

EUROPAM the European Herb Growers Association**GAP/GWP – Subcommittee**

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Guidelines for Good Wild crafting Practice (GWP) of Medicinal and Aromatic Plants*
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Note:

***It is acknowledged by the members of Europam that F.I.P.P.O.-ASSOERBE has contributed substantially to the establishment of the drafted GWP guidelines.**

****In *italic* the differences between GAP and GWP**

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1. General introduction

1.1 Scope

The guidelines for the *Good Wild Crafting Practice* of Medicinal and Aromatic (Culinary) plants are intended to apply to the *harvesting* and primary processing of all such plants collected, traded and used in the European Union. Hence they apply to the production of all herbal 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.

According to the World Health Organization (WHO), more than 21.000 species of plants in the world are used for these productions. Only about 100 plants are regularly cultivated, whereas the remaining plants are harvested in their natural habitat. Wild crafting production is mainly developed in the regions with a low technological and economical development, particularly in Asia, Africa, Middle and South America and East European Countries.

The main reasons why wild crafting of medicinal and aromatic plants are:

- a) The long growth periods for ripening and consequently for the harvest, in particular regarding trees and bushes (Horse-Chestnut, Birch, Linden tree, Hawthorn, Elder, Bearberry, etc.)*
- b) The plant cannot normally be cultivated (symbiotic relationship with other plants: e.g. Mistletoe, Moss etc.)*
- c) Difficult to germinate, in finding the seeds, in transplanting, etc., which does not justify the time and the costs necessary for an attempt of using the plant for cultivation purposes. (e.g. Baptista tinctoria)*
- d) The quantity required of the plant is too small to justify the economic costs of cultivation.*

1.2 The Environment

Wild crafting of medicinal and aromatic plants very often negative situations, especially in developing countries. 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 that 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 Wild crafting Practice* Guidelines provide additional standards for the production and processing of raw materials, focussing 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:

- a) are produced hygienically, in order to reduce microbiological load to a minimum,
- b) are produced with care, so that the negative impacts affecting plants during *cultivation*, 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 harvester in order to reduce plant (raw material) contamination to the greatest extent.

1.5 Realisation

All participants of the production process (from primary *harvester* to traders) are required to comply with these guidelines voluntarily and to elaborate practical measures in order to realise 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 the Batch Documentation (Records and/or labels).

Harvester, traders and processors of medicinal and aromatic plants should be encouraged to respect and comply with the *GWP* Guidelines, and demand that their partners also meet these requirements.

2. Personnel and Education

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

2.2 *The harvester 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 harvester must be periodically verified from a competent person put in charge by the harvesting organisation.*

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

2.4 The personnel entrusted with the plant material must be required to have a high degree of personal hygiene (including the personnel working in the fields) and have received adequate training regarding their hygienic 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 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 harvesting 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 Harvest

3.1 The harvest should take place when the plants are of the best possible quality according to the different utilizations.

3.2 Harvest should preferably take place under the best possible conditions (wet soil, dew, rain or exceptionally high air humidity are generally unfavourable). If harvest is performed under wet conditions, extra care should be taken in order to avoid the unfavourable influence of moisture.

3.3 Equipment must be kept both in a clean state and technically perfect working order.

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

3.5 All containers used in the harvest 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.

3.6 The harvested 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.

3.7 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 crop should be transported and kept in containers or bags in such way that the occurrence of heating is prevented.

3.8 The time between the harvesting 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.

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

3.10 The responsible harvesting organisation should put one person in charge, *in order to control the correct identification of plants harvested*, to check the conformity of the processing according to paragraphs 3.1 to 3.9. and should sign, in order to accept the responsibility, the documentation required (see Documentation).

4 Primary processing

4.1 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.

4.2 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.

4.3 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.).

4.4 Buildings must be constructed in order 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.

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

4.6 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 directly for drying. Direct drying should not be allowed except with butane, propane, or natural gas.

4.7 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.

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

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

4.10 Clearly marked waste-containers should be kept ready, emptied daily and cleaned.

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

4.12 The responsible primary processing organisation should put one person in charge, in order to control the conformity of the processing according to paragraphs 4.1 to 4.11 and should sign, in order to accept the responsibility, the documentation required (see Documentation).

5 Packaging

5.1 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.

5.2 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.

5.3 Information must conform with 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

5.4 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.

6 Storage and Transport

6.1 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.

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

6.3 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.

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

6.5 In the case of bulk, it is important to secure dry conditions and furthermore, in order to reduce the risk of mould formation or fermentation, 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.

6.6 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 must be reported in the documentation (see Documentation).

6.7 For fumigation of warehouses, only permitted substances should be used, according to

European or national regulations.

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

7 Equipment

7.1 Equipment used in *harvesting* and processing should be easy to clean, in order to eliminate the risk of contamination.

7.2 All machinery should be mounted in an easily accessible way. They must be well serviced and regularly cleaned.

7.3 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 material, so that contamination/infection of the plant material can be prevented

8 Documentation

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

8.2 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.

8.3 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.

8.4 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.

8.5 A complete traceability between *the harvesting data (8.1)* and the processing of the vegetable material (Batch processing Records) is recommended.

8.6 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.

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

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

8.9 To assure sure 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.

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

8.11 Copies of all documents (*Harvesting* Records, Schlagkartei, Audit Reports, Analyse Reports Batch Processing Records) to be stored for a minimum of 7 years from the harvest date.

9 Education

9.1 It is extremely advisable to educate all personnel dealing with the crop or those engaged in the direction of the production regarding production techniques and the appropriate use of pesticides.

10 Quality Assurance

10.1 Agreements between producers and buyers of medicinal and aromatic plants, with regard to quality (e.g. active principles and other characteristic ingredients, botanical aspect, microbiological

content, plant protection chemical residues and heavy metals) must be based on internationally recognized or national specifications and must be laid down in written form.

11 Self inspection

11.1 Self inspections should be conducted in order to monitor the implementation and compliance with Good Wild crafting Practice principles and to propose necessary corrective measures.

11.2 Personnel matters, premises, equipment, documentation, production, quality control, distribution of the 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.

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

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

12 Conclusion

12.1 The present guidelines are a first attempt to describe some procedures, which are to be followed in wild crafting of medicinal and aromatic plants. They are open to any kind of modification, particularly on the basis of direct experiences of the producers, which we kindly request to collaborate to this project, in order to improve this text. The scope of observing these norms of Good Wild crafting Practice of medicinal and aromatic plants is to guarantee the quality and the quantity of wild crafted plants.