdf>

- Specific labelling on the presence of GMO derived ingredients<sup>18</sup>:

☐ No

☐ Yes

*[ Specify the specific components. Where relevant, attach a certificate. ]*

### 3.7. Treatment of raw materials

- One or more components have been treated by irradiation<sup>19</sup>:

☐ No

☐ Yes

*[ Specify ..... ]*

- One or more components have undergone another treatment<sup>20</sup>:

☐ No

☐ Yes

*[ Specify ..... ]*

### 3.8. Presence of allergens (from raw materials or processing aids)<sup>21</sup>:

☐ Allergens absent

☐ Allergens present (Specify below:)

**Allergen**

**Present**

<sup>18</sup> Reference texts: Regulation 1829/2003 and Regulation 1830/2003.

The information can be included directly in the questionnaire and an additional certificate is not necessary, given the signature to comply.

It is noted that in accordance with Regulation 1830/2003 products consisting of or containing GMOs must contain the following statement on the label : 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]'

<sup>19</sup> Reference texts: Directive 1999/2 and Directive 1999/3.

The information can be included directly in the questionnaire and an additional certificate is not necessary given the signature to comply.

It is noted that in accordance with Directive 1999/2 Ingredients treated with ionising radiation shall be indicated in the list of ingredients accompanied by the words 'irradiated' or 'treated with ionising radiation'.

<sup>20</sup> e.g. fumigation by ethylene oxide or other fumigants such as phosphine or methyl bromide performed outside EU in 3rd countries.

<sup>21</sup> Reference text : Regulation 1169/2011.

The information can be included directly in the questionnaire and an additional certificate is not necessary given the signature to comply

It is noted that it is obligatory to mention the presence of any ingredient or processing aid containing or derived from a substance or product listed in Annex II of Directive 1169/2011 used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form. The name of the substance or product as listed in Annex II shall be emphasised through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example by means of the font, style or background colour

The information can be completed by e.g. specifying the total absence in the manufacturing plant.

<b>Cereals containing gluten</b> , namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof, except wheat based glucose syrups including dextrose *, wheat based maltodextrins *, glucose syrups based on barley, and cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin. * And the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by EFSA for the relevant product from which they originated	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Crustaceans and products thereof</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Eggs and products thereof</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Fish and products thereof</b> , except fish gelatine used as carrier for vitamin or carotenoid preparations, and fish gelatine or Isinglass used as fining agent in beer and wine	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Peanuts and products thereof</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Soybeans and products thereof</b> , except fully refined soybean oil and fat *, natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources, vegetable oils derived phytosterols and phytosterol esters from soybean sources, and plant stanol ester produced from vegetable oil sterols from soybean sources	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Milk and products thereof</b> (including lactose), except whey used for making alcoholic distillates including ethyl alcohol of agricultural origin and lactitol	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Nuts and products thereof</b> , namely: almonds ( <i>Amygdalus communis</i> L.), hazelnuts ( <i>Corylus avellana</i> ), walnuts ( <i>Juglans regia</i> ), cashews ( <i>Anacardium occidentale</i> ), pecan nuts ( <i>Carya illinoensis</i> (Wangenh.) K. Koch), Brazil nuts ( <i>Bertholletia excelsa</i> ), pistachio nuts ( <i>Pistacia vera</i> ), macadamia or Queensland nuts ( <i>Macadamia ternifolia</i> ), except nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Celery and products thereof</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Mustard and products thereof</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Sesame seeds and products thereof</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Sulphur dioxide and sulphites</b> at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO <sub>2</sub>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Lupin and products thereof</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Molluscs and products thereof</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No

### 3.9. Nanomaterials

- One or more components are present in the form of engineered nanomaterials:<sup>22</sup>

☐ No

☐ Yes

[ Specify ..... ]

<sup>22</sup> Article 2.2(t) of Regulation 1169/2011 defines ‘engineered nanomaterial’ as « any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale. Properties that are characteristic of the nanoscale include:

(i) Those related to the large specific surface area of the materials considered; and/or

(ii) Specific physico-chemical properties that are different from those of the non-nanoform of the same material »

It is noted that all ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word ‘nano’ in brackets.

## 3.10. Purity criteria of the additives (including carriers)

Additive	Covered by Regulation 231/2012		Conform with Regulation 231/2012	
.....	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
.....	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No
.....	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No

## 4. ANALYTICAL DATA OF THE BOTANICAL PREPARATION

Attach the product specifications file (PSF)<sup>23</sup>

- Monograph: ☐ Internal  
[ Specify ..... ]
- ☐ Official  
[ Specify ..... ]

## 4.1. Physico-chemical characterisation: data from the PSF

## 4.1.1. Organoleptic properties (appearance, odor, color, ...):

[ Specify the analyses performed ]

## 4.1.2. Identity (TLC, HPLC, ....):

[ Specify the analyses performed ]

<sup>23</sup> The product specifications of the supplier of a botanical preparation must at least contain the following information:

- Name of the preparation
- Scientific name of the plant and plant part or product used.
- Description: extraction solvent and titre (with specification of the extraction method), ratio P/native extract, composition (Types and levels of additives present)
- Organoleptic characterisation: appearance, odor, color identification (TLC, HPLC, ...)\*
- Tests \*
- Loss on drying, total ash, dry residue, viscosity, turbidity, etc
- Assay: markers \* / Reference document: Annex I (heading: Substances requiring monitoring, restrictions...)
- Assay: substances subject to restrictions of use \*

\* The reference of the methods of analysis applied needs to be specified (Pharmacopeia, internal methods etc).

In case the botanical preparation (or where appropriate the plant) is not in a Pharmacopeia (Eur, Ph., French, DAB, USP...), the methods for identification and dosage must be included in the submission, as well as their validation.

Reference document: Annex I (heading : substances requiring monitoring, restrictions...), Where relevant, consult the EFSA compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements. EFSA Journal 2012;10(5):2663.

<http://www.efsa.europa.eu/en/efsajournal/doc/2663.pdf>

The absence of quantification of a substance must be justified. Technical arguments or arguments based on bibliographic references can be sufficient.

Analytical results must confirm the values of the specifications files and be available for each of the lots supplied. It must be specified if the preparations has been subject of an official or internal monograph and the reference must be provided

4.1.3. Tests (e.g. ash, viscosity, ...):

*[ Specify the analyses performed ]*

4.1.4. Dosages (substances to be monitored, Ethanol content. ...)

*[ Specify the analyses performed ]*

4.1.5. Purity tests (residues, relative density, microbiological results, etc)

*[ Specify the analyses performed ]*

## 4.2. Substances to be monitored

4.2.1. Markers<sup>24</sup>

Type	Content limit	Method (HPLC, UV-VIS, GC, ...)	Standard (expressed as .....) / wave length of reading	Reference, official method / internal method	Validated
....	....	....	....	....	....
....	....	....	....	....	....
....	....	....	....	....	....

4.2.2. Compounds that are subject to restrictions of use<sup>25</sup>

Type	Content limit	Method (HPLC, UV-VIS, GC, ...)	Comments
....	....	....	....
....	....	....	....
....	....	....	....

## 5. STORAGE, PACKAGING, TREATMENT, TRANSPORT OF THE BOTANICAL PREPARATION

5.1. Storage conditions

*[ Specify the optimal conditions for Storage and conditions applicable to storage ]*

5.2. Retest period<sup>26</sup>

<sup>24</sup> Markers / tracers / active compounds in the preparation. Specify for each of the markers the identity, nature, minimum and/or maximum levels and method of assay (UV, HPLC, UPLC, GC, GC-MS, quantitative TLC, etc...). Specify the standard used and a brief description (e.g. C18 - 210nm, HPLC as cyaniding, etc). Specify if the method is internal (in case an official method does not exist) or official. Analytical results must confirm the values of the specifications files and be available for each batch supplied.

<sup>25</sup> Where applicable, as with markers and tracers, specify the substances that are subject to restrictions of use, level and method of analysis, etc. Where not applicable, justify the reason Under the heading “ comments “.

<sup>26</sup> The dates of the reanalysis are usually determined on the basis of the results of stability studies available. The supplier needs to justify the date of recontrol of the preparation

- Stability data:

☐ No

☐ Yes

*[ Specify ..... ]*

### 5.3. Homogenisations (sampling, use)

- Required before sampling:

☐ No

☐ Yes

*[ Specify ..... ]*

- Required before use:

☐ No

☐ Yes

*[ Specify ..... ]*

### 5.4. Labelling / Conditions for transport and storage

*[ Specify ..... ]*

### 5.5. Packaging

- Type:

*[ Describe the container ]*

- Food contact material safe for use in food (certificate):

☐ No

☐ Yes

### 5.6. Other information

- Linked to packaging (e.g. desiccant, nitrogen):

.....

- Indicated?

☐ No

☐ Yes

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For information, the requirements ICH (Which is the pharmaceutical standard) Specify that :

Shelf life testing must apply to 3 batches Under the following conditions:

- ☐ Accelerated conditions: (40°C/ 75% HR): T0, T3, T6
- ☐ Intermediate conditions: (30°C/ 65% HR) : T0, T3, T6, T9, T12
- ☐ Long term conditions: (25°C/ 60% HR): T0, T3, T6, T9, T12, T18, T24, T36

The parameters are likely to vary over time: physical, chemical, biological and microbiological properties must be retested regularly. These conditions may be adapted to specific climatic zones.



- Further treatment:

.....

**Attach the Material Safety Data Sheet (MSDS) of the preparation**

**Attach the certificate of conformity with food contact of the primary packaging**

### **RISK ANALYSIS AND QUALITY CONTROL**

To be established in function of the supplier, the nature of the plant or the botanical preparation, the manufacturing process, etc.

In case of a new supplier: Systematic analysis of the lots received until a sufficient experience has been gathered to proceed to periodic controls

The analysis can be focused in function of the potential risks identified:

- Adulteration: Identification tests (e.g. : Ginseng leaf instead of root, Cimicifuga foetida instead of C. racemosa, etc)
- Contaminants: Raw materials which present potential risk (e.g. : pesticides on Ginseng, ...)
- Process related: Solvent residues
- Added substances: Vitamins, beta-sitosterols, etc
- Dilutions with additives or bulking substances: levels of markers.
- Consistency with the price of the raw material, the ratio plant/extract, the declared solvents and level of markers

### **ANNEXES**

- Product Specifications File
- Material Safety Data Sheet
- Process Flow Chart
- GACP, where available
- Control Plan, where applicable
- Example of a Certificate of Analysis
- Stability data, if available:
- Any other relevant document

This questionnaire is courtesy of SYNADIET (French Food Supplements Association).

Translation and adaptations are the sole responsibility of the European Botanical Forum