TEA & HERBAL INFUSIONS EUROPE

Formerly: European Tea Committee (ETC) and European Herbal Infusions Association (EHIA)

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

(Former EHIA document)

CONTENT

Sonninstrasse 28 · 20097 Hamburg · Germany · Tel.: +49 40 236016-21 · Fax: +49 40 236016-10/-11 · E-Mail: thie@wga-hh.de · http://www.thie-online.eu
Commerzbank AG · IBAN: DE67 2004 0000 0102 5881 00 · BIC: COBADEFFXXX

VII. ANNEXES

I. INTRODUCTION

Tea & Herbal Infusions Europe (THIE) readily acknowledges its responsibilities for food safety. In recognition of these obligations in 1993 EHIA (European Herbal Infusions Association), the predecessor of THIE, 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 Food Hygiene Regulation (1) (2) 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 (12) to ensure food safety has caused THIE 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 and fruit 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'. THIE 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 THIE 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.

THIE 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. These Guidelines provide a basis for member companies to establish a procedure which is based on the HACCP system.

But they do not replace an in-house approach for food safety management. Furthermore, it must be pointed out that the measures have to be set according to the extent of the quality assurance and hygiene control in previous stages in the food chain when setting up the above-mentioned procedure.

Raw material for herbal and fruit 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) (2) 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 THIE members an instrument for exerting influence on cultivation and processing, thereby encouraging the application of GAHP and HACCP at the various stages of production. These guidelines provide specialised knowledge for THIE members on how to identify, evaluate and control potential food safety hazards so that they are in a position to integrate them in their own HACCP-Plans.
Consequently, this document has been produced for use by THIE members to:

- Encompass the differing food safety issues relating to both cultivated and 'wild gathered' raw material for herbal and fruit infusions,
- 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 and fruit infusions and their primary raw materials and
- Produce national guidelines or codes of practice where appropriate.

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

II. SCOPE

These guidelines (GAHP) apply to:

- Raw materials for herbal and fruit infusions.
- Cultivation, harvesting and manufacturing in the country of origin.
- In-House HACCP Plan of THIE member companies.

- Excluded from these guidelines (GAHP) are:
- Raw materials for pharmaceutical preparations.
- 'Tea' (Infusions) prepared from Camellia sinensis.

III. DEFINITIONS

- ***Raw materials for herbal and fruit infusions*** are plants and parts of plants that do not originate from the tea plant (Camellia sinensis L. Kuntze) and are intended for use by brewing with freshly boiling water. Plants and parts of plants commonly used in herbal and fruit infusion are listed in the THIE Inventory List of Herbals Considered as Food in its current version available under www.thie-online.eu. This list is not exhaustive and updated regularly. The Novel Food Regulation (EC) No 258/1997 applies without prejudice.

- ***'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.

IV. BACKGROUND TO GAHP

- The Guidelines for Good Agricultural and Hygiene Practice (GAHP) are guidelines to the production and handling of raw materials for herbal and fruit infusions. This document is a revised version of a previous document (3) and has been further developed from both the literature cited in Annex 3 and the expertise of THIE members, taking into consideration the relevant requirements for cultivated and 'wild gathered' raw materials of the EU Regulation on the Hygiene of Foodstuffs (1) (2).
- The objectives are to ensure that herbal and fruit infusions are:
  a. safe for human consumption.
  b. produced hygienically to minimise microbiological contamination and to minimise the formation of mould toxins (mycotoxins).
  c. produced with care to minimise physical and chemical contaminants.
  d. in line with HACCP requirements by identifying, evaluating and controlling the potential food safety hazards from raw materials.
  e. of the highest quality.
- This document provides guidelines designed to minimise contamination of materials at the primary producer level.
- Herbal and fruit 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.
- There are no generally applicable methods for reducing the microbial load of dried herbal and fruit materials. Farmers and distributors are encouraged to devise practical measures for their workers to implement the code.
- 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) (2).
- It is intended that company buyers should circulate these Guidelines to producers and distributors of raw materials for herbal and fruit infusions with a strong recommendation to comply with them. Application of the Guidelines can be advised when preparing agreements.
- Apart from Part 1, subpara. 1. (Cultivation), Chapter V of the guidelines applies to wild gathering as well as cultivation on fields. HACCP considerations in Chapter VI also apply to processing in establishments with a certain degree of organisation for raw material either 'wild gathered' or cultivated on fields.
- 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 which can be caused by microbiological, chemical and physical factors in raw materials are identified in Chapter VI, Part 1 (hazard analysis). The measures to be applied to control/handle them and corrective actions are described in Chapter VI, Part 2. Examples for default documents for the HACCP system can be found in Chapter VI, Part 3: Part 3a describes harvesting and processing of typical 'wild gathered' raw material. Using this example, Part 3b illustrates a HACCP Plan for drying in establishments with a

certain degree of organisation. Part 4 contains a flow diagram for controlling food safety hazards during processing in establishments with a certain degree of organisation.

- The Guidelines will be available in different languages to improve circulation, adoption and thus their effectiveness.

V. GUIDELINES FOR CULTIVATION OF RAW MATERIALS USED FOR HERBAL AND FRUIT INFUSIONS IN THE COUNTRIES OF ORIGIN

Part 1 Basic requirements applicable to all operators (growers, traders, processors) in the countries of origin

1. Cultivation

1.1 Raw materials for herbal and fruit infusions are not cultivated in soils contaminated with for example, sewage sludge, heavy metals, pesticides, radioelements and other industrial chemicals. Growing plants (other than herbal and fruit materials) which might cause a possible contamination, e. g. due to their active principles, before growing herbal and fruit material or growing such plants (other than herbal and fruit materials) on a neighbouring field, has to be checked carefully to prevent cross contamination.

1.2 The soil is well drained, and irrigation (if necessary) is regularly 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 complies with local (national) standards where they exist.

1.4 Organic fertilisers (no human faecal material) are well composted before use. Fertilisers are only applied after the final harvest and before planting. When using chemical fertilisers, manufacturers' instructions for use will be followed.

1.5 No cattle is allowed in the cultivation area.

1.6 No sewage sludge is used for fertilisation.

1.7 Plants are spaced to minimise weed growth. Weeding is done regularly and dead weeds with other plant debris are removed from the crop cultivation area and destroyed to minimise fungal infection and pest damage.

1.8 Pesticides are only used when necessary. In case of need, they have to be used with the minimum effective amount of authorised pesticides. Only pesticides authorised for use in the EU, or pesticides for which an EU MRL is fixed may be applied. 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 repealed by (32) and must fulfil the respective legal requirements (notably 22, 23, 24). 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 must 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, must be cleaned regularly and kept free of accumulated plant material and other debris.

2.4 Cutter blades are adjusted to avoid soil pick up.

2.5 All containers used for primary collection of the crop 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 as well as birds.

2.6 Damaged and spoiled crop material will be sorted and discarded.

2.7 Harvested material will be collected in dry sacks, baskets, trailers or hoppers. It must not be collected on the ground. The collecting container is fit for the purpose, it is not made from plants which might cause a contamination due to their active principles.

2.8 Mechanical damage, which promotes composting, should be avoided:

- mechanical compaction.
- plastic sacks will not be used during harvesting
  (exception: woven plastic sacks which allow exchange of humidity, e.g. woven poly-propylene).
- 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, in any case it is necessary to avoid a temperature rise of harvested material due to composting or mould grow (see also 3.5).

2.10 The harvested crop is protected from all types of pests (rodents, insects); farm and domestic animals as well as birds.

2.11 Water that comes in contact with raw material (e.g. washing water) must 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 will be unloaded and unpacked as soon as possible on arrival at the drying facilities.

3.2 Buildings used for drying crops are well ventilated and should never be used for livestock.

3.3 The buildings should be constructed to protect the crop from birds, insects, rodents, farm and domestic animals.

3.4 Drying racks will be kept clean and regularly maintained, particularly in order to avoid cross contamination with other crops or foreign matter.

3.5 Crops are 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 and fruit infusions 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 Drying furnaces as well as other suitable drying chambers have to be kept clean in order to prevent cross contamination with crops, substances dried before. All equipment has to be maintained and inspected regularly to ensure food grade processing. Drying areas are non-smoking areas.

3.8 Dried crops are inspected and sieved or winnowed to remove discoloured, mouldy and damaged material and soil, stones and other foreign matter. Sieves must be kept clean and maintained regularly, particularly in order to avoid cross contamination with other crops or foreign matter.

3.9 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 must be provided, emptied daily and cleaned.

3.10 Dried and drying crops must be protected from infestation, farm and domestic animals as well as birds.

3.11 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. Packaging

4.1 Damaged material and foreign matter have to be eliminated before packing.

4.2 The sound dried crop is 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 are stored in a clean dry place free from pests and inaccessible to farm and domestic animals and birds. It is stored in such a way that it should not be contaminated with for example chemical substances (e. g. cleaning agents, smoke) and foreign materials (e. g. jewellery) which come from human environment as far as reasonably practicable.

4.4 Re-usable packaging materials such as jute sacks, woven plastic bags, etc. should be well cleaned and dried before re-use. The re-usable packaging material should only be used for packaging raw materials for herbal and fruit infusions. Re-usable packaging material should be inspected prior to use.

4.5 Packaging 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 is stored in a dry, well-ventilated building, with minimal variation in diurnal temperature.

5.2 The packed crop has to be stored in a dry place away from the wall and off the ground so that sufficient space for protection measures against pests is available. Furthermore, it has to be protected from pests, farm and domestic animals as well as birds. It has to be stored in such a way that the risk of contamination with objects and substances from human environment (e. g. smoke, jewellery) is reduced so far as reasonably practicable.

5.3 Shutter and door openings have to 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) will be used.

5.4 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.
- Storage areas should be non-smoking areas.

5.5 For bulk deliveries the use of vented containers and transport vehicles is highly recommended to minimise mould risks.

5.6 The transport vehicles are clean and in good condition in order to protect the crop from contamination.

5.7 In case of bulk transport of crop (e. g. unpacked crop in direct contact with the contact surface of the food transportation unit and the atmosphere), it is necessary to ensure that cross contamination with e. g. other crops (e. g. with other previously transported plant material), chemical substances or foreign matter is avoided.

5.8 During transport an appropriate spatial separation between driver and crop is recommended. If other crops or goods are transported at the same time, it is recommended to separate them in an appropriate way.

5.9 Fumigation* to control pests should only be applied where necessary; only 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.

5.9 Fogging of warehouses and other parts of buildings in which herbal and fruit infusion raw materials are stored or processed must only be done by trained personnel and with preparations that are authorised in the EU.

5.10 Chemicals used as pesticides, fumigants etc., have to be kept in a separate, closable 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 can be easily cleaned to minimise contamination and cross-contamination with other crops. Dry cleaning is recommended. Where the use of water is unavoidable, equipment will be dried as quickly as possible. The used equipment should be inspected prior to use.

6.2 All equipment is installed to allow easy access and is well maintained and cleaned regularly.

6.3 Equipment is made of appropriate material (e.g. stainless steel). The use of wood should be avoided wherever possible.

6.4 Wooden equipment (e.g. pallets, hoppers etc.), if used, must not have chemical treatments, such as chemical fungicides, which could be a source of taint, (e.g. chlorophenols). Methyl bromide 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 and fruit infusions raw material handling area, if they are known to be suffering from, or carriers of, diseases likely to be transmitted through food, including diarrhoea and if there is a likelihood of direct or indirect contamination. Any person so affected is to report immediately to his supervisor about the illness directly after outbreak and, if possible, has to undergo a medical examination. The person can only restart work, if there is no obstacle anymore (e.g. the medical certificate).

7.3 Personnel with open wounds, sores and skin infections should be transferred away from herbal and fruit infusions raw material handling areas until completely recovered, if there is a likelihood of direct or indirect contamination.

7.4 Personnel should always wash their hands when personal cleanliness may affect food safety, for example: at the start of food handling activities, immediately after using the toilet, and after handling any contaminated material, where this could result in contamination of other food items.

7.5 Food handlers should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering, and footwear.

7.6 People engaged in food handling activities should refrain from behaviour which could result in contamination of food, for example: smoking, spitting, chewing or eating, sneezing or coughing over harvested material and dried crops (packaged or unpackaged).

7.7 Personal effects such as jewellery, watches, pins or other items should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.

8. Documentation & Traceability

8.1 Farmers keep records about

- the use of fertiliser,

- the use of pesticides,
- previously cultivated plants and treatments such as fertilisers and pesticides (for annual plants and cultivation that requires field rotation)
- any occurrence of pests or diseases that may affect the safety of raw materials used for herbal and fruit 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

Personnel, whether handling crops or managing crop production, have to be trained in adequate production techniques and instructed in food hygiene matters (particularly personal hygiene), respectively. This can be achieved by using experts from local agricultural institutes or those provided by the buyers. Training should also aim to make staff familiar with the content of these guidelines. The training resp. instruction should be done regularly and commensurate with their work activity. The training and instruction, respectively has to be documented.

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.

Further product-related parameters such as purity criteria, visual and sensory properties, active principles and characterising constituents, other chemical residues and mycotoxins may be included.

[†] *See also*

a) THIE Compendium of Guidelines for Herbal and Fruit Infusions, Extracts thereof and Preparations, Tea & Herbal Infusions Europe, Hamburg, current version available at www.thie-online.eu (17)

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

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.

Part 2 Additional requirements applicable to organised establishments that can support implementation and operation of HACCP

In addition to Part 1 of the present guidelines, Annex 2 of the EU Food Hygiene Regulation (1) (2) contains additional food hygiene requirements which establishments with a certain degree of organisation (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). Chapter VI, Part 3 of the present guidelines includes examples for default documents according to the HACCP system.

VI. GUIDELINES FOR IDENTIFICATION, EVALUATION AND CONTROL OF FOOD SAFETY HAZARDS IN ESTABLISHMENTS WITH A CERTAIN DEGREE OF ORGANISATION

Part 1 Hazard analysis: Identification of Potential Food Safety Hazards of Raw Materials used for Herbal and Fruit Infusions

1. Preface

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

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 these guidelines. However, by way of illustration a typical process relating to harvest and processing of rosehip is given in Chapter VI, Part 3a.

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 (20) (29).

Chemical contamination can arise because of environmental pollution, inappropriate use of agrochemicals, residues of fogging or fumigation substances, the use of non-authorised agrochemicals or the geological nature of the soil (natural load of heavy metals, see Chapter V, Part 1, 1. Cultivation, point 1.1).

- 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 (20) 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.

- Chemical contamination could also arise from inappropriate personal behaviour which might contaminate food, for example smoking when handling harvested material and dried crops (packaged or unpackaged).

- 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 Chapter V, Part 1, no. 1.8 of these guidelines.

  In some raw materials from some origins residues exceeding MRLs may be detected; however in these instances the raw materials will not be purchased without prior analysis

to verify their legal conformance.

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 material 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 foreign 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. The contamination with allergens within the meaning of Directive 2003/89/EC (32), e. g. during harvesting by picking up foreign plants (e. g. nuts), is unlikely but has to be considered. 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 and contamination with mycotoxins (e.g. ochratoxin A)

Raw materials for herbal and fruit infusions contain a natural load of micro-organisms. It can be possible that this includes pathogenic germs, such as salmonella. On the one hand this natural occurrence of microbiological germs present no hazard, as an increase in microbiological load during storage can be excluded due to the low water activity when stored dry. On the other hand salmonella which might be present are eliminated by brewing with boiling water and infusing for an appropriate period. If the raw materials are not dried sufficiently or become wet during storage, transportation or processing, mould growth may occur. However, the presence of mould results in taints so that it is unacceptable and will be rejected for quality as well as health reasons. In a limited number of herbal and fruit infusions, certain species of moulds could result in the formation of mycotoxins as for example ochratoxin A. A contamination of liquorice root with the mycotoxin ochratoxin A is possible, for instance. The companies who are members of THIE take all necessary precautions to ensure that, in future, only such material is purchased and processed which has ochratoxin A levels lower than 20 ppb. Besides that, the processors will influence the suppliers of liquorice root in order to put them in a position to avoid the formation of ochratoxin A on the roots as far as possible. It is necessary to harvest liquorice root under dry conditions, if possible, to dry them enough and to keep them dry at all processing steps and at storage. Peeling the fresh roots is recommended, because unpeeled goods have a higher contamination risk.

The hazard of a subsequent microbiological contamination during processing is controlled by hygiene measures.

THIE has published microbiological specifications, one for raw materials used for herbal infusions (18) and another one for herbal infusions (dry) (19), which are reviewed and validated periodically. They are given in Chapter VII, Part 2, Annex 1 and 2 (see also Chapter VI, Part 2a, no. 2.3).

Part 2 Description of control measures and corrective actions

Part 2a Measures to be applied by the processor to prevent, eliminate or reduce potential food safety hazards in raw materials used for herbal and fruit infusions

1. Preface

This part of the guidelines 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 raw material for herbal and fruit infusions, its origin and the supplier (see also Chapter VI, Part 1), 'wild gathered' raw materials will generally merit greater attention than cultivated ones.

Food safety hazards are 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' raw material for herbal and fruit infusions are collected and initially processed before sale, THIE 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' raw material for herbal and fruit infusions are collected and sold. For this reason it is recommended that the processor's in-house HACCP programme encompasses suitable checks on the raw material for herbal and fruit infusions 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 check raw materials as received for possible chemical contamination. In particular on receipt of raw material originating from regions with possible safety hazards, it should regularly be analysed for pesticide residues and contaminants (control measures). In case of exceedances of the acceptable maximum levels the material e.g. has to be rejected unless there is a legally permitted corrective action. The critical limits for chemical contamination are inter alia given in EU and/or national legislation (30) (31) as well as in THIE Compendium of Guidelines for Herbal and Fruit Infusions, Extracts thereof and Preparations (17).

In the case of pesticides and heavy metals, results of the checks carried out by a number of THIE 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 raw material for herbal and fruit infusions from regions with possible food safety hazards (as described in Chapter VI, Part 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, control 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. Allergenic raw materials should be identified on receipt and segregated, if possible; accidental contamination during cultivation, harvesting and further process steps has to be avoided. If appropriate, as a corrective action the material can be rejected, particularly when glass or metal is present.

2.3 Microbiological Contamination

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

Regulation (EC) No 401/2006 (26) as well as Regulation (EC) No 2073/2005 (27) give an example and orientation when setting up the sampling plan. Way and frequency, at which stage of the respective process stage samples have to be taken, are risk-oriented and company specific. To fix the sampling plan all well-known and relevant circumstances, like e.g. delivery, reliability, country/region of origin and possible microbiological contamination, have to be taken into consideration. The individual sampling plan developed accordingly and the criteria it is based on must be documented in a reasonable way.

The results of microbiological analyses carried out by a number of processors and packers are collated by THIE 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 raw material for herbal and fruit infusions and/or countries of origin require careful monitoring.

Where a material does not comply with THIE's recommended microbiological specification for trade in herbal infusion raw materials (Chapter VII, Annex 1) (18), different measures 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.

The finished product manufactured by the European processor has to comply with THIE's microbiological specification for herbal infusions (dry) (Chapter VII, Annex 2) (19).

In liquorice root deliveries or blends containing liquorice root exceed a limit of 20 µg ochratoxin A, the goods will be rejected. The supplier should be asked to apply corrective actions in cultivating and harvesting liquorice root (see Chapter VI, Part 1, no. 2.3).

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

Part 2b Summary of the potential food safety hazards identified in raw material for herbal and fruit infusions and measures to be applied by the processor to prevent, eliminate or reduce them

PROCESS STEP	HAZARD	CONTROL MEASURES	MAXIMUM LIMITS TOLERANCES	FREQUENCY	RESPONSIBILITY	DOCUMENTATION	CORRECTIVE ACTIONS
Processes taking place in the country of origin (see Chapter V, Part 1 and 2)	• Due to raw material and/or • Due to suppliers practices	THIE's GAHP in its current version; all requirements laid down in the GAHP must be met by the supplier	According to European / national food law and (if available) specifications for raw material	Periodical rating of supplier	Supplier: regular controls according to the requirements of THIE's GAHP Importer/Processor in the EU: regular rating of supplier	Documentation according to THIE's GAHP and reports of visits	Supplier: measures to correct the determined deviations Importer/processor in the EU: checking the measures carried out by supplier; eventually new rating of supplier
Processes applied by importer/processor in the EU, processing, final product	Goods • Chemical hazards: e.g. pesticide residues • Physical hazards: e.g. foreign matters • Microbiological hazards: e.g. salmonellae	HACCP-Plan • Monitoring: company own and THIE database • Manufacturing techniques • Monitoring: company specific and THIE database, reconditioning, consumer information	• European / national food law, e.g. on pesticide residues • THIE Compendium of Guidelines for Herbal and Fruit Infusions, Extracts thereof and Preparations • THIE's Recommended Microbiological Specification for Herbal Infusions (dry) as part of THIE's GAHP	• According to sampling schedule • Continuously • According to sampling schedule	Importer/Processor in the EU	• Report of findings • Processing documentation • Report of findings	• Blocking and decision on further measures • Adjustment of processing • Blocking and decision on further measures

Part 3 Examples for default documents for the HACCP system: Rose-hip harvesting and processing in Chile

Introduction

Part 3a contains an overview of possible processing steps in rose-hip harvesting and processing in Chile. Part 3b gives an example for an HACCP plan for the drying of raw material. It must be adapted to the effectively applied, individual process in the drying establishment with a certain degree of organisation.

Herbal and fruit infusions are made of a multitude of raw materials. The rose-hip harvesting and processing/drying in Chile described hereafter has been picked up as a descriptive example. Also within the process sequence variations are possible, as the production steps themselves can differ. Accordingly, also the hazard analysis and resultant control measures and corrective actions are different. Due to the multitude of possible process sequences for all the different raw materials a comprehensive documentation for all raw materials and processes is neither appropriate nor possible. However, the chosen example describes one of the most important raw materials for herbal and fruit infusions and, in addition, it comprises typical process steps which also apply to other raw materials similarly.

Part 3 a Rose-hip harvesting and processing in Chile (example for implementation of GAHP)

GROWING

Rose-hips grow wild in the fields and hedgerows.

HARVESTING

Ripe rose-hips manually harvested by local population.

TRANSPORT TO COLLECTION POINT

Rose-hips taken to the collection point.

CONSOLIDATION

Daily harvest from the individual 'harvesters' consolidated.

SALE TO PROCESSOR

Rose-hips sold in bulk to the processor.

CLEANING

Rose-hips 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.

Part 3 b Documentation HACCP plan

Drying raw material for herbal and fruit infusions in organised establishments (e.g. Drying Rose-hip in Chile)

Example: Drying rosehip in Chile (sub-process of Part 3a)

CCP is a critical control point as defined by Codex Alimentarius (12)
The decision tree provided in the compendium of the Codex Alimentarius is a decision guide for identification of CCP.

RAW MATERIAL/ PRODUCTION STEP	POSSIBLE HAZARD	CCP	CONTROL MEASURE	CRITICAL LIMITS	MONITORING PROCEDURE	CORRECTIVE ACTION
Delivery	• soiled packs • cross contami-nation from other raw materials • infestation	No	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	No	Removal by hand and/or by sieves	No obvious contamination	Visual inspection before and after removal	
Drying in hot air chambers, in the sun etc.	Inadequate drying, composting, formation of mould	No	E.g. spread in thin layers, boxes with ventilation slits, wire mesh grids, ensure proper air circulation, optimise drying conditions	• e.g. maximum layer thickness • e.g. turning frequency (e.g. twice daily) • temperature control • sufficient ventilation • humidity	• check layer thickness, drying time and if necessary temperature • sensory perception • visual inspection • humidity gauge	• re-dry • sorting out
	Contamination by gas emissions	No	For direct drying use only propane or butane	No emission onto the material	Sensory perception	Maintenance of drying chambers and equipment
	Cross contamination with other crops and/or their ingredients dried before	No	Cleaning of the dryer before drying of raw materials for herbal infusions; or separate dryer for raw materials for herbal and fruit infusions	No cross contamination	Visual inspection	Sorting out Maintenance of drying chambers and equipment Repeat cleaning of the dryer
	Contamination with refuse, e.g. sieved soil, eliminated plant material	No	Clearly labelled refuse bins, to be emptied and cleaned daily	No contamination	Cleaning rota	Sorting out
	Metal fragments (e.g. broken pieces of shovels or metal grids)	No	Inspect equipment regularly, observe maintenance procedures	No metal fragments in the material	• magnets can be used when filling material into sacks • e.g. metal detectors at a later produc-tion stage	• repair and replace damaged equipment • install magnets

Table continues on the following page.

RAW MATERIAL/ PRODUCTION STEP	POSSIBLE HAZARD	CCP	CONTROL MEASURE	CRITICAL LIMITS	MONITORING PROCEDURE	CORRECTIVE ACTION
Dried crop	Soil, stones, other foreign material	No	• 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)	No	• 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
	Cross contamination by smoking	No	• implement non-smoking area • training of staff	No contamination	Inspection of non-smoking area	• adapt non-smoking area • training of staff

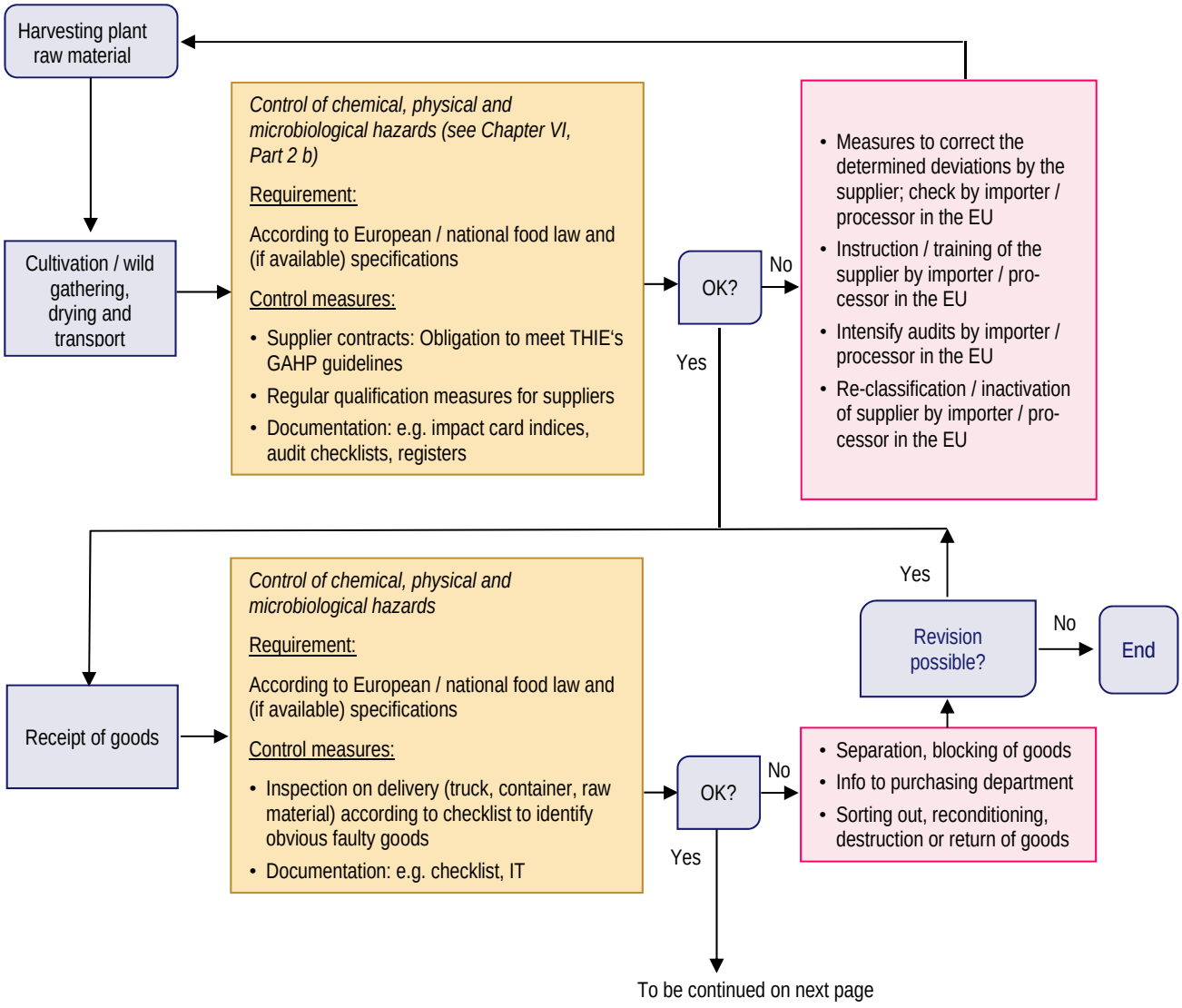
Records to be kept as appropriate for the size of the establishment in question (e.g. results of humidity measurements, maintenance books).

Note:

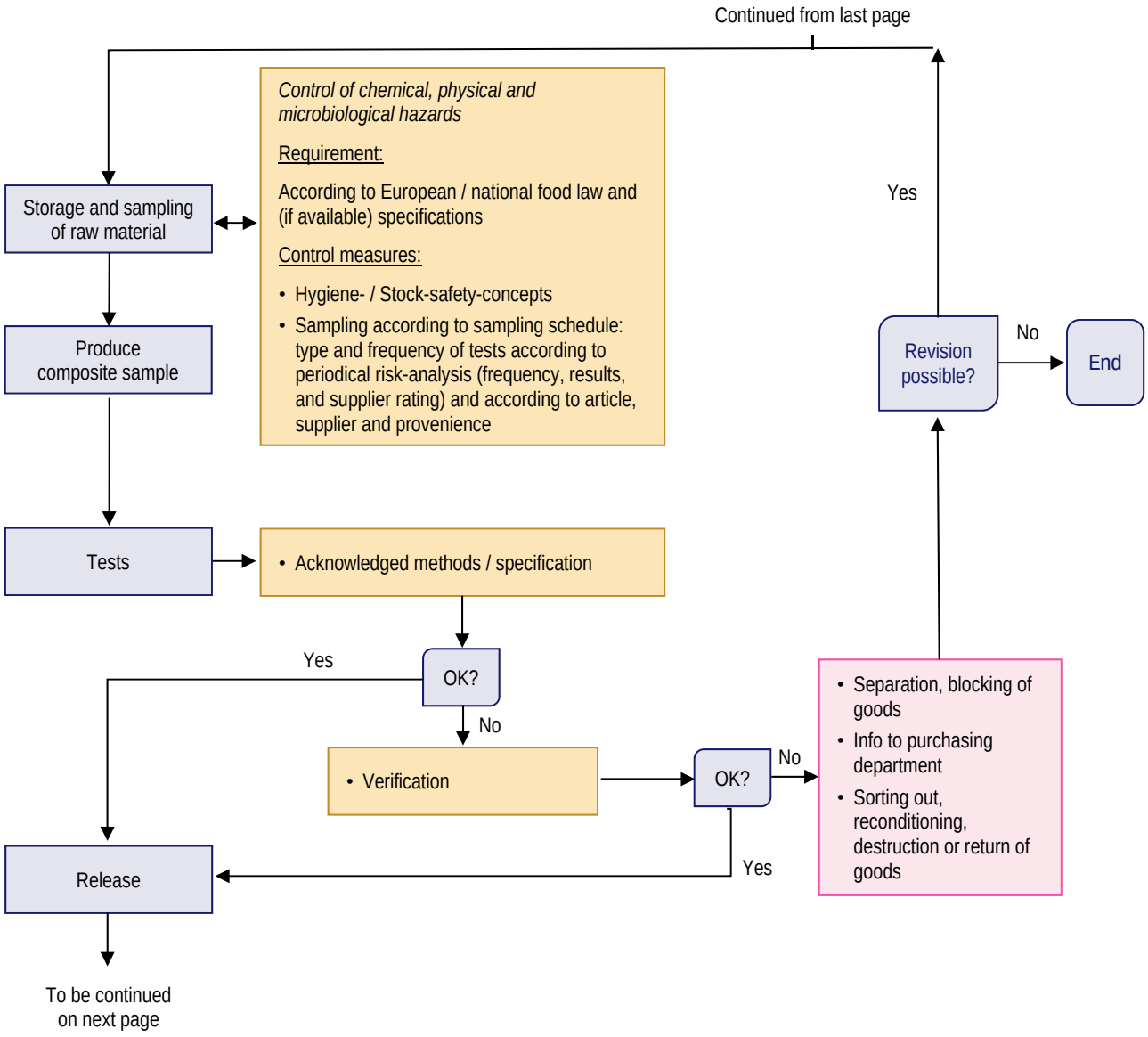
The drying process may differ in the respective establishments with a certain degree of organisation in Chile. Accordingly, the established HACCP plan has to be specific and characteristic for the possible hazards and measures in the individual plant. The company specific HACCP plan of THIE members, which buy dried rose-hips, consider the hazards, control measures and corrective actions which exist/are applied in the country of origin and determine accordingly the Critical Control Points (CCP).

Part 4 Process Diagram for Control Measures and Corrective Actions concerning Food Safety Hazards during Processing

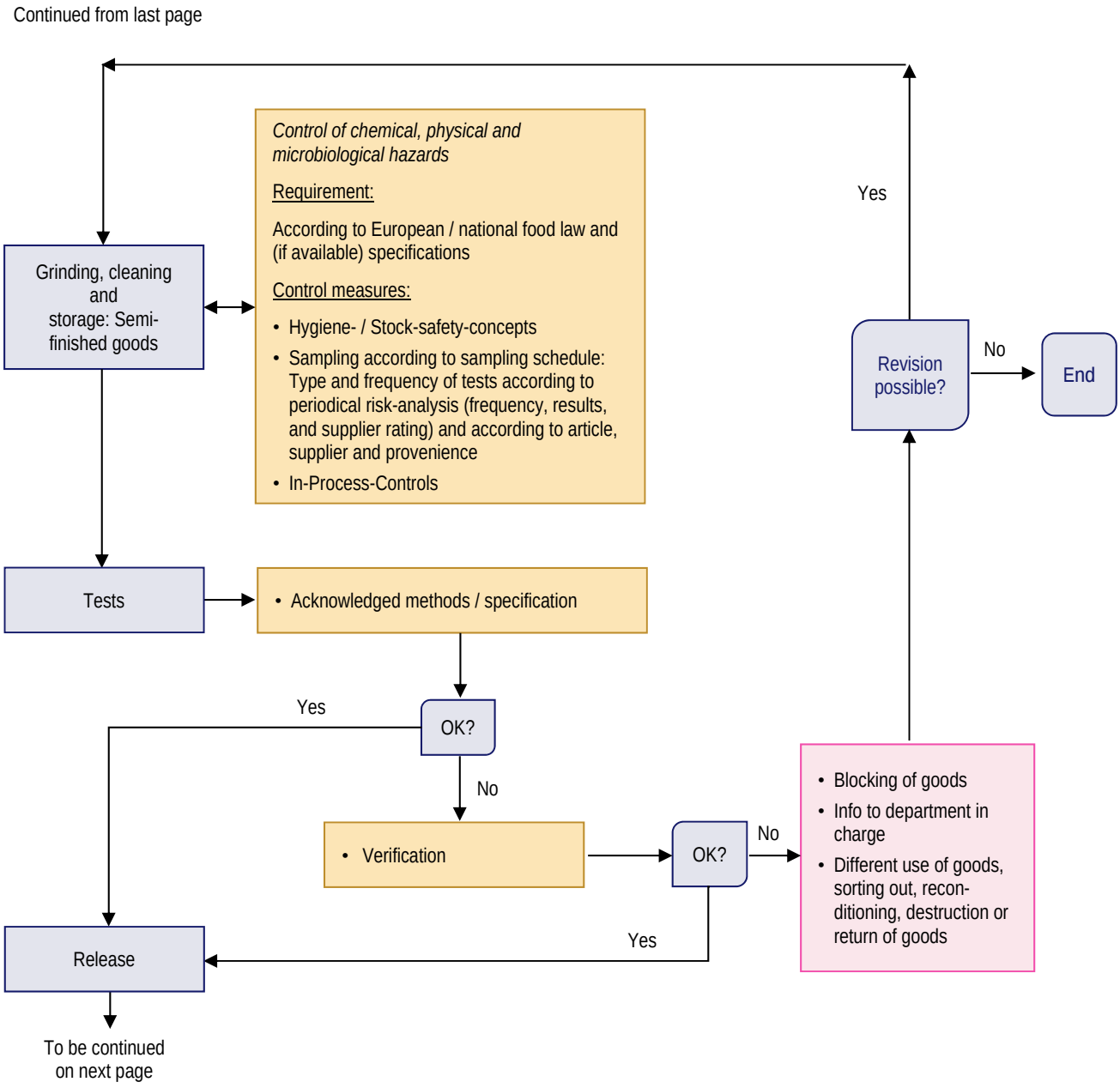
Process step **Requirements / Control measures** **Corrective actions**



Process step **Requirements / Control measures** **Corrective actions**

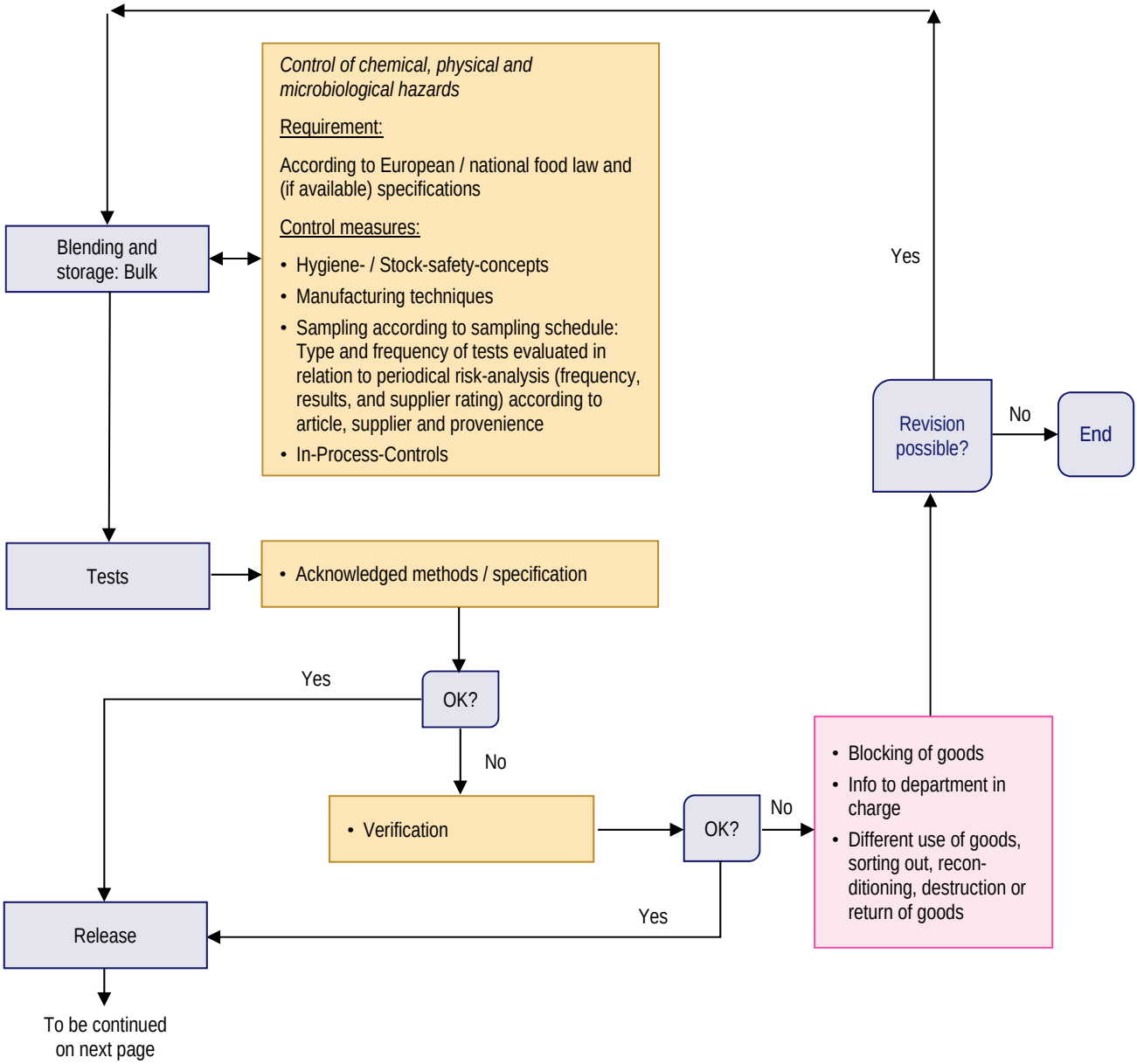


Process step **Requirements / Control measures** **Corrective actions**

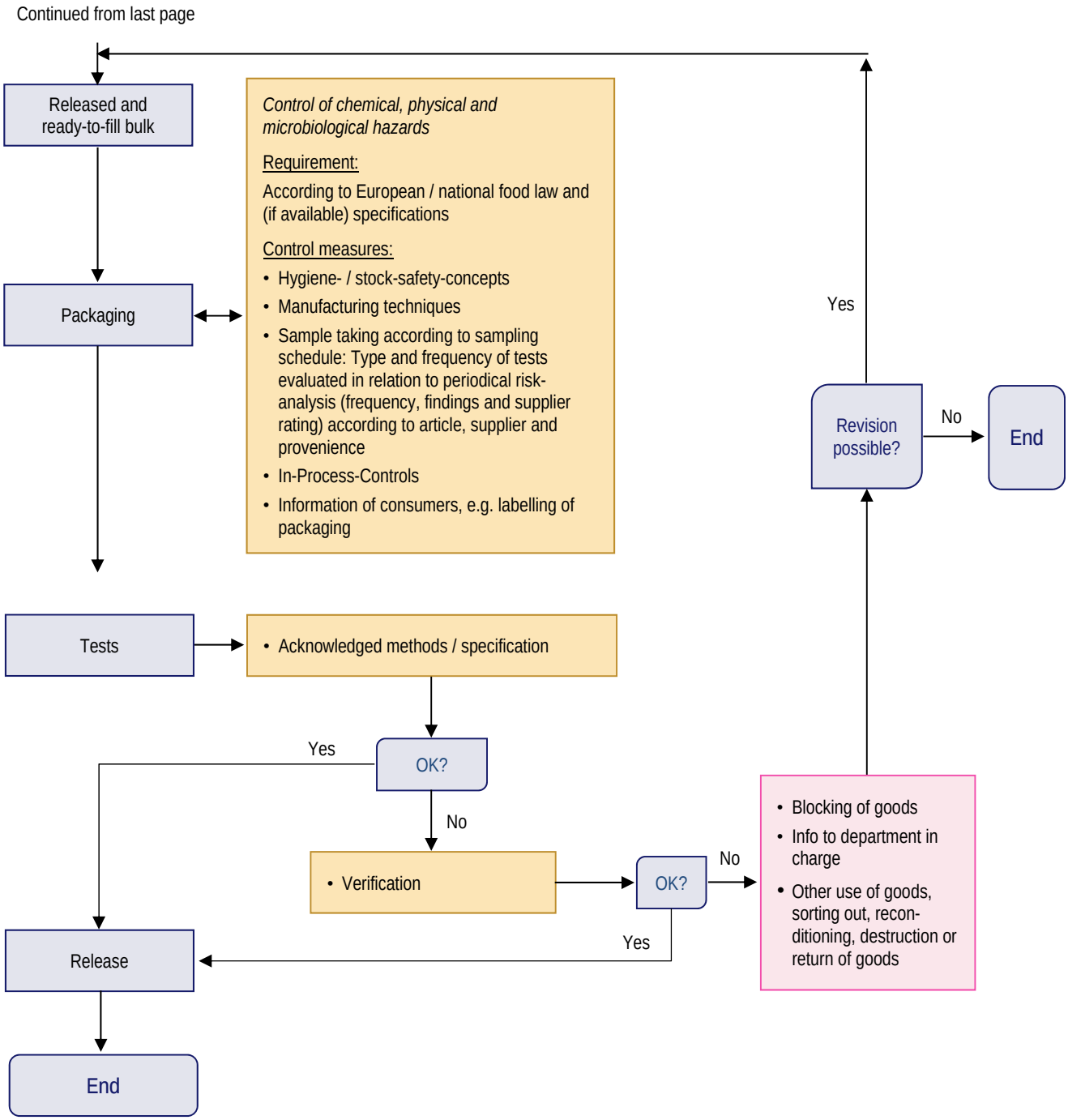


Process step **Requirements / Control measures** **Corrective actions**

Continued from last page



Process step **Requirements / Control measures** **Corrective actions**



VII. ANNEXES

Annex 1

Issue 11, June 2018

THIE'S RECOMMENDED MICROBIOLOGICAL SPECIFICATION FOR TRADE IN HERBAL INFUSIONS RAW MATERIALS (DRY)

MICROBIOLOGICAL LIMITS

Aerobic Plate Count	≤ 10^8 / g
Yeasts (Mint excluded) [1)]	≤ 10^6 / g
Moulds	≤ 10^6 / g
E. coli	≤ 10^4 / g
Salmonella	absent in 125 g

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 of the food chain – Horizontal method for the enumeration of microorganisms – Part 1: Colony count at 30 degrees C by the pour plate technique (ISO 4833-1:2013); Microbiology of the food chain – Horizontal method for the enumeration of microorganisms – Part 2: Colony count at 30 degrees C by the surface plating technique (ISO 4833-2:2013 and ISO 4833-2:2013/Cor 1:2014); European Reference Method according to Regulation (EC) No 1441/2007

Yeasts and Moulds
Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of yeasts and moulds – Part 2: Colony count technique in products with water activity less than or equal to 0.95 (ISO 21527-2:2008)

E. coli
Microbiology of the food chain – Horizontal method for the enumeration of beta-glucuronidase-positive Escherichia coli – Part 1: Colony-count technique at 44 degrees C using membranes and 5-bromo-4-chloro-3-indolyl beta-D-glucuronide (ISO 16649-1:2018) or Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of beta-glucuronidase-positive Escherichia coli – Part 2: Colony-count technique at 44 degrees C using 5-bromo-4-

chloro-3-indolyl beta-D-glucuronide (ISO 16649-2:2001); European Reference Method according to Regulation (EC) No 1441/2007

Salmonella
Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of Salmonella – Part 1: Detection of Salmonella spp. (ISO 6579-1:2017); European Reference Method according to Regulation (EC) No 1441/2007

ADDITIONAL REMARK

All THIE Recommended Microbiological Specifications are reviewed annually.

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

* Other methods can be used if they are checked against a reference method (official method and suitability tested [recovery of reference microorganisms]).

Annex 2

Issue 8, June 2018

THIE'S RECOMMENDED MICROBIOLOGICAL SPECIFICATION FOR HERBAL INFUSIONS (DRY)

MICROBIOLOGICAL LIMITS

Aerobic Plate Count	≤ 10^7 / g
Yeasts	≤ 10^5 / g
Moulds	≤ 10^5 / g
E. coli	≤ 10^3 / g
Salmonella	absent in 125 g

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 of the food chain – Horizontal method for the enumeration of microorganisms – Part 1: Colony count at 30 degrees C by the pour plate technique (ISO 4833-1:2013); Microbiology of the food chain – Horizontal method for the enumeration of microorganisms – Part 2: Colony count at 30 degrees C by the surface plating technique (ISO 4833-2:2013 and ISO 4833-2:2013/Cor 1:2014); European Reference Method according to Regulation (EC) No 1441/2007

Yeasts and Moulds
Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of yeasts and moulds – Part 2: Colony count technique in products with water activity less than or equal to 0.95 (ISO 21527-2:2008)

E. coli
Microbiology of the food chain – Horizontal method for the enumeration of beta-glucuronidase-positive Escherichia coli – Part 1: Colony-count technique at 44 degrees C using membranes and 5-bromo-4-chloro-3-indolyl beta-D-glucuronide (ISO 16649-1:2018) or Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of beta-glucuronidase-positive Escherichia coli – Part 2: Colony-count technique at 44 degrees C using 5-bromo-4-chloro-3-indolyl beta-D-glucuronide (ISO 16649-2:2001); European Reference Method according to Regulation (EC) No 1441/2007

Salmonella
Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of Salmonella – Part 1: Detection of Salmonella spp. (ISO 6579-1:2017); European Reference Method according to Regulation (EC) No 1441/2007

ADDITIONAL REMARK

Herbal infusions are parts of plants which are intended for infusing with freshly boiling water and brewing for at least 5 minutes/5-x minutes.

All THIE Recommended Microbiological Specifications are reviewed annually.

* Other methods can be used if they are checked against a reference method (official method and suitability tested [recovery of reference microorganisms]).

Annex 3

Issue 1, September 2018

THIE's RECOMMENDED MICROBIOLOGICAL SPECIFICATION FOR HERBAL INFUSIONS EXPLICITLY LABELLED AS COLD BREW PRODUCTS (CBP)

MICROBIOLOGICAL LIMITS

Aerobic Plate Count	≤ 10^4 / g
Yeasts	≤ 10^2 / g
Moulds	≤ 10^2 / g
E. coli	≤ 10^1 / g
Salmonella	absent in 125 g

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 of the food chain – Horizontal method for the enumeration of microorganisms – Part 1: Colony count at 30 degrees C by the pour plate technique (ISO 4833-1:2013); Microbiology of the food chain – Horizontal method for the enumeration of microorganisms – Part 2: Colony count at 30 degrees C by the surface plating technique (ISO 4833-2:2013 and ISO 4833-2:2013/Cor 1:2014); European Reference Method according to Regulation (EC) No 1441/2007

Yeasts and Moulds

Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of yeasts and moulds – Part 2: Colony count technique in products with water activity less than or equal to 0.95 (ISO 21527-2:2008)

E. coli

Microbiology of the food chain – Horizontal method for the enumeration of beta-glucuronidase-positive Escherichia coli – Part 1: Colony-count technique at 44 degrees C using membranes and 5-bromo-4-chloro-3-indolyl beta-D-glucuronide (ISO 16649-1:2018) or Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of beta-glucuronidase-positive Escherichia coli – Part 2: Colony-count technique at 44 degrees C using 5-bromo-4-chloro-3-indolyl beta-D-glucuronide (ISO 16649-2:2001); European Reference Method according to Regulation (EC) No 1441/2007

Salmonella

Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of Salmonella – Part 1: Detection of Salmonella spp. (ISO 6579-1:2017); European Reference Method according to Regulation (EC) No 1441/2007

ADDITIONAL REMARKS

In order to ensure the microbiological safety of the products, appropriate measures and suitable bacteria reduction treatments of the raw materials must be applied.

All THIE Recommended Microbiological Specifications are reviewed annually.

* Other methods can be used if they are checked against a reference method (official method and suitability tested [recovery of reference microorganisms]).

Annex 4

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33. Directive 2003/89/EC amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs, OJ L 308, 25.11.2003, p. 15–18

Revision History

Date	Issue No.	Amendment/s	Reason
28.06.1993	0	EHIA Code of Good Agricultural Practice for Herbal Infusion Raw Materials (GAP)	
14.06.2002	1	Guidelines For Good Agricultural And Hygiene Practices For Raw Materials Used For Herbal Infusions (GAHP)	Implementation of the provisions of the DRAFT Regulation (EC) No 852/2004 on the hygiene of foodstuff; and of HACCP
2./3.06.2005	2	Section A: Basic requirements applicable to all operators (growers, traders, processors) in the country of origin Section B: Additional requirements applicable to organised establishments that can support implementation and operation of HACCP HACCP Plan	Adopted Regulation (EC) No 852/2004, HACCP for organised establishments
16.01.2008	3	Clarification of document structure, rephrasing microbiological contamination: OTA formation	New perceptions
13.06.2008	4	Inclusion of 'EHIA's recommended microbiological specification for herbal infusions (dry)'	New specification
18.01.2012	5	Additional requirements concerning allergens, personal hygiene, cross contamination	Periodical update
26.06.2014	6	Replace EHIA's Recommended Microbiological Specifications	Revision of the microbiological specifications
20.07.2015	7	Transformation to THIE document	Dissolution of EHIA and foundation of THIE
13.06.2018	8	Update Text and Annexes	Revision of the microbiological specifications
03.09.2018	9	Inclusion of THIE's recommended microbiological specification for herbal infusions explicitly labelled as cold brew products (CBP)	New specification