



EUROPAM, the European Herb Growers Association

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. This means 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 respective legal regulations.

EUROPAM GACP-MAP Version 2022

Document History:

- August 1998: First EUROPAM version
- December 1998: Discussion in EMA ad hoc working group
- February 1999: Comments by EMA ad hoc working group EMEA/HMPWG/17/99 draft and 18/99 draft
- June 1999: Updated to EUROPAM version 1999
- November 2010: GACP-MAP version 2010
- October 2022: GACP-MAP Version 2022



Contents

1	Scope.....	3
2	Personnel and training.....	3
3	Wild collection and cultivation	4
3.1	Wild collection.....	4
3.2	Cultivation.....	5
4	Harvest (wild collection and cultivation).....	6
5	Primary processing.....	7
6	Packaging	8
7	Storage and further transport.....	8
8	Equipment	9
9	Documentation	9
10	Quality assurance	10
11	Self-inspection	11
12	References.....	12
13	Glossary of Terms	13



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 in Europe. This means they apply to the production of all plant materials utilized either in a direct or processed form for humans and/or animals as, for example, pharmaceuticals, food and feed supplements and cosmetics. They also apply to all methods of production, including organic production, in accordance with respective legal regulations.

In view of the fact that medicinal and aromatic plants and their derivatives are exposed to a large number of both microbiological and other contaminants during the course of their production process, the main aim of the following Guideline is to provide guidance for producers and collectors in order to reduce plant (raw material) contamination as far as possible.

This GACP Guideline provides additional standards for the production and processing of raw materials, focusing on identifying the critical steps needed to comply with good quality. In this respect, they will be aimed at minimizing insufficient quality by means of prevention.

A main aim is to ensure that the plant raw material meets the demands of the consumer and the standards of the highest quality. Particularly important aspects are (1) hygienic production to reduce microbiological load to a minimum and (2) production with care in a sustainable way, so that the negative impacts affecting plants during cultivation, wild collection and processing and storage can be limited.

Depending on the final use, processing procedures must conform to food, feed or pharmaceutical regulations applicable in the country of purchase.

Growers, collectors, traders and processors of medicinal and aromatic plants should be encouraged to respect and comply with the GACP-MAP Guidelines, and insist that their partners also meet these requirements.

2 Personnel and training

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

The collectors should have appropriate training in order to identify the target plants and to avoid accidental co-harvests or the target species being confused. The collectors should in particular be familiar with indigenous toxic plants. The degree of knowledge of the collectors must be verified each season by a competent person put in charge by the collection organisation. Training and verification of plant knowledge should be documented in written form and signed by the trainee, the trainer and/or the responsible person (see Documentation).

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.

Changing facilities as well as toilets and hand-washing facilities must be available as per the respective regulations.

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



Persons with open wounds, inflammations and skin infections should be suspended from the areas where the plant processing takes place or have to apply appropriate wound dressing and wear protecting clothing or gloves, until they have completely healed.

The welfare of all staff involved in the growing and processing must be ensured. Workplace safety regulations should be displayed in the working area. Personnel should be protected from contact with dust and/or with toxic or potentially allergenic plant materials by means of adequate protective measures. Personnel should be properly trained in the safe use of equipment.

3 Wild collection and cultivation

3.1 Wild collection

All the parties involved in the collection of wild plants must ensure that they avoid causing damage to existing wildlife habitats.

In particular, the collectors must:

- a) Obtain the necessary permits, licenses, and permissions before the collection where necessary. In the case of plants intended for export from the country of collection, the Convention on International Trade in Endangered Species of wild Fauna and Flora (CITES) certificate must be obtained if necessary.
- b) Collect only plant populations that are clearly abundant and healthy, with multiple plants of differing ages (seedling, juvenile, and mature), to ensure population stability. Use responsible technique to prevent negative impact on the resource. Avoid over-exploitation and apply collection rotation until the populations have sufficiently re-established. Where applicable, the collector should leave the seeds of the collected plants in the collection area.
- c) Avoid destroying the entire plant, when in most cases it would be sufficient to harvest only part of it.
- d) Wild collectors should limit their collection to plants that they can correctly identify (preferably to the species level; to the level of subspecies and/or variety where applicable and necessary).
- e) Avoid collecting endangered species, according to local or international regulations.

Wild collection should take place when the plants are of the best possible quality in line with the different uses.

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

The collection process should avoid collection sites with possible risks of contaminations (e.g. close to cultivated fields treated with pesticides, in soils particularly rich in heavy metals, near roads or railroads).

During harvest/wild collection, care should be taken to ensure that no unwanted weeds, in particular no toxic weeds, can mix with the harvested crop (e.g. pyrrolizidine and tropane alkaloid containing weeds).



3.2 Cultivation

Growers should follow the crop farming manual (to be elaborated).

3.2.1 Soil and fertilization

Medicinal and aromatic plants must not be grown in soils that are contaminated by sludge. Soils should be as low as reasonably achievable in heavy metals, persistent pesticides and other contaminants.

The manure applied should not contain any human faeces and it should be thoroughly composted prior to application.

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

3.2.2 Irrigation

The grower should be aware of the quality of the irrigation water.

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

Irrigation water should be in accordance with applicable quality standards and as free as possible of contaminants.

3.2.3 Seeds and propagation material

Seeds and vegetative propagation materials are to be identified botanically to the species level and, wherever necessary and possible, to subspecies plant variety, cultivar, chemotype and origin. The material used should be traceable (see Documentation).

Seeds must have an appropriate degree of purity, viability, and germination rate. The starting material should be as free as possible of pests, diseases, and seeds of (toxic) weeds such as pyrrolizidine and tropane alkaloid plants to guarantee healthy plant growth.

When producing seeds and vegetative propagation material, identity should be controlled and non-conforming, especially non-conforming toxic plants, need to be eliminated as far as possible.

3.2.4 Crop maintenance and plant protection

Toxic weeds: Special attention should be paid to monitoring and removing toxic weeds (e.g. pyrrolizidine and tropane alkaloid containing weeds).

Tillage should be adapted to plant growth and requirements.

Pesticide 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. Maximum residue limits (MRL) of pesticides must conform to the respective regulations (e.g. EU Pesticides Database (European Commission, 2022) or (European Pharmacopoeia, 2019) if the product is intended for the European market). Application and storage of plant protection products must be in accordance with the recommendations of manufacturers and official regulations.

The application of pesticides should only be carried out 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.



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

The responsible cultivation organisation should put one person in charge to check the conformity of the processing and who should sign the documentation required to accept the responsibility (see Documentation).

4 Harvest (wild collection and cultivation)

Equipment must be kept both in a clean state and technically appropriate working order. Machine parts including their housings that have direct contact with the harvested crop should be regularly cleaned and kept free of oil and other contaminants (including plant leftovers).

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

Damaged and perished plant parts must be promptly eliminated.

All containers used in the harvest must be clean and must be kept free of the remnants of previous crops; containers not being used must also be preserved in a dry condition, free of pests and inaccessible for mice and other rodents as well as livestock and domestic animals.

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

Harvested goods must be protected from other sources of contamination.

- Plant contamination – example PA-containing hairs of *Echium* spp. picked up during transport; cross-contamination with other harvested crops such as *Symphytum officinale* or *Tussilago farfara* or *Digitalis* spp.;
- Chemicals (lubricants, stored pesticides/chemicals, cigarette smoke, house and industry smoke and exhaust gases (PAHs),
- Bags and packaging materials treated and/or contaminated with mineral oils (MOSH/MOAH problem) and other contaminants.
- Plastic fibres (e.g. leftovers from hay production)

Attention must be paid to avoid:

- Mechanical damage (e.g. damage to flower heads caused by incorrect threshing or transport)
- Compaction of the crop during harvesting by overfilling the containers or by stacking up containers,
- Self-heating during transport and storage of the freshly harvested crop in containers or bags.

The time between harvesting and the start of drying should be as short as possible to avoid damage, loss of quality and increase in microbiological burden.

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

The responsible organisation should put one person in charge to check the conformity of the processing and who should sign the documentation required to accept the responsibility (see Documentation).



5 Primary processing

Primary processing includes a set of product-specific steps, which can be undertaken along the supply chain at farmers' sites and also at industrial processing sites such as cleaning, classification, comminuting, cutting, sifting, cooling, destemming, distilling, drying, expressing, freezing, grinding, milling, packaging, sampling, sieving, soaking, winnowing, washing, etc. All these processes, whether for food or medicinal use, fall under GACP and must conform to relevant European and national regulations.

Arriving at the processing facility, the harvested crop must be promptly unloaded, unpacked or processed.

The harvested crop must be protected from environmental influences (e.g. rainfall, dust, local animals).

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

Buildings dedicated to processing 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.

Processing equipment must be kept clean and regularly serviced. Service measures must be documented.

In the case of natural open air drying, the crop must be spread out in a thin layer. In order to ensure sufficient air circulation, the drying frames must be located at a sufficient distance from the ground. Efforts must be made to ensure crops are dried in a uniform way and, as a consequence, to prevent mould from forming. Indirect drying using a heat exchanger is strongly recommended in order to avoid contamination with PAH, for example. Direct drying with exhaust gases is only allowed with propane, butane or natural gas, if there is no risk of contamination.

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

The parameters for processing (e.g. temperature, size) must be selected taking into consideration the type (e.g. root, leaf or flower) and active substance content (e.g. essential oils and others) or in line with product specifications.

All material must be inspected and processed to eliminate sub-standard insufficient material and foreign matters.

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



The responsible processing organisation should put one person in charge to control the conformity of the processing. The person in charge should confirm conformity by signing the required documentation (see Documentation).

6 Packaging

Once a final check has been carried out and any sub-standard materials and foreign matter eliminated, the product should be packed in clean and dry, food-grade sacks, bags, bales or boxes, preferably new ones. The label must be clearly visible, permanently fixed and made from non-toxic material.

Reusable packaging materials should be thoroughly cleaned and dried prior to being used. It must be guaranteed that reusing bags does not lead to contamination.

Information on the label must be comply with the relevant national and international labelling regulations. In particular labels should show the following:

- Common and scientific name of the plant
- Used parts of the plant
- Name and address of the producer
- Batch number
- Weight of the package
- Conservation techniques (if applicable)
- Origin (if applicable)
- Hazard information (if applicable)
- Packaging and transport modalities (if applicable)
- In case of organic products: control number of the organic certifier

Packaging materials should be stored in a clean and dry place that must be free of pests and inaccessible for livestock and domestic animals. It must be guaranteed that the product is not contaminated by the packaging material.

7 Storage and further transport

Packaged dried materials and essential oils should be stored in a dry, well -ventilated building in which the daily temperature fluctuations are limited and there is proper ventilation. Fresh products (except plants sensitive to cold such as basil) should be stored between 2 °C and 8 °C, while frozen products should be stored below -15 °C. Essential oil storage and transport must conform to the appropriate chemical storage (ISO, 2014) and transport standards (European Commission, 2008b).

Window and door openings are to be covered, e.g. by wire netting, to provide protection against pests, birds, rodents and domestic animals.



Bulk storage as well as the packaged material must be stored in suitable buildings: in buildings with concrete or similarly easy to clean floors, on pallets (ideally heat-treated in case of wooden pallets¹), with a sufficient distance to the wall, clearly separated from other crops to avoid cross-contamination.

Organic products must be stored in accordance with relevant national and international organic regulations.

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 transports, mould formation or fermentation. In case of fresh material, it is strongly advisable to use chilled (if needed) and ventilated containers. Essential oil transport must conform to appropriate regulations. National and international regulations on transport must be followed.

Disinfection against pests should be carried out only if needed and exclusively by licensed or responsible staff. Only officially permitted disinfection agents must be used. Any disinfection should be recorded in the documentation (see Documentation).

When disinfection is carried out by freezing or by using saturated steam, the humidity of the material must be controlled after treatment. A product can only be released when humidity is within specifications.

8 Equipment

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

All machinery should be mounted in an easily accessible way. It must be properly serviced and regularly cleaned (e.g. before a new product is processed, but especially after processing allergenic / pharmacologically highly active / toxic plants). Fertilizer and pesticide application machinery must be regularly calibrated.

Preferably non-wooden equipment should be used, unless tradition demands wooden material. When wooden equipment (such as pallets, hoppers, etc.) is used, it should not come into direct contact with chemicals and contaminated / infected materials to prevent plant material contamination.

9 Documentation

Field Records showing previous cropping and inputs should be maintained. 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,

¹ Wooden pallets may be sources of contamination with residuals of disinfection compounds, etc. (International Plant Protection Convention, 2021)



fertilizer and growth regulator or any chemical plant protection (specified as: name of the product, date, quantity and reason of the treatments), person performing the work.

Special circumstances during the cultivation which may influence the chemical composition such as extreme weather conditions, pests (particularly in the harvest period) should be recorded in the Field Records.

The organisation in charge of collection should certify the general data about the collection in a written document and for each crop, indicating the area or district involved and other data influencing the quality of the product.

The whole product – both finished and semi-finished – must be unambiguously and distinctively identified by a batch number. Batch numbers must assigned at an early stage.

The Batch Processing Records must be a collection of records which describe the relevant processing made on a batch of production.

The Batch Processing Records should contain 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 responsible person.

Full traceability between cultivation, wild collection and the processing of the plant material is recommended.

Batches from different areas can only be mixed if it is guaranteed that the materials are produced under similar conditions. Full traceability must be guaranteed.

Use of the fumigation agents such as phosphine or any other plant protection substance must be documented.

All agreements (production guidelines, contracts, etc.) between producer and buyer should be made in writing.

To ensure full traceability, the plant material should always be accompanied by a waybill (records or labels) which contains (at the very least): name of the producer, name and part of the plant material, batch number and date of production.

Copies of relevant documentation should be stored for a minimum of three years from the harvest date.

(A) sample(s) representative for each batch should be taken using an appropriate written sampling procedure. It is recommended to keep retention samples for a minimum of three years, unless otherwise justified.

10 Quality assurance



Agreements between producers and buyers of medicinal and aromatic plants, with regard to quality questions, should be set out in writing.

They must be based on internationally recognized or national specifications.

These quality criteria may comprise aspects such as identity, active principles and other characteristic ingredients, optical and sensorial properties, limit values of microbiology, plant protection chemical residues and heavy metals.

In certain cases, quality criteria from buyers that go beyond what is demanded by regulations may be required.

The results of audits need to be documented in an Audit Report.

11 Self-inspection

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

Self-inspection includes aspects such as personnel matters, premises, equipment, documentation, production, quality control, logistics, arrangements for dealing with complaints and recalls.

Self-inspection should be examined at intervals defined in a pre-arranged programme or in maximum intervals of three years in order to verify its conformity with the principles of Quality Assurance.

Self-inspection should be conducted in a detailed way by designated competent person(s) from the company. Audits by external experts (such as customers) may be useful.

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 documented.



12 References

- European Commission. (2008a). *EudraLex, Volume 4: EU Guidelines to Good Manufacturing Practice. Medicinal Product for Human and Veterinary Use. Annex 7: Manufacture of Herbal Medicinal products.*
- European Commission. (2008b). Directive 2007/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods.
- European Commission. (08. 06 2022). *EU Pesticides Database.* Von https://ec.europa.eu/food/plants/pesticides/eu-pesticides-database_en abgerufen
- European Pharmacopoeia. (2019). *Ph.Eur. 10.0, 2.8.13 Pesticide Residues.* EDQM.
- FAO. (2002). *International Code of Conduct on the Distribution and Use of Pesticides.* Rome: FAO.
- International Plant Protection Convention. (2021). *International Standards for Phytosanitary Measures (ISPM) 15: Regulation of wood packaging material in international trade.* Rome: FAO.
- ISO. (2014). *ISO/TS 210 Essential oils - General rules for packaging, conditioning and storage.*
- Spurgeon, D. (1976). *Hidden Harvest. A systems approach to postharvest technology.* Ottawa: International Development Research Centre.



13 Glossary of Terms

- **Batch (or Lot):** A defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous (European Commission, 2008a).
- **Batch number (or Lot number):** A distinctive combination of numbers and/or letters which specifically identifies a batch (European Commission, 2008a).
- **Bulk Product:** Any product which has completed all processing stages up to, but not including, final packaging (European Commission, 2008a).
- **Cross Contamination:** Contamination of a material or of a product with another material or product (European Commission, 2008a).
- **ISPM:** International Standards for Phytosanitary Measures.
- **Medicinal Plant:** Plant the whole or part of which is used for medicinal purpose (European Commission, 2008a).
- **Packaging Material:** Material used in supporting, protecting or carrying a commodity (ISPM 20, 2004).
- **Pesticide:** Any substance or mixture of substances intended for preventing, destroying, or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals, causing harm during or otherwise interfering with the production, processing, storage, transport, or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or substances that may be administered to animals for the control of insects, arachnids, or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, or agent for thinning fruit or preventing the premature fall of fruit. Also used as substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport (FAO, 2002).
- **Postharvest System:** a system encompassing the delivery of a crop from the time and place of harvest to the time and place of consumption, with minimum loss, maximum efficiency and maximum return for all involved (Spurgeon, 1976).
- **Primary Processing:** part of the postharvest system. Depending on the product, some processes of ‘Primary Processing’ need to be repeated and/or combined with other processes. Processes of ‘Primary Processing’ can be grouped as follows:
 - Cleaning (e.g. washing and watering, sifting, sieving, screening, winnowing, metal separation)
 - Crushing (e.g. cutting, chopping, comminuting, grinding, shredding)
 - Sterilizing and disinfesting
 - Conserving (e.g. chilling, drying, freezing)
 - Distilling and expressing
 - Packaging
 - Transporting