



# EHPM Botanical Suppliers' Questionnaire



## IDENTIFICATION: DETAILS OF SUPPLIER AND BOTANICAL PREPARATION

### Supplier

Company Name

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### Supplier status

- Grower/Harvester 

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- Manufacturer 

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- Distributor/Broker 

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- Sales representative 

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## 1 - INFORMATION RELATING TO THE PLANT

### 1.1 - Plant name

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

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Common (vernacular) name:

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1.1.2 - Risk of adulteration

No             Yes

Specify if a risk of adulteration 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)

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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*

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

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1.2.3 - Where applicable, specific 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

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**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*

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**1.5 - Stage of harvesting / collection**

*Indicate the stage of plant growth at the time of harvesting / collection*

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**1.6 - Process used for drying**

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

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### 1.7 - Treatments (e.g. phytosanitary) applied

*Before harvesting / collection*

- No  Yes (*Specify*)
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*After harvesting / collection*

- No  Yes (*Specify*)
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### 1.8 - 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*)
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- Complete plant (including both aerial and underground parts)  
*Specify if relevant*
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## 3 - BOTANICAL PREPARATION

### 3.1 - Preparation type

- Comminuted or dried herb  Powder  Liquid extract  
 Tincture  Macerate  Soft extract  Oleoresin  
 Essential Oil  Dry extract  Other (*Specify*)
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### 3.2 - Manufacturing process

Cutting / Comminuting / Grinding

Pressing

Distillation

Extraction

Process

*Specify the extraction process: dry/liquid, maceration, percolation, etc*

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Solvents used (*Specify*)

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Purification

Process

*Specify process of purification: liquid/liquid, chromatographic, etc*

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Solvents used (*Specify*)

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Other process(es)

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

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### 3.3 - Ratios

Ratio dried plant / native extract (*Specify*)

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Ratio dried plant / final extract (*Specify*)

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**Attach a flow chart describing the ingredient's manufacturing process, including In Process Controls (IPC)**

### 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 of the preparation (including additives and other food ingredients)

Ingredient	Theoretical %	Type and function
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

### 3.6 - Contaminants and residues of the preparation

Contaminants and Residues	Control				Level / Limit	Reference, method of analysis, Accreditation (external/internal)
	Plant		Preparation			
	Lot	Plan	Lot	Plan		
Residual Solvent	_____	<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	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"/>	_____
Microbiology	Total plate count	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
	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"/>	_____

	Contaminants and Residues	Control				Level / Limit	Reference, method of analysis, Accreditation (external/internal)
		Plant		Preparation			
		Lot	Plan	Lot	Plan		
<b>Microbiology</b>	Escherichia coli	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
	Salmonella 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
	Ethylene Oxide	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
	Mycotoxins (e.g. <i>Aflatoxins B1, B2, G1, G2, Ochratoxin A</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
	Polycyclic Aromatic Hydrocarbons (PAHs)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
	3-MCPD (3-monochloro-propanol-1,2-diol)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
	Nitrate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
	Dioxins and PCBs (Polychlorobiphenyls)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
	Melamine and other structural analogues	<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"/>	_____	_____
	Perchlorate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
	Pyrrrolizidine alkaloids	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____

**Attach the control plan where appropriate**



### 3.7 - Genetic modification

Specific labelling on the presence of GMO derived ingredients

- No  Yes (*Specify the specific components. Where relevant, attach a certificate*)
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### 3.8 - Treatment of raw materials

One or more components have been treated by irradiation

- No  Yes (*Specify*)
- 

One or more components have undergone another treatment

- No  Yes (*Specify*)
- 

### 3.9 - Presence of allergens (from raw materials or processing aids)

- Allergens absent  Allergens present (*Specify below*)

#### Allergen

#### Present

##### Cereals containing gluten

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.

- Yes  No

\* 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

##### Crustaceans and products thereof

- Yes  No

##### Eggs and products thereof

- Yes  No

##### Fish and products thereof

except fish gelatine used as carrier for vitamin or carotenoid preparations, and fish gelatine or Isinglass used as fining agent in beer and wine

- Yes  No

##### Peanuts and products thereof

- Yes  No

Allergen	Present	
<p><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</p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p><b>Milk and products thereof</b> (including lactose), except whey used for making alcoholic distillates including ethyl alcohol of agricultural origin and lactitol</p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p><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</p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p><b>Celery and products thereof</b></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p><b>Mustard and products thereof</b></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p><b>Sesame seeds and products thereof</b></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p><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></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p><b>Lupin and products thereof</b></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p><b>Molluscs and products thereof</b></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No

### 3.10 - Nanomaterials

One or more components are present in the form of engineered nanomaterials

No  Yes (*Specify*)

Are the component(s) to be labelled according to Reg. (UE) 1169/2011 (Article 20)?

No  Yes (*Specify*)

### 3.11 - Purity criteria of the additives (including carriers)

Additive	Covered by Regulation 231/2012		Conformity 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
_____	<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)

Monograph

Internal (*Specify*)

\_\_\_\_\_

Official (*Specify*)

\_\_\_\_\_

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

4.1.1 - Organoleptic properties (appearance, odour, colour, ...)

*Specify the analyses performed*

\_\_\_\_\_

4.1.2 - Identity (TLC, HPLC, ...)

*Specify the analyses performed*

\_\_\_\_\_

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*

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4.1.5 - Purity tests (residues, relative density, microbiological results, etc.)  
*Specify the analyses performed*

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#### 4.2 - Substances to be monitored

4.2.1 - Markers

Type	Content limit	Method (HPLC, UV-VIS, GC, ...)	Reference, official method / internal method	Validated
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

4.2.2 - Compounds that are subject to restrictions of use

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

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

### 5.1 - Storage conditions

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### 5.2 - Retest period

Stability data

No  Yes (*Specify*)

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### 5.3 - Homogeneity (*sampling, use*)

Required before sampling

No  Yes (*Specify*)

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Required before use

No  Yes (*Specify*)

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### 5.4 - Labelling / Conditions for transport and storage (*Specify*)

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### 5.5 - Packaging

Type (*Describe the container*)

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## 5.6 - Other information

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

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Indicated?

No  Yes (*Specify*)

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Further treatment

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**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

It is a fundamental principle of food regulation that safety should be assured through systematic risk assessment and management procedures. Both the quality and level of information supplied by the supplier and the evaluation of this information by the buyer should therefore reflect appropriate risk assessment and management procedures.

Risk management measures should be decided on a case-by-case basis as the nature of risks may vary from one botanical to another:

- Identification tests to address potential adulteration (e.g.: Ginseng leaf instead of root, Cimicifuga foetida instead of C. racemosa, etc.)
- Analysis of certain raw materials for potential contaminants (e.g.: pesticides on Ginseng, Pyrrolizidine alkaloids in dandelion leaf...)
- Process related analyses (e.g. for solvent residues);

- Analyses of added substances: (e.g. Vitamins, beta-sitosterols, etc.).
- Levels of markers to reflect dilutions with additives or bulking substances.

The buyer may:

- Systematically analyse each lot received from a new supplier until sufficient experience has been gathered to proceed to periodic controls;
- Evaluate whether the price of the raw material, of the ratio plant/extract and the declared solvents and level of markers is consistent with the price quoted;
- Require a number of specific analytical parameters are met to address the requirements of the food supplements they are placing on the market.

If the buyer is not satisfied with the data provided, the buyer may reject the botanical on offer or subject it to additional quality assurance measures before deciding whether or not to purchase.

**ANNEXES INCLUDED WITH THE COMPLETED QUESTIONNAIRE**

- 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

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**DECLARATION:**

The information given above is to the best of my knowledge correct as at *(insert date)*

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Signed *(Signature)*

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Name in capital letters

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Status of person signing Questionnaire

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Date

