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1. INTRODUCTION

The European Herbal Infusions Association (EHIA) readily acknowledges its responsibilities for food safety. In recognition of these obligations in 1993 EHIA produced a Code of Good Agricultural Practice (3) that details the manner in which they ensured the safety of the products they placed in the marketplace.

The introduction of the EU Hygiene Regulation (1) with its *farm to fork* approach to managing food safety coupled with its legal requirement to use the Hazard Analysis Critical Control Point (HACCP) system (2) to ensure food safety has caused EHIA to consider the implications of these 'new' rules particularly in relation to their primary raw materials. Although the formal application of the HACCP system will not initially be legally required for primary production there is a requirement to identify and control possible hazards present in primary raw materials, with these being addressed, where possible, in guidelines or codes of practice.

Raw Materials for herbal infusions are agricultural products that are grown widely throughout the world in both developed and developing countries either as cultivated crops or in the wild. GAHP may be applied unconditionally to cultivated crops, the same is not true of those that are uncultivated and 'wild gathered'. EHIA members processing raw materials source them from suppliers employing controlled cultivation (with whom they frequently have long term relationships) as well as those whose raw material is 'wild gathered'.

With cultivated raw materials EHIA members can exert some control over food safety issues at an early stage, for example by advising on the application of GAHP - Guidelines when preparing agreements.

'Wild gathered' raw materials grow in the wild rather than being cultivated and are harvested in a classical cottage-garden industry format by local smallholders. They sell them daily to a local collector who accumulates a truckload that is then sold in bulk to buyers representing the processors.

EHIA members take into account the different growth conditions of their raw material, whether cultivated or gathered wild, and also of the different food safety aspects arising from the parts of the plants which are used, by reflecting this appropriately in their HACCP plan as the individual case requires.

Raw material for herbal infusions is commonly traded in dried form. Drying takes place directly after harvesting and is carried out in the countries of origin. There are essentially two situations to consider:

- Firstly: The material can be grown, gathered and dried in the traditional manner by smallholders and then sold to a professional trader. HACCP does not apply to smallholders. However, it does apply to professional traders since they can provide the required degree of organisation as specified by the EU Regulation on Food Hygiene (1) for the application of HACCP (Considerations 9, 2nd sentence, and 16, 1st sentence).
- Secondly: Freshly gathered material is taken to a special drying plant by various different producers or collectors. In such cases the necessary organisation is expected to be available to support the implementation of HACCP.

These guidelines give EHIA members an instrument for exerting influence on cultivation and processing, thereby encouraging the application of GAHP and HACCP at the various stages of production.

Consequently, this document has been produced for use by EHIA members to:

- Encompass the differing food safety issues relating to both cultivated and 'wild gathered' herbal raw materials,
- Facilitate a common approach to discharging their food safety responsibilities,
- Define from which stage of production onwards a HACCP system should be implemented.
- Assist in discussions with national authorities regarding compliance with the EU Hygiene Regulation in relation to manufactured herbal infusions and their primary raw materials and
- Produce national guidelines or codes of practice where appropriate.

National and European regulations for herbal infusions are enforced without prejudice to the guidelines.

2. SCOPE

This guidelines apply to:

- Those raw material plant parts (e. g. herbals, fruits and specific spices) used for the preparation of herbal infusion drinks.
- Cultivation, harvesting and manufacturing in the country of origin.

Excluded from this guidelines are:

- Raw materials for pharmaceutical preparations.
- 'Teas' (Infusions) prepared from *Camellia sinensis*.
- Processing steps performed by the final EU-based processor.

3. DEFINITIONS

- *Raw materials for herbal infusions*: are parts of plants, fruits, spices which do not originate from the tea plant (*Camellia sinensis* L. Kuntze) and which are intended for preparing infusions using boiling water.
- *'Wild gathered'* raw materials are defined as those that grow in the wild rather than being cultivated and are harvested in a classical cottage-garden industry format.

4. BACKGROUND TO GAHP

4.1 The Guidelines for Good Agricultural and Hygiene Practice (GAHP) are guidelines to the production and handling of raw materials for use as herbal infusions. This document is a revised version of a previous document (3) and has been further developed from both the literature cited in Appendix 6 and the expertise of EHIA members, taking into consideration the relevant requirements for cultivated and 'wild gathered' raw materials of the EU Regulation on the Hygiene of Foodstuffs (1).

4.2 The objectives are to ensure that herbal infusions are:

- a. safe for human consumption.
- b. produced hygienically to minimise microbiological contamination and to prevent the formation of mould toxins (mycotoxins).
- c. produced with care to minimise physical and chemical contaminants.
- d. to identify the potential food safety hazards from raw materials and related HACCP requirements.
- e. of the highest quality.

4.3 This document provides guidelines designed to minimise contamination of materials at the primary producer level.

4.4 Herbal infusion raw materials are exposed to microbiological and other types of contamination as well as other potentially detrimental conditions from a wide variety of sources in the field and on the farm. Such contamination cannot always be removed effectively by washing and peeling techniques that are applicable to many other crops, nor is microbial load significantly reduced by the low temperature drying necessary for the conservation of colour and flavour characteristics of infusions.

4.5 There are no generally applicable methods for reducing the microbial load of dried herbal materials. Farmers and distributors are encouraged to devise practical measures for their workers to implement the code.

4.6 Wherever possible, all working practices should comply with the General Principles of Food Hygiene of Codex Alimentarius (12) and the EU Regulation on the Hygiene of Foodstuffs (1).

- 4.7 It is intended that company buyers should circulate these GAHP Guidelines to producers and distributors of raw materials for herbal infusions with a strong recommendation to comply with them. Application of the GAHP Guidelines can be advised when preparing agreements.
- 4.8 With the exception of the section dealing with 'cultivation', all other elements of the Guidelines including the Appendices and the Table are applicable to both 'wild gathered' and cultivated raw materials for herbal infusions. To discharge their responsibilities for food safety relating to the raw materials the processor must identify what food safety hazards are posed by the raw materials and ensure that these are taken into account within his own operation. The potential food safety hazards for raw materials are identified in Appendix 1 and the measures to be applied to reduce/eliminate them are described in Appendix 2 and summarised in Table 1. Appendix 3 describes the harvesting and processing of a typical "wild gathered" raw material. Using this example, Appendix 4 illustrates a HACCP Plan for drying in organized establishments.
- 4.9 The EHIA-GAHP will be available in different languages to improve its circulation, adoption and thus its effectiveness.

GUIDELINES FOR GOOD AGRICULTURAL AND HYGIENE PRACTICES FOR RAW MATERIALS USED FOR HERBAL INFUSIONS (GAHP)

Section A Basic requirements applicable to all operators (growers, traders, processors) in the countries of origin

1. CULTIVATION

- 1.1 Herbal materials should not be cultivated in soils contaminated with for example, sewage sludge, heavy metals, pesticides, radioelements and other industrial chemicals.
- 1.2 The soil should be well drained, and irrigation (if necessary) should be regular and uniform to avoid water logging of the soil and high humidity microclimates which promote mould growth and fungal infection.
- 1.3 Water used for irrigation should be fit for the purpose, i.e. substantially free from contaminants, such as faeces, heavy metals, agrochemicals (e. g. pesticides, fertilisers) and toxicologically hazardous substances. The water shall comply with local (national) standards where they exist.
- 1.4 Organic fertilisers (no human faecal material) should be well composted before use. Fertilisers should only be applied after the final harvest and before planting. When using chemical fertilisers, manufacturers instructions for use should be followed.
- 1.5 No cattle should be allowed in the cultivation area.
- 1.6 No sewage sludge should be used for fertilisation.
- 1.7 Plants should be spaced to minimise weed growth. Weeding should be regular and dead weeds with other plant debris should be removed from the crop cultivation area and destroyed to minimise fungal infection and pest damage.
- 1.8 The use of pesticides should be avoided as much as possible. When necessary, they have to be used with the minimum effective amount of authorised pesticides. Please use only pesticides that are authorised for use in the EU unless a satisfactory EU-MRL has been obtained. Application must be carried out at pre-harvest intervals advised by the manufacturer of the chemicals used. The application may only be carried out by qualified personnel with the use of authorised equipment.
- 1.9 Genetically modified seeds should not be used. If they are used, the seeds and their use must be authorised by EU-authorities according to Directive 2001/18/EC (21) and must fulfil the respective legal requirements (notably 22, 23).
The customer must be informed and each sack has to be clearly labelled with the fact that genetically modified seeds have been used.

2. HARVESTING

- 2.1 Crop harvesting should not be carried out in wet (ground moisture, dew or rain) or high humidity conditions, i.e. wherever possible harvesting should be carried out in dry, low humidity conditions. In this way the growing of mould and possible formation of mycotoxins can be avoided.
- 2.2 Harvesting equipment should be clean and well maintained.
- 2.3 Where mechanical cutters/harvesters are used, the machine parts in contact with the crop, together with their housing, should be cleaned regularly and kept free of accumulated plant material and other debris.
- 2.4 Cutter blades should be adjusted to avoid soil pick up.

- 2.5 All containers used for primary collection of the crop (see 2.7) must be kept free from previously accumulated plant material, and when not in use it must be kept in a dry place free from vermin and inaccessible to farm and domestic animals.
- 2.6 Damaged and spoiled crop material should be sorted and discarded.
- 2.7 Harvested material should be collected in dry sacks, baskets, trailers or hoppers. It must not be collected on the ground.
- 2.8 Mechanical damage, which promotes composting, should be avoided:
 - mechanical compaction.
 - plastic sacks should not be used during harvesting (exception: woven plastic sacks which allow exchange of humidity, e.g. woven polypropylene).
 - sacks must not be overfilled to ensure a proper seal.
 - compression with stacking should be avoided.
- 2.9 The time between harvest and transport of crop to the drying site should be kept as short as reasonably practicable.
- 2.10 The harvested crop should be protected from all types of pests (rodents, insects) and farm and domestic animals.
- 2.11 Water that comes in contact with raw material (e.g. washing water) should not contaminate the raw material.
- 2.12 The harvested crop must not be allowed to stand for extended periods in direct sunlight and must be protected from rain.

3. DRYING

- 3.1 The crop should be unloaded and unpacked as soon as possible on arrival at the drying facilities.
- 3.2 Buildings used for drying crops should be well ventilated and never used for livestock.
- 3.3 The building should be constructed to protect the crop from birds, insects, rodents, farm and domestic animals.
- 3.4 Drying racks should be kept clean and regularly maintained.
- 3.5 Crops should be placed in thin layers, on wire mesh racks standing off the floor to allow free air circulation, and stirred intermittently to ensure uniform drying and prevent composting or mould growth.
- 3.6 Drying on the floor and in direct sunlight is not recommended. With drying processes using oil, natural gas or wood firing, the fuel, the exhaust fumes and gas emissions must not come in direct contact with the herbal infusion raw materials. Drying furnaces must be maintained in good working order to prevent contamination with gas emissions. Direct drying is only allowed when using butane or propane. The temperature and drying time must be sufficient to give properly dried products and must be selected in such a way that the flavour and the active components (e.g. essential oils) are maintained as much as possible.
- 3.7 Dried crops should be inspected and sieved or winnowed to remove discoloured, mouldy and damaged material and soil, stones and other foreign matter. Sieves should be kept clean and maintained regularly.
- 3.8 Contamination of the raw materials with waste should be prevented through appropriate measures, such as strict physical separation of harvested materials from waste containers. Clearly marked waste bins should be provided, emptied daily and cleaned.
- 3.9 Dried and drying crops should be protected from infestation and farm and domestic animals.

- 3.10 Dried crops should be packed as soon as possible for protection and to lessen the opportunity of pest infestation, as well as to prevent ingress of foreign matter.

4. PACKING

- 4.1 Damaged material and foreign matter have to be eliminated before packing.
- 4.2 The sound dried crop should be packed in clean dry sacks, bags or boxes, preferably new. Labelling must be clear and appropriate and must not contaminate the harvested material. The details on the label should be sufficient to facilitate lot traceability.
- 4.3 Packaging materials should be stored in a clean dry place free from pests and inaccessible to animals.
- 4.4 Re-usable packaging materials such as jute sacks, woven plastic bags, etc. should be well cleaned and dried before re-use.
- 4.5 The packed crop should be stored in a dry place away from the wall and off the ground and be protected from pests and farm and domestic animals.
- 4.6 Packing materials must be suitable for the raw materials being packed. Wherever possible, the packaging materials used should be agreed between supplier and processor.

5. STORAGE AND TRANSPORT

- 5.1 Packed dried crop should be stored in a dry, well-ventilated building, with minimal variation in diurnal temperature.
- 5.2 Shutter and door openings should be protected by wire screens to keep out pests (insects and rodents), birds and farm and domestic animals. Appropriate pest-control measures, such as traps, electrical insect-control devices, as well as measures for identifying an infestation (such as pheromone traps) should be used.
- 5.3 It is recommended that packed dried crops should be stored:
- in buildings with concrete floors or similar easy-to-clean floors,
 - on pallets,
 - away from the wall,
 - well separated from all other crops whenever cross-contamination is possible.
- 5.4 For bulk deliveries the use of vented containers and transport vehicles is highly recommended to minimise mould risks.
- 5.5 The transport vehicles should be clean and in good condition.
- 5.6 Fumigation* to control pests should only be applied where necessary; trained personnel should carry out fumigation. Only fumigants that are authorised in the EU may be used. Residues in the fumigated raw materials must be within the EU limits or national or customer limits where they are lower.
- 5.7 Fogging of warehouses and other parts of buildings in which herbal infusion raw materials are stored or processed must only be done by trained personnel and with preparations that are authorised in the EU.
- 5.8 Chemicals used as pesticides, fumigants etc., should be kept in a separate area.

* *Fumigation is a generic term and encompasses the application of any legally approved technique for the control and elimination of insect infestation.*

6. EQUIPMENT

- 6.1 Equipment used for the gathering, handling and processing of crops should be easily cleaned to minimise contamination. Dry cleaning is recommended. Where the use of water is unavoidable, equipment should be dried as quickly as possible.
- 6.2 All equipment should be installed to allow easy access and should be well maintained and cleaned regularly.
- 6.3 The use of wood should be avoided wherever possible.
- 6.4 Wooden equipment (e.g. pallets, hoppers etc.), if used, should not have chemical treatments, such as chemical fungicides, which could be a source of taint, e.g. chlorophenols. Methylbromide should not be used for fumigation of pallets or any other wooden packaging.

7. PERSONNEL & FACILITIES

It is a basic requirement that all persons having contact with raw materials should observe a strict level of personal hygiene.

The following requirements should apply as much as possible.

- 7.1 Personnel handling food material should have access to suitable changing rooms and toilets with hand washing facilities.
- 7.2 Personnel must not be permitted to work in the herbal material handling area if they are known to be suffering from, or carriers of, diseases likely to be transmitted through food, including diarrhoea.
- 7.3 Personnel with open wounds, sores, and skin infections should be transferred away from herbal material handling areas until completely recovered.

8. DOCUMENTATION & TRACEABILITY

- 8.1 Farmers shall keep records about

- the use of fertiliser,
- the use of pesticides,
- any occurrence of pests or diseases that may affect the safety of raw materials used for herbal infusions
- the use of fumigants or fogging substances,
- results of analyses (e. g. loss in mass) carried out on samples

for each batch of harvested material. They shall be available for the customers on request.

These documents are to be kept for at least 5 years.

- 8.2 The buyer must be advised each time a batch or delivery of raw material is fumigated and this must also be recorded in the shipment papers.
- 8.3 Suppliers are advised to (where necessary and possible):
 - be able to identify the incoming goods (in order to follow its source of supply).
 - install a documented purchasing control system.
 - provide accompanying documents which carry all relevant information available for the customers on request.

Such requests may be part of the food business contractual arrangements.

9. TRAINING

Training of personnel, whether handling crops or managing crop production, in appropriate production techniques and hygiene practices is highly recommended. This can be achieved by using experts from local agricultural institutes or those provided by the buyers.

10. QUALITY CONTROL

10.1 Compliance with the recommendations of this GAHP should be checked through regular audits or inspection visits by representatives of producer and buyer with expertise in good agricultural and hygienic practice.

10.2 Specification for raw materials should be agreed between producer and buyer*; these may as a minimum include the following safety criteria: microbial load, pesticide residues, heavy-metal content, and radioelements.

Other parameters such as purity criteria, visual and sensory properties, active principles and characterising constituents, other chemical residues, may be included.

11. INFORMATION

If the farmer identifies a possible food safety hazard could come from the raw materials, he must inform the purchasing departments of the buyers of the raw material immediately. When there is a risk to human health, the information will be passed to the responsible authorities.

* See also

a) *EHIA Foodstuff Specifications for Herbal Infusion Products (17)*

b) *EHIA's Recommended Microbiological Specification for Trade In Herbal Infusion Raw Materials (18)*

Section B
**Additional requirements applicable to organised establishments that can support
implementation and operation of HACCP**

In addition to Section A, Annex 2 of the EU Hygiene Regulation (1) contains additional food hygiene requirements which organised establishments (as described in the introduction of this present document) are expected to comply with.

A key requirement is the development of food safety programmes and procedures based on the HACCP principles contained in the Codex Alimentarius (12). An illustrative HACCP plan is shown in Appendix 4.

APPENDIX 1

IDENTIFICATION OF POTENTIAL FOOD SAFETY HAZARDS OF RAW MATERIALS USED FOR HERBAL INFUSIONS

1. PREFACE

The potential food safety hazards posed by 'wild gathered' and cultivated raw materials are identified in this Appendix.

The raw materials received by the European processor may have undergone none or some processing before receipt; this will clearly vary and not all possible variations can be covered in this guide. However by way of illustration a typical process relating to rosehips is given in Appendix 3.

2. DESCRIPTION OF POTENTIAL FOOD SAFETY HAZARDS

Each process step can be analysed and the potential food safety hazards identified; for all raw materials the food safety hazards will generally fall into the following categories:

- Chemical contamination
- Foreign matter
- Microbiological contamination

2.1 Chemical Contamination

The problems and possible reasons for chemical contamination are described in published literature (19).

Chemical contamination can arise because of environmental pollution, inappropriate use of agrochemicals, and residues of fogging or fumigation substances or the use of non-authorized agrochemicals.

- Environmental pollution may for example result in enhanced levels of heavy metals from a variety of sources, e.g. nearby industry, traffic on nearby roads.
The available literature (19) and in-house monitoring by processors clearly demonstrate that the incidence of high levels of heavy metal contamination is low. Hence heavy metals present only a very low food safety hazard. Another environmental pollution problem is the contamination of soil with pesticides from former treatments. If pesticides are persistent (e.g. DDT, HCH), residues may stay in the soil for more than 5 years and can be assimilated by the herbal plants.
- Agrochemicals may be present as a consequence of carry-over from adjacent cultivated crops rather than their deliberate use, the use of non-approved chemicals or their use without adherence to GAHP.
In some raw materials from some origins residues exceeding the limit values may be detected; in these instances the raw materials will not be purchased without prior analysis to verify their legal conformance.
The monitoring of 'pesticide' residues by the trade shows that, apart from a few specific occurrences, values exceeding the Maximum Residue Limits (MRLs) are rare. As such food safety is not compromised. In addition, for the infusion, the low water solubility of most pesticide residues has to be considered. Hence, the food safety hazards from agrochemicals are considered to be low.

2.2 Foreign Matter

Foreign matter may be introduced during 'wild gathering' or harvesting of cultivated raw material, e.g. stones, wood, glass, metal, insect fragments, jewellery, parts of cigarettes, dirt, bird-feathers or foreign plant parts which are picked up during the crop.

It is known that the majority of raw materials received by processors do contain a wide variety of extraneous matter. The quantity present in the raw materials is generally relatively low and its nature

presents as a rule minimal food safety hazards when considered in conjunction with the manner in which the final product is ultimately presented to, and used by, the consumer. Only the presence of glass and metal might be a significant food safety hazard.

Infestation of raw materials with insects can occur and insects may be present at all stages of their life cycle. Any infestation is unacceptable and this aspect should be the subject of vigorous inspection and control procedures by the processor.

2.3 Microbiological contamination

Herbal materials contain a natural level of microorganisms but as they have a low water activity these present no hazard providing that the materials are kept dry. Most of the microorganisms are killed during the infusion with hot water. If the raw materials are not dried sufficiently or become wet during storage, transportation or processing, mould growth may occur. Mould growth could result in the formation of mycotoxins in a limited number of herbal materials. However the presence of mould results in taints and thus the material is unacceptable on quality grounds and will result in rejection.

EHIA has established microbiological standards, which are periodically reviewed and validated; these are given in Appendix 5.

APPENDIX 2 ONLY FOR PROCESSORS

MEASURES TO BE APPLIED BY THE PROCESSOR TO REDUCE/ELIMINATE POTENTIAL FOOD SAFETY HAZARDS IN RAW MATERIALS USED FOR HERBAL INFUSIONS

1. PREFACE

This appendix outlines the measures that the processor should take on receipt of raw materials.

The frequency of checks will depend on the specific risks identified for the herbal material, its origin and the supplier, 'wild gathered' raw materials will generally merit greater attention than cultivated ones.

Food safety hazards can be identified at the processing factory and it is there that the primary monitoring activity occurs and corrective actions determined. While there is growing evidence that hygiene standards are improving at the points where 'wild gathered' herbal materials are collected and initially processed before sale, EHIA recognises that its members cannot reliably devolve their responsibilities for food safety to the producers of the primary raw material. Buyers may frequently visit the producers but they can only inspect/audit a tiny fraction of the many hundreds of locations where 'wild gathered' herbal materials are collected and sold. For this reason it is recommended that the processor's in-house HACCP programme encompasses suitable checks on the herbal materials as received. This is necessary to ensure compliance with their legal obligations relating to food safety and to demonstrate 'due diligence', i.e. reliance is not placed on the primary producers' controls.

2. DESCRIPTION OF MEASURES

2.1 Chemical Contamination

Processors are recommended to carry out checks for chemical contamination on raw materials as received.

In the case of pesticides and heavy metals, results of the checks carried out by a number of EHIA Members are collated and summaries prepared; similarly, members of the trade share information on other chemical hazards. The collation of data in this area facilitates wider coverage of raw materials on the world market than would be possible by one company on its own and ensures that issues are rapidly identified and addressed by the trade as a whole. The aim is to avoid the sourcing of herbal materials from regions with possible safety risks (as described in Appendix 1).

2.2 Foreign Matter

Although the presence of foreign matter in raw materials as received is likely and would, if not removed, provide only a low food safety hazard, the measures are implemented by the processors both on receipt of the raw material and as an integral part of their processing operations. All available methods of removing foreign matter (e.g. magnetic separation of ferrous metals, sieving processes, air separation etc) should be considered and those most applicable to the material and foreign matter present employed.

2.3 Microbiological Contamination

Processors are recommended to carry out checks with regard to the microbiological contamination of the raw materials received.

The results of microbiological analyses carried out by a number of processors and packers are collated by EHIA and summaries prepared. The collation of data in this area facilitates wider coverage of raw materials on the world market than would be possible by one company on its own and identifies which herbal materials and/or countries of origin require careful monitoring.

Where a material does not comply with EHIA's recommended microbiological specification for trade in herbal infusion raw materials (Appendix 5), different strategies can be applied:

- Rejection of the raw materials and information of the raw material supplier to provoke corrective actions on the primary production level
- Application of suitable, legally permitted decontamination processes, e.g. steam treatment.

Processors are recommended to provide the guideline to their suppliers to enable microbial loads to be kept to a minimum.

APPENDIX 3

Rosehip Harvesting and Processing in Chile

GROWING

Rosehips grow wild in the fields and hedgerows.

HARVESTING

Ripe rosehips manually harvested by local population.

TRANSPORT to COLLECTION POINT

Rosehips taken to the collection point.

CONSOLIDATION

Daily harvest from the individual 'harvesters' consolidated.

SALE TO PROCESSOR

Rosehips sold in bulk to the processor.

CLEANING

Rosehips mechanically pre-cleaned to remove branches, leaves etc.

DRYING

Dried in the sun or in hot air drying chambers.

PACKING

Processed material packed and shipped.

DRYING RAW PLANT MATERIAL FOR HERBAL INFUSIONS IN ORGANISED ESTABLISHMENTS

Example: Drying rosehip in Chile (see appendix 3 of GAHP)

CCP is a critical control point as defined by Codex Alimentarius

QCP is a quality control point as defined by a quality management system

Raw material/ Production step	Possible hazard	CCP/ QCP	Control measure	Critical limits	Monitoring procedure	Corrective action
Delivery	<ul style="list-style-type: none"> - Soiled packs - Cross contamination from other raw materials - Infestation 	QCP	Visual inspection of incoming deliveries and removal of packs which do not meet requirements	Material and packs meet requirements	Visual inspection	Rejection, sorting, instructions to supplier
Mechanical pre-cleaning	Soil, stones, twigs, leaves, other foreign bodies	QCP	Removal by hand and / or by sieves	No obvious contamination	Visual inspection before and after removal	

Raw material/ Production step	Possible hazard	CCP/ QCP	Control measure	Critical limits	Monitoring Procedure	Corrective action
Drying in hot air chambers, in the sun etc.	inadequate drying, composting, formation of mould	QCP	e.g. spread in thin layers, boxes with ventilation slits, wire mesh grids, ensure proper air circulation, optimise drying conditions	<ul style="list-style-type: none"> - e.g. maximum layer thickness - e.g. turning frequency (e.g. twice daily) - Temperature control - Sufficient ventilation - Humidity 	<ul style="list-style-type: none"> - Check layer thickness, drying time and if necessary temperature - Sensory perception - Visual inspection - Humidity gauge 	<ul style="list-style-type: none"> - Re-dry - Sorting out
	Contamination by gas emissions	QCP	For direct drying use only propane or butane	- No emission onto the material	- Sensory perception	Maintenance of drying chambers and equipment
	Sun-drying: Pollution by animals	QCP	Use covering nets, fencing or provide a roof	No contamination	Visual inspection	Sorting out
	Contamination with refuse, e.g. sieved soil, eliminated plant material	QCP	- Clearly labelled refuse bins, to be emptied and cleaned daily	No contamination	Cleaning rota	Sorting out
	Metal fragments (broken pieces of shovels or metal grids)	QCP	Inspect equipment regularly, observe maintenance procedures	No metal fragments in the material	<ul style="list-style-type: none"> - magnets can be used when filling material into sacks - e.g. metal detectors at a later production stage 	<ul style="list-style-type: none"> - Repair and replace damaged equipment - install magnets



Raw material / Production step	Possible hazard	CCP/ QCP	Control measure	Critical limits	Monitoring Procedure	Corrective action
Dried crop	Soil, stones, other foreign material	QCP	e.g. sieving (keep sieves clean, observe maintenance measures), winnowing	As per specification	- Optical - Check by sieving	- Repeated sieving - Sieve and winnow at a later stage of production (e.g. in the European processing establishment)
	Infestation (insects, rodents, insect damage, contamination (by farm animals and domestic animals, birds))	QCP	- Pack as soon as possible - Keep material protected by using wire mesh to cover shutters and doorways; constructional modifications	No infestation	Suitable control measures (traps, electric insect eradicators, monitoring for pests)	Sorting out, fumigate if necessary

Record to be kept as appropriate for the size of the establishment in question (e.g. results of humidity measurements, maintenance books).

APPENDIX 5

EHIA'S RECOMMENDED MICROBIOLOGICAL SPECIFICATION for TRADE in HERBAL INFUSION RAW MATERIALS ²⁾

<i>Aerobic Plate Count</i>	max. 1 x 10 ⁸ /g
<i>Yeasts (Mint excluded)¹⁾</i>	max. 1 x 10 ⁶ /g
<i>Moulds</i>	max. 1 x 10 ⁶ /g
<i>E. coli</i>	max. 1 x 10 ⁴ /g
<i>Salmonella</i>	absent in 25g

¹⁾ For mint no yeast specification is applicable due to the high natural yeast load.

SAMPLING

- 5 random samples of 50 g are to be collected from the shipment.
- The 5 samples will be mixed to a composite sample.
- The composite sample is the basis for all laboratory investigations, including salmonella.

METHODS

Aerobic Plate Count

Microbiology – General guidance for enumeration of microorganisms – Colony count technique at 30 °C – 1991 (ISO 4833)

Yeasts & Moulds

Microbiology – General guidance for enumeration of yeasts and moulds – Colony count technique at 25 °C – 1987 (ISO 7954)

E.coli

Meat & meat products - Enumeration of Escherichia coli - Colony count technique at 44 °C – 1988 (ISO 6391)

Salmonella

Microbiology – General guidance on methods for detection of Salmonella – 1993 (ISO 6579)

²⁾ Issue 3, Sept. 3th 1998

APPENDIX 6

References and Literature

- 1 Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the Hygiene of Foodstuffs. OJ L 139, 30.04.2004, p. 139; Corrigendum OJ L 226, 25 June 2004, p. 3 - 21
- 2 Codex Alimentarius Commission 1993 - Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System ALINORM 93/13A, App. II
- 3 EHIA Code of Good Agricultural Practice for Herbal Infusion Raw Materials, Version dated 28 June 1993
- 4 Sammeln von Arzneipflanzen Richtlinien, organisatorische und technische Hinweise für Sammler und Sammelstellenleiter

VEB Pharmazeutisches Werk Halle, Staatliches Versorgungskontor für Pharmazie und Medizintechnik, Drogenkontor Leipzig, 1986
- 5 Schlagkartei Bayerische Landesanstalt für Bodenkultur und Pflanzenbau, Sachgebiet Heil- und Gewürzpflanzen, D-8050 Freising
- 6 Council Directive 93/43/EEC of 14 June 1993 on the Hygiene of Foodstuffs. OJ L 175, 19 July 1993, p. 1 - 11
- 7 Codex Alimentarius Commission:
Proposed Draft Code of Hygienic Practices for Spices and Condiments
Codex Committee on Food Hygiene, 24th Session, Washington DC,
16-20 October 1989
- 8 Codex Alimentarius Commission:
Proposed Draft Code of Hygienic Practice For Spices and Condiments
Codex Committee on Food Hygiene, 26th Session, Washington DC,
1-5 March 1993
- 9 Proposal for a draft Council Directive on the protection of human health by monitoring the wholesomeness of foodstuffs and observing basic principle of hygiene during their production, handling and sale, EC, III 8420/89-EN
- 10 M. Wedel, personal communications 31 May 1990
- 11 H. Schilcher, Proposed rules for Good Agricultural Practice. Acta Horticulturae 249, 123, 1989
- 12 Codex Alimentarius, Volume A
Recommended International Code of Practice.
General Principles of Food Hygiene. CAC/RCP 1-1969, Rev. 4 (2004)
- 13 Draft supplementary guidelines for the manufacture of herbal medicinal products
Working party on "Control of medicines and inspections" EC III/3919/90-EN
- 14 Food processing machinery, safety and hygiene specifications.
Basic standard
Doc. CEN/TC 153 N 10 February 1990
- 15 Hinrich Mrozek: Produktionshygiene zur Qualitätssicherung
Zbl. Bakt. Hyg. I Abt. Org. B 180, 241, 1985
- 16 E. F. Heeger: Handbuch des Arznei- und Gewürzpflanzenanbaues
Deutscher Bauernverlag, Berlin W 8, 1956.

- 17 Compendium of EHIA-Guidelines: Foodstuff Specifications For Herbal Infusion Products: European Herbal Infusions Association, Hamburg, Edition 2000
- 18 EHIA's Recommended Microbiological Specification For Trade in Herbal Infusion Raw Materials, 3. Version of 3 September 1998
- 19 The European Journal of Herbal Medicine, 4, 1, 1-9
- 20 Guidelines for Good Agricultural Practise (GAP) of Medicinal and Aromatic Plants, EUROPAM, Version August 1998
- 21 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC – Commission Declaration. OJ L 106, 17 April 2001, p. 1 – 39
- 22 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18 October 2003, p. 1 - 23
- 23 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. OJ L 268, 18 October 2003, p. 24 - 28
- 24 CIAA Guidelines on Traceability. FCP/275/04E-Final, 30 November 2004

TABLE 1
SUMMARY of the POTENTIAL FOOD SAFETY HAZARDS IDENTIFIED in RAW MATERIALS USED for HERBAL INFUSIONS & the MEASURES to be APPLIED by the PROCESSOR to REDUCE / ELIMINATE THEM

POTENTIAL FOOD SAFETY HAZARDS	MEASURES to be APPLIED¹⁾
<p>Chemical Contamination Environmental pollution</p> <p>Agrochemicals</p> <p>Fumigant & Fogging substances</p>	<p>a. Appropriate monitoring for contaminants (e.g. heavy metals and/or pesticides).</p> <p>b. Audits to assess the potential hazards posed by environmental pollution and that agrochemicals and fumigants are used by trained personnel and in line with GAHP.</p> <p>c. Submission of monitoring results to EHIA for inclusion in databases for use by Members.</p>
<p>Foreign Matter Non plant materials (e.g. stones, metal)</p> <p>Foreign plants (e.g. weeds)</p> <p>Insect infestation</p>	<p>a. Visual inspection on receipt.</p> <p>b. In case of infestation fumigation/fogging according to legal requirements.</p> <p>c. Removal of foreign matter using appropriate techniques, e.g. sieving, air separation, magnets etc.</p>
<p>Microbiological Contamination E. Coli, Salmonella, Mould</p> <p>Mycotoxins</p>	<p>a. Visual inspection on receipt.</p> <p>b. Appropriate monitoring against EHIA specification respectively legal requirement.</p> <p>c. Rejection or sorting to remove non-complying material.</p> <p>d. Submission of monitoring results to EHIA for inclusion in database for use by Members.</p>

¹⁾ The measures to be applied may be used singly or in combination as appropriate.