Partnerséget építünk

EDUCATIONAL MATERIAL FOR BASIC TRAINING

HERBALAND (INTERREG SKHU /1601/4.1/150)

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1. The European medicinal herb growing and trading today

The usage of organic materials has become the center of attention over the last couple of decades, and it will most likely increase even further. 25% of modern medicines contain organic materials even today. Recent research results have discovered new organic resources, that can be used for diseases that are barely curable even with synthetics.

More than 400 organic drugs were already being used by the early 80's in Western-Europe, which meant a yearly 80,000 tons of import. The export of medicinal herbs produced in Eastern-Europe occurs in raw material transportation even to this day. The international transportation of these products is somewhat held back by the lack of unified laws regarding their production, registration, and their distribution. The export of raw materials with average quality to the Western-European countries appears to be the most logical solution in the short term. In the long term however, the optimal solutions seems to be the increased exportation of highly processed products.

The European Union is the world's biggest medicinal and aromatic herb market. The annual import is around 130,000 tons on average, which is about equal to 350 millions USD. The annual growth rate is 5-10%. It is one of the biggest medicinal herb producers with approximately 70,000 ha of fields. The most important medicinal herb suppliers are USA (15.8 %), India (8.1%), China (7.45%), Egypt (5.47%), and Turkey recently.

The 10 most sold medicinal herbs are Ginkgo / Fern pine, (Ginkgo biloba L.),the common St. John's wort (Hypericum perforatum L.), sago palm (Metroxylon sagu Rottb.), ginseng (Panax ginseng L.), coneflower (Echinacea spp.) cohosh (Cimicifuga racemosa L.), valerian (veriana officinalis L.), garlic (Allium sativum L.), vitex (Vitex agnus-castus L.), and wild cherry (Prunus avium L.).

Germany is the center of medicinal herb commerce and distribution inside the Union. The supplies coming from the Balkan and far-Eastern countries get to the member nations through Germany. This makes it a very important partner for the Eastern-European countries, and the observed tendencies and changes over there have an impact the commerce back here. Germany is the biggest exporter of shredded and powdered medicinal herbs used for cosmetics and plant protection available in commercial traffic. It had an export share of 26.7% (extra and intra) with an export value of 106.9 million USD of the EU's total export. Out of the countries joined in 2004, Poland is the biggest exporter, its export value almost doubled between 2004 and 2007. In contrast, Hungary's export has somewhat declined since then.

Due to the more and more rigorous quality regulations and increased prices for the pharmaceutical industry, it's favorable to use organic materials made by growing, with

known qualities and agents in them. There are around 130-140 plant species produced in Europe.

The biggest producers are France, Hungary, Poland and Spain. Lavender, poppy, cumin, fennel and mint are grown in the biggest quantities. In terms of global medicinal herb production, Argentina, Chile, China and India are the biggest ones.

Herbs containing essential oils are produced in large quantities in France. Parsley, horse-radish, elderberry, fennel, marjoram, chamomile, thistle, chives, common St. John's wort, dill, peppermint and buckthorn are produced in almost 8000 ha in Germany.

The demand by consumers and processors for medicinal herb production is getting higher and higher.

The most important reasons for this are the following:

- Homogeneity and a demand for certain quality (milfoil, horsetail).
- Quality assurance and required documentation (ISO, etc.).
- The increased interest over natural ingredients, rise in demand for quantity (common St. John's wort, varieties of goldenrod).
- Demand for regional produce (instead of importing rosemary, they grow it locally).
- The protection of nature, the extinction of species, or them becoming endangered (mountain wandering, pheasant's eye)
- They are considered alternative plants for plough land growing.
- To avoid the accumulation of pesticide and heavy metals (horsetail, nettle, blood-leaved swallowtail)
- The area where the gathering of medicinal herbs has decreased and there are fewer skilled gatherers.

There are factors that are making growing and cultivation more difficult:

- The Eastern-European growers have a disadvantage over their Western-European competitors in most of the cases. Ineffective, out of date methods. More common plough field growing (for example: wheat, corn, sunflower, rape flower).
- Due to the high labor and energy prices, the medicinal herb growing is more expensive.

- Medicinal herbs can be grown without permit but their purchasing or processing requires certain qualifications.
- Lack of an effective branch information system.

The sector's processing industry has multiple branches. Thanks to the primary processing – selection, drying, cleaning, cutting, grinding – 80% of the materials are exported (whole, cut drug, and in filter forms).

During the secondary processing and after the quality control, the production of the market-ready medicine, organic drug, tea, remedy, cosmetics, spice(mix), or dietary supplement begins. The processing industry's most important problem is that some of the modern mechanical and technological elements are missing but fixing this requires financial aid from the government.

The export mostly consists of low-processed and low added value products (e.g.: dried medicinal herbs). After processing in other countries (extracts), these extracts are imported back to Hungary as high added value intermedier - or finished products.

Illustration no. 1: *Finished goods warehouse in Hungary.*

2. Definitions

Medicinal herbs: In the widest sense, those plant species can be classified as medicinal, that have been or currently being used for curing ailments based on tradition or literature.

Illustration no. 2: *Milfoil*

Drug: The agent containing part of a plant commonly preserved by drying, or any kind of liquid (essential oil) or solid (resin) substance, that hasn't taken part in any processing phase other than the primary one.

The organic drugs are products made from medicinal plants in accordance of the national prevailing provisions and the pharmacopoeia: *[...]*

[...organic drug:]

- The part of a medicinal herb that **contains the highest amount of active agents**, and it was only preserved by drying, or peeled, cleaned, shredded if necessary, but was not processed or altered in any other way.

Illustration no.3: *Marigold drug*

- Products made from organic materials (essential oil, fatty oil, resin, balm).

Illustration no. 4*: Milfoil's essential oil*

- Substance made by transforming organic materials (medical coal, tar).

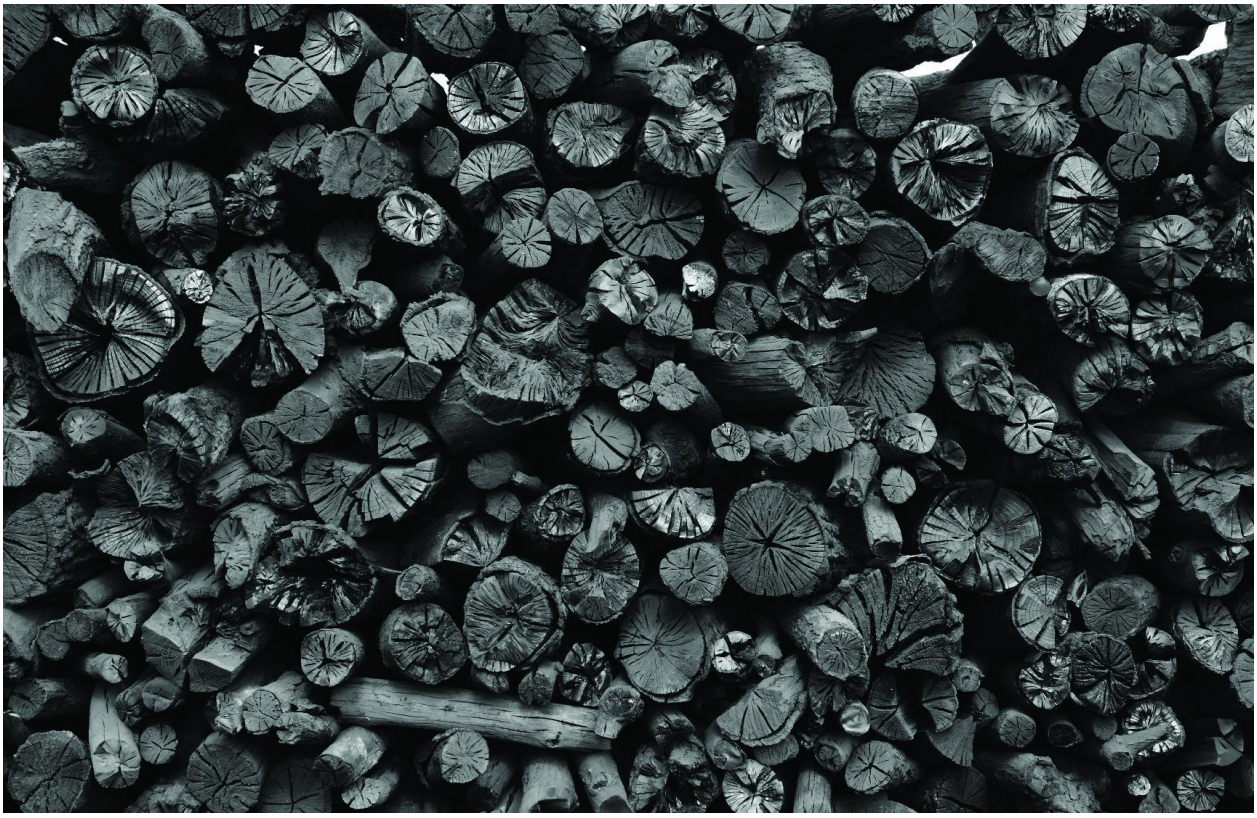

Illustration no. 5: *wood carbonization*

The durg's chemical substances:

- Content substance: The sum of drug specific chemical substances.
- Active agent: The compound responsible for the healing effects of the drug.
- Accompanying material: Boosts the active agent's effect but has no other uses in itself.
- Leading material: It serves as classification for the drug's chemical composition. It's not necessarily the same as the active agent but its amount is drug specific. *(E.g.: hypericin – tutsan.)*

Active agent: Those substances that have verifiable effects, therefore biologically active, health maintaining, disease process halting and healing substances. Several similar appellations are often mixed in the literature.
The active agents can be found in different parts of plants. They can accumulate in the chlorophyll containing leaves (basil, sage), in the flowers (milfoil, mallow), in the root (gentian), in the crops (hawthorn, fennel), in the seeds (flax), in the wood and cortex (alder buckthorn). The drug can be manufactured from these parts by drying, among other methods. The drugs' name, that must always be listed on the product, were made according to the rules of the latin nomenclature.

Chart no. 1: Drug name examples

English name	Scientific	Example	English counterpart
Root	*Radix*	*Levistici radix*	lovage root
Cortex	*Cortex*	*Cinnamomi cortex*	Cinnamon crust
Leaf Shoot	*Herba*	*Hyperici herba*	St John's wort
Flower	*Flos*	*Levendulea flos*	Lavender flower
Seed	*Semen*	*Hippocastani semen*	Horse chestnut seed
Essential oil	*Aetheroleum*	*Anisi aetheroleum*	Anise essential oil

Folk medicine: The sum of healing methods not recognized by the official healthcare system.
Groupin of the plants used in folk medicine:

1. Plant species that are used for the same purpose in both folk medicine and the healthcare system (Chamomille, coneflower).
2. Plant species that were eventually dropped by the healthcare system (ground ivy).
3. Plant species that are used by both but for different purposes (Cannabis).
4. Plant species are used in folk medicine and its other varieties recognized by the official healthcare system (primrose)
5. Plant species that are used by folk medicine but their effects are not confirmed by scientific research (burgundy glow).

Phytotherapy: Treatment by using medicinal herbs, their parts, or concoctions. It's not an alternative medicine. Its medications are called phylotherapeuthicum. It can provide independent or complementary treatment in certain acute or chronic diseases. There are concontions with both strong effect (forte, there are associated side effect), and mild effect (mite). These can be mono or complex preparations. There are usually numerous substances in these concoctions. These always contain additional elements beside the active agents that are not neutral in terms of its effects.

Its sub-group is the **galenic concoctions**. These medications can be produced with simple methods by the drugs of the medicinal herbs. Even the patiens themselves can create them in certain cases. These provide unlimited ways in terms of medicinal herb usage. These are usually used as concoctions.

Aroma therapy: The sum of therapies based on using essential oils and herbs containing essential oils. The essential oils are called Aetheroleum. These do not dissolve in water, mix with water, but certain ingredients can turn into an aqueous phase in small amounts. Based on their chemical compositions, the essential oils made up by dozens of compounds, their common feature is their volatility. The essential oil is the sum of a given plant's volatile compounds. The environmental factors have a significant effect on the composition of the essential oil. Plants grown at the same location have their essential oil content increased proportionately to the sun rays' intensity. The essential oils and drugs containing them can be absorbed even through a healthy skin.

Their major effects and their medicinal utilization:

- Antibiotic properties (e.g.: savory)

Illustration no. 6: *savory*

- Affecting the respiratory system (e.g.: thyme)

Illustrationno.7:*thyme*

- Carminative properties (e.g.: anise)

Illustration no. 8: *anise*

- Stomach strengthening, and appetite increasing properties (e.g.: lovage).

Illustration no. 9: *lovage*

- Affecting the liver and biliary tract (e.g.: peppermint).

Illustration no.10: *peppermint*

- Diuretic properties (e.g.: juniper).

Illustration no. 11: *common juniper*

- Anti-inflammatory properties (e.g.: milfoil)

Illustration no. 12: *milfoil*

Homeopathy: While it's still an independent school in medicine, the number of people opposing it are increasing. Its main principle is that the nature, the human body has the self-healing ability which it supports with medication. The materials used for its products are minerals, plant and animal based products, while compounds are only used in negligible numbers. More than half of the starting materials are plant based. The homeopathy uses decreased, often barely measurable amounts of active agents that in bigger doses cause similar symptoms in a healthy body to the ones observed on the patients. Its unique production method is based on gradual dilution. Its effectiveness is based on the information that gets into the system. It uses plants that are otherwise considered poisonous or ineffective. In terms of concoctions, only their harmlessness must be proven. It isn't part of the medicinal treatment.

3. Quality assurance systems in the medicinal herb industry

Quality: The sum of the qualities and features of a product or service, that make it capable of satisfying the needs that are expected from it.

Quality assurance: It focuses on the production process and its adequacy, while also encompasses everything that can affect the finished product's quality. Its purpose is to assure a constant good quality.

The purposes of classifications:

- Health protection
- Prevention of any kind of misuse
- Interest protection (producer, distributor, consumer)

Requirements:

- Work in accordance of written instructions.
- Quality control must be performed before, during, and after the production process.
- The processes must be documented.

The quality produced by quality assurance will be verified by a quality certificate. The system becomes complete with the proper control process.

In terms of medicinal and aromatic plants the official quality control means a one time inspection of the drugs, a comparison to the pharmacopoeia or to the standard specifications, and the allowance or disallowance of its distribution.
The quality assurance encompasses the production of the ingredients, the primary and secondary processing. It is done in parallel of the production.
There are three principles in the quality assurance of the products made from medicinal herbs:

- **Effectiveness:** The proving of healing effectiveness based on previous observations of empirical data and more recently on literature and pharmacological researches. The typical number value of these researches is the ED50 value (Effective Dosage), that represents the amount of dosage required to achieve the expected results in 50% of the test subjects.

- **Safety:** It is based on measurements performed to avoid poisoning. Its typical number is the LD50 value (Lethal Dosage), that represents the amount of dosage that caused 50% of the test subjects to perish. The substances used in medicine cannot be toxic in the recommended dosage, limited amounts of side effects are allowed to occur, **it is required to know their optimal usage and the conditions of their contraindications.**

- **Quality:** It can be achieved by ensuring the quality assurance of the production process.

To determine the actual strength and direction of the effect, pharmacological and clinical researches are conducted.

The pharmacological research serves to determine the effect (ED50) and toxicity (LD50) of the active agent or extract.

- In vitro: tests performed on cells, tissue, enzyms,
- In vivo: tests performed on mice, rats, guinea pigs, cats, dogs, monkeys.

The clinical test are performed on humans.

To make the three principles complete the HMPC (Committe on Herbal Medicinal Products) of the EMA (European Medicines Agency) published the principle of quality assurance conditionalities for appropriate gathering and growing called GACP (Good Agricultural and Collecting Practice). Only those plant based substances are allowed to enter the GMP's (Good Manufactural Practice) quality assurance system, that have been produced in the GACP system and are up to the standards of the pharmacopoeia.

Quality assurance in drug production:

GCP (Good collection Practice): A quality assurance system developed for the gatherers of medicinal herbs.

Its major requirements:

1. Solid knowledge regarding plant appearance and morphology: It is required to know the given plant's morphological characteristics that make it discernable from others.

Illustration no. 13: the ground-ivy's leaf on the left and forest mallow's leaf on the right

2. Solid knowledge regarding toxic plants: It is required for the gatherer to be able to distinguish the toxic plants, those cannot be gathered together with other medicinal herbs.

Illustration no. 14: *Jimsonweed*

3. Solid knowledge regarding endangered and protected species:
It is required to know the protected plants. Special attention must by payed to the protected or endangered species that can be found at the given area, these help increase nature's diversity.

Illustration no 15: *pheasant's eye*

4. Solid knowledge regarding the collection method: It is recommended to gather the plants gently, preferably not causing the whole plant to perish. It is also recommended to use a variety of tools (secateurs, ladder, basket, spade) to make the process easier.

Illustration no. 16: collection of juniper berries by gentle tapping

5.Solid knowledge regarding the correct gathering date and parts to be collected:
The plants should be collected when their active agent content is at its maximum based on scientific knowledge. Since this varies from species to species, it is recommended to keep the pharmacopoeia and drug standards in mind.

The flowers should be collected when they are in full bloom, without their stems. The parts that have withered of fallen to the ground shouldn't be put together with the good materials. The drying is ought to be done in a clean, dry, breezy place that is protected from direct sunlight, thinly spread out.

The leaf drug material should be collected when the leaves are already fully developed.
It should be free of any insects and fungal infections. Frequent rotation is required during the drying process.

The flowery sprousts should be collected in their full bloom.
Usually 30-50 cm's from the top.
Some flowers however should be collected at the start of their blooming process (e.g.: goldenrod, wormwood) because they keep developing and could eventually wither during drying.

The roots and rhizomes should be collected in the spring and autumn.
Depending on the state of the soil (they cannot be collected from frozen or arid round). The active agent content is the highest in the plant's dormancy and the lowest during blooming.

By pulling out the root, the plant will perish.

Crops (hawthorn, juniper) should usually be collected ripe, without their stems.
The one exception is the rosehip, which should be collected in semi-rape state, just when it has obtained its bright red color.

Illustration no. 17: *Collecting rosehip in the autumn.*

It is recommended to start gathering the bark in the spring, at the beginning of the sap circulation, in a 2cm diameter.

6. Knowing the habitat: It is not recommended to gather in polluted areas (heavy metals, chemical residues, other toxic substances).
You can only collect in nature conservation areas with a permit. In private properties only with the owner's permission.

Illustration no. 18: *Nature conservation area*

GAP (Good Agricultural Practice): A quality assurance system developed for the growing and processing of medicinal herbs, which – unlike the current practice – doesn't only examine the finished product but the complete production process.

Based on three principles:

- Finished product focused plant growing (the plant growing technology is divided to certain steps, pre-defines methods, assets);
- Detailed documentation on the processes (farming diary, spraying diary, etc.)
- Audit/Revision (inspections done by inner quality assurance employee and independent outside sources, fixing errors in certain intervals).

The quality can only be guaranteed on plants with well known genetical background. In case of gathering the initial agent should be a well identifiable chemical taxon, a mother spawn inspected in the production process.

The importance of choosing the production site: It is important to utilize the biological potential, ensure the integrity of the natural environment, protect the biodiversity, and to help the plant fit into the soil, knowing its ecological needs.

When choosing, we should also be vary of keeping the dangers of biological, chemical, and physical contamination to a minimum. The species specific growing guidelines contain the quality influencing technological steps.

Illustration no. 19: *Anise production*

GHP (Good Hygiene Practice): Simple, easy to understand, practical description of the hygiene standards in the sector (the method of keeping the occasional threats under control).
It has to pay attention to every major activity and threat that can occur in its field.
To make sure that the GHP is fulfilled, certain Food Safety programmes and procedures (852/2004/EK) are in effect based on HACCP principles. While the GHP regulates the basic environmental and operational conditions, the HACCP oversees certain points with the most risk factors.
The hygiene principles regarding medicinal herb processing are also in effect in food manufacturing factories and machines and they also contain information on personal hygiene.

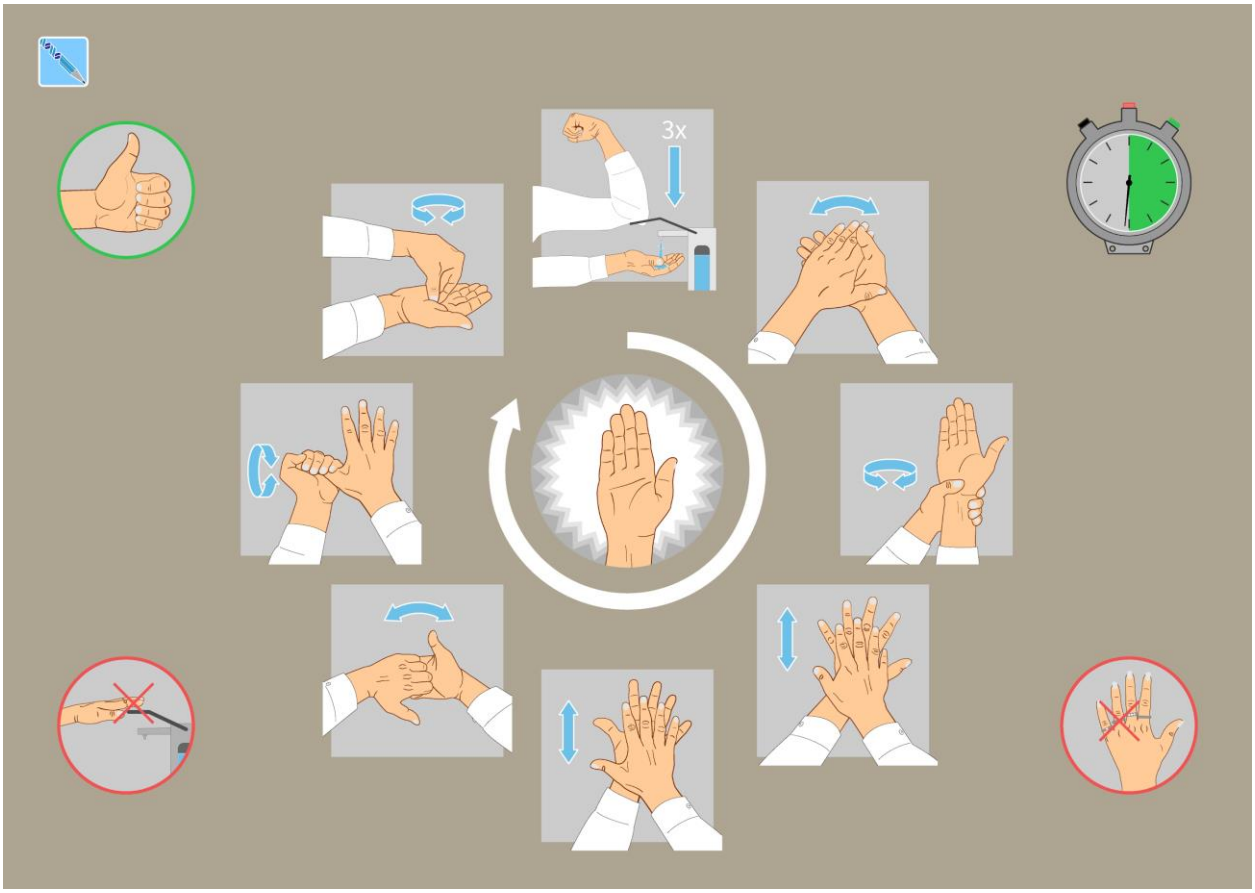

Illustration no. 20: *Correct hand washing technique*

GLP (Good Laboratory Practice): The quality control system that plans, executes, oversees, registers, writes and archives reports on non-clinical health- and environmental safety tests.

The GLP's principles include the health and environmental inspection of every non-clinical products, like medicinal products, pesticides, food and forage supplements, cosmetics, veterinary medicine, industrial chemicals and other similar products.

Illustration no 21: *Preparation of a lavender sample for distillation*

GMP (Good Manufacturing Practice): The sum of every practice and regulation that servers to ensure the quality and safety of the finished product.

It provides practical advices and solutions on meeting the food safety and quality standards.

They use the quality assurance system of the food or the pharmaceutical industry for handling medicinal herbs.

It includes the standard collecting practice (GCP), environmental practice (GAP), processing methods (GHP), and the correct laboratory test practice (GLP).

In Hungary, it is monitored by the National Pharmaceutical Institute (OGYI), in the EU by the EDQM (European Directorate for the Quality of Medicines) based on the CEP (Certificate *of suitability of Monographs of the* European Pharmacopoeia).

Illustration no. 22: *anise seed cleaning*

ISO 9000 (International Organization for Standardisation):
An international series of standards that was originally designed for industrial production. The important goal is to create a nature friendly, so called integrated medicinal herb production that takes the natural ecological and economical points into consideration based on the principals of environmental management and safety systems. (ISO 14000) The ecological crop management's quality assurance and certificate system is considered exemplary for the making of the integrated production's quality assurance system.
From the raw materials to the finished product, every part of the process must be documented in detail, the standards of production must be established.
Such a detalied quality assurance system is primarily used for certain vegetable cultures.

HACCP (Hazard Analysis Critical Control Point): Its goal is the identification and prevention of threats that may arise during the process of food production (physical, chemical, biological). Medicinal herbds are also used by the food industry, therefore in this case the HACCP quality control system applies to them since January 1, 2002.
Its principles: Hazard analysis, critical control points, critical limit determination, establishing monitoring systems, correcting function determination, and creating certifications and documentations.

Food safety: Ensuring during the production and distribution that the food is not harmful to the consumer's health, if it is used and consumed the way it was intended.

The aspects of classifications for medicinal herbs used in the food industry: place of origin, similarity, purity, content examinations, classification for the senses, the prevention of mixing, pesticide content, falsification test, identification of freshness.

4. Aspects of herbal drug qualification

The qualification of herbal drugs made of medicinal plants or culinary herbs is based on the substantiation of their compliance with certain product summaries.

Drugs and essential oils shall be qualified in case of direct use, commercial distribution and further industrial processing as well.

Purpose of qualification: Health protection, prevention of misuse, protection of consumer interests, protection of producer and commercial interests.

Quality is included in the applicable pharmacopoeia, as well as in the national and industrial standards on herbal examination. Provisions of the pharmacopoeia are stricter, since it acknowledges only a single quality.

A drug is of pharmacopoeia quality if it complies with the general chapters, as well as with the provisions stipulated in the article of the drug, from every perspective.

In case of exports, the buyer shall state their quality requirements.

4.1. Analysis of drugs:

4.1.1.Origin: Exact botanical determination of the mother plant of the drug and acquisition of main details with respect to its origin (place of collection and cultivation; date of harvest).

4.1.2.Identity:

The analysis of morphological specialities typical of the species.

- *Macroscopic test:* the identification of dried but not yet ground drugs can be conducted by the naked eye.

Figure 24.: *Dried bloom shoots of Ajuga reptans*

- *Microscopic test:* it is used in case of drugs that cannot be identified by the macroscopic test (e.g. powdered drugs).

Figure 25.: *Finely ground bloom shoots of Ajuga reptans*

- *Identification by chemical reaction:* It is conducted by the detection of active substances typical of certain drugs, with test-tube reactions.

- *Identification by thin-layer chromatography:* It is a method that can be used to identify most active substances (not for quantitative determination, only for detection of presence).

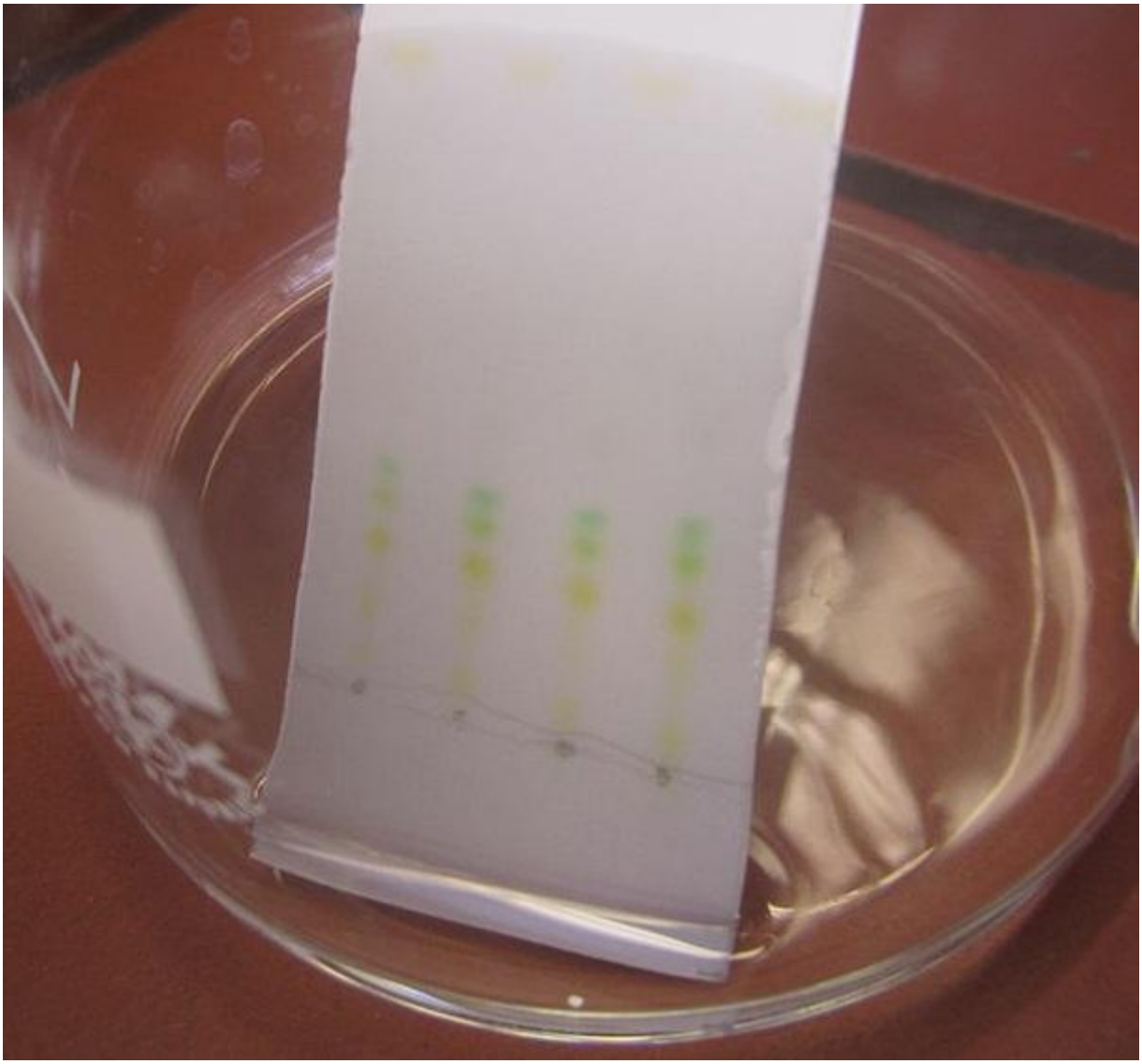

Figure 26.: *Chromatogram*

- *Identification by gas chromatography:* It is mainly used to identify components of drugs containing essential oils (not for quantitative determination).

Figure 27.: *Gas chromatograph*

- *Identification method by spectroscopy:* active substance identification by spectroscopy (not for quantitative determination).

Figure 28.: *Gas chromatograph mass spectrometer*

4.1.3.Purity test:

Appearances of drugs are qualified, as well as the presence of contaminants, foreign substances, etc. is tested.

- *Organoleptic test:* Testing of other parts of plants, foreign substances and toxic drug contaminations.
- *Loss from drying:* loss of mass, expressed in %, caused by drying at a temperature of 105 °C.
- *Ash and sand content:* The quantity per 100 g of drugs of the residue of ash insoluble in concentrated hydrochloric acid, remaining after the heating and ignition of the drug at 600 °C.
- *Pesticide residue test*: Testing of pesticide residue.
- *Microbiological purity*: To determinte the microbiological contamination of drugs (fungal spores, bacteria).
- *Heavy metal contamination test:* Determination of iron, arsenic, lead and cadmium contamination.

4.1.4.Determination of content:

Determination of the main and typical active substance(s) of the drug.

- *Extract content*: It is used for testing of unknown drugs.
- *Swelling value:* It is tested in case of drugs containing mucilage (e.g. white mallow). Liquid is added to 1 g of drug (water), and its swelling is measured after 5 hours, at room temperature, in ml.
- *Bitter substances:* The bitterness value of the drug means the largest dilution of the aqueous extract per 1 g of drug, the 5 ml portion of which causes a bitter taste in the mouth within 30 seconds (e.g. Gentiana lutea).
- *Determination of tanning substances*: It is used to determine a group of compound containing several phenolic hydroxyl groups (tanning substances).
- *Testing drugs containing saponins by determining the haemolytic index*: The dilution of the extract of the drug, which still causes a full haemolysis (dissolution of red blood cells).
- *Alkaloid content:* determination of the quantity of alkaloids by instrument analytic measurements.
- *Determination of essential oils:* Quantitative determination of essential oil active substance with various methods.

5. The role of the characteristics of areas in the production of medicinal plants

The concept of production areas means a specific geographical environment, which contains characteristics in relation to the existence of the plants produced (climate, soil, hydrological conditions). In the course of production, efforts shall be made to meet the biological needs of plant species to be produced, as far as possible. A plant in a good condition is more resistant to pathogens, pests, weather conditions. Plant production has more risks in a poor production area. Under similar conditions of plant production areas, the growth, development of the species will also be similar, as a result of which, an almost identical pant material is produced from the aspect of nature and composition. For this reason, the exact knowledge of the production area fundamentally defines the success of plant production.

However, in case of certain medicinal plants, adverse environmental conditions (stress effect) may occasionally result in higher content of active substances. The main reason for this is that stress changes the metabolism of plants and protective substances are produced. However, biomass production and the yield of plants produced under such conditions fall behind expectations.

Figure 29.: *Diverse production area*

5.1. Soil conditions

The soil has several characteristics, for example, acidity, lime content, nutrient content, type and structure of soil, thickness and uniformity of tilth, level of groundwater, water storage capacity and airiness. Before planting and sowing the plants, it is recommended to conduct soil analyses to get a picture of the characteristics of soil and to make sure that the area is suitable for the selected species.

Several plants, such as peppermint, yarrow, white mustard, dill, marigold, or safflower are undemanding in terms of acidity of soil. There are, however, species that are sensitive to this.

Blueberry, sweet chestnut, and arnica can grow only in strongly acid soils, while lemon balm, sea buckthorn, hyssop, chamomile, coneflower, lavender, valerian, marshmallow, mullein prefer alkaline soils.

The nutrient content and nutrient capacity of the soil can be improved to a significant extent either by natural methods (e.g. green manure, organic manure) or by artificial methods (by applying fertilizers). Certain plants have high nutrient demand, such as angelica, henbane, peppermint, styrian pumpkin, ruta graveolens, while others have low nutrient demand, such as holy thistle, yarrow, white mustard, fenugreek, sea buckthorn, hyssop, chamomile, evening primrose, milk thistle, mullein, and pyrethrum.

Types of soil are classified by the size of their particles. Some soils contain all three main sizes. In this case, the dominant particle size determines the type of soil and the characteristics of the given soil. Knowledge of the given soil is essential for the cultivation of the land.

The most common types of soil in the Carpathian Basin:

Chernozem soil: They are of good quality, have a deep tilth, they are medium compact, and have rich nutrition. 25% of soils in Hungary belong to this type. These are the soil formations of loessial lowland reliefs with dry climate and a maximum of moderate level of groundwater.

Figure 30.: *Chernozem soil*

Brown earth**:** The most common type of soil in the country (around 40%). It has several types but their common characteristics are that their color is brown, they are lacking in calcium and have a high clay content. Generally, they are difficult to cultivate, often they have a thin layer of tilth and the area is mostly sloping and stony.

Figure 31.: *Brown earth*

Sandy soil: They are typically loosely structured, liable to deflation, have a good water reception capacity and permeability, although their water retention capacity is poor. They are poor in mineral substances, generally they have a low level of natural nutrient supply. This type of soil quickly heats up and gets cold, and it is difficult for animal pests to live in this soil.

Figure 32.: *Sandy soil*

Saline soil: This type of soil can be found in patches in the Great Plain region, and one of their characteristics is the high water-soluble sodium salt content. These are very consistent soils with poor water reception capacity and permeability but with good water retention and nutrient capacity. These are suitable to produce only a few plant species (e.g. chamomile).

Meadow soil: These are soils created by flow of water. It can be the effect of surface or groundwater. Degradation is not complete due to the lack of air: accumulation of humus is visible. The accumulation of salt and consistency are their main characteristics that make their cultivation difficult. Their humus substances are of black or grey color and adhering. It is difficult to reveal phosphorus and nitrogen. They have a good water retention capacity but their water reception capacity and permeability are poor.

Figure 33.: *Meadow soil*

Floodplain: These can be found in regions with constant water exposure. Typical processes are peat formation, degradation and drying.

Figure 34.: *Floodplain*

Alluvial and colluvial soils: These are generally soils formulated by the stacking of substances, carried and deposited by the water. There are no levels, therefore they can have significantly different characteristics. They can be found mostly in river floodplains.

In case of each type, the nature of the soil can be changed, its content can be improved to make it more suitable for the production of the selected plant. The structure, as well as the nutrient content of both the loose, sandy and the consistent, clayey types of soils can be improved by adding organic manure, for example, compost that we prepared, natural manure or leaf mould mixed with tilth and peat, on an annual basis.

Organic substances added to the soil hold sandy soil together, improving its water and nutrient retention capacity. These substances make consistent, clayey soils loose to a certain extent, improving their permeability. To achieve the best possible result, sandy soils have to be treated at the end of winter and early spring, while clayey soils in fall and in winter.

It is also recommended to inspect the contamination of the soil by pests as larvae, worms, maggots and other contaminating formulae living in the soil can cause serious problems. From medicinal herbs, peppermint is very sensitive to the damage caused by wireworms (Limonus spp.), root knot nematodes (*Meloidogyne hapla*), crane flies (*Tipula spp.*) or agrotis species (*Agrotis spp.*) that chew the roots and rhizomes. In case of high contamination, a serious soil decontamination must be conducted or another production area must be selected.

5.2. Quantity and distribution of precipitation

Precipitation is one of the most important and most diverse weather element of agricultural production, both in space and time. Its quantity can be improved by agrotechnical means (irrigation), however, it is costly and the producer encounters legal difficulties on several occasions. The most rainy region of Hungary is Alpokalja, where the annual quantity of precipitation can exceed 800 mm. The least rainy region is the central part of the Great Plain, in Nagykunság, where the annual amount of water falling does not even reach 500 mm. The precipitation in this region generally does not satisfy the needs of plants.

When selecting the production area, the quantity of precipitation in the growing season (which is usually 55-65% of the annual quantity in the growing season), the intensity of

precipitation (mm/min or mm/hour), the number of days with measurable quantity of precipitation, the frequency of hail, as well as the frequency of rainless periods must be considered.

With respect to water demand, we distinguish water demanding plants, such as basil, digitalis lanata, coneflower, hops, marigold, lovage, valerian, styrian pumpkin, marjoram, peppermint, and species requiring less water or drought-tolerant species, such as holy thistle, hyssop, thyme, lavender, clary sage, mullein, pyrethrum, and fleawort.

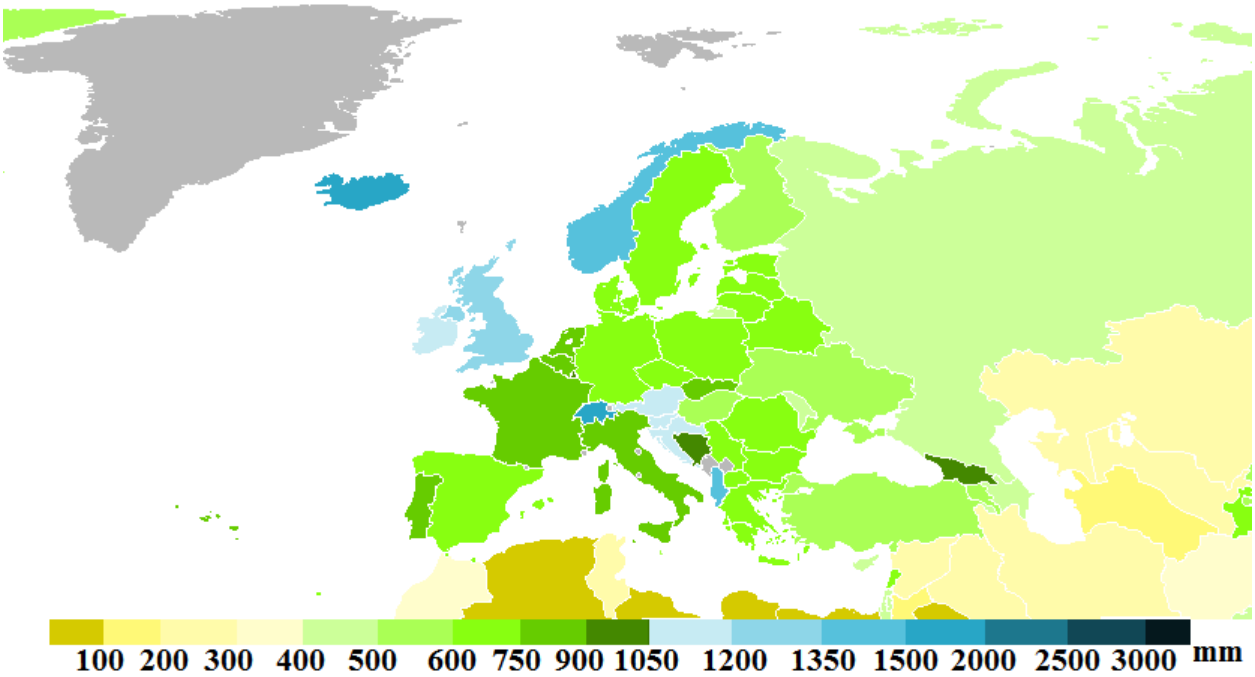

Figure 35.: *Annual quantities of precipitation in countries of Europe*

5.3. Geomorphologic conditions

The location of the area, exposure and inclination of slopes, its altitude in relation to its surroundings, the proximity of lowland areas all affect light and temperature conditions of the production area, thus the living conditions of species produced there. On southern slopes of the northern hemisphere, the incidence angle of sunrays is higher, causing stronger warming, than on northern slopes, where the incidence angle of sunrays is lower. Wormwood, hyssop, sage, thyme, lavender prefer southern, sunny slopes that warm up easily, as they are light- and warmth-loving species. So there is a reason for the region of lake Balaton being the primary location of lavender production in Hungary. In case of certain medicinal plant species, frost pocket areas must be especially avoided, such as for pyrethrum, marjoram, anise, rosemary. It is not recommended either to grow marigold in lowland and humid areas, because the risk of mildew contamination is high under such conditions.

5.4. Wind conditions, wind force, frequency of gusts of wind

Frequent and strong wind may cause harm to the soil (deflation) and to plants. Strong winds blowing constantly from the same direction may ravage the leaves of plants, while the sand carried by the wind is deposited on the leaves of plants, clogging stomas. The wind enhances the extent of evaporation and dries the top layer of the soil. In spring, it can prevent young and weak plants from growing, while at the time of blooming, it can prevent the activity of pollinating insects. Protection against wind can be implemented by planting forests, hedges, tree-lines around the area, or by installing windbreaking grids, fences. Besides its negative effects, the wind also has advantages, for example, it can balance adverse weather conditions, dusty winds dry the soil yet unsuited to cultivation in spring, it can promote pollution and fertilization, and it can also enrich the tilth by carrying fine dust and loess. The most common wind direction in Hungary is from the northwest.

Tall plant species generally require a place protected from wind, such as high mallow, milk thistle, mullein, and windy weather during ripening can also cause a serious loss for plant species with easily rolling fruits or seeds. At the same time, however, we can utilize effects of the wind in plant protection, for example, when planting marjoram, we create lines aligned with the direction of prevailing winds, and the wind terminates the warm

and humid microclimate inside the plant population, by which the probability of alternaria contamination can be reduced.

5.5. Natural vegetation of the area, vegetation of surrounding areas

When selecting a production area, it is also important to consider what the natural vegetation of the area is (or was), because it will later appear from time to time, making the produced culture weedy. Vegetation of surrounding areas (e.g. forest or wooded strips, field, meadow, pasture) can also have an impact on the produced culture as they affect the living conditions of those plants. Besides a number of positive effects, for example, they reduce the speed of wind, protect the soil, reduce the extent of evaporation and increase air moisture and soil moisture, they are natural boundaries around the area and also provide an environment for polluting insects; they can also have negative effects on produced plant culture. For instance, they abstract nutrient and water, create a heat cauldron and shadows, they can promote the proliferation and establishment of pests and pathogens, make the area weedy, etc. It can be observed that within 1.5 times of the distance of the height of belt, reduced yields are caused in the production area.

6. Production technologies of major plants

6.1. One-year medicinal plants of Apiacea leaves:

6.1.1. Anise (*Pimpinella anisum* L.)

Botanical description, ecological demand: It is a one-year, herbaceous, moisture-, warmth- and light-loving plant. Its hairy, ridged stems have leaves of different shapes. Its spindle-like root is thin and sparsely branched. It grows wild in Mediterranean regions.

Previous cropping: Cereals sown in fall and spring, or green fodder plants.

Soil preparation and nutrient supply: Shucking of previous cropping stubble, then deep ploughing. Application of 40-60 kg/ha of nitrogen, 60-90 kg/ha of phosphorous, and 40-60 kg/ha of potassium. Preparation of the soil of small crumbs in spring. It is recommended to distribute 20 kg/ha of foliar fertilizers at the beginning of growth.

Sowing: Late March – early April, with a line distance of 25-30 cm, at a depth of 2-3 cm. Seed requirement: 15-20 kg/ha.

Care: Due to its poor capacity to supress weeds, it is recommended to apply an herbicide treatment after sowing and before growth, as well as to treat the plant population. Its most significant disease is the bacteria attacks, which can be prevented by products containing copper, before growth.

Harvest: Its fruit ripens unevenly and it rolls easily. Its single harvest has to be conducted at the time of full ripening of main clusters, by cereal cutting combine harvester. Yield: 400-600 kg/ha.

Primary processing, storage: Following the cleaning of seeds, the fruit must be dried at a maximum temperature of 40°C and spread, after which it is recommended to store the product in sacks. Essential oil is distilled from its fruit.

Drug: fruit of anise (*Anisi fructus),* essential oil *(Aetheroleum anisi)*. Main active substance: essential oil (anethole).

Physiological effects: anti-convulsant therapy, disinfection, dissolving mucilage.

Figure 36.: *Anise in blossom*

6.1.2. One-year caraway (*Carum carvi* L.)

Botanical description, ecological demand: It is a two-year, herbaceous, water-, warmth- and nitrogen-demanding plant. Its stem can grow up to 100 cm high, its leaves are flowery ridged. It grows a flourishing stem from its carrot-shaped root in the second year. It is common in areas of reaping.

Previous cropping: Cereals sown in fall and spring.

Soil preparation and nutrient supply: Shucking of previous cropping stubble, then deep ploughing. Application of 50-70 kg/ha of phosphorous, and 50-80 kg/ha of potassium. Preparation of the soil of small crumbs in spring and it is recommended to distribute 50-70 kg/ha of nitrogen.

Sowing: Late March, with a line distance of 24-36 cm, at a depth of 2 cm. Seed requirement: 11-14 kg/ha.

Care: It is recommended to conduct a chemical weed control after sowing and before growth, as well as for the plant population. Its main pests are the Eryophyes peucedani and the Depressaria daucella. In case of the first one, acaricides, while in case of the latter, contact products can be used as prevention.

Harvest: Single harvest is recommended due to the easy rolling of the fruit. The time of this is the full ripening of main clusters, and the method is cereal cutting combine harvester. Yield: 500-1500 kg/ha.

Primary processing, storage: The drying of the fruit is recommended at a maximum temperature of 40°C, after which the fruit is suggested to be stored in sacks. Essential oil is distilled from its fruit.

Drug: fruit of caraway (*Carvi fructus),* essential oil *(Aetheroleum carvi).* Main active substance: essential oil (d-carvone, d-limonene) Physiological effects: anti-convulsant therapy, disinfection and elimination of wind-dampness.

Figure 37.: *Caraway in blossom*

6.1.3. Coriander (*Coriandrum sativum* L.)

Botanical description, ecological demand: It is a one-year herbaceous plant, which indigenous in the mediterranean regions of Europe. Its root is mildly branched, stick-like and its stem can grow up to 30-120 cm high. The roundish leaves formulate the rosette, the correct growing of which requires a low temperature for a long time.

Previous cropping: Cereals sown in fall and spring, or green fodder plants.

Soil preparation and nutrient supply: Deep ploughing in fall, then application of 40 kg/ha of nitrogen, 15 kg/ha of phosphorous, and 20-30 kg/ha of potassium. Preparation of the soil of small crumbs in spring and it is recommended to distribute 10 kg/ha of nitrogen.

Sowing: It can be sown between mid-March and the end of March, with a line distance of 25-30 cm, at a depth of 4-5 cm. Seed requirement: 16-20 kg/ha.

Care: It is recommended to apply an herbicide treatment after sowing and before growth. Its most significant diseases are the bacteria attacks and ramularia coriandri that can be prevented by products containing copper, before growth.

Harvest: Its fruit ripens unevenly and it rolls easily. Its single harvest has to be conducted at the time of full ripening of main clusters, by cereal cutting combine harvester. Yield: 1000-1500 kg/ha. Essential oil is distilled from its fruit.

Primary processing, storage: Following the cleaning of seeds, the fruit must be dried at a maximum temperature of 40°C and spread, after which it is recommended to store the product in sacks.

Drug: fruit of dill (*Coriandri fructus*), essential oil (*Coriandri aetheroleum*), Main active substance: essential oil (linalool), fatty oil Physiological effect: elimination of wind-dampness, improving digestion, smooth muscle relaxation.

Figure 38.: *Coriander in blossom*

6.2. Perennial medicinal plants of Apiacea leaves:

6.2.1. Fennel (*Foeniculum vulgare*)

Botanical description, ecological demand: It is a plant, which grows up to 150-200 cm high, and its multiply pinnated leaves are distributed on its cylindrical, naked, branched stem. Its root is spindle-shaped and penetrates deep in the soil. It is a warmth-loving and nutrient-demanding plant, which can freeze in cold winters.

Previous cropping: Cereals sown in fall and spring, and root crops.

Soil preparation and nutrient supply: Deep ploughing in fall, then application of 80-100 kg/ha of phosphorous, 40-60 kg/ha of potassium and 20-40 kg/ha of nitrogen from the second year, in early spring. Preparation of the soil of small crumbs in spring and it is recommended to distribute 10 kg/ha of nitrogen.

Sowing: It can be sown between early March and the end of March, with a line distance of 42-48 cm, at a depth of 2-3 cm. Seed requirement: 8-10 kg/ha.

Care: It is recommended to apply a treatment after sowing and before growth because later on, the population closes. Its most significant diseases are species of bedbugs that can be prevented by bee-friendly contact products.

Harvest: Due to the large green mass, two-time harvest is recommended. Cutting must be done at a height of 30-40 cm, then placed in order and finally to collect the fruit after a drying of 5-10 days with combine harvester. Yield: 1000-1500 kg/ha.

Primary processing, storage: Following the cleaning of seeds, the fruit must be dried at a maximum temperature of 40°C and spread, after which it is recommended to store the product in sacks. Essential oil is distilled from its fruit.

Drug: fruit of fennel (*Foeniculi amari fructus*), essential oil (*Foeniculi amari fructus aetheroleum*), Main active substance: essential oil (anethole), fatty oil Physiological effect: dissolving mucilage, elimination of wind-dampness, improving digestion, anti-convulsant therapy.

Figure 39.: *Fennel in blossom*

6.2.2. Lovage (*Levisticum officinale*)

Botanical description, ecological requirement: Herbaceous, biennial plant, which develops its inflorescence stem in the second year, which can grow up to 150-200 cm. It has a vertical sticklike rhizome. The heat-loving plant has a high nutritional need, and may die in colder winters.

Previous cropping: Fall- and spring-sown cereals, and root crop of late harvesting time.

Soil preparation and plant nutrition: Deep plowing, then 60-70 kg/ha nitrogen, 100-120 kg/ha phosphorus, 140-145 kg/ha potassium, then 20-40 kg/ha nitrogen active substance application from the second year in early spring. Preparation of fine, crumbly soil in the fall or spring.

Sowing: It can be sown at the end of October in fall, from the beginning until the end of March in spring, the distance between rows should be 50-60 cm, 1-1,5 cm deep. Seed requirement: 10-12 kg/ha.

Care: Management is recommended after sowing and before coming up, after that crops close up. Typical pests are the aphids, we can defend the plant against them with absorption agents.

Harvest: It is gathered in the fall with an elevator after removing the foliage. Yield: 1500-2000 kg/ha.

Primary processing, storing: After cleansing, washing, then cutting, it is dried at 40-50 degrees Celsius and stored in sacks. Essential oil is evaporated from its root.

Drug: root of lovage (*Levistici radix*), essential oil (*Levistici aetheroleum*), Main active subctance: essential oil (butilftalid), Physiological effects: diuretic, anticonvulsant, aids the digestion.

Figure 40: *Lovage*

6.2.3. Garden angelica (*Angelica archangelica*)

Botanical description, ecological requirement: Biennial, herbaceous plant requiring a cooler climate. It develops well on low-lying, damp, nutrient-rich, friable, loamy, medium hard soils. It has a high potassium and phosphorus need. It develops a carrotlike, 20-30 cm long, barely branching root in the first year, and thick, adventitious roots in the second year. Its basal leaves are big, double pinnate, the basis of the stalk is an inflated pod.

Previous cropping: Except from Apiaceae those, after which the fall soil preparation is possible.

Soil preparation and plant nutrition: Deep plowing in fall, then 40-50 kg/ha nitrogen, 80-100 kg/ha phosphorus, 120-130 kg/ha potassium active substance application.

Sowing: November or March (seeds should be previously frozen), the distance between rows should be 60 cm, 1-1,5 cm deep. Seed requirement: 8kg/ha (in the fall) and 10 kg/ha (in the spring).

Care: Management is recommended after sowing and before coming up, after that crops close up. Typical pests are the aphids, the Angelica archangelica seed wasp, we can defend the plant against them with absorption agents.

Harvest: Its root is gathered in the first or second year, in the beginning of October with a plow or a spade. Yield: 1,6-1,8 t/ha dry root, 6-10 kg/ha root oil. In the second year, essential oil can be made from the green seed plants as well, at the wax-ripening of the main umbel crops. Yield: 6-8 kg/ha seed oil.

Primary processing, storing: Roots are cleansed, then washed with running water, the thick roots are cut in two and dried at 40-45 degrees Celsius at most. Essential oil is evaporated from the washed and chopped roots.

Drug: Garden angelica root (*Angelicae radix et rhizoma)*, garden angelica crop (*Angelicae fructus*), essential oil (*Angelicae radix aetheroleum*). Main active substance: essential oil (alpha- and beta-Pinene, alpha- and beta-Phellandrene), bitter substance. Physiological effects: improving appetite, strenghtening the stomach, slight anticonvulsant, pain relief.

Figure 41: Garden angelica flower bud

6.3. Annual herbs of Lamiales

6.3.1. Basil (*Ocimum baslicum*)

Botanical description, ecological requirement: It is an annual plant, growing to 40-70cm. Its features an pinnate leaf venetition. Its flowers are small, they open in loose terminal clusters in July. It is warm- and water-loving and water- and nutrient requiring, it requires a quickly warming soil.

Previous cropping: The most significant ones are the row crops treated by livestock manure.

Preparation of soil and nutrient supply: Deep ploughing in the autumn, then preparation of well finished-off even-surfaced soil. Fertilisation: the basic fertiliser in autumn and after the first cut.

Sowing: It is sowed in late April - early May in a depth of 0.5-1.0cm, with a spacing of 40-50cm, which is closed by rolling. Seed necessity: 3-4 kg/ha.

Care: Its weed control is mechanically performed.

Harvesting: It takes place for the first time in the middle of July when the flowers appear and prior to the frosts for the second time, above the first branch, cut to stubbles of 6-8cm. Crumbled drug, 1,500-2,000kg/ha, essential oil 8-10kg/ha.

Primary processing and storage: It is stored in bags after drying, crumbling and cleaning.

Drug: leaf of basil (*Basilici herba*) essential oil (*Basilici aetheroleum*). Main agent: Essential oils (linalool, metilchavicol). Physiological effect: It is appetising, digestive and carminative.

Figure no. 42: *Basil*

6.3.2. Marjoram (*Majorana hortensis*)

Botanical description, ecological requirement: It is an annual plant, growing to 20-50cm. Stout stem with grey hairs. It blossoms in July-August. It is sensitive to cold and frost, warm- and light-loving and requires a lot of water and nutrient.

Previous cropping: It is the most advantageous after the row crops treated by livestock manure.

Preparation of soil and nutrient supply: Deep ploughing in the autumn, then preparation of well finished-off even-surfaced soil. Fertilisation: the basic fertiliser in autumn and after the first cut.

Sowing: It is sowed in late April - early May in a depth of 0.5-1.0cm, with a spacing of 30-40 cm, which is closed by rolling. Seed necessity: 3-4 kg/ha.

Care: Sub-soiling inter-row tillage, regular irrigation.

Harvest: It takes place for the first time in the middle of July when the flowers appear and prior to the frosts for the second time, above the first branch, cut to stubbles of 6-8 cm.

Primary processing and storage: It is stored in bags after drying, crumbling and cleaning.

Drug: leaf of marjoram (*Majoranae herba)*, essential oil *(Majoranae aetheroleum*). Main agent: essential oil, tannin and bitter substance. Physiological effect: It is appetising, digestive, carminative and reduces bloating.

Figure 43: *marjoram*

6.3.3. Summer savory *(Satureja hortensis)*

Botanical description, ecological requirement: It is an annual or overwintering herbaceous plant, growing to 30-60cm. The petioles are arranged oppositely on its stout, densely ramifying stem. It is warm- and water-loving and water- and nutrient requiring, it requires a quickly warming soil.

Previous cropping: The most advantageous after the row crops treated by livestock manure. Crop rotation of two-three years is necessary afterwards.

Preparation of soil and nutrient supply: Deep ploughing in the autumn, then preparation of well finished-off even-surfaced soil. Fertilisation: the basic fertiliser in autumn and after the first cut.

Sowing: It is sowed in late March - early April in a depth of 0.5-1.0cm, with a spacing of 30-50cm, which is closed by rolling. Seed necessity: 6-8 kg/ha.

Care: Sub-soiling inter-row tillage, regular irrigation.

Harvest: It takes place for the first time in the middle of July when the flowers appear and prior to the frosts (September-October) for the second time, above the first branch, cut to stubbles of 6-8cm.

Primary processing and storage: It is stored in bags after drying, crumbling and cleaning.

Drug: leaf of summer savory (*Saturejae herba*) essential oil (*Saturejae aetheroleum*).

Main agent: Essential oil (carvacrol, cimol), tannins and iron compounds. Physiological effect: It is appetising, digestive and carminative.

Figure no. 44: *Summer savory*

6.4. Perennial harbs of Lamiales:

6.4.1. Bastard balm *(Melittis melissophyllum)*

Botanical description, ecological requirement: It is a herbaceous, perennial plant of 30-60 cm. Its leaves are oval, serrate-dentate. They are shadow-loving species. It requires a clayey soil with good water management.

Previous cropping: It is not sensitive to previous cropping.

Preparation of soil and nutrient supply: Preparation of even-surfaced soil in the autumn. Its average nutrient requirement is 60kg/ha of nitrogen, 50-60kg/ha of phosphorus and 70-80kg/ha of potassium.

Sowing: It is sowable in October to a depth of 1-1.5cm with a row space of 40-50cm. Seed necessity: 6-7 kg/ha.

Care: Sub-soiling inter-row tillage, mechanical weed control, regular irrigation.

Harvesting: It takes place for the first time in the middle of July when the flowers appear and prior to the frosts for the second time, above the first branch, cut to stubbles of 6-8 cm.

Primary processing and storage:

Drug: leaf of bastard balm (*Melittidis herba*). Main agent: Essential oil (citronellal, tannins and coumarins). Physiological effect: It is digestive and mildly sedative.

Figure no. 45: *Bastard balm*

6.4.2. Hyssop (*Hysopus officinalis*)

Botanical description, ecological requirement: It is a woody, perennial plant growing to 50-70cm. Densely ramifying, fine hairs. It features an entire pinnate leaf venetion.

Previous cropping: The most advantageous ones are grains, mustard and corn. Medick or red clover are not recommended.

Preparation of soil and nutrient supply: Following a stubble cleaning, deep ploughing is recommended, then preparation of even-surfaced soil in early spring.

Sowing: middle-late March to a depth of 1.5-2cm with spacing of 50-70cm. Seed necessity: 3-5 kg/ha.

Care: Regular mechanical weed control is necessary. Its main disease is powdery mildew and main insects are thrips.

Harvest: From the start of blossoming to the main blossoming, harvesting takes place by cutting above the lower woodened parts. Yield leaves: first year 2-3 tonnes/ha, further 6-9 tonnes/ha, essential oil yield 8-14kg/ha.

Primary processing and storage: It is wiltable on the stubble in dry weather. It must be cut at the main blossoming for essential oil. It must be turned and baled at drying.

Drug: leaf of hyssop (*Hyssopy herba*) essential oil of hyssop (*Hyssopi aetheroleum*).

Main agent: Essential oil (pinocamphone), flavonoids.

Physiological effect: It is a mild antispasmodic and expectorant.

Figure 46: *hyssop*

6.4.3. Common thyme (*Thymus vulgaris*)

Botanical description, ecological requirement: Perennial woody subshrub, 20-50cm high. It fares best in calcareous, fertile soils with good permeability. It is a warm-loving plant requiring light, but it may freeze in frost pockets.

Previous cropping: Legumes are the most advantageous.

Preparation of soil and nutrient supply: Deep ploughing in autumn, the soil finished off in a gardenlike manner Manuring It must be treated with livestock manure prior to sowing/planting. An event-surfaced sowing bed must be prepared in spring.

Sowing: It is bred by broadcast of seeds or propagation by division. Due to the initially slow growth, a free-range growth of seedlings is applied. The two-three nursery plants of 5-7cm are planted. To the spot, 50 x 25cm of line and planting space. The plant necessity is 160-240,000pcs/ha. In case of a free-range sowing, seeds are broadcast in the middle of March with a spacing distance of 25-30cm and a depth of 1-2cm.

Care: Sub-soiling inter-row tillage, mechanical weed control, regular irrigation.

Harvest: It may be cut once in the first year and twice in the later years. Harvesting takes place at the beginning of the blossoming, in sunshiny weather, it should be cut above the woody parts.

Primary processing and storage: The cut part of the plant must be dried immediately at 40°C, it is stored in bags after crumbling and then cleaning.

Drug: leaf of common thyme (*Thymi vulgaris herba*) essential oil (*Thymi aetheroleu*).

Main agent: Essential oil (thymol, p-cimol), tannins and iron compounds.

Physiological effect: It is antibacterial and immunising, expectorant and antispasmodic.

Figure 47: *common thyme*

6.5. Annual herbs of Asterales:

6.5.1. Safflower *(Carthamus tinctorius)*

Botanical description, ecological requirement: It is an annual, herbaceous plant, grows to 140-170cm, it requires warm and light and fares in drought-tolerant soil. The first flowers open early July, the blossoming period is 35-40 days.

Previous cropping: The most advantageous after the row crops treated by livestock manure.

Preparation of soil and nutrient supply: It requires ploughing in autumn and even, settled seed bed in spring.

Sowing: Sowing period is early April, the spacing distance is 40-60cm, the sowing depth is 3-5cm. Seed necessity is 18-20kg/ha.

Care: Weed control is performed by inter-low tillage. Presowing and pre-emergent fertilisers may be used previously. In a plantation of 15-20cm, post-emergent fertilisers may be used.

Harvest: The flaming red ray florets are picked out manually, in every three-four days from the middle of July. After the entire blossoming, the petals lean on the capitulum and they will have a flaming red colour. Its blossoming period is four-five weeks. The achene is harvested by a harvesting-threshing machine, it must be dried to 10-12% of moisture, if necessary. Flower drug 160-200kg/ha, seed yield: 1.5-2.5 tonnes/ha.

Primary processing and storage: The petals must be dried immediately, it should be dried in a spread manner in a thin layer. It is sensitive to harm.

Drug: safflower (*Carthami flos*) and its fatty oil (*Carthami oleum*). Main agent: The yellow dye accumulating in the flower (safflor yellow), solves in water and alcohol 0.3-0.6% cartamine (safflor red): solves in fat

Physiological effect: It is a harmless dye, the oil is rich in insaturated lipid acids, it slows down arteriosclerosis.

Figure no. 48: *Safflower*

6.5.2. Milk thistle *(Silybum marianum)*

Botanical description, ecological requirement: It is an annual herbaceous plant, which may grow to 1-1.5m. It requires a sunny and warm weather. It is not really sensitive to soil, it is produceable in the most soils, including bog soil, but poor sandy soil and not good for its production.

Previous cropping: It is not sensitive to previous cropping. Crop rotation of three years is necessary afterwards. Volunteer plants may weed in follow-up croppings.

Preparation of soil and nutrient supply: deep ploughing in the autumn, its rough finish-off then preparation of a seed bed.

Sowing: From late March to early April, depth of sowing is 3-5cm, spacing and planting distance is: 50x40cm. Seed norm: 8-12 kg

Care: The mechanical weed control must be performed after shooting, in the four-palmate venetion of the plants. Until the lines are closed, inter-row tillage and increasing the planting distance can be repeated, if the planting distance is denser than 15-20cm.

Harvest: When the squama dried in the majority of the florets of the primer offshoots and the middle of the inflorescence is whitening.

Primary processing and storage: The seed got out of the harvesting-threshing machine must be dried and cleaned. It is storable in bags.

Drug: produce of milk thistle (*Silybi mariani fructus*)).

Main agents: flavonoids (silybin, silymarin), fatty oil. Physiological effect: It reduces hepatitis and regenaretes cells.

Figure no. 49: *milk thistle*

4. Aspects of herbal drug qualification

The qualification of herbal drugs made of medicinal plants or culinary herbs is based on the substantiation of their compliance with certain product summaries.

Drugs and essential oils shall be qualified in case of direct use, commercial distribution and further industrial processing as well.

Purpose of qualification: Health protection, prevention of misuse, protection of consumer interests, protection of producer and commercial interests.

Quality is included in the applicable pharmacopoeia, as well as in the national and industrial standards on herbal examination. Provisions of the pharmacopoeia are stricter, since it acknowledges only a single quality.

A drug is of pharmacopoeia quality if it complies with the general chapters, as well as with the provisions stipulated in the article of the drug, from every perspective.

In case of exports, the buyer shall state their quality requirements.

4.1. Analysis of drugs:

4.1.1.Origin: Exact botanical determination of the mother plant of the drug and acquisition of main details with respect to its origin (place of collection and cultivation; date of harvest).

4.1.2.Identity:

The analysis of morphological specialities typical of the species.

- *Macroscopic test:* the identification of dried but not yet ground drugs can be conducted by the naked eye.

Figure 24.: *Dried bloom shoots of Ajuga reptans*

- *Microscopic test:* it is used in case of drugs that cannot be identified by the macroscopic test (e.g. powdered drugs).

Figure 25.: *Finely ground bloom shoots of Ajuga reptans*

- *Identification by chemical reaction:* It is conducted by the detection of active substances typical of certain drugs, with test-tube reactions.

- *Identification by thin-layer chromatography:* It is a method that can be used to identify most active substances (not for quantitative determination, only for detection of presence).

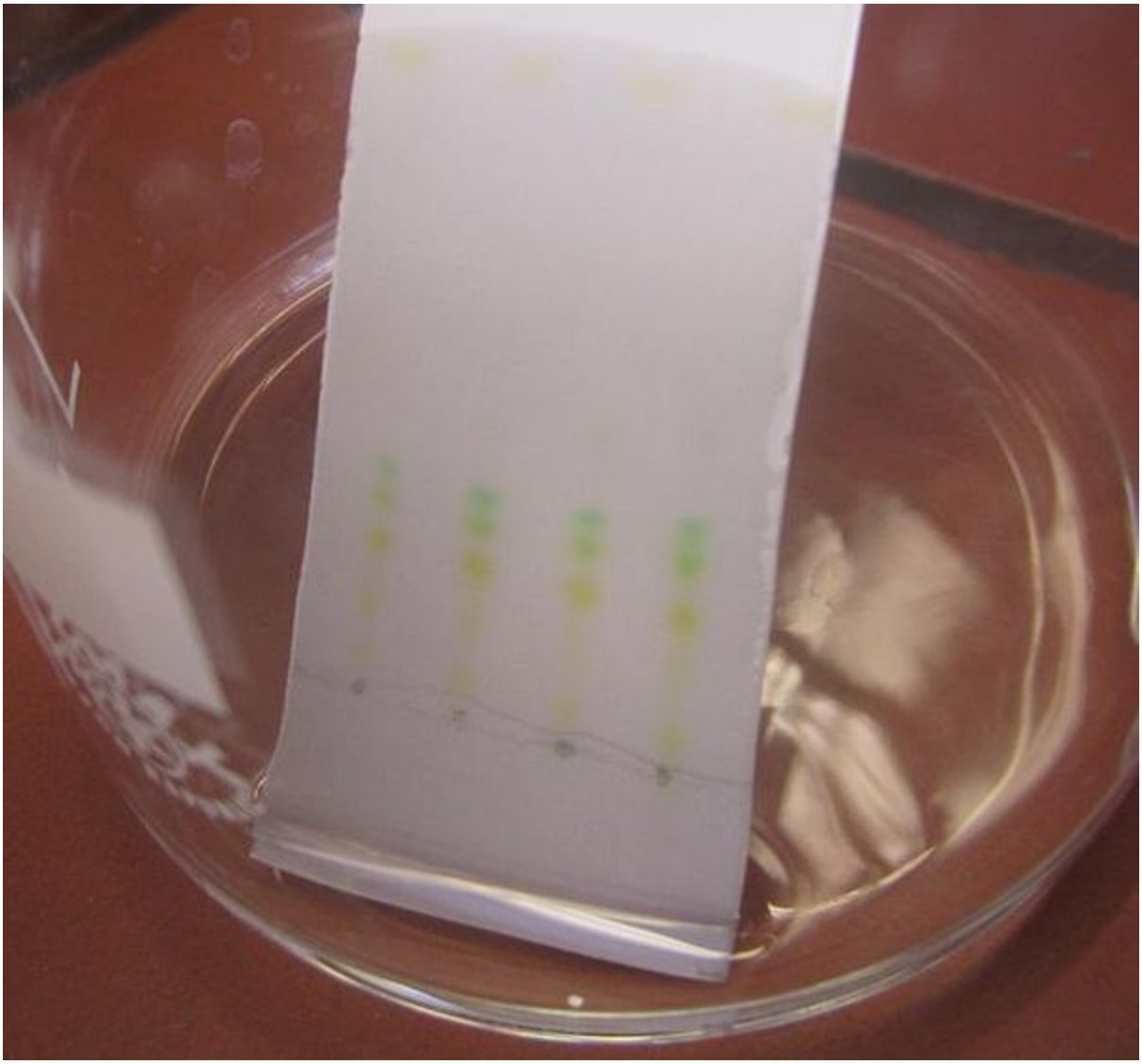

Figure 26.: *Chromatogram*

- *Identification by gas chromatography:* It is mainly used to identify components of drugs containing essential oils (not for quantitative determination).

Figure 27.: *Gas chromatograph*

- *Identification method by spectroscopy:* active substance identification by spectroscopy (not for quantitative determination).

Figure 28.: *Gas chromatograph mass spectrometer*

4.1.3.Purity test:

Appearances of drugs are qualified, as well as the presence of contaminants, foreign substances, etc. is tested.

- *Organoleptic test:* Testing of other parts of plants, foreign substances and toxic drug contaminations.
- *Loss from drying:* loss of mass, expressed in %, caused by drying at a temperature of 105 °C.
- *Ash and sand content:* The quantity per 100 g of drugs of the residue of ash insoluble in concentrated hydrochloric acid, remaining after the heating and ignition of the drug at 600 °C.
- *Pesticide residue test*: Testing of pesticide residue.
- *Microbiological purity*: To determinte the microbiological contamination of drugs (fungal spores, bacteria).
- *Heavy metal contamination test:* Determination of iron, arsenic, lead and cadmium contamination.

4.1.4.Determination of content:

Determination of the main and typical active substance(s) of the drug.

- *Extract content*: It is used for testing of unknown drugs.
- *Swelling value:* It is tested in case of drugs containing mucilage (e.g. white mallow). Liquid is added to 1 g of drug (water), and its swelling is measured after 5 hours, at room temperature, in ml.
- *Bitter substances:* The bitterness value of the drug means the largest dilution of the aqueous extract per 1 g of drug, the 5 ml portion of which causes a bitter taste in the mouth within 30 seconds (e.g. Gentiana lutea).
- *Determination of tanning substances*: It is used to determine a group of compound containing several phenolic hydroxyl groups (tanning substances).
- *Testing drugs containing saponins by determining the haemolytic index*: The dilution of the extract of the drug, which still causes a full haemolysis (dissolution of red blood cells).
- *Alkaloid content:* determination of the quantity of alkaloids by instrument analytic measurements.
- *Determination of essential oils:* Quantitative determination of essential oil active substance with various methods.

5. The role of the characteristics of areas in the production of medicinal plants

The concept of production areas means a specific geographical environment, which contains characteristics in relation to the existence of the plants produced (climate, soil, hydrological conditions). In the course of production, efforts shall be made to meet the biological needs of plant species to be produced, as far as possible. A plant in a good condition is more resistant to pathogens, pests, weather conditions. Plant production has more risks in a poor production area. Under similar conditions of plant production areas, the growth, development of the species will also be similar, as a result of which, an almost identical pant material is produced from the aspect of nature and composition. For this reason, the exact knowledge of the production area fundamentally defines the success of plant production.

However, in case of certain medicinal plants, adverse environmental conditions (stress effect) may occasionally result in higher content of active substances. The main reason for this is that stress changes the metabolism of plants and protective substances are produced. However, biomass production and the yield of plants produced under such conditions fall behind expectations.

Figure 29.: *Diverse production area*

5.1. Soil conditions

The soil has several characteristics, for example, acidity, lime content, nutrient content, type and structure of soil, thickness and uniformity of tilth, level of groundwater, water storage capacity and airiness. Before planting and sowing the plants, it is recommended to conduct soil analyses to get a picture of the characteristics of soil and to make sure that the area is suitable for the selected species.

Several plants, such as peppermint, yarrow, white mustard, dill, marigold, or safflower are undemanding in terms of acidity of soil. There are, however, species that are sensitive to this.

Blueberry, sweet chestnut, and arnica can grow only in strongly acid soils, while lemon balm, sea buckthorn, hyssop, chamomile, coneflower, lavender, valerian, marshmallow, mullein prefer alkaline soils.

The nutrient content and nutrient capacity of the soil can be improved to a significant extent either by natural methods (e.g. green manure, organic manure) or by artificial methods (by applying fertilizers). Certain plants have high nutrient demand, such as angelica, henbane, peppermint, styrian pumpkin, ruta graveolens, while others have low nutrient demand, such as holy thistle, yarrow, white mustard, fenugreek, sea buckthorn, hyssop, chamomile, evening primrose, milk thistle, mullein, and pyrethrum.

Types of soil are classified by the size of their particles. Some soils contain all three main sizes. In this case, the dominant particle size determines the type of soil and the characteristics of the given soil. Knowledge of the given soil is essential for the cultivation of the land.

The most common types of soil in the Carpathian Basin:

Chernozem soil: They are of good quality, have a deep tilth, they are medium compact, and have rich nutrition. 25% of soils in Hungary belong to this type. These are the soil formations of loessial lowland reliefs with dry climate and a maximum of moderate level of groundwater.

Figure 30.: *Chernozem soil*

Brown earth**:** The most common type of soil in the country (around 40%). It has several types but their common characteristics are that their color is brown, they are lacking in calcium and have a high clay content. Generally, they are difficult to cultivate, often they have a thin layer of tilth and the area is mostly sloping and stony.

Figure 31.: *Brown earth*

Sandy soil: They are typically loosely structured, liable to deflation, have a good water reception capacity and permeability, although their water retention capacity is poor. They are poor in mineral substances, generally they have a low level of natural nutrient supply. This type of soil quickly heats up and gets cold, and it is difficult for animal pests to live in this soil.

Figure 32.: *Sandy soil*

Saline soil: This type of soil can be found in patches in the Great Plain region, and one of their characteristics is the high water-soluble sodium salt content. These are very consistent soils with poor water reception capacity and permeability but with good water retention and nutrient capacity. These are suitable to produce only a few plant species (e.g. chamomile).

Meadow soil: These are soils created by flow of water. It can be the effect of surface or groundwater. Degradation is not complete due to the lack of air: accumulation of humus is visible. The accumulation of salt and consistency are their main characteristics that make their cultivation difficult. Their humus substances are of black or grey color and adhering. It is difficult to reveal phosphorus and nitrogen. They have a good water retention capacity but their water reception capacity and permeability are poor.

Figure 33.: *Meadow soil*

Floodplain: These can be found in regions with constant water exposure. Typical processes are peat formation, degradation and drying.

Figure 34.: *Floodplain*

Alluvial and colluvial soils: These are generally soils formulated by the stacking of substances, carried and deposited by the water. There are no levels, therefore they can have significantly different characteristics. They can be found mostly in river floodplains.

In case of each type, the nature of the soil can be changed, its content can be improved to make it more suitable for the production of the selected plant. The structure, as well as the nutrient content of both the loose, sandy and the consistent, clayey types of soils can be improved by adding organic manure, for example, compost that we prepared, natural manure or leaf mould mixed with tilth and peat, on an annual basis.

Organic substances added to the soil hold sandy soil together, improving its water and nutrient retention capacity. These substances make consistent, clayey soils loose to a certain extent, improving their permeability. To achieve the best possible result, sandy soils have to be treated at the end of winter and early spring, while clayey soils in fall and in winter.

It is also recommended to inspect the contamination of the soil by pests as larvae, worms, maggots and other contaminating formulae living in the soil can cause serious problems. From medicinal herbs, peppermint is very sensitive to the damage caused by wireworms (Limonus spp.), root knot nematodes (*Meloidogyne hapla*), crane flies (*Tipula spp.*) or agrotis species (*Agrotis spp.*) that chew the roots and rhizomes. In case of high contamination, a serious soil decontamination must be conducted or another production area must be selected.

5.2. Quantity and distribution of precipitation

Precipitation is one of the most important and most diverse weather element of agricultural production, both in space and time. Its quantity can be improved by agrotechnical means (irrigation), however, it is costly and the producer encounters legal difficulties on several occasions. The most rainy region of Hungary is Alpokalja, where the annual quantity of precipitation can exceed 800 mm. The least rainy region is the central part of the Great Plain, in Nagykunság, where the annual amount of water falling does not even reach 500 mm. The precipitation in this region generally does not satisfy the needs of plants.

When selecting the production area, the quantity of precipitation in the growing season (which is usually 55-65% of the annual quantity in the growing season), the intensity of

precipitation (mm/min or mm/hour), the number of days with measurable quantity of precipitation, the frequency of hail, as well as the frequency of rainless periods must be considered.

With respect to water demand, we distinguish water demanding plants, such as basil, digitalis lanata, coneflower, hops, marigold, lovage, valerian, styrian pumpkin, marjoram, peppermint, and species requiring less water or drought-tolerant species, such as holy thistle, hyssop, thyme, lavender, clary sage, mullein, pyrethrum, and fleawort.

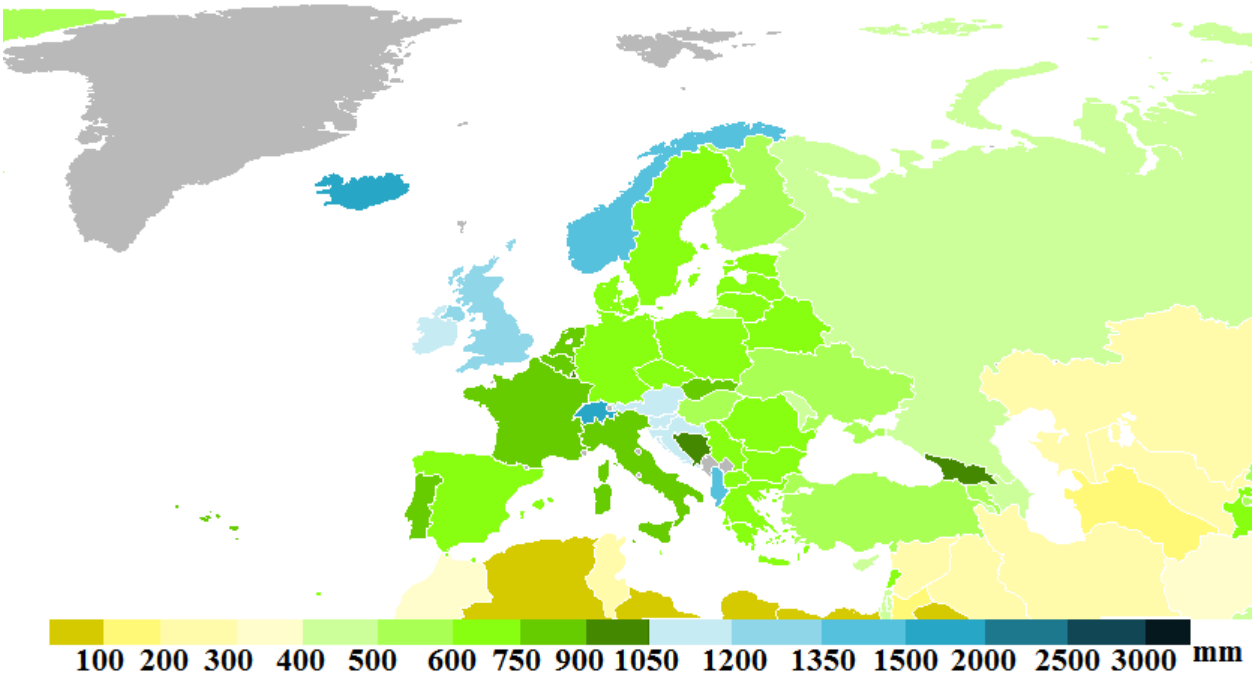

Figure 35.: *Annual quantities of precipitation in countries of Europe*

5.3. Geomorphologic conditions

The location of the area, exposure and inclination of slopes, its altitude in relation to its surroundings, the proximity of lowland areas all affect light and temperature conditions of the production area, thus the living conditions of species produced there. On southern slopes of the northern hemisphere, the incidence angle of sunrays is higher, causing stronger warming, than on northern slopes, where the incidence angle of sunrays is lower. Wormwood, hyssop, sage, thyme, lavender prefer southern, sunny slopes that warm up easily, as they are light- and warmth-loving species. So there is a reason for the region of lake Balaton being the primary location of lavender production in Hungary. In case of certain medicinal plant species, frost pocket areas must be especially avoided, such as for pyrethrum, marjoram, anise, rosemary. It is not recommended either to grow marigold in lowland and humid areas, because the risk of mildew contamination is high under such conditions.

5.4. Wind conditions, wind force, frequency of gusts of wind

Frequent and strong wind may cause harm to the soil (deflation) and to plants. Strong winds blowing constantly from the same direction may ravage the leaves of plants, while the sand carried by the wind is deposited on the leaves of plants, clogging stomas. The wind enhances the extent of evaporation and dries the top layer of the soil. In spring, it can prevent young and weak plants from growing, while at the time of blooming, it can prevent the activity of pollinating insects. Protection against wind can be implemented by planting forests, hedges, tree-lines around the area, or by installing windbreaking grids, fences. Besides its negative effects, the wind also has advantages, for example, it can balance adverse weather conditions, dusty winds dry the soil yet unsuited to cultivation in spring, it can promote pollution and fertilization, and it can also enrich the tilth by carrying fine dust and loess. The most common wind direction in Hungary is from the northwest.

Tall plant species generally require a place protected from wind, such as high mallow, milk thistle, mullein, and windy weather during ripening can also cause a serious loss for plant species with easily rolling fruits or seeds. At the same time, however, we can utilize effects of the wind in plant protection, for example, when planting marjoram, we create lines aligned with the direction of prevailing winds, and the wind terminates the warm

and humid microclimate inside the plant population, by which the probability of alternaria contamination can be reduced.

5.5. Natural vegetation of the area, vegetation of surrounding areas

When selecting a production area, it is also important to consider what the natural vegetation of the area is (or was), because it will later appear from time to time, making the produced culture weedy. Vegetation of surrounding areas (e.g. forest or wooded strips, field, meadow, pasture) can also have an impact on the produced culture as they affect the living conditions of those plants. Besides a number of positive effects, for example, they reduce the speed of wind, protect the soil, reduce the extent of evaporation and increase air moisture and soil moisture, they are natural boundaries around the area and also provide an environment for polluting insects; they can also have negative effects on produced plant culture. For instance, they abstract nutrient and water, create a heat cauldron and shadows, they can promote the proliferation and establishment of pests and pathogens, make the area weedy, etc. It can be observed that within 1.5 times of the distance of the height of belt, reduced yields are caused in the production area.

6. Production technologies of major plants

6.1. One-year medicinal plants of Apiacea leaves:

6.1.1. Anise (*Pimpinella anisum* L.)

Botanical description, ecological demand: It is a one-year, herbaceous, moisture-, warmth- and light-loving plant. Its hairy, ridged stems have leaves of different shapes. Its spindle-like root is thin and sparsely branched. It grows wild in Mediterranean regions.

Previous cropping: Cereals sown in fall and spring, or green fodder plants.

Soil preparation and nutrient supply: Shucking of previous cropping stubble, then deep ploughing. Application of 40-60 kg/ha of nitrogen, 60-90 kg/ha of phosphorous, and 40-60 kg/ha of potassium. Preparation of the soil of small crumbs in spring. It is recommended to distribute 20 kg/ha of foliar fertilizers at the beginning of growth.

Sowing: Late March – early April, with a line distance of 25-30 cm, at a depth of 2-3 cm. Seed requirement: 15-20 kg/ha.

Care: Due to its poor capacity to supress weeds, it is recommended to apply an herbicide treatment after sowing and before growth, as well as to treat the plant population. Its most significant disease is the bacteria attacks, which can be prevented by products containing copper, before growth.

Harvest: Its fruit ripens unevenly and it rolls easily. Its single harvest has to be conducted at the time of full ripening of main clusters, by cereal cutting combine harvester. Yield: 400-600 kg/ha.

Primary processing, storage: Following the cleaning of seeds, the fruit must be dried at a maximum temperature of 40°C and spread, after which it is recommended to store the product in sacks. Essential oil is distilled from its fruit.

Drug: fruit of anise (*Anisi fructus),* essential oil *(Aetheroleum anisi)*. Main active substance: essential oil (anethole).

Physiological effects: anti-convulsant therapy, disinfection, dissolving mucilage.

Figure 36.: *Anise in blossom*

6.1.2. One-year caraway (*Carum carvi* L.)

Botanical description, ecological demand: It is a two-year, herbaceous, water-, warmth- and nitrogen-demanding plant. Its stem can grow up to 100 cm high, its leaves are flowery ridged. It grows a flourishing stem from its carrot-shaped root in the second year. It is common in areas of reaping.

Previous cropping: Cereals sown in fall and spring.

Soil preparation and nutrient supply: Shucking of previous cropping stubble, then deep ploughing. Application of 50-70 kg/ha of phosphorous, and 50-80 kg/ha of potassium. Preparation of the soil of small crumbs in spring and it is recommended to distribute 50-70 kg/ha of nitrogen.

Sowing: Late March, with a line distance of 24-36 cm, at a depth of 2 cm. Seed requirement: 11-14 kg/ha.

Care: It is recommended to conduct a chemical weed control after sowing and before growth, as well as for the plant population. Its main pests are the Eryophyes peucedani and the Depressaria daucella. In case of the first one, acaricides, while in case of the latter, contact products can be used as prevention.

Harvest: Single harvest is recommended due to the easy rolling of the fruit. The time of this is the full ripening of main clusters, and the method is cereal cutting combine harvester. Yield: 500-1500 kg/ha.

Primary processing, storage: The drying of the fruit is recommended at a maximum temperature of 40°C, after which the fruit is suggested to be stored in sacks. Essential oil is distilled from its fruit.

Drug: fruit of caraway (*Carvi fructus),* essential oil *(Aetheroleum carvi).* Main active substance: essential oil (d-carvone, d-limonene) Physiological effects: anti-convulsant therapy, disinfection and elimination of wind-dampness.

Figure 37.: *Caraway in blossom*

6.1.3. Coriander (*Coriandrum sativum* L.)

Botanical description, ecological demand: It is a one-year herbaceous plant, which indigenous in the mediterranean regions of Europe. Its root is mildly branched, stick-like and its stem can grow up to 30-120 cm high. The roundish leaves formulate the rosette, the correct growing of which requires a low temperature for a long time.

Previous cropping: Cereals sown in fall and spring, or green fodder plants.

Soil preparation and nutrient supply: Deep ploughing in fall, then application of 40 kg/ha of nitrogen, 15 kg/ha of phosphorous, and 20-30 kg/ha of potassium. Preparation of the soil of small crumbs in spring and it is recommended to distribute 10 kg/ha of nitrogen.

Sowing: It can be sown between mid-March and the end of March, with a line distance of 25-30 cm, at a depth of 4-5 cm. Seed requirement: 16-20 kg/ha.

Care: It is recommended to apply an herbicide treatment after sowing and before growth. Its most significant diseases are the bacteria attacks and ramularia coriandri that can be prevented by products containing copper, before growth.

Harvest: Its fruit ripens unevenly and it rolls easily. Its single harvest has to be conducted at the time of full ripening of main clusters, by cereal cutting combine harvester. Yield: 1000-1500 kg/ha. Essential oil is distilled from its fruit.

Primary processing, storage: Following the cleaning of seeds, the fruit must be dried at a maximum temperature of 40°C and spread, after which it is recommended to store the product in sacks.

Drug: fruit of dill (*Coriandri fructus*), essential oil (*Coriandri aetheroleum*), Main active substance: essential oil (linalool), fatty oil Physiological effect: elimination of wind-dampness, improving digestion, smooth muscle relaxation.

Figure 38.: *Coriander in blossom*

6.2. Perennial medicinal plants of Apiacea leaves:

6.2.1. Fennel (*Foeniculum vulgare*)

Botanical description, ecological demand: It is a plant, which grows up to 150-200 cm high, and its multiply pinnated leaves are distributed on its cylindrical, naked, branched stem. Its root is spindle-shaped and penetrates deep in the soil. It is a warmth-loving and nutrient-demanding plant, which can freeze in cold winters.

Previous cropping: Cereals sown in fall and spring, and root crops.

Soil preparation and nutrient supply: Deep ploughing in fall, then application of 80-100 kg/ha of phosphorous, 40-60 kg/ha of potassium and 20-40 kg/ha of nitrogen from the second year, in early spring. Preparation of the soil of small crumbs in spring and it is recommended to distribute 10 kg/ha of nitrogen.

Sowing: It can be sown between early March and the end of March, with a line distance of 42-48 cm, at a depth of 2-3 cm. Seed requirement: 8-10 kg/ha.

Care: It is recommended to apply a treatment after sowing and before growth because later on, the population closes. Its most significant diseases are species of bedbugs that can be prevented by bee-friendly contact products.

Harvest: Due to the large green mass, two-time harvest is recommended. Cutting must be done at a height of 30-40 cm, then placed in order and finally to collect the fruit after a drying of 5-10 days with combine harvester. Yield: 1000-1500 kg/ha.

Primary processing, storage: Following the cleaning of seeds, the fruit must be dried at a maximum temperature of 40°C and spread, after which it is recommended to store the product in sacks. Essential oil is distilled from its fruit.

Drug: fruit of fennel (*Foeniculi amari fructus*), essential oil (*Foeniculi amari fructus aetheroleum*), Main active substance: essential oil (anethole), fatty oil Physiological effect: dissolving mucilage, elimination of wind-dampness, improving digestion, anti-convulsant therapy.

Figure 39.: *Fennel in blossom*

6.5.3. Medicinal Chamomile *(Matricaria recutita)*

Botanical description, ecological needs: It is a perennial plant, but it often germinates in the autumn, as it is not frost tender. The branched stem grows to a height of 5-80cm - erect or growing flat; it flowers from the end of April to early June. Climatic requirements: chamomile requires light and heat; seeds buried in the soil remain ready for germination for 10-15 years; tolerates alkaline soils and drought, but needs extra water for the developing of the young plants.

Preceding crop: It has no special requirements in respect of preceding crops. It can be grown in monoculture production; rotation is only necessary if resistant weed flora appears.

Soil preparation and nutrients: in the first year it only needs phosphorous supplement of 40-60kg/ha if planted in sandy soil; in the second year fertilizers with phosphorous (P) content of 60-70kg/ha, potassium (K) content of 50-70kg/ha and nitrogen (N) content of 10-40kg/ha should be spread prior to sowing - N content in the spring should be 40-60kg/ha. Soil preparation: shallow ploughing or disking, preparing a smooth and even seed bed.

Sowing: in late August or early September, using 8-10kg/ha grinded flower mixture (achenes and floret) on soil surface; rolling with disc roller after sowing.

Plant protection: Pre-sowing and pre-emergent herbicides may be used.

Harvesting: when most of the flowers are in full bloom, the cutting height for producing essential oil should be determined in a way that the harvested chamomile should contain the lowest amount of stem parts.

Primary processing, storage: removing contaminants and foreign materials; natural and artificial drying.

Drug: Chamomile matricaria flower (*Matricariae flos*), essential oil (*Matricariae aetheroleum*)

Active ingredient: essential oil (chamazulene, matricin), flavonoids, coumarins, pectin mucilage.

Physiological effect: anti-inflammatory, antiseptic, antispasmodic.

Figure 50: *Chamomile*

6.6. Perennial herbs belonging to the family of Asteracee:

6.6.1. Common goldenrod *(Solidago virigi-aurea)*

Botanical description, ecological needs: It is a 60-100cm tall herbaceous perennial plant. The clustered yellow flower heads are 0.5-1cm in diameter with low aromatic smell; in bloom from June to September. It is mildly acidophilous.

Preceding crop: May be sowed after cereal crops; solanaceous plants are not suitable as preceding crop.

Soil preparation and nutrients: deep ploughing in the autumn, spring-like land-levelling of soil.

Sowing: Seedlings are grown in early spring, and they are planted in the middle of April; spacing should be 50x30cm.

Plant cultivation: Soil loosening between rows, mechanical weed control.

Harvesting: the floral shoots are collected at the beginning of flowering, in a way that only the uppermost - no more than 30-40cm - part of the shoots are cut, ensuring that as few thick stems end up in the drug as possible.

Primary processing, storage: can be dried at a temperature of up to 40°C. It can be stored in bales. For storage in bales, first the parts above the ground are removed, then the roots and the rhizomes are dried without peeling.

Drug: floral shoots of common goldenrod (*Virgae aureae herba)* and root (*Virgae aureae radix*).

Main active ingredient: flavonoids, essential oil, tannins, triterpene saponins.

Physiological effect: diuretic, reduces inflammation (immune-stimulant), anti-inflammatory, analgesic

Figure 51: *Common goldenrod*

6.6.2. Purple Coneflower *(Echinacea purpurea)*

Botanical description, ecology needs: Herbaceous, perennial plant that can grow up to a height of 1.2 m. Its cone-shaped, rough, jagged leafs are rounded at the base. It prefers soils with sufficient water supply; less sensitive to soil pH. It can tolerate drought once established.

Preceding crop: It is recommended to plant after root crops and organic fertilizer.

Soil preparation and nutrients: deep ploughing in the autumn, spring-like land-levelling of the soil. Fertilization: sufficient organic fertilizer (30 t/ha).

Sowing: seedlings planted in their permanent location in the middle of May or the middle of September (row and plant spacing: 40-60 x 30cm)

Plant cultivation: Weeding with row cultivation.

Harvesting: Floral shoots can be cut in the second year, when in full bloom. Roots can be rotated in the October of the third year, using a plow without ploughshare.

Primary processing, storage: Floral shoots are processes fresh. The roots need to be washed, cut into 6 pieces, and dried.

Drug: floral shoots of purple coneflower (*Echinaceae purpureae* herba) and root (*Echinaceae purpureae radix*).

Active substance: caffeic acid derivatives, alkilamids, polysaccharides, essential oil.

Physiological effect: boosts the body's immune system

It may interact with drugs damaging the liver, anti-cancer drugs, synthetic hormones.

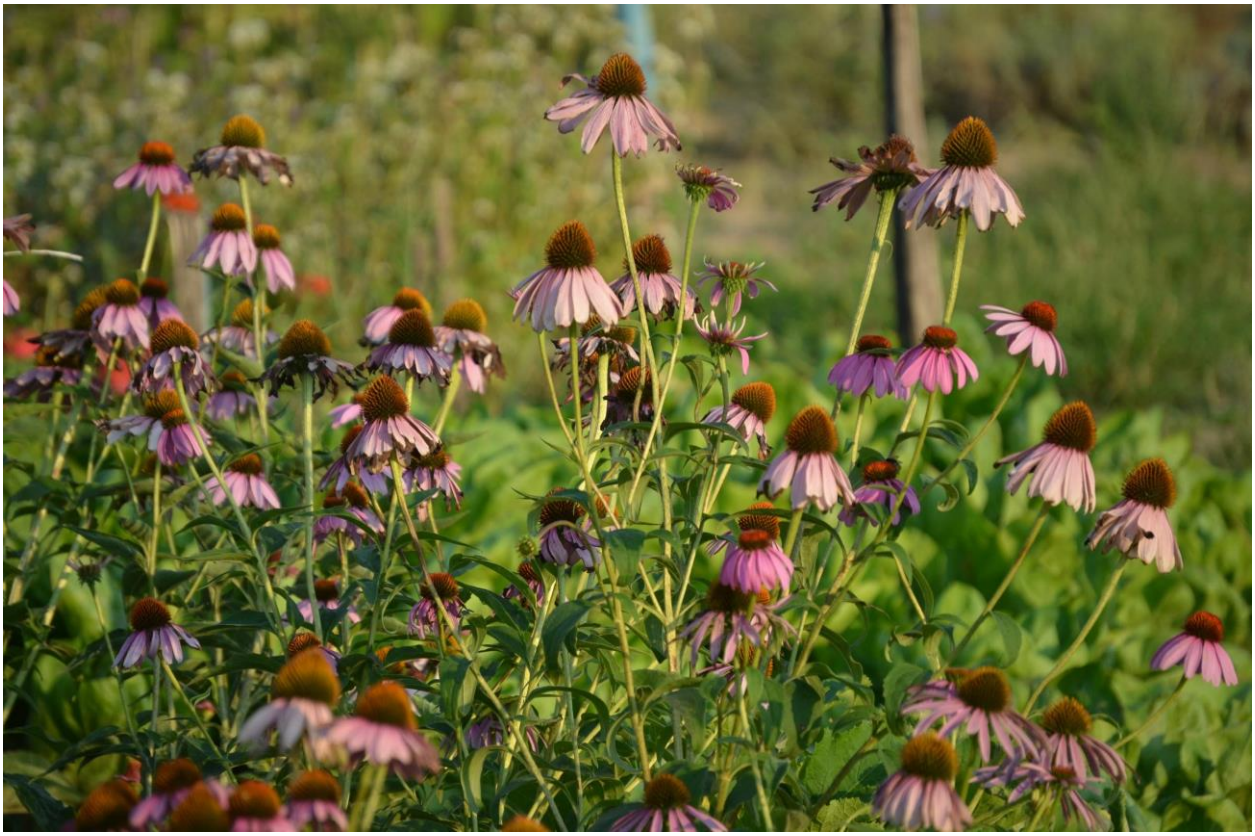

Figure 52: *Echinacea purpurea*

6.6.3. Achillea millefolium *(Achillea collina)*

Botanical description, ecological needs: It is an herbaceous, perennial plant, which grows up to a height of 50-80cm. The leaves are cauline, and more or less clasping. Its white flowers start opening in June.

Preceding crop: Cereal crops harvested early. Avoid preceding crops from the family of Asteracee, as it increases damage caused by leafroller moth.

Soil preparation and nutrients: after the preceding crop is harvested: stubble stripping and autumn deep ploughing followed by seedbed preparation. In the autumn it is recommended to spread 40kg/ha nitrogen and 90-100 kg/ha phosphorus.

Sowing: at the end of August - beginning of September: with rows 60-70cm apart, at a shallow sowing depth (0.5cm). Seed standard: 1.5-3kg/ha.

Plant cultivation: Chemical weed control on several occasions.

Harvesting: It is harvested during full bloom, with a reaping loader. For essential oil extraction, the entire blooming shoot is cut.

Primary processing, storage: After drying, the flowers are chopped and stored in bags.

Drug: the essential oil (Achilleae aetheroleum) of the floral shoots of achilleae millefolium (*Achilleae herba*).

Active substance: essential oil (chamazulene), tannin, flavonoids.

Physiological effect: Improves appetite and digestion; carminative.

Figure 53: *Achillea millefolium*

7. Processing technologies and basic hygiene rules

7.1. Processing procedures

7.1.1. Preparatory procedures

The processing of herbs is divided into two major groups. It consists of primary and secondary processing. The purpose of the primary processing is to produce drugs meeting the quality standards specified in the Pharmacopoeia. During the secondary processing the purpose is to ensure that the product is marketable, and to arrange for packaging.

Preparatory procedures are performed before the primary processing. Products meeting the criteria of high-quality requirements with appropriate value can only be produced using the plant part containing the best active ingredient. This can be ensured by determining the correct time of the harvest (technological maturity - when the active ingredient content is at its peak) and by using the appropriate collection method.
Fast delivery of the raw material to the place of processing is of primary importance, since the plant may be damaged if scorched. To avoid any damage, the plants may only be dried for 3-5 hours, spread in a thin layer.

Figure 54: Ivy leaves spread in a thin layer for drying.

The plants are graded before processing; their external properties (colour, odor) must meet the requirements, and the purity of the consignment is examined as well. Prior to processing it must be stored separately to avoid contamination and mixing with other crops. Special attention should be paid to herbs with strong active ingredient content, and to those with characteristic smell.

The aim of the preparatory procedures is to make the drug suitable for drying, for reasons of efficiency. This includes cleaning, peeling, chopping and dehusking.

During the process of cleaning, foreign materials and thicker stems are removed. Soil and harmful materials are also removed. This process can be done manually, using a sieve, or by washing.

Figure 55: Manual cleaning of comfrey root

The peeling process is used for drugs with the active ingredient contained in the root. During this process the outer part not containing active ingredient is removed.

Chopping is a procedure typically used for plant parts bigger in size, or for those that are difficult to dry. The plant parts usually sliced or chopped are the roots.

Figure 56: Chopping roots

During dehusking the leaves are removed from the stem. This procedure can be performed either when the plant is raw, or after drying.

Figure 57: Dehusking lemon grass

7.1.2. Drying processes

The most common procedure for the primary processing of herbs is drying. During the process the moisture content of the plant is reduced to 8-14% in order to ensure preservation and to ease usability. During drying higher temperature air with low relative humidity is circulated through the fresh plant parts. During the process, the relative humidity of the air increases, while the temperature decreases. Heat transfer is directed from the drying air toward the plant parts to be dried, and in this way the plant part is heated and the thermal motion of water molecules is accelerated. At higher temperatures it causes steaming, while at lower temperatures it causes evaporation. Warmer temperature of drying air and faster speed of circulation increases the speed of drying. However, if the process is too fast, a layer can be formed on the surface of the raw material, which blocks water evaporation from the internal parts.

Water is present in the plant raw material in a variety of ways. For technical aspects these are grouped as:

- Chemically or structurally bound water: in this case water is completely bound within the structure of the molecules, and can only be removed by using a high amount of energy, which is damaging the material.
- Physicochemically bound water, with two connection methods:
    - adsorption: with physical interaction or chemical bindings,
    - osmotic process: intracellular concentration-equilibration processes (osmosis).
- Mechanically bound water: water connected to the surface of the raw material by adhesion, and water present in intercellular space.

Drying is suitable for removing mechanically and osmotically bound moisture, while the structure of the raw material is retained.

- Natural drying process: Water and vapour is evaporated from the fresh plant parts with the use of the thermal energy of the Sun, assisted by air circulation. This is usually

done in the shade, such as lofts, barns and airy sheds. The plant raw materials are hung in bundles on a wire, or spread across drying frames.

Figure 58: Natural drying process

- **Artificial drying process:** Air circulation is triggered by ventilators; thermal energy is produced by burning wood, gas or oil. Drying air is grouped on the basis of the temperature:

  - **Cold-air drying:** 15-25°C air is circulated - the drying period is 8-12 days. It is mainly used for drying sensitive materials (feverfew-*Tanacetum parthenium*)

- **Warm-air drying:** the most commonly used method for drying herbs. Air temperature is between 25-80°C; drying time is 6-12 hours.

- **Hot-air drying**: air temperature is between 200-1000°C, but it gets in contact with the raw material for only 2-5 minutes, which is heated to no higher than a temperature of 60-70°C (due to the heat extraction effect of evaporation). It is mainly used for pharmaceutical raw materials (Foxglove species - *Digitalis spp.)*

Figure 59: Drying floor suitable for blowing air of various temperatures

7.1.3. Processes for the extraction of essential oil

Essential oils are liquid mixtures with a distinctive scent; they are made up of compounds - in particular terpene - that easily evaporate at room temperature. They are not soluble in water, but are well dissolved in organic solvents (alcohol, ether); they mix

well with each other as well. Their boiling point is usually between 150°C-300°C, however, when mixed with water vapour, distillation takes place at around 100°C. Their specific gravity (0.8 - 1.1) is lower than that of water, although there are some exceptions, such as lovage, cinnamon and cloves.

These volatile compounds are usually accumulated in essential oil plants in quantities of about 20-50 ml/kg in external (exogenous) or internal (endogenous) essential oil holders typical of the different plant families.

(Figure 60: essential oil of fennel, orange and lavender)

Essential oils are sensitive compounds; therefore, the structure of their components may change during maceration, losing their positive physiological effects. To avoid such loss, various extraction processes have been developed; the best-known ones are presented here:

- **Distillation**

This is one of the oldest ways of extracting essential oils: such heating process is mainly used for extracting less sensitive compounds.

During the process, the plant part is placed in a container called distiller, and water vapour is circulated through it. This will evaporate the volatile compounds, which will then travel through a chilled pipeline system, and be condensed into a container/florentini glass placed next to it. This distillate is practically a sort of condense liquid, with the essential oil concentrated on the surface, or at the bottom of the water - depending on the herb variety.

The procedure is based on the principle that in case of two immiscible liquids, the vapour pressure is the sum of the vapour pressure of the two components. The boiling point of such mixture is lower than the boiling point of the component with the lowest boiling point. Since one of the compounds of the mixture is water, the distillation may usually be performed at a temperature lower than 100°C. Therefore, this process is suitable for the gentle distillation of materials with high boiling point that are immiscible with water - such as essential oils.

(Figure 61: Distillation process)

Figure 60: Essential oil of fennel, orange and lavender

- **Expression**

In case of plant species where an extraction temperature of about 80 -100°C would cause deterioration in the quality of the essential oil, cold expression or centrifugation is used. In case of the former plants, the volatile compounds are extracted from the pericalp of these plants by expression, while in the case of the latter, after pulping, the essential oil and the aqueous compound is separated by centrifugation. This procedure is mainly used for lemon (Citrus × limon), sweet orange (*Citrus silences*), grapefruit (*Citrus x paradisi*) species within the sub-family of citrus fruits (*Aurantioideae*), and it is usually performed by pressing the fruit juice during a mechanical workflow. (Figure 62: Expressing lemon peel)

- **Extraction - with solvents**

In case of plant species sensitive to heat, where the processes of expression or centrifugation cannot be used either, extraction with solvents is used.

During this process the plant part is soaked in non-polar solvent (methanol, ethanol, acetone). The resulting extract contains resin, fat, wax and colorants. These must first be removed, and then the residual solvent is evaporated at low pressure and so is pure essential oil produced.

Extraction with solvents may be performed with volatile or non-volatile solvents, at low or higher temperatures. (Figure 63: Extractor using solvents)

7.1.4. Processes for extracting fatty oils

Fatty oils are made up of fatty acids containing saturated or unsaturated carbon chains, and glycerol (sugar alcohol). They are non-volatile, and most of them are scentless. The consistency of the fat is determined by the length of the carbon chain, the frequency of the unsaturated fatty acid parts and their proportion to unsaturated fatty acids - the consistency can be solid or liquid at room temperature. They are mainly stored in the seeds and the fruit of a plant, and serve as nutrient reserves.

Based on their effect on the human body, they can be divided into two groups. Some of them are indifferent in their effect - such as sunflower oil - therefore they are mostly used as ingredients in ointments or vehicle injections, while others have special health effects - such as castor bean - which is used as a strong laxative.

The fatty oils are generally extracted from the plants by expression and/or extraction with solvents. In our country, the previous method is used for herbs.

(Figure 64: Extracting oil)

7.2. Hygienic principles

Plant protection in herb production: Only authorized plant protection products may be used, and the withdrawal periods must be observed. The use of the plant protection product must be recorded in the record of pesticides.

Harvesting: Only healthy, fully mature plants can be harvested and collected.

Storage: The harvested material must be stored in a dry, cool place until processing.

Production: The product must be manufactured in a way that the processes performed in the contaminated and the clean locations are not mixed with each other; such processes must be isolated in place or time. The production process begins with the sorting of raw plants, followed by other procedures aimed at preparing the final product ready for consumption. The kitchen must be cleaned before the start of the processing, and it must be in order with sufficient space for the processes. Pets must be kept away from the kitchen. Care should be taken to disinfect hands, tools and utensils, as well as to thorough rinsing after disinfection. The producer should wear clean work clothes (e.g. apron, hat, shawl) when preparing the products. Windows can only be kept open during the production of the product, if they have mosquito nets installed.

Production process, documentation and records: If the principles of good manufacturing and hygienic practice are observed, high-quality and safe food will be produced by the producer. During the production process any possible health risks were taken into account, and they can be eliminated by appropriate supervision. When producing vegetables, fruits, mushrooms, ground red pepper, spices and herb dried products, the contents of Table 2. may be suitable for documentation as good hygiene practices, if the condition of the premise of production (kitchen) is appropriate and it is signed by the small producer.

Mandatory records kept by the small producer:

- Record of pesticides
- Record of growing
- Record of production

The record of growing should contain all plants purchased from growers and used for the production. The record of production should contain the production of the dried plant materials and their sale. Any defects (detected internally or complaints by

customers) in connection with the products must be entered in the records, as well as the remedial actions (e.g. the product is exchanged; thorough cleaning and disinfection in the future). The defect must be entered next to the product questioned internally or by customers.

Table 2: Documentation of control processes according to the provisions of GHP.

Technological process	Requirement	Regulation	Procedure in case of deviations
Sorting	Use of healthy plant parts.	Sorting out rotten and mouldy pieces.	Disposing of rotten and mouldy pieces into waste
Washing roots or rootstocks.	No soil or sand should remain on the plant part.	Thorough washing; soil and sand must be removed from the surface.	Repeated washing, until the surface is free from soil and sand.
Post-cleaning of roots or rootstocks.	The plant part should be clean.	The procedure should be carried out with clean hands or knife. Cleaning with drinking water.	Removing mouldy, rotten parts, or pieces with insect bites.
Slicing and chopping of roots, rootstocks, or plant parts above soil surface.	Clean slices of 2-3mm thick.	The procedure should be carried out with clean hands and knife, on a cutting board.	Cleaning of hands, knives, cutting board
Spreading and hanging	Spreading out in a thin layer, tied in small bunches and suspended, to allow for the passage of air.	With clean hands, spread out on a clean tray or baking sheet. The bunches should be tied with clean string.	Cleaning of hands, tray, and baking sheet
Drying	The dried plant material is a little springy, no moisture can be felt when crushed by hand, has a characteristic colour, flavour and aroma.	When dried in the open air, it must be protected from contamination with a clean mosquito net/cheesecloth. The place must be clean. When dried in a dryer, the equipment must be clean. The dried plant material must be stirred several times.	Cleaning of the equipment. Additional drying.
Packaging	Use clean	Buying packaging	Re-packaging into clean

	packaging material suitable for food storage.	material suitable for food storage, and keeping it clean. The expiry date must be indicated on the packaging.	packaging material suitable for food storage.
Storage	The dried plant material must be clear and characteristic in colour and aroma.	Store in a dark, dry, cool place, below +20 °C. The dried plant material should be checked on a monthly basis.	Any contaminated bags must be re-packaged. If the dried plant material is mouldy or contaminated by insects, it must be destroyed or composted.
Transportation and sale	The bags must be kept clean.	The sack, basket, or table must be clean.	Any bags with dirt (dust) on them must be wiped with a clean, dry cloth.

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Place and date Small Producer

8. Legal framework

EEC no. 65/65, 75/318, 75/319 Directives: Plant origin drug: plants (or parts of plants) used for the purpose of treatment. Plant origin drug-preparations: either in powder form, extracts, alcoholic solutions, fat- or essential oils, pressed juices. These products - similarly to other medications - need to be inspected and validated according to the EEC 75/318 as well as the Guideline Quality of Herbal Remedies.

2004/24/EK Directive: Determines the cessation of the non-medicinal pharmaceutical products' product category, the reclassification and marketing of products.

Laws regarding food supplements:

37/2004. (IV.26.) ESZCSM order regarding food supplements. The Union directive-basis for the 37/2004. (IV.26.) ESZCSM order: http://eur-lex.europa.eu/legal-content/HU/TXT/?qid=1481993840007&uri=CELEX:02002L0046-2**0150402 89/102 THE COMMITTEE (EU) 2017/1203 ORDER (2017. July 5.)** for the change of the production of food additives and food supplements regarding the utilized organic silicon (monomethyisilanetriol) and the calcium phosphoryl oligosaccharides (POsCa®). COMMITTEE REPORT TO THE COUNCIL AND THE EUROPEAN PARLIAMENT on the utilization of material aside from vitamins and minerals within food supplements http://ec.europa.eu/transparency/regdoc/rep/1/2008/HU/1-2008-824-HU-F1-1.Pdf COMMISSION STAFF WORKING DOCUMENT CHARACTERISTICS AND PERSPECTIVES OF THE MARKET FOR FOOD SUPPLEMENTS CONTAINING SUBSTANCES OTHER THAN VITAMINS AND MINERALS http://ec.europa.eu/food/safety/docs/labelling_nutrition-supplements-2008_2976_f_wd1_en.pdf COMMISSION STAFF WORKING DOCUMENT AVAILABLE SCIENTIFIC INFORMATION ON THE USE OF SUBSTANCES OTHER THAN VITAMINS AND MINERALS IN FOOD SUPPLEMENTS http://ec.europa.eu/food/safety/docs/labelling_nutrition-supplements-2008_2977_f_wd2_en.pdf Guidance Food supplements: guidance and FAQs: https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs This Guidance explains how, and on what basis, the MHRA decides whether products are

medicines or not and clarifies the MHRA's position on traditional herbal medicinal products
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/506397/a_guide_to_what_is_a_medicinal_pro duct.pdf Food Supplements Europe guidelines: http://www.foodsupplementseurope.org/publications-guidelines/ Setting of tolerances for nutrient values declared on a label Guidance For Food Supplements http://www.foodsupplementseurope.org/sites/0023/uploads/content/publications/fse-setting-of-tolerances-for-nutrient-valuesdeclared-on-a-label.pdf?1393609771 OVERVIEW REPORT ON A SERIES OF FACT FINDING MISSIONS CARRIED OUT IN MEMBER STATES IN 2013 AND 2014 IN ORDER TO GATHER INFORMATION REGARDING THE CONTROLS ON FOOD SUPPLEMENTS http://ec.europa.eu/food/fvo/overview_reports/details.cfm?rep_id=80 1993/2015. (XII. 28.) Gov. order on the measures regarding the realization of a sports-dietetic institution suitable for the inspection regarding prohibited performance-enhancement by food supplements used by athletes. Information of food supplements on the OÉGYI website: https://www.ogyei.gov.hu/etrend_kiegeszitok/ List of reported food supplements: https://www.ogyei.gov.hu/ETREND_LISTA/

8.3. Health-related claims and guidelines:

- The European Parliament and the Council's 1924/2006/EK ORDER (2006. December 20.) regarding claims concerning food, nutrition and health.
- THE COMMITTEE'S 2013/63/EU IMPLEMENTING DECISION (2013. January 24.) the 1924/2006/EK article 10. of the European and Council order regarding the acceptance of guidelines on the execution of special conditions of claims regarding health.
- 353/2008/EK Committee ORDER (2008. April 18.) on the 1924/2006/EK Article 15. of the European and Council order regarding the determination of implementing rules regarding requests for validating claims regarding health.
- 907/2013/EU COMMITTEE ORDER (2013. September 20.) on determining the regulations regarding requests for the usage of general designations (terms).
- 432/2012/EU COMMITTEE ORDER (2012. May 16.) on determining the list of validated claims not related to the reducing of illness-risks or the development and health of children, related to food products, regarding health.

- 983/2009/EK Committee ORDER (2009. October 21.) on validation or the rejection of validation regarding certain claims related to health, on reducing illness-risks or the development and health of children related to food products.
- 984/2009/EK Committee ORDER (2009. October 21.) regarding the rejection of the validation of health-based claims regarding food products related not to the reduction of illness-risks as well as to the development and health of children.
- 1024/2009/EK Committee ORDER (2009. October 29.) on the reduction of illness-risks, and on the validation or rejection of validation of certain claims regarding health regarding food products in view of the development and health of children.
- 1025/2009/EK Committee ORDER (2009. October 29.) regarding the rejection of the validation of health-based claims regarding food products related not to the reduction of illness-risks as well as to the development and health of children.
- 1167/2009/EK COMMITTEE ORDER (2009. November 30.) regarding the rejection of the validation of health-based claims regarding food products related to the reduction of illness-risks as well as to the development and health of children.
- 1168/2009/EK COMMITTEE ORDER (2009. November 30.) regarding the rejection of the validation of health-based claims regarding food products not related to the reduction of illness-risks or to the development and health of children.
- 375/2010/EU COMMITTEE ORDER (2010. May 3.) regarding the rejection of the validation of health-based claims regarding food products not related to the reduction of illness-risks or related to the development and health of children.
- 382/2010/EU COMMITTEE ORDER (2010. May 5.) regarding the rejection of the validation of health-based claims regarding food products not related to the reduction of illness-risks or related to the development and health of children.
- 383/2010/EU COMMITTEE ORDER (2010. May 5.) regarding the rejection of the validation of health-based claims regarding food products not related to the reduction of illness-risks or related to the development and health of children.
- 384/2010/EU COMMITTEE ORDER (2010. May 5.) regarding the validation or the rejection of the validation of health-based claims regarding food products related to the reduction of illness-risks as well as related to the development and health of children.
- 957/2010/EU COMMITTEE ORDER (2010. October 22.) regarding the validation or the rejection of the validation of health-based claims regarding food products related to the reduction of illness-risks as well as related to the development and health of children..

Instructions on the utilization of the 1924/2006/EK order:

http://elelmiszerlanc.kormany.hu/download/0/95/60000/elelm_allitas_utmutato_080421.pdf

List of validated and rejected claims in English:

http://ec.europa.eu/nuhclaims/

Information on claims regarding health on the EFSA website in English:

http://ec.europa.eu/nuhclaims/

Q&A on the Nutrition and Health Claims Regulation (EC/1924/2006):

http://www.hsis.org/factsheets/EuropeanHealthClaimsfactsheet.pdf

9. Market entry conditions, sales methods

Food supplement:

May be marketed with reporting obligation, needs to adhere to the formal and content requirements of the food supplement regulations. The use of herbs within food supplements is possible with regard of the negative list and the limitation of EU monographs.

Claims of physiological effects on the product can be made in limited manner - only claims listed in the EU monographs may be applied. The data and warnings according to the regulations regarding the food supplements need to be highlighted on the product packaging.

Traditional herbal medicine:

Herbal medicine or the combination thereof which can be utilized without the exclusive medical diagnosis, supervision and recipe based on the given strength and dosage; applied orally, externally or through inhalation: based on literature data or expert's reports, it can be determined that the product the request is being based on or the suitable reference herbal medicine was in pharmaceutical use for at least 30 years preceding the request, and for at least 15 years in the EGT area.

Market entry is dependent on the authorization procedure of a Pharmaceutical Institute. Physiological effect claims on the product can be made according to that.

Herbal medicine:

Herbal medicine or the combination thereof which can be utilized without the exclusive medical diagnosis, supervision and recipe based on the given strength and dosage; the applicant can prove that the active substance of the medicine possesses a well-grounded pharmaceutical utilization of at least 10 years in the EGT, moreover it possesses a recognized effectiveness and acceptable security.

Medicine:

Medicine is any substance or combinations thereof, which are displayed as products for the prevention or treatment of human diseases, or substances or combinations thereof which - due to their pharmacological, immunological or metabolic effects - are to be utilized for the restoration, improvement or modification of any of the human

physiological function, or the utilization of them on- or within the human organism for a medical diagnosis.

The market entry permission of pharmaceutical products is issued exclusively by the National Institute of Pharmacy and Nutrition.

Magistral formula:

Magistral formula is a pharmaceutical product which is prepared by a pharmacist in the pharmacy based on medicinal recommendation or on his or her own initiative according to the Pharmacopoeia, based on the regulations of the Hungarian or the European Pharmacopoeia (hereinafter: Pharmacopoeia) or the regulations of the Formulae Normales (FO-NO) (hereinafter: Formulae Normales).

Food product containing medicinal herbs: Can be marketed as food product, if it is intended for human consumption, wholly or partially processed or unprocessed. Medicinal properties cannot be highlighted, however, medical claims permitted within the framework of a separate procedure are allowed. The food product needs to adhere to the provisions of food legislation.

Cosmetics:

Cosmetic products – cosmetics – are substances or mixture serving the purpose of contacting different areas of the human body (epidermis, hair and body hair, nails, lips, external genitalia, teeth, mucous membranes of the oral cavity), exclusively or primarily for the purpose of the cleansing, perfuming, changing the appearance thereof, as well as their protection, maintenance, or for the purpose of the neutralization of body odor.

The cosmetic products need to be secure during the usage within due- or reasonably foreseeable conditions. Especially references aimed at benefit-risk arguments cannot be the basis for the endangerment of human health.

According to the 1223/2009/EK order, safety assessment and product information documentation (TID).

The CPNP registration of the product can be done on a uniform online interface.

10. References

NÉBIH - Az élelmiszer szabályozás jogi háttere(2017):
http://portal.nebih.gov.hu/documents/10182/765581/80.+kiadás+ÉLELMISZER+jogszabálygyűjtemény.pdf/34af05a8-13eb-4d77-bf9e-72ed9d58bc34

GYÓGYNÖVÉNYEK TERMESZTÉSE ÉS FELDOLGOZÁSA (Egyetemi jegyzet, 2012):
https://www.agr.unideb.hu/ebook/gyogynoveny/index.html

VADON TERMŐ ÉS TERMESZTETT GYÓGYNÖVÉNYEK - Bernáth Jenő, Mezőgazda Lap- és Könyvkiadó Kft., 2013

FARMAKOBOTANIKA - A GYÓGYNÖVÉNYTAN ALAPJAI (KEMOTAXONÓMIA) - A GYÓGYNÖVÉNYTAN ALAPJAI - Dános Béla, Argumentum, 2008

A gyógynövénygyűjtés és termesztés ma Magyarországon – sikerágazat? (Zámboriné dr. Németh Éva, Agrofórum, 2013.07, pp12-16)

A VERSENYESÉLYEK JAVÍTÁSÁNAK LEHETŐSÉGEI AZ ÉLELMISZERGAZDASÁGBAN (AKI, Agrárgazdasági Tanulmányok 2008/8.):
http://repo.aki.gov.hu/3074/1/at_2008_08%20versenyesely.pdf

A GYÓGYNÖVÉNYÁGAZAT HELYZETE (AKI, Agrárgazdasági Tanulmányok 2008/4.):
https://uni-eszterhazy.hu/public/uploads/gyogynovenyagazat-helyzete_5812354905176.pdf

HAZÁNK JELLEMZŐ TALAJTÍPUSAI - SULINET TUDÁSBÁZIS (Hozzáférés: 2018.03.05):
http://tudasbazis.sulinet.hu/hu/szakkepzes/mezogazdasag/a-mezogazdasagi-termeles-fobb-okologiai-tenyezoi/talajtani-adottsagok/hazank-jellemzo-talajtipusai