Guidelines for Good Agricultural and Wild Collection Practices for Medicinal and Aromatic Plants (GACP-MAP)

The guidelines for the *Good Agricultural and Wild Collection Practices* for Medicinal and Aromatic (Culinary) plants are intended to apply to the cultivation, wild collection and primary processing practices of all such plants and their derivatives traded and used in the European Union. Hence they apply to the production of all plant materials utilized either in a direct or processed form for humans and/or animals. They also apply to all methods of production including organic production in accordance with the European regulations.

EUROPAM, the European Herb Growers Association

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1. General Introduction

1.1. Scope.

The guidelines for the *Good Agricultural and Wild Collection Practices* of Medicinal and Aromatic (Culinary) plants (GACP-MAP) are intended to apply to the cultivation, wild collection and primary processing practices of all such plants and their derivatives traded and used in the European Union. Hence they apply to the production of all plant materials utilized either in a direct or processed form for humans and/or animals as e.g. pharmaceuticals, food and feed supplements and cosmetics. They also apply to all methods of production including organic production in accordance with the European regulations.

1.2. The Environment.

1.2.1 Cultivation

In the course of the entire production process, in general, care should be taken to avoid environmental disturbances. The principles of good crop husbandry must be followed including an appropriate rotation of crops. Growers involved in the production of medicinal and aromatic plants must ensure that they avoid damage to existing wildlife habitats, and that they make efforts to maintain and to enhance the biodiversity of their farms. These efforts should include:

a) Monitoring plant and animal species whose on-farm presence is evidence of good environmental practice.

b) Good Management the aquatic environment of the farm to encourage wildlife.

c) Conserving and good management of landscape elements with ecological importance (e.g. hedgerows, forest patches and buffer zones).

1.2.2 Wild collection

All the involved parties in the harvesting of wild plants must ensure that they avoid damage to existing wildlife habitat.
In particular the harvester must avoid:
a) Extinction of particular species in certain zones or certain rare genetic populations due to over-exploitation. Where possible, the principle of "collection rotation" to facilitate biological propagation and resource renewal should be employed.

b) Destruction of the entire plant, due to carelessness and inexperience on behalf of the harvester, when in most cases it would be sufficient to harvest only a part of it.

c) Confusion (due to ignorance or bad faith) in the harvesting of different species those are at first sight similar.

d) Collection of endangered species, according to local regulation. For plant intended for export from the country of collecting the Convention on International Trade in Endangered Species of wild Fauna and Flora (CITES) certificate must be obtained.

1.3. Quality.

The present *Good Agricultural and Wild Collection Practices* Guidelines provide additional standards for the production and processing of raw materials focusing on the identification of those critical steps that are needed to comply with good quality. In this respect, they will be aimed at minimizing insufficient quality by prevention. The recommendations of this document are aimed at offering guidelines for national regulations.

1.4. Hygiene.

A main aim is to ensure that the plant raw material meets the demands of the consumer and the standards of the highest quality. Especially important aspects are that they are:

a) produced hygienically, in order to reduce microbiological load to a minimum,

b) produced with care, so that the negative impacts affecting plants during cultivation, wild collection and processing and storage can be limited.

Since medicinal and aromatic plants and their derivatives are exposed, in the course of production process, to a large number of both microbiological and other contaminants, the main aim of present guidelines is to provide guidance for producers and collectors in order to reduce plant (raw material) contamination to the greatest extent.

1.5. Realisation.

All participants of the production process (from primary producers to traders) are required to comply with these guidelines voluntarily and to elaborate practical measures in order to realize them; moreover they, as far as it is concerned, should gather all the documentation (Confidential), in order to keep the traceability of the production process. The most important information about the batch should always follow the material by a Batch Documentation (Records and/or labels). Growers, collectors, traders and processors of medicinal and aromatic plants should be encouraged to respect and comply with the GACP-MAP Guidelines, and demand that their partners also meet these requirements.

2. Personnel and Facilities

2.1. Personnel should receive adequate education before performing tasks that require this knowledge and to know the best techniques for cultivation, harvesting, processing, drying and conservation, in order to guarantee the highest possible quality of the product.

2.2 The collectors should have an appropriate botanical education, in order to identify the plants to harvest, without making any mistakes between the plant to crop and similar ones, in order to avoid undesired mixings. The degree of knowledge of the collectors must be periodically verified from a competent person put in charge by the collection organisation.

2.3. The development of the knowledge of the persons has to be documented in a written form.

2.4. Personnel entrusted with the plant material should be required to have a high degree of personal hygiene (including personnel working in the fields) and have received adequate training regarding their hygiene responsibilities.

2.5. The buildings where the plant processing is carried out have to be provided with changing facilities as well as toilets including hand washing facilities, according to the respective regulations.

2.6. Persons suffering from known infectious diseases transmittable via food, including diarrhoea, or being transmitters of such diseases, must be suspended from areas where they are in contact with the plant material, according to the respective regulations.

2.7. Persons with open wounds, inflammations and skin-infections should be suspended from the areas where the plant processing takes place, or have to wear appropriate protecting clothing or gloves, until their complete recuperation.

2.8. Personnel should be protected from contact with toxic or potentially allergenic plant materials by means of adequate protective clothing.

2.9. The welfare of all staff involved in the growing and processing shall be ensured. Health regulations should be displayed in the working area.

2.10. All processing procedures must completely conform to both EU-Guidelines on Food Hygiene and the General Principles for Food Hygiene of the Codex Alimentarius as well as the European Directive on Good Manufacturing Practice.

3. Seeds and propagation material

3.1. Seeding materials are to be identified botanically, indicating plant variety, cultivar, chemotype and origin. The material used should be traceable (see Documentation). The same applies to vegetatively propagated starting material. Starting materials used in organic production have to be certified as 'organic'.

3.2. Starting material should meet the requirements/standards concerning purity and germination (wherever available: certified seed/propagation material should be used). The starting material should be as free as possible of pests and diseases in order to guarantee healthy plant growth. When resistant or tolerant species or origins are available, they should be preferred.

3.3. The occurrence of not species/variety-identical plants and parts of plants has to be controlled in the course of the entire production process (cultivation, harvest, drying, packaging). Such impurities have to be eliminated promptly. Plant material or seeds derived from or comprising Genetically Modified Organisms have to be in accordance with national and European regulations.

4. Cultivation

4.1. Depending on the mode of cultivation e.g. conventional or organic, growers should be allowed to follow different Standard Operating Procedures for cultivation (to be elaborated).

4.2. Soil and Fertilization

4.2.1. Medicinal and aromatic plants must not be grown in soils that are contaminated by sludge. Soils should not be contaminated by heavy metals and residues of plant protection products and other not naturally occurring chemicals, etc. For this reason, minimum effective chemical input should be achieved.

4.2.2. The manure applied should be void of human faeces and prior to application it should be thoroughly composted.

4.2.3. All other fertilizing agents should be applied sparingly and in accordance with the demands of the plant and the particular species (including application between harvests). The use of fertilizers should be in accordance with efforts to minimize leaching.

4.3. Irrigation

4.3.1. Irrigation should be minimized as much as possible and applied according to the needs of the plant.

4.3.2. Irrigation-water should be in accordance with national and potential European quality standards and should be as free as possible of contaminants, such as faeces, heavy metals, pesticides, herbicides and toxicologically hazardous substances.

4.4. Crop maintenance and plant protection

4.4.1. Tillage should be adapted to plant growth and requirements.

4.4.2. Pesticide and herbicide application should be avoided as far as possible. When necessary they should be carried out using the minimum effective rates of approved plant protection products. Products for chemical plant protection have to conform to the European Union's maximum residue limits (European Pharmacopoeia, European Directives, Codex Alimentarius). Application and storage of plant protection products has to be in accordance with the recommendations of manufacturers and regulations of the authorities.

4.4.3. The application should be carried out only by qualified staff using approved equipment. Application should precede the harvest by a period either defined by the buyer or indicated by the producer of the plant protection product.

4.4.4. The use of pesticides and herbicides has to be documented (see Documentation) and made available to the buyer on request.

4.4.5. All measures regarding nutrient supply and chemical plant protection, should secure the marketability of the product. The buyer of the batch could be informed of the brand, quality and date of pesticide use in a written form (see Documentation).

4.5. The responsible cultivation organisation should put one person in charge, in order to check the conformity of the processing according to paragraphs 4.1 to 4.4. and should sign, in order to accept the responsibility, the documentation required (see Documentation).

5. Harvest/wild collection

5.1. The harvest/wild collection should take place when the plants are of the best possible quality according to the different utilizations.

5.2. Harvest/wild collection should preferably take place under the best possible conditions (wet soils, dew, rain or exceptionally high air humidity can be unfavourable). If harvest/wild collection is performed under wet conditions, extra care should be taken in order to avoid the unfavourable influence of moisture.

5.3. Equipment must be kept both in a clean state and technically perfect working order. Those machine parts including their housings that have a direct contact with the harvested crop should be regularly cleaned and kept free of oil and other contamination (including plant left-overs).

5.4. Cutting devices of harvesters/collectors must be adjusted so that the collection of soil particles can be reduced to a minimum.

5.5. In the course of harvest/wild collection, care should be taken to ensure that no toxic weeds can mix with the harvested crop.

5.6. Damaged and perished plant parts must be promptly eliminated.

5.7. All containers used in the harvest/wild collection must be clean and must be kept free of the remnants of previous crops; containers out of use, must also be preserved in a dry condition, free of pests and inaccessible for mice/rodents as well as livestock and domestic animals.

5.8. The harvested/collected crop should not be exposed to direct contact with the soil. It must be promptly collected and under dry, clean conditions (e.g. sacks, baskets, trailers and containers, etc.) submitted to transport, with the exception of windrowed and root products prior to washing.

5.9. Mechanical damage and compacting of the crop that would result in undesirable quality changes must be avoided. In this respect, attention must be paid to

a) avoiding the overfilling of the sacks,

b) the stacking up of sacks should not result in thickening of the crop,

c) the harvested/wild collected crop should be transported and kept in containers or bags in such way that the occurrence of heating is prevented.

5.10. The time between the harvesting/wild collection and the drying or processing of the plant should be very short, in order to avoid that the product could be damaged in its quality and increase its microbiological content.

5.11. The harvested/wild collected crop must be protected from pests, mice/rodents, livestock and domestic animals. Pest control measures should be documented (see Documentation).

5.12. The responsible harvesting/wild collection organisation should put one person in charge to check the conformity of the processing according to paragraphs 5.1 to 5.11 and should sign, in order to accept the responsibility, the documentation required (see Documentation).

6. Primary processing

6.1. Primary processing includes steps of processing such as washing, freezing, distilling, drying, etc.. All these processes whether for food or medicinal use must conform to relevant European and national regulations.

6.2. Arriving at the processing facility the harvested crop has to be promptly unloaded or unpacked or processed. Prior to processing the material should not be exposed directly to the sun (except in case there is a specific need e.g. for distillation) and if washing is not involved it must be protected from rainfall.

6.3. Buildings used in the processing of harvested crops must be clean, as well as thoroughly aerated and must never be used for other aims (housing livestock etc.).

6.4. Buildings must be constructed so as to provide protection for the harvested crop against birds, insects, rodents as well as domestic animals. In all storage (including packaging stores) and processing areas suitable pest control and monitoring measures, such as baits, pheromone traps and electric insect killing machines, must be operated and maintained by professionally qualified staff or contractors.

6.5. Processing equipment must be maintained clean and must be regularly serviced.

6.6. In the case of natural open air drying, the crop must be spread out in a thin layer. In order to secure unlimited air circulation, the drying frames must be located at a sufficient distance from the ground. Attempts must be made to achieve uniform drying of the crop and as a consequence to avoid mould formation. When drying with oil, the exhaust fumes must not be reused for drying. Direct drying should not be allowed except with butane, propane, or natural gas.

6.7. Except in the case of natural open air drying, the conditions (e.g. temperature, duration, etc.) must be selected taking into consideration the type (e.g. root, leaf or flower) and active substance content (e.g. essential oils and others) of the crude drug to be produced.

6.8. Drying directly on the ground or under direct exposure to the sun-light should be avoided unless it is required for a particular plant.

6.9. All material must be inspected and processed in order to eliminate sub-standard products and foreign matters.

6.10. Clearly marked waste-bins should be kept ready, emptied daily and cleaned.

6.11. In order to protect it, to respect quality and to reduce the risk of contamination, the product should be promptly packaged.

6.12. The responsible primary processing organisation should put one person in charge, in order to control the conformity of the processing according to paragraphs 6.1 to 6.11 and should sign, in order to accept the responsibility, the documentation required (see Documentation).

7. Packaging

7.1. After the repeated control and eventual elimination of low-quality materials and foreign matters, the product should be packaged in clean and dry, preferably new sacks, bags or cases. The label must be clear, permanently fixed and made from non-toxic material.

7.2. Reusable packaging materials should be well cleaned and perfectly dried prior to their usage. It must be guaranteed that no contamination takes place by reusing bags.

7.3. Information must conform to the European and national labelling regulations. In particular labels should indicate:

• common and Latin name of the plant (in special evidence)

• used parts (in special evidence)

• name and address of the producer (in special evidence)

• lot number (in special evidence)

• conservation techniques

• danger indication

• packaging and transport modalities

7.4. Packaging materials should be stored in a clean and dry place that has to be free of pests and inaccessible for livestock and domestic animals. It must be guaranteed that no contamination of the product takes place by the use of packaging material, particularly in the case of fibre bags.

8. Storage and Transport

8.1. Packaged dried materials and essential oils should be stored in a dry, well aerated building, in which the daily temperature fluctuations are limited and good aeration is given. Fresh products (except Basil) should be stored between 1 °C and 5 °C while frozen products should be stored below -18 °C (or below -20 °C for longer term storage). Essential oil storage must conform to the appropriate chemical storage and transport standards concerning risks and labelling requirements in accordance with national regulations and in particular EU Council Directive 94/55/EEC .

8.2. As a protection against pests, birds, rodents and domestic animals, the window and door openings are to be protected, e.g. by wire netting.

8.3. Bulk storage as well as the packaged dry crop must be stored appropriately: in buildings with concrete or similar easy to clean floors, on pallets, with a sufficient distance to the wall, thoroughly separated from other crops to avoid cross-contamination.

8.4. Organic products must be stored in accordance with national organic regulations and EU Directive 2092/91.

8.5. In the case of bulk transport, it is important to secure clean and dry conditions in order to reduce the risk of cross contamination with previous transport and mould formation or fermentation. In case of fresh material it is extremely advisable to use aerated containers. As a substitute, the use of sufficiently aerated transport vehicles and other aerated facilities is recommended. Essential oil transport must conform to appropriate regulations. National and European regulations on transport have to be respected.

8.6. Fumigation against pest attack should be carried out only in the case of necessity and it must be carried out exclusively by licensed personnel. Only registered chemicals must be used. Any fumigation against pest attack should be reported in the documentation (see Documentation).

8.7. For fumigation of warehouses, only permitted substances should be used, according to European or national regulations.

8.8. When frozen storage or saturated steam is used for pest control, humidity of the material must be controlled after treatment.

9. Equipment

9.1. Equipment used in plant cultivation/wild collection and processing should be easy to clean, in order to eliminate the risk of contamination.

9.2. All machinery should be mounted in an easily accessible way. They must be well serviced and regularly cleaned. Fertilizer and pesticide application machinery must be regularly calibrated.

9.3. Preferably non-wooden equipment should be used unless tradition demands wooden material. When wooden equipment (such as e.g. pallets, hoppers, etc.) is used, it should not come into direct contact with chemicals and contaminated/infected materials, so that infection of the plant material can be prevented.

10. Documentation

10.1. Field Records showing previous cropping and inputs should be maintained and signed by the person charged with responsibility. Field Records should gather any information about the cultivation such as: previous crop, seed used, name of the plant cultivated, exact location of the field, any treatment with pesticide, herbicide, fertilizer and growth regulator or any chemical plant protection (specified as: name of the product, date, quantity and reason of the treatments). A complete traceability of the materials and equipments used is recommended.

10.2. Each Field Record must be unambiguously and unmistakingly identified by a number or mark (in according to a written procedure).

10.3. Special circumstances during the cultivation which may influence the chemical composition like extreme weather conditions, pests (particularly in the harvest period) should be recorded on the Field Record.

10.4. The organisation in charge of the collection should certify in a written document and for each crop, the general data about the collection, indicating the area or district involved and other data influencing the quality of the product, as much: habitat, climate, kind of soil etc.

10.5. All the product - finished and semi finished - must be unambiguously and distinctively identified by batch number. Assignment of batch number must take place at an early stage.

10.6. All processes and procedures that could bear an impact on the quality of the product must be entered into the Batch Processing Records. The Batch Processing Records must be a collection of records which describe the relevant processing made on a batch of production.

10.7. The Batch Processing Records should gather the following information: name of the vegetable material, batch number, date (beginning and end of the process), equipment (name, type, number), parameter used and description of the process. The records should be dated and signed by the person responsible for the processing operation.

10.8. A complete traceability between the cultivation (Field Records), wild collection data and the processing of the vegetable material (Batch Processing Records) is recommended.

10.9. Batches from different areas shall be mixed only if it is guaranteed that the materials are perfectly similar under all points of view (botanical and phytochemical). Such mixing procedures should also be documented in a Batch Processing Records. The traceability between the mix batch number and the number of the original batches should be evident in the Batch Processing Record.

10.10. The application of the fumigation agents such as phosphin or any other plant protection substance must be entered into Batch Processing Records.

10.11. All agreements (production guidelines, contracts, etc.) between producer and buyer should be fixed in a written form.

10.12. To assure a complete traceability, the vegetable material should always travel with a way bill (records or labels) which reports at least: name of the producer, name and part of the vegetable material, N. of the Batch and date of production.

10.13. The results of audits should be documented in an Audit Report.

10.14. Copies of all documents (Fields Records (‘Schlagkartei’), wild Collection data, Audit Reports, Analyse Reports batch processing Reports) to be stored for a minimum of 7 years from the harvest date.

10.15. Take a retention sample of each batch of material produced by use an appropriate written sampling procedure. It is recommended keep the retention samples for not less than three years.

11. Quality Assurance

12.1. Agreements between producers and buyers of medicinal and aromatic plants, with regard to quality questions, e.g. active principles and other characteristic ingredients, optical and sensorial properties, limit values of germ numbers, plant protection chemical residues and heavy metals, must be based on internationally recognized or national specifications and should be laid down in a written form.

12. Self Inspection

13.1. Self inspection should be conducted in order to monitor the implementation and compliance with Good Agricultural Practice principles and to propose necessary corrective measures.

13.2. Personnel matters, premises, equipment, documentation, production, quality control distribution of herbal medicinal products, arrangements for dealing with complaints and recalls, and self inspection, should be examined at intervals following a pre-arranged programme in order to verify their conformity with the principles of Quality Assurance.

13.3. Self inspection should be conducted in an independent and detailed way by designated competent person(s) from the company. Independent audits by external experts may be useful.

13.4. All self inspections should be recorded. Reports should contain all the observations made during the inspections and, where applicable, proposals for corrective measures. Statements on the actions subsequently taken should also be recorded.