food supplements europe

Quality of Botanical Preparations

Self-Assessment Questionnaire to accompany the Specific Recommendations for the Manufacturing of Botanical Preparations, Including Extracts as Food Supplements

October 2016

Questionnaire to Assist with Assessment of Botanical Preparations

The following questionnaire has been designed to accompany the Food Supplements Europe guidance on 'Quality of Botanical Preparations'. Its aim is to assist food supplement manufacturers with assessing the quality of botanical preparations when selecting their raw materials and to highlight areas where further information may need to be requested from the supplier; and also to help suppliers ensure that they provide adequate information to their customer.

All botanical preparations used in food supplements intended for sale in the European Union (EU) must comply with all relevant requirements of EU food legislation with regard to composition, quality and safety. The quality of the preparation and consistency of production is particularly important where a quantitative or qualitative claim is to be made for a botanical for one or more of its constituents.

For the purposes of this questionnaire, and as defined in this guidance, botanical preparations include 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.

The Section numbers under Parts A and B relate to the sections in the Quality of Botanical Preparations guidance.

Supplier Company information

Supplier Company Name: .....

Supplier Company Address: .....
.....
.....
.....

Telephone No: .....

Email: .....

Is the supplier company the manufacturer of the botanical preparation? Yes ☐ No ☐

– If No, provide Manufacturing Company's name and address:

Manufacturer's Name: .....

Manufacturer's Address: .....
(manufacturing facility) .....
.....

PART A: SELECTION OF RAW MATERIAL

The Section numbers relate to the relevant sections in the Quality of Botanical Preparations guidance.

1. Origin of Botanical Sources and Compliance with Good Agricultural and Collection Practices

1.1. Origin of the botanical:

– Country: .....

– Region: .....

1.2. Botanical traceability:

– Batch/lot number present? Yes ☐ No ☐

– Shipment ID number relates to batch/lot number? Yes ☐ No ☐

– Is other identification of consignment given? Yes ☐ No ☐

Specify .....

1.3. Is the consignment in more than one container? Yes ☐ No ☐

– If Yes, are the individual containers clearly identified? Yes ☐ No ☐

1.4. Is written confirmation available for the relevant batches/lots to show that cultivation/collection, harvest, storage and processing (as applicable) were in compliance with the basic principles of good agricultural and collection practice, particularly in relation to identification and traceability? Yes ☐ No ☐

– If Yes, please attach to this questionnaire

1.5. Is the botanical preparation in compliance with the requirements of the Convention on International Trades in Endangered Species of Wild Flora and Fauna (CITES)? Yes ☐ No ☐

2. Botanical Identification and Characterisation

Identity of Source Material

2.1. Scientific (Latin) name (the following as applicable):

– Botanical family: .....

– Genus: .....

– Species: .....

– Variety: .....

– Subspecies: .....

– Author's name: .....

– Chemotype: .....

2.2. Known synonyms: .....

.....

2.3. Common name(s): .....

.....

2.4. Is the botanical:

– Wild-growing? ☐

– Cultivated? ☐

2.5. Harvesting conditions of the unprocessed botanical:

– Date/Date range/Season of harvest: .....

– Stage of plant growth at time of harvest: .....

2.6. Is the unprocessed botanical (tick all that apply):

– Harvested by hand? ☐

– Mechanically harvested? ☐

2.7. Describe drying process: .....

2.8. Has the drying process been designed so as to reduce contamination by polycyclic aromatic hydrocarbons (PAHs)? Yes ☐ No ☐

– If Yes, describe the precautions taken

.....

.....

.....

2.9. Plant part(s) used in the botanical preparation:

– Whole plant: ☐

– Underground parts only: ☐ (Specify below)

Root: ☐ Rhizome: ☐ Tuber: ☐ Bulb: ☐

Other ☐ Details: .....

– Aerial parts only: ☐ (Specify below)

Stem: ☐ Bark: ☐ Leaves: ☐ Flower: ☐

Fruit: ☐ Seed: ☐

Other ☐ Details: .....

Confirmation of Identity

2.10. Identification of the unprocessed botanical has been confirmed by:

– Macroscopic examination: Yes ☐ No ☐

– Microscopic examination: Yes ☐ No ☐

– Chromatographic/spectroscopic examination: Yes ☐ No ☐

Specify method: .....

– Other characteristic assay: Yes ☐ No ☐

Specify method: .....

– Physical tests: Yes ☐ No ☐

Specify: .....

.....

.....

2.11. Test results provided for each batch/lot. Yes ☐ No ☐

3: Traceability

3.1. Traceability records from point of plant growth meet the requirements of the EU Regulation on General Food Law? Yes ☐ No ☐

4. Treatments of the Source Material

4.1. Has the unprocessed or processed botanical been irradiated? Yes ☐ No ☐

4.2. Is the botanical sourced from a genetically modified plant? Yes ☐ No ☐

– If Yes, give EU authorisation details:

.....

4.3. Has any form of fumigant been applied? Yes ☐ No ☐

– If Yes, give details:

.....

5. Integrity of Botanical Material

5.1. Is the unprocessed botanical material screened for extraneous foreign matter? Yes ☐ No ☐

5.2. Are controls in place to ensure co-harvesting with other species is avoided and only one species of botanical is present in the harvested material? Yes ☐ No ☐

5.3. Are controls in place to ensure that the unprocessed botanical material contains only those plant parts intended for use? Yes ☐ No ☐

6. Contaminants and Residues

6.1. Has the unprocessed botanical and/or the botanical preparation been tested for:

Heavy Metals:

- – Lead Yes ☐ No ☐
- – Cadmium Yes ☐ No ☐
- – Mercury Yes ☐ No ☐
- – Arsenic Yes ☐ No ☐

Mycotoxins:

- – Aflatoxins Yes ☐ No ☐
- – Ochratoxin A Yes ☐ No ☐
- – Other Yes ☐ No ☐

Specify .....

Environmental Contaminants:

- – Dioxins, furans and dioxin-like Polychlorinated Biphenyls (PCBs) Yes ☐ No ☐
- – Polycyclic Aromatic Hydrocarbons (PAHs) Yes ☐ No ☐
- – Radioactivity Yes ☐ No ☐

Plant metabolites:

- – Pyrrolizidine alkaloids (PAs) Yes ☐ No ☐
- – Tropane alkaloids (TAs) Yes ☐ No ☐

Residues:

- – Pesticide, herbicide and fungicide residues Yes ☐ No ☐
- – Ethylene Oxide Yes ☐ No ☐
- – Other fumigants Yes ☐ No ☐

Specify .....

6.2. Are test results provided for each batch/lot? Yes ☐ No ☐

6.3. Where relevant, are the test results within the limits laid down in EU legislation? Yes ☐ No ☐

6.4. Where the unprocessed botanical has been tested, do the test results ensure compliance under EU contaminants and pesticides legislation if the botanical is concentrated through processing? Yes ☐ No ☐

7. Microbiological contamination

7.1. Has the unprocessed botanical and/or the botanical preparation been tested for:

– Total Plate Count (Total Viable Count) Yes ☐ No ☐

– Escherichia coli Yes ☐ No ☐

– Salmonella spp. Yes ☐ No ☐

– Enterobacteriaceae Yes ☐ No ☐

– Total combined Moulds/Yeasts Yes ☐ No ☐

7.2. Are test results provided for each batch/lot? Yes ☐ No ☐

7.3. Have the test results been checked against the specifications set out in the European Pharmacopoeia (where no limits are set under EU legislation) to ensure they are within acceptable levels? Yes ☐ No ☐

PART B: BOTANICAL (EXTRACT) PREPARATION

Although this section is primarily focussed on botanical extracts, in cases where the questions can also be applied to other botanical preparations, these should be answered in relation to the particular botanical preparation.

The Section numbers relate to the relevant sections in the Quality of Botanical Preparations guidance.

Form of botanical preparation:

- – Extract ☐
- – Comminuted or powdered herbal substance ☐
- – Tincture ☐
- – Essential oil ☐
- – Expressed juice ☐
- – Processed exudate ☐
- – Other ☐

Specify .....

1. Definitions and Legal Aspects of Different Forms of Extract/Other Preparation

1.1. Is the botanical extract:

- – A standardised extract? Yes ☐ No ☐
- – A quantified extract? Yes ☐ No ☐
- – Other extract? Yes ☐ No ☐

1.2. Is the botanical preparation considered 'not novel' in food supplements under the EU novel foods Regulation? Yes ☐ No ☐

- – If Yes, confirmation should be retained and provided upon request

2. Marker Determination

2.1. Markers present in the botanical extract/other preparation:

– Active markers: ☐

Specify .....

– Analytical markers: ☐

Specify .....

3. Botanical/Extract Ratio

3.1. State the dried plant : native extract ratio on dry weight basis

.....

4. Selection of Extraction Solvent

4.1. Are all solvents used to prepare the extract compliant with EU legislation on extraction solvents used in the production of foodstuffs and food ingredients? Yes ☐ No ☐

4.2. Solvents used:

.....

.....

.....

4.3. Solvent ratio:

.....

4.4. Solvent residues in compliance with EU legislation? Yes ☐ No ☐

5. Composition of Extract/Other Preparation as Marketed (Commercial Extract)

5.1. Details of all added components in the commercial extract/other preparation:

Additive/Other material	E number of additive (where applicable)	Additive is compliant with EU purity criteria
.....	.....	Yes ☐ No ☐
.....	.....	Yes ☐ No ☐
.....	.....	Yes ☐ No ☐
.....	.....	Yes ☐ No ☐
.....	.....	Yes ☐ No ☐
.....	.....	Yes ☐ No ☐

5.2. Actual quantity (in g) of native extract per 100g/100 ml of commercial extract:

.....

6. Product stability and shelf-life

6.1. Has the stability of the botanical preparation been assessed in the packaging in which it is sold to the customer? Yes ☐ No ☐

– If Yes, have the assessments included 'in use' stability tests? Yes ☐ No ☐

6.2. Expected shelf-life of the botanical preparation:

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REMARKS

The European food supplement sector brings together many of the most innovative and dynamic companies in the food area, making a substantial contribution to Europe's public health goals.

Food Supplements Europe combines the unique expertise of associations and companies committed to building partnership with regulatory, scientific and consumer bodies to help shape the future regulatory and policy framework in this area and to ensure that consumers can benefit from safe and high quality products.

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supplements
europe

International Non-Profit Organisation

Rue de l'Association 50, 1000 Brussels, Belgium

Tel: +32 2 209 11 51
Fax: +32 2 219 73 42
secretariat@foodsupplementseurope.org
www.foodsupplementseurope.org