European Herb Growers Association (EUROPAM)

GACP Working Group

A Practical Implementation Guide to Good Agricultural and Wild Collection Practices (GACP)

This guide was compiled by the GACP Working Group of the European Herb Growers Association (EUROPAM). Final version 2016. For questions and comments please contact office@europam.net.
This document is available at
www.europam.net/documents/gacp/EUROPAM_Practical_GACP_Implementation_Guide.pdf.

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Waldland Naturstoffe GmbH (page 40)

Content

Introduction

Good Agricultural Practice (GAP) is a set of standards that addresses environmental, economic and social sustainability for on-farm crop production and post-production processes, resulting in safe and high quality food and non-food agricultural products (FAO, 2003). Within agriculture, GAP needs to be adapted to the specificities of the different sectors.

In many agriculture-related QA systems, GAP is regarded as base requirement. A practical GAP-level already implemented on farm or in a company will subsequently simplify the introduction of HACCP, ISO or other quality related standards.

The production of medicinal and aromatic plants is characterised by a high degree of wild collection that still co-exists with field production. Therefore, a proposal of guidelines for wild collection (Harnischfeger, 2000) was integrated into the GAP of Medicinal & Aromatic Plants (MAPs), resulting in the "Good Agricultural and Wild Collection Practice (GACP)" of MAPs (EMA, 2005; EUROPAM, 2010; WHO, 2003). In Europe, GACP has become obligatory for the production of medicinal plants (EMA, 2005).

Producers of MAPs need to translate these (general) guidelines into their specific quality assurance system. To support this process, EUROPAM offers this 'Practical Implementation Guide' in the form of general (top) standard operating procedures (SOPs) on important topics of GACP, accompanied by practical examples. EUROPAM recommends that the SOPs and examples should not be taken over literally from this document. The intention is rather to present meaningful ideas, because a QA-system should always be set up according to the real on-site situation. The examples presented here are deliberately diverse in structure to demonstrate several different possible approaches. In contrast to the educational examples of the 'Practical Implementation Guide' a QA-system of a farm/company should be more consistent.

This document addresses all actors under the umbrella of GACP from wild collection and field cultivation to post-harvest processing and – under certain conditions - essential oil distillation (for an exact delimitation between GACP and GMP refer to EudraLex (2008)).

References

- EMA, 2005. Guideline on Good Agricultural and Collection Practice (GACP) for Starting Material of Herbal Origin. EMA/HMPC/246816/2005. Available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003362.pdf (Accessed 18.11.2016).
- EudraLex, 2008. The Rules Governing Medicinal Products in the European Union. Volume 4. EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use. Annex 7. Manufacture of Herbal Medicinal Products. Available at http://ec.europa.eu/health/files/eudralex/vol-4/vol4_an7_2008_09_en.pdf (Accessed 18.11.2016).
- EUROPAM, 2010. Guidelines for Good Agricultural and Wild Collection Practices for Medicinal and Aromatic Plants (GACP - MAP). Available at http://www.europam.net/documents/gacp/EUROPAM_GACP_MAP_8.0.pdf (Accessed 18.11.2016).
- FAO, 2003. Development of a framework for Good Agricultural Practices. COAG/2003/6. Available at http://www.fao.org/docrep/meeting/006/y8704e.htm (Accessed 18.11.2016).
- Harnischfeger G, 2000. Proposed guidelines for commercial collection of medicinal plant material. Journal of Herbs, Spices & Medicinal Plants, 7: 43-50.
- WHO, 2003. WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants (http://whqlibdoc.who.int/publications/2003/9241546271.pdf (Accessed 18.11.2016).

Abbreviations

- **EMA**: European Medicines Agency
- **EUROPAM**: European Herb Growers Association
- **GACP**: Good Agricultural and Wild Collection Practice
- **MAPs**: Medicinal and Aromatic Plants
- **PAH**: polycyclic aromatic hydrocarbons
- **QA:** quality assurance
- **QA/QC person**: quality assurance /quality control appointed person
- **QM**: Quality Management
- **SOP**: Standard Operating Procedure

SOP 1: Standard Operating Procedure (SOP)

Purpose

GACP should be used as a basis for the establishment of an appropriate quality assurance (QA) system. A serious QA-system provides the adoption of:

- documented procedures (e.g. SOPs) covering the entire production process in detail from the cultivation/collection to the storage,
- a complete system of internal traceability,
- methods, contracts, record-keeping, specifications, and reports, all well documented and updated.

A possible list of processes and actions that have a particular importance on the quality of the product:

- Contract (definition of quality)
- Numbering of the Batches
- Sampling
- Collection
- Cultivation
- Post-Harvest Processing
- Packaging, Labelling and Storage

Procedure

- Identification of the manufacturing processes that needs a specific SOP.
- The SOP is written, approved and distributed by qualified staff.
- SOP is routinely applied.
- In case it is necessary to revise an SOP a new version is released.

Responsibilities

The SOP must be prepared by competent staff and approved at least by the Technical Director and or by the person responsible for QA.

References

- GACP by EMEA/HMPC/246816/2005 (Att.). Chapter 7.1

SOP 2: Training

Purpose

Training is an essential step for a qualified production and enables people to perform their tasks correctly. Training records are a proof that measures were undertaken to guarantee the qualified production.

Training should be provided for all the personnel involved in cultivation, wild collection and processing. Training can be performed any time needed under the supervision of the QA/QC person. A training plan shall be elaborated in order to include all the staff and to monitor the periodic trainings. It is useful to provide an alternative date for training so that all staff can participate.

A list of possible training topics:

- Hygiene of personnel
- Hygiene of building and facilities
- Procedures of cultivation or wild collection
- Primary processing
- Packaging and labelling
- Storage and transport
- Other legal compliance
- Quality control and sampling

Frequency

Each staff member shall be trained when he is newly employed or appointed to a new field of activity. Afterwards the staff member shall be trained at least once a year. Unskilled and seasonal workers shall be trained as appropriate.

Special requirements

Training sessions should be adapted to the field of responsibility of the staff member and conducted either by internal or external experts. It has to be kept in mind that the training shall be in an understandable language.

In order to train internal experts, the possibilities of trainings from different providers shall be used. Internal experts need to have the necessary expert knowledge and the ability to communicate the training matters.

Control of the training

The efficacy of the training shall be controlled in regular intervals. If necessary, measures (e.g. additional trainings sessions) shall be taken.

Procedure

- Setting up the training plan
- Organizing the training
- Training
- Documentation of the training

Recording

1. Training Plan: The training plan shall include educational objectives and training subjects.

2. Documentation of the training: Completed training has to be recorded in written form. Documentation shall contain in form of a list:

- place, date and time of training
- participants
- the topic and learning target
- duration
- trainer

Responsibilities

The responsible person for organising trainings

Example(s):

- Example 2: Training – examples of Different Training Options
- Example 3: Training – Example of a Training Documentation

References

- GACP by EMEA/HMPC/246816/2005 (Chapters 4.6, 4.8, 4.10).

SOP 3: Contracts

Purpose

Contracts and agreements are necessary arrangements (mutual consents) between producer and buyer. They are an important instrument for a good business relationship.

Procedure

- Definition of the contracting parties (in most cases producer and buyer)
- Negotiating specific terms
- Agreement on specific terms (use Incoterms wherever possible)
- Fixation of the agreed terms in a written form

Responsibilities

Contracts and agreements are concluded by the responsible management.

Example(s)

- Example 4: Template of a Sales Contract

References

- GACP by EMEA/HMPC/246816/2005 (Chapter 7.9).

SOP 4: Hygiene and Contamination

Purpose

The main aim of this SOP is to ensure consumer safety by including essential principles of hygiene in MAP production in order to reduce contamination to a minimum. Hygiene comprises the areas of contamination/cross-contamination, personal hygiene and hygienic production of MAPs.

Procedure

- **Contamination / Cross-contamination**
    - Every co-worker is also a consumer and wants clean, safe products. Therefore it is in their own interest to avoid and remove any contamination.
    - Measures should be taken to minimise dangerous contamination.
    - Examples of dangerous contamination:
        - Glass (can be minimized e.g. by using casings for neon tubes or by a ban of all glass bottles in the production).
        - Metal (can be minimized e.g. by using magnets for ferro-magnetic metals. These need to be calibrated regularly and this needs to be documented).
        - Stone.
        - Fuel, oils, lubricants (can be minimised by strictly separating maintenance, cleaning and production. Control before production restart! Use of food compliant lubricants.).
        - Chemicals.
    - Nauseating contaminations
- **Personal hygiene**
    - Illness and Injuries. Conditions to be reported to management / possible exclusion from product handling:
        - Jaundice.
        - Diarrhoea.
        - Vomiting.
        - Fever.
        - Sore throat with fever.
        - Visibly infected skin lesions (boils, cuts, etc.).

        - Discharges from the ear, eye or nose.
    - Personal Cleanliness. Personnel should always wash their hands when personal cleanliness may affect product safety, for example:
        - At the start of product handling activities.
        - Immediately after using the toilet.
        - After handling any contaminated material.
        - After breaks for eating and drinking.
    - Personal Behaviour. People engaged in product handling activities should refrain from behaviour which could result in contamination of the product, for example:
        - Smoking.
        - Spitting.
        - Chewing or eating.
        - Sneezing or coughing over unprotected product.
        - For post-harvesting processes: personal effects such as jewellery, watches, pins or other items should not be worn or brought into production.
    - Training (see SOP 2: Training)
    - Visitors
        - Protective clothing.
        - Obeying hygiene regulations.

- **Hygienic production of MAPs**
    - Requirements for Buildings and Facilities
        - Known history of the building.
        - Never been used for producing, storing or using hazardous materials (pesticides, etc.).
        - Never been used for housing livestock.
        - Clean.
        - Well aerated.
        - Protected against birds, insects, rodents and domestic animals.
        - Storage in buildings with concrete or similar easy to clean floors, well separate from other herbal substances.
        - Storage avoiding direct contact with the floor.
    - Equipment
        - Machine parts in direct contact with the harvested MAPs must be cleaned after use.
        - Machinery should be checked for broken parts which could potentially contaminate harvested MAPs.
        - Equipment must be made from appropriate materials to avoid

cross-contamination.
        - Equipment must be kept in dry conditions free of pests and not accessible for mice/rodents, livestock and domestic animals.
    - Soil and Fertilisation
        - Only thoroughly composted manure void of human faeces can be used.
    - Irrigation
        - Water used in irrigation should be in compliance with regional/national quality standards.
    - Harvest
        - Delivery of harvest material as quickly as possible to the processing facility, especially when the crops are of high moisture levels or at high temperatures.
        - Protection of harvest material from pests, mice/rodents, livestock and domestic animals.
    - Primary Processing
        - Unloaded/unpacked as soon as possible on arrival at the processing facility.
        - Protected from rainfall, insect infestation etc.
        - Open air drying: thin layers, drying frames with sufficient distance from the ground.
        - Achieve uniform drying.
        - Clearly marked waste-bins, emptied regularly and cleaned.
    - Packaging
        - Clean and dry, preferentially new packaging materials.
        - Reused packaging material well cleaned and properly dried.
        - Storage of packaging material in a clean and dry place free of pests and inaccessible to livestock and domestic animals.

Responsibilities

Personal hygiene: personnel and management

Hygienic production of MAPs: management

Example(s)

- Example 5: Hygiene – Pictogram ‘Hand Washing’
- Example 6: Hygiene – Pictogram ‘Smokers’

References

- GACP by EMEA/HMPC/246816/2005 (Personal Hygiene: Chapters 2.2, 4.4, 4.5, 5.4 Hygienic production of MAPs: Chapters 5.1. 5.2., 5.3., 6.2., 6.3., 11.3., 11.7., 11.9., 11.10., 12.2., 12.3., 12.5., 12.6., 13.2., 13.3., 13.4.).
- Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. Official Journal of the European Communities L226/3.
- Recommended International Code of Practice – General Principles of Food Hygiene including Annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application. Codex Alimentarius Commission CAC/RCP1-1969, Rev 4-2003.

SOP 5: Batch Identification ('BATCH-ID') / Traceability

Purpose

It is essential for every produced quantity to be traced back unambiguously to the primary producer and therefore additionally to the field or location where the plants are cultivated or collected. The instrument for guaranteeing full traceability is the unique number assigned to each homogeneous quantity of material along the production chain (batch number).

Procedure

- A Batch-ID should be assigned to each material as early as possible.
- The definition of a batch has to be transparent (guaranteeing traceability).
- The material should remain identified by a Batch-ID along the process till the finished product.
- During production it could be necessary to mix material of different Batch-IDs (coming from different fields or collection areas) assigning a new Batch-ID. Anyway, the producer should mix different origin only if the material can be considered homogeneous within specific limits and always with a guarantee to maintain full traceability to the origin.

Responsibilities

Each person in charge of a specific process along the production chain is responsible for the correct batch identification in order to secure full traceability.

Example(s)

Example 8: Different possibilities for batch numbering

References

- GACP by EMEA/HMPC/246816/2005 (Chapters 7.7, 7.8)

SOP 6: Wild Collection

Purpose

Wild collection is the process of gathering MAPs from natural stands. The purpose of standardising wild collection is to guarantee a botanically correct product of high quality (fulfilling acceptance criteria) and to certify a correct legal framework (permissions/authorisations) and sustainable collection practice.

Procedure

A correct wild collection should include the following points:

- Official authorisation for the collection (landowner, public authorities, etc.).
- If no official authorisation is received, the following information should be gathered:
    - the plant to be collected is not protected and allowed to be traded (by checking with CITES or other systems).
    - availability of natural resources.
    - influence of wild collection methods and quantities on sustainability of the species.
- Botanical description of the herb to ensure that the correct species is collected.
- Defined harvest period.
- Defined acceptance criteria.

Recordings

- Permission for wild collection.
- Goods receipt at chief collector.
- Labels: The label on each bag must contain:
    - Name of producer
    - Product name
    - Origin
    - Harvest time (from – to)

Responsibilities

Collector: collection of correct species; drying; transport to collection point.

Chief collector: recording and record keeping of goods receipt; control of acceptance criteria; if necessary additional drying; first assignment of a batch number; correct labelling; good storage conditions at the collection point; transport to the exporter.

Exporter: control of acceptance criteria; if necessary processing (sieving, etc.); good storage conditions; assignment of an (export) batch number; organisation of export and transport.

Importer: organisation of import and transport; eventually post-harvest processing.

Example(s)

- Example 9: SOP Wild Collection of Primulae flos in Albania

References

GACP by EMEA/HMPC/246816/2005 (Chapters 1., 2.3, 4.7, 6.1 – 6.3, 7.1, 7.2, 7.6, 7.10, 8.2, 10.1 - 10.4, 11.1 – 11.9)

SOP 7: Cultivation

Purpose

Cultivation is the production of medicinal and aromatic plants in the field. The purpose of standardising cultivation practices and inputs is to guarantee a high and consistent quality of production.

Procedure

Besides standard agricultural procedures of field cultivation (field choice (crop rotation!), preparation of the field, organisation of seeds/plants, sowing/transplanting, field maintenance and harvest) the following points are specific for MAPs:

- Ensure the correct botanical identity and quality of the seeds/plants.
- Availability of special equipment (especially adaptation of sowing/harvesting techniques, post-harvest, especially a fast access to drying facilities).

Records

Field records should be of one of the following types:

- Official field records, mandatory to fulfil national requirements.
- Field records, cooperative or customer format.
- Free-form field records.

The recording of information from fields should include at least the following points:

- Identity (botanical species), variety/cultivar/accession used.
- Steps of agricultural production, until harvesting.
- Traceability.
- Product, field, harvest, harvest time.
- Definition of a batch number as soon as possible in the process (see document SOP 4: Batch Identification ('BATCH-ID') / Traceability).

Responsibilities

The correct botanical identity is in the responsibility of the producer. Field records are generally documented by trained persons (see document 'SOP 2: Training'). The responsibility for the information recorded should be taken by the farmer.

Example(s)

- Example 10: Example for the Content of a Field Record
- Example 11: SOP Organic Field Production of Coriander Seeds

References

- GACP by EMEA/HMPC/246816/2005 (Chapters 2.3., 4.9, 6.1 – 6.3, 7.1 – 7.4, 7.10, 8.1, 8.2, 9.1 – 9.3, 11.1- 11.9)

SOP 8: Post-Harvest Processing

Purpose

Post-harvest processing is the stage of crop production immediately following harvest, including conserving (cooling, drying), separating, cleaning, sorting, packaging and storing. Postharvest treatments have a big impact on final quality and may be sources of contaminations (e.g. PAH by direct heating, splinters of processing machines, etc.). Therefore it is important to define the process well and record important parameters and any deviation from the process.

Procedure

- Choose appropriate process.
- Follow the process specific procedure.
- Record information, especially deviations from the defined process.

Records

- The recording of information from fields should include the following points (if applicable):
    - The information of cultivation/wild collection records as basis.
    - A process flow (a list of all processes applied from harvest to storage).
- Proposal for the recording of specific post-harvest steps:
    1. Washing
        - Equipment
        - Water volume
        - Water quality
    2. Cutting
        - Equipment
        - Cutting size
    3. Drying
        - Type of dryer/drying
        - Drying temperature
        - Duration
    4. Cleaning / Sorting
        - Equipment(s) used
    5. Packaging including labelling (cf. to SOP 4: Batch Identification ('BATCH-ID') / Traceability)

6. Storage
    - Storage conditions, type of storage, recording of termperature and humidity is recommended

Responsibilities

Post-harvest-processing records are generally documented by trained persons (see document 'SOP 2: Training'). The responsibility of the information recorded should be taken by the farmer or the owner of the primary processing company.

Example(s)

- Example 12: SOP Drying of Ginkgo
- Example 13: SOP Post-Harvest Treatment of Primulae flos from Wild Collection

References

- GACP by EMEA/HMPC/246816/2005 (Chapters 4.9, 5.1 – 5.4, 6.1 – 6.3, 7.1, 7.5, 7.10, 8.2, 11.10, 12.1 – 12.6, 13.1 – 13.4, 14.1 – 14.5)

SOP 9: Quality Control / Specification

Purpose

Quality control is an activity necessary to ensure appropriate and consistent quality. It is an important instrument for the assessment of essential production steps. It can help to identify failures and introduce corrective measures.

Procedure

1. Definition of the quality specifications in a written form (numerical limits, ranges, or other criteria).
2. Definition (in written form) of the method of testing and/or references.
3. Set up control at the appropriate step during the production and primary processing according specification and methods at the point 1 and 2.

Responsibilities

Quality control is generally carried out by trained persons (see SOP 2: Training). The responsibility of the quality control should be taken by a QA/QC appointed person.

Example(s)

- Example 14: SOP for the Determination of Foreign Matter
- Example 15: SOP for the Gravimetric Determination of Loss on Drying

References

- GACP by EMEA/HMPC/246816/2005 (Chapters 7.10, 8.2)

SOP 10: Sampling

Purpose

Samples of material can be taken or provided for testing, analysis, inspection, investigation, demonstration, retention or trial use.

They are important to verify, for example, the quality of the material coming into or leaving the site of production. Moreover samples are an essential part of any business relationship along the supply chain as well as of the traceability system.

Procedure

The sampling procedure may be different from case to case depending on the purpose, the material and circumstances. The sampling procedure must be defined in written form.

The sampling procedure should include the following points:

1. The formula regarding the numbers of containers to be sampled.
2. The minimum quantity produced by the sampling.
3. Sample identification system.
4. Sample handling (e.g. quartering, storing etc).

Responsibilities

The sampling is generally carried out by trained persons (see SOP 2: Training). The responsibility of the sampling should be taken by a QA/QC person.

Example(s)

- Example 16: SOP for Sampling Ginkgo

References

- GACP by EMEA/HMPC/246816/2005 (Att.). no reference

ANNEX A: Glossary of Terms

Batch (synonymous: 'lot'): A batch is a specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. It is homogeneous or comparable, harvested in a similar period and processed in a similar way.

Batch ID (or Lot ID): A unique combination of numbers, letters, and/or symbols that identifies a batch (or lot) and from which the production and distribution history can be determined.

CITES: The **C**onvention on **I**nternational **T**rade in **E**ndangered **S**pecies of Wild Fauna and Flora ("The Washington Convention") is a multilateral treaty containing lists of species not allowed to be traded or with trade restrictions.

Contamination: the presence or introduction of a hazard.

Contract: a contract is an agreement with specific terms between two or more persons or entities in which there is a promise to do something in return for a valuable benefit.

Field Records: documents used during the cultivation of medicinal and aromatic herbs to record all the steps of production from seeds to final bags of herbs, the materials used, and the exceptional weather conditions.

Hygiene: the measures and conditions necessary to control hazards.

Incoterms: (= International Commercial Terms) a series of pre-defined commercial terms published by the International Chamber of Commerce (ICC) widely used in international commercial transactions. A series of three-letter trade terms related to common contractual sales practices, the Incoterms rules are intended primarily to clearly communicate the tasks, costs, and risks associated with the transportation and delivery of goods.

Potable water: water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

Quality Assurance (QA): the part of quality management focused on providing confidence that quality requirements will be fulfilled (ISO 9000, 2005).

Quality Control (QC): Checking or testing material to verify the quality according defined specifications (e.g. foreign matters).

Specification: A set of criteria to which a material should conform to be considered acceptable for its intended use (e.g. foreign matters ≤ 2 %).

Sample: A sample is a limited quantity of material which is representing a larger

amount of that material, for instance the batch or lot (see Batch numbering/traceability document).

Sampling: An act of obtaining a sample is defined as sampling.

SOP: Standard **O**perating **P**rocedure. An SOP is a written document or instruction detailing all steps and activities of a process or procedure used in any manufacturing process that could affect the quality of the product.

Training*:* Training is the acquisition of knowledge, skills and competencies as a result of the teaching of practical skills and knowledge that relate to specific useful competencies.

ANNEX B: Examples

Example 1: Suggestion of an SOP structure

The components of an SOP listed below are suggestions how to organize an SOP. Any other way to organize an SOP is allowed as long as it is in compliance with the goal of quality management.

- Header
    - Name of the company
    - ID Number of the SOP.
    - Title of the SOP
    - Revision Number: often it will be necessary to revise an SOP over time. The company should track the changes and use revision numbers. This ensures that all personnel use the current version of the SOP.
    - Effective Date: allows employees, clients and auditors to control if e.g. batches were processed before or after a certain revision of an SOP took place.
    - Written by
    - Approving Signatures: the SOP should be signed by (a) supervisor(s). The employees know that the SOP has been reviewed and is approved.
- Distribution List: identifies the individuals that have received a copy of the SOP. This list helps managing SOP distribution (recalling old versions and hand out new versions) in order that all personnel involved in a specific process are using the same version of the SOP.
- Definitions: meaning or explanation of abbreviations, words, terms and acronyms.
- Purpose: short description of the purpose and importance of the activity/document/record.
- Equipment and Supplies: the company should list the equipment and supplies needed to execute the respective process.
- Procedure: describes the activities of the process in a logic sequence.
- Recording: regulates recording, e.g. documents to be filled in, taking photos.
- Responsibilities: determines who is responsible for which part in the process.
- References: lists the reference documents that are either the (legal) basis for a specific procedure or were used to set up the standard procedure.

Example 2: Training – examples of Different Training Options

- Lectures
- Demonstrations
- Practical courses
- QM-Audits
- Excursions
- Field days
- Visit of fairs
- Participation in meetings of professional MAP organisations

Example 3: Training – Example of a Training Documentation

Header:

- Topic/learning target
- Type of training
- Trainer(s)
- Date
- Location

List of Participants

- consecutive numbering of participants
- name of the participant
- signature of the participant

Example 4: Template of a Sales Contract

Sales Contract Between

_____

based in _____

represented by _____

hereinafter called the BUYER

and

The cooperative or farm _____

based in _____

represented by _____

hereinafter called the VENDOR

It has been agreed as follows:

Article 1: Object

The object of this contract is the sale of

Article 2: Duration

This contract is drawn up for the duration of:

Article 3: Price

The price is:

Add incoterms

Article 4: Quality

The quality standards are set by the BUYER (customer specification, etc.)

The quality standards refer to AFNOR, ISO, PHARMACOPOEIA, etc.

The type of packaging will be developed according to the following terms…..

Article 5: Quantities

The quantity ....

Article 6: Sampling

In order to avoid dispute, the product will be sampled on harvesting. A representative sample of the harvest must therefore be sent to the BUYER, who will validate it. Once this validation has been carried out, the product may be considered as deliverable.

Article 7: Delivery

A schedule of delivery of the products will be determined in advance, in consultation between the BUYER and the VENDOR. It details the dates and places of harvesting, as well as the projected quantities to be bought/sold at each date and place.

Article 8: Obligations

The VENDOR will be responsible for his products up to the time of reception by the BUYER. The VENDOR is owner of the product until full payment.

Article 9: Payment of the value of the products

Payment will be carried out according to the following terms _____ and within a maximum of 30 days of invoicing.

Article 10: Termination

This contract may be terminated in the case of force majeure, subject to notice provided by one or the other of the parties by registered letter with recorded delivery, at least …… months before the end of the contract.

Article 11: Dispute

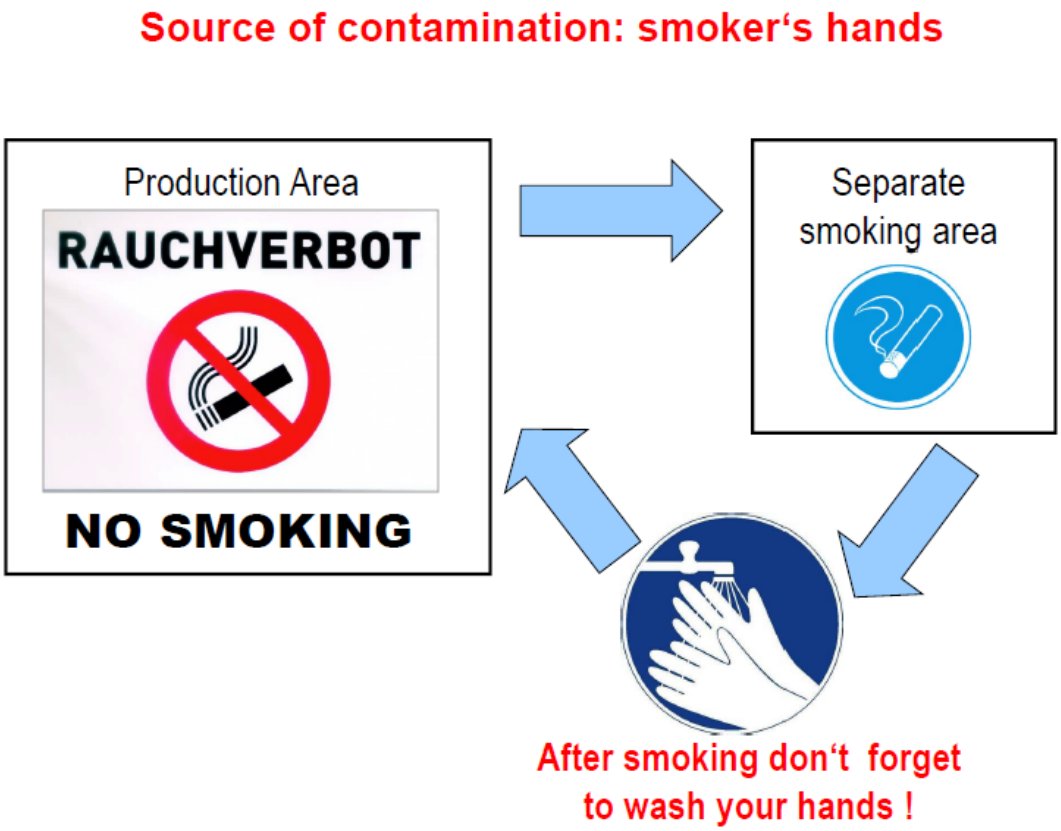
Any dispute arising from the interpretation or implementation of this agreement will be submitted to the competent jurisdiction (court of _____).

Drawn up in_____ on _____

For the VENDOR For the BUYER

Example 5: Hygiene – Pictogram ‘Hand Washing’

Example 6: Hygiene – Pictogram ‘Smokers’



Example 7: Risk assessment questionnaire

Assessment of risks to the product

Company Name:

According to the following list possible risks for the product were evaluated and noted under II. “Identified risks”

I. Exemplary descriptive list of possible risks

1. Risks from factors on the plants’ growing location
   - Neighboring crops (cross contamination)
   - Soil borne contamination (heavy metals, microbiology)
   - Evaluation of emissions from traffic and industry
2. Cultivation
   - Seeds and plantlets (GMO, origin, pretreatment)
   - fertilising (nitrate, microorganisms, heavy metals)
   - plant protection (preparation, pre-harvest interval, application rate, approval, application devices)
   - Weeds (toxic/allergenic plants)
3. Harvest
   - Time of harvest
   - Time interval between harvest and beginning of drying
4. Drying
   - Direct/indirect heating
   - Temperature
   - Duration of drying
   - Residual moisture content
5. Processing / packaging
   - Risks of contaminations (lubricants, cleaning agents, foreign matter)
   - Packaging materials
6. Storage and dispatch
   - Fumigation
   - Pests
   - Conditions of storage
   - Inspection of means of transportation (vehicles, containers)
7. General risks
   - Hygiene
   - Glass breakage
   - Nicotine
8. Others (please name them)

II. Identified risks

1.
2.
3.
4.

Location and Date

Signature

Example 8: Different possibilities for batch numbering systems

- 0035903: consecutive numbering.
- HYP/11/001: drug ID, year of harvest, consecutive number within drug and year.
- DK-CT1-1001: site of processing, type of product, consecutive number within processing site and type of product.
- M14A1151B00100: drug ID, part of the plant, year, grower identification number, number of cut, final size quality.

Example 9: SOP Wild Collection of Primulae flos in Albania

Definitions

Plant material sources: *Primula veris* L. (syn. *P. officinalis* (L.) HILL), cowslip; and/or *Primula elatior* (L.) HILL, oxlip (Primulaceae).

Description: The drug consists of the entire flowers (corolla and calyx). The ca. 15 mm long corolla tube is light yellow to brownish yellow with a lemon-yellow margin which have an orange yellow spot at the base that fades on drying. The calyx is greenish brown with five prominent ribs and short pointed teeth.

Local name: agulice

Purpose

The purpose of this SOP is to set up a guideline to sustainably collect Primulae flos from the wild. This SOP is adjusted to the situation in Albania.

Procedure

Wild collection of Primulae flos is performed by many collectors that deliver mostly dried drug to the collection point (chief collectors). The chief collector delivers predominantly to the exporter who is organising storage and export and eventually processes the material.

Legal situation of wild collection of Primulae flos and collection permissions

- Primulae flos is not CITES listed and no collection permission is necessary nor are collection quota defined in Albania.

Harvest

- Depending on altitude above sea level *Primula* sp. flowers in March, April or May. The flowering extends over 2 to 3 weeks. The ripe open flowers (yellow, yellow green) should be harvested before they build a fruit capsule (with seeds).
- Harvest should preferentially take place during dry weather only.
- Fresh material must be carried in clean, dry, well aired baskets or in woven bags.

Acceptance criteria

- Flower colour: yellow to greenish yellow.
- Odour: accepted: light, characteristic, reminiscent of honey, without foreign notes, not accepted: untypical odour, foreign notes (e.g. mouldy, fumy).
- Taste: faintly sweetish.
- Humidity: material must be dried, free of perceptible rest humidity.
- Content of dark green (blackish) flowers must not be higher than 30%.
- Foreign organs: parts of the source plant itself, but not defined as the drug (e.g. Primula leaves, stems longer than 5 cm, rhizome fragments).
- Ripe seeds: max. 2%.

- Leaves and rhizome fragments: max. 5%.
- Whole plants (Figure 1): not accepted.
- Damaged, rotten, spoiled material: not accepted.
- Foreign contamination: parts of foreign plants or other matter of vegetable or mineral origin, other garbage (e.g. straw, grass, hair, metal parts; noticeable matter of animal origin): max. 5%.

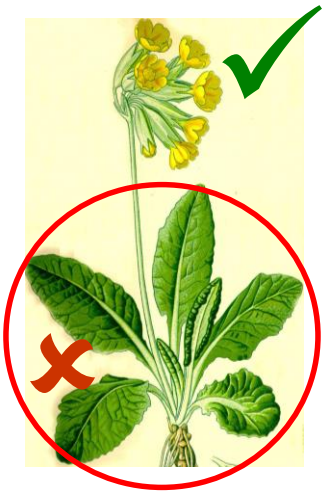


Figure 1: Plant parts to be harvested (green) and not to be harvested (red)

fresh cowslip flowers

dried cowslip flowers

Plant parts not allowed

Figure 2: fresh (left) and dried (right) cowslip flowers and plant parts not allowed (bottom)

Recordings

- Goods receipt at chief collector
- Labels: The label on each bag must contain:
- Name of producer
    - Product name
    - Origin
    - Harvest time (from – to)

Responsibilities

Collector: collection of correct species; drying; transport to collection point.

Chief collector: recording at the goods receipt; control of acceptance criteria; if necessary additional drying; first assignment of a batch number; correct labelling; good storage conditions at collection point; transport to the exporter.

Exporter: control of acceptance criteria; if necessary processing (sieving, etc.); good storage conditions; assignment of (export) batch number; organisation of export and transport.

Importer: organisation of import and transport; eventually post-harvest processing.

References

- EUROPAM SOP wild collection records
- EUROPAM SOP post-harvest processing
- EMA GACP

Example 10: Example for the Content of a Field Record

- Farmer
- Name of the field
- Area
- Location of the field (only province, country)
- Main crops in the neighbourhood
- Species
- Variety/cultivar/accession of propagation material
- Pre-crop
- Description of the vegetative development:
    - Date
    - Stage of plant development/cultivation
    - Observations/pictures
- Use of fertiliser:
    - Date of application
    - Type (organic/mineral)
    - Composition
    - Concentration
    - Amount
    - Development stage
- Pesticides
    - Date of application
    - Name of the pesticide
    - Active component
    - Amount
    - Concentration
    - Development stage
    - Reason
- Harvest
    - Date and time to harvest
    - Stage of development
    - Part of plant harvested
    - Surface harvested
    - Weight of plants harvested
    - Harvesting technique
    - Observations
- Produced according to GACP guidelines (yes / no / not applicable)
- Location, Date, Signature

Example 11: SOP Organic Field Production of Coriander Seeds

Definitions

Plant material sources: *Coriandrum sativum* L. var. *microcarpum*; coriander;

Plant material harvested: Coriander fruits (often referred to as coriander seeds).

Description of the plant: Annual, up to 50 cm high. The leaves are variable in shape, broadly lobed at the base of the plant, slender shape higher on the flowering stems. The flowers in small umbels, white or very pale pink, asymmetrical, with the petals pointing away from the centre of the umbel longer (5–6 mm) than those pointing toward it (only 1–3 mm). The fruit is a globular, dry schizocarp of 1.5 - 3 mm (*C. sativum* var. *microcarpum*). TSW: 4-10g, Composition: 0.5% - 1% essential oil.

Figure 1: left: fruiting coriander plant; right: coriander field

Procedure

Site: light and well-drained soils, chalk-loving plant.

Cultivation: seed rate: 6-10 kg/ha (depending on the cultivar used), sowing with spacing drill or seed drill, row spacing 24-40 cm, depth of sowing as exact as possible at 2-5 cm (deviation leads to irregular seedling emergence = yield loss).

Nutrient withdrawal and fertilisation: farmyard manure before sowing; 50-60 kg N (not more, danger of too lush leaf and stem growth); 60 kg P_2O_5; 80 kg K_2O for a good fruit development; on well supplied soils abstain from fertilisation; organic fertilisers like farmyard or liquid manure are favourable.

Field maintenance: minimum 1x hoeing (4-leaf stage, before closing of the rows), hoeing is important for weed control and promotes optimum soil condition.

Diseases and pests:

Bacterial Leaf Spot (*Pseudomonas syringae* pv. *coriandricola*): necrosis, leaf spot, water-soaked lesions on foliage and reduced number of fruits in the umbels. Lesions with a purplish margin and tan, necrotic centres. Especially during flowering, clusters

of brownish plants. Cold and wet weather promotes spreading. Disease pressure and yield losses increase from year to year. Seed-borne, spreading by rain or sprinkler irrigation. Control: heat treatment of the ripe fruits before sowing (hot water 50°C for 20 min. Or 65° for 6 days with dry heat); furrow or drip irrigation (dry foliage).

Bugs (transfer of the bacterial leaf spot disease).

Harvest and yield: Mid to end of July when the field becomes yellowish-brownish, gentle threshing, yield 700-1000 kg/ha, max. water content 8%.

Crop rotation: interval of 4 years (due to bacterial leaf spot disease), during this period also no cultivation of caraway (*Carum carvi*), fennel (*Foeniculum vulgare*), lovage (*Levisticum officinale*), bishop's flower (*Ammi majus*) and anise (*Pimpinella anisum*).

Example 12: SOP Drying of Ginkgo Folium

1. Evenly load the fresh leaves into drying machine:
    a. Loading rate: 12-16t fresh leaves/6 hours shift.
    b. Drying Time and Temperature: Tumble Dryer: 6 min at 650/700°C (Entrance) approx. 130-140°C (Exit).
2. Move the dried leaves to the "Cooling Area" cooling down for 3 to 4 hours.
3. Pre-Pack the dried leaves in new polypropylene bags or into 75kg bales.
4. Mark the bags/bales with field ID, factory ID and production date (= Factory batch No.).
5. Take random samples according to Example 16: SOP for Sampling Ginkgo, mark the samples as in point 4, and send them to the lab for pre-analysis.
6. Fill the data into the Production Record (Appendix xy).

Example 13: SOP Post-Harvest Treatment of Primulae flos from Wild Collection

Fresh collected plant material should be protected at any time from:

- Wetness or moisture
- Compression
- Heat

Transport

Fresh harvested material should be transported in clean, dry and well aerated containers as soon as possible to the drying place.

Drying

Drying rate: 5:1, it means, 10 kg fresh material is equivalent to approx. 2 kg dry material.

At the drying place the fresh material must be spread in thin layers on a clean surface (e.g. drying frames or plastic sheets), avoiding direct contact with the soil and any time protected from:

- Rain and humidity.
- Foreign matters (other plants from the surroundings, stones, soil, dust, metal, glass, hair, paper, plastic, any other kind of garbage…).
- Contaminants (excrements, detergents, gasoline/diesel, machine oil, pesticide dust, smoke, emissions, allergenic stuffs …).
- Pests (rodents, insects, birds,...) and domestic animals.

Damaged, rotten or spoiled harvested material (distinguishable by bite traces, untypical colour, texture and/or smell) must be excluded.

Packaging and labelling

Dried plant material should be packed as soon as possible in proper packaging material. It must be ensured, that no contamination of the product may occur, e.g. due to the packaging material (loose plastic fibres, chemical residues, foreign odours or any kind of household garbage) or due to infestation by storage pests (packaged material must be timely closed). The packaged material must be labelled.

Storage

Crops in storage must any time be protected against:

- Humidity
- Direct sunlight (risk of bleaching)
- Rodents, insects, birds and domestic animals

Stored crops should be placed away from roof, walls and floor, preferentially on pallets.

Example 14: SOP for the Determination of Foreign Matter

Definition

Foreign Matter: material consisting of any or all of the following:

- Foreign organs: matter coming from the source plant but not defined as the drug.
- Foreign elements: matter not coming from the source plant and either of vegetable or mineral origin.

Purpose

Herbal drugs should be free from moulds, insects and other animal contamination. Therefore it is necessary to examine any foreign matter in source plant material.

Procedure

Weigh 100 g to 500 g of the substance to be examined and spread it out in a thin layer.

Examine for foreign matter by inspection with the unaided eye or by use of a lens.

Separate foreign matter and weigh it and calculate the percentage present.

References

- European Pharmacopoeia 012008:20802 (2.8.2. Foreign Matter), modified.

Example 15: SOP for the Gravimetric Determination of Loss on Drying

Definition

Loss on drying (LOD) is a classical gravimetric method of measuring moisture in solid or semi-solid materials.

Purpose

Loss on drying is necessary to determine the residual water content e.g. in dried drugs.

This SOP applies to plant raw materials with the exception of essential oil containing plant materials.

Procedure

In this technique a sample of material is weighed, dried at defined conditions for an appropriate period, cooled and then reweighed. The residual moisture content (as per cent) of the test product is calculated based the product weight loss during the drying cycle.

- Place the prescribed quantity of the substance to be examined in a weighing container previously dried at under the conditions prescribed for the substance to be examined.
- Dry the substance to constant mass or for a prescribed time in an oven at within the temperature range prescribed in the drug-specific SOP.*)
- Determine the quantity of the substance after drying.
- Calculate the residual moisture content:

$$Residual\ Moisture\ Content\ [\%] = \frac{W - D}{D}$$

W...mass of original sample

D...mass of dried sample

*) exemplarily: often cited temperature and time are 105°C for 3h. Please note that temperature and time should be adjusted to your drug.

References

- European Pharmacopoeia 01/2008:20232 (2.2.32. Loss on Drying), modified.

Example 16: SOP for Sampling Ginkgo Folium