



Study book

PART I. INTRODUCTION AND WILD GATHERING OF MEDICINAL AND AROMATIC PLANTS

 Introduction to medicinal and aromatic plants. Traditional and industrial m 	ain uses.
Main species produced and marketed	1
2. Wild harvesting collection	
PART II. CULTIVATION OF MEDICINAL AND AROMATIC PLANTS	
3. Production of medicinal and aromatic plants	15
4. Cultivation statges of medicinal and aromatic plants	22
5. Good farming practices	
PLANTS 6. Processing of medicinal and aromatic plants: conservation, drying, dis	stillation,
extraction	
7. Development of herbal products. Good manufacturing practices	
8. Marketing and commercialization. Legislation, standards and certification	52
INFORMATION SOURCES	
Bibliography	78
Internet	0.4





Autorship: Astrid van Ginkel – http://www.fitomon.com

Proofreading and edition: Eva Moré, Centro Tecnológico Forestal de Cataluña – <u>www.ctfc.cat</u>





PART I. INTRODUCTION AND WILD GATHERING OF MEDICINAL AND AROMATIC PLANTS

1. Introduction to medicinal and aromatic plants. Traditional and industrial main uses. Main species produced and marketed.

The use of medicinal and aromatic plants (MAPS) has a very ancient origin. Their use, collection and cultivation have been linked to human needs related to food, curing diseases, beauty, building houses and utensils, or rites, among others.

With dexterity, humans were trying to get to differentiate between toxic and useful plants, and to transmit knowledge from generation to generation until our days, first orally and then in writing. This traditional and local culture is studied by ethnobotany. It is composed by many disciplines, including botany, medicine, food, ecology, ethnology, linguistics, anthropology, history and sociology. It is considered that very important part of this information from our ancestors has been lost.

Fortunately, today there is a desire to return to have knowledge of these issues because the human needs a connection with nature, with an activity and a utility. These plants are still used to beautify gardens, to spice, to heal, to make cosmetics, for use in crops such as pest and disease control, to dye, or as additives in animal feed. The information fruit of scientific research is an advantage that was not available until recently, ie the combination of active ingredients, mechanisms of action, other applications in addition to the traditional, toxicity problems or interactions, and a long list of knowledge, which confirms or contradicts traditional uses.

It is estimated that approximately 70,000 plant species are used in folk medicine throughout the world (Farnsworth and Soejarto, 1991), a number that has been recently confirmed by different studies. Therefore, there is a demand for products obtained from these plants for domestic use and for trade at local, regional, national and international level. Medicinal plants are recognized by international organizations (OMS, European Medicines Agency -EMEA-through its committee HMPC: Herbal Medicinal Products Committee) and various legislations.

These plants are growing in nature where sustainable wild collection is carried out, or grown in orchards and field crops to obtain a raw material that can be fresh, mainly dried, and which extract their active ingredients will be interesting.

They are different aspects of the MAPS knowledge. One is the botany, the description of the main families, as well as distribution and habitats optimal for each one, are essential to correctly identify each useful wild species, which will lead to their subsequent collection. A domestic organic farming, with condiments or pots in the orchard or garden, complements the method of production. Once the plant has collected there are several options for transformation and a better conservation. These simple preparations include essential oil distillation or extraction with water, oil or alcohol, to finally use the infusion, essential oil or extract.





CONCEPTS

Medicinal plants:

According to the World Health Organization is any plant that contains, in one or more of their organs, substances that can be used for therapeutic or preventive purposes or which are precursors to chemical-pharmaceutical semisynthesis.

Phytotherapy:

It is the science that studies the use of plant products for therapeutic purposes, either to prevent, mitigate or cure a disease state. Therefore, it is about the use of plant species, its derivatives and formulations for the diseases treatments.

Drug (or vegetable drug):

Part of a medicinal plant used for the purposes mentioned above.

Active principles:

Chemical constituents of plants equipped with pharmacological activity. According to the European Union (it should be indicated the corresponding organization), substances or groups of substances which are known to contribute to the therapeutic activity of plant drugs or preparations.

1.1. Botany. Useful plants and main families

Botany is the science that deals with the study of plants. Having some knowledge of botany allows and facilitates us the correct identification of wild plants, in addition to name them. Although popularly, thanks to the wealth of languages, there are several different names for one plant or different plants are called the same. Hence the importance of knowing each species with its Latin name.

The vegetables are classified systematically; individuals who share similar characteristics are grouped into families. The useful plants belong to very different families. It is advisable to have guides, books with pictures or websites to consult. Although, the best option is to go to the field with an expert, who shows us on the ground each species and help us distinguish them from similar plants.





TABLE 1. Main species marketed in Brazil, Costa Rica and Jamaica

Country	MAPS
Brazil	Rosmarinus officinalis, Ocimum basilicum (O. selloi, O. gratissimum, O. suave), Lavandula angustifolia, Ruta graveolens, Tanacetum parthenium, Arctium lappa, Borago officinalis, Calendula officinalis, Chamomilla recutita, Tropaeolum majus, Foeniculum vulgare, Mentha piperita (M. sylvestris, M. pulegium, M. arvensis), Linum usitatissimum, Artemisia absinthium, Laurus nobilis, Achillea millefolium, Chamaemelum nobile, Malva sylvestris, Alcea rosea, Origanum vugare (O. majorana), Sinapis alba, Brassica nigra, Papaver rhoeas, Rosa centifolia, Salvia officinalis, Santolina chamaecyparissus, Saponaria officinalis, Plantago major, Cyperus sculentus, Thymus vulgaris, Valeriana officinalis, Viola odorata, Silybum marianum, Equisetum arvense, Allium fistolosum, Cichorium intybus, Coriandrum sativum, Symphytum officinale, Vitex agnus-castus, Taraxacum officinale, Melissa officinalis, Pimpinella anisum. Curcuma longa (C. zeodaria), Malpighia emarginata, Catharanthus roseus (Vinca rosea), Peumus boldus Cymbopogon citratus, Centella asiatica, Camellia sinensis, Lippia alba, Aloysia tryphylla, Tagetes minuta (T. erecta), Turnera ulmifolia, Chenopodium ambroisoides, Stevia rebaudiana, Zingiber officinale, Cephaelis ipecacuanha, Bixa orellana, Passiflora, Momordica charantia, Justicia pectoralis, Hibiscus sabdariffa, Smilax officinalis, Aloe vera.
Jamaica	Dianthera pectoralis (Justicia pectoralis), Evolvulus arbuscula, Vinca rosea, Cassia obovata, Chenopodium ambrosioides, Momordica charantia, Cymbopogon citratus, Mentha viridis, Micromeria sp., Ocimum basilicum, Aloe vulgaris, Hibiscus sabdariffa, Passiflora sp., Plantago major, Turnera ulmifolia, Zingiber officinale, Aloe vera
Costa Rica	Lippia alba, Tagetes Iucida, Smilax sp., Uncaria guianensis, Ruta chalepensis, Quassia amara, Justicia pectoralis, Ipecacuanha, Curcuma. Aloe vera, Mentha sp, Chenopodium ambrosioides, Cympopogon citratus, Stevia rebaudiana, Hibiscus sabdariffa, Smilax officinalis, Passiflora incarnata, Ocimum basilicum, Melissa officinalis, Chamomilla recutita, Lippia citriodora.

Source: Own elaboration.

1.2. Distribution

Useful plants are found in every corner of the planet. All cultures have vegetables as their basic food and as the basis of their traditional medicine. Vegetables grow spontaneous in a particular place due to climatic factors, soil, human impact and geological history. To begin with, we find different landscapes depending on the altitude and latitude.

The growth of wild plants in a particular site will depend on whether the environmental conditions are favorable, depending on the requirements of each one regarding sun exposure,





rain, temperature, soil type, etc. Most of them grow in communities, along with other living beings, for example on the margins of a road or a field, inside a forest, shrublands, grasslands or meadows. Also near a river or a rock wall, at the height of sea or in the mountain tops, in very sunny or moist and fresh places, in saline places near the sea, in acid or calcareous soils.

1.3. Traditional and industrial main uses.

Ethnography is the systematic study of people and cultures in specific scenarios. Ethnobotany is the study of relationships between plants and humans, including traditional applications and uses as described below:

1 Herbs - uses and applications in humans	1.1 Medicinal Herbs
and animals	1.2 Toxic Herbs
	1.3 Nutritional Herbs
2 House, work (industry and	2.1 Tools and utensils
small craft industries), daily life	2.2 Firewood
	2.3 Measurements
	2.4 Games, stories, popular sayings, songs,
	beliefs, rituals
	2.5 Tobacco substitutes
	2.6 Clothing
	2.7 Pests
	2.8 Ornamental
	2.9 Paper
	2.9 Dyes

Nowadays, industrial applications that move large volumes of plants are the following:

1 Food	Spices and condiments, teas, infusions for food and food supplements.	
2 Cosmetics, Biocides and Herbal medicines	Extracts, vegetable oils and essential oils.	
3 Animal feeding	Extracts and essential oils.	
4 Agriculture	Fertilizers and phytosanitary products:	
	extracts.	





TABLE 2: Main species produced in Brazil, Jamaica and Costa Rica.

Country	Wild plants	Cultivated plants
Brazil	Astronium urundeuva (Allemã o)	Achillea millefolium L.
	Engl.	Artemisia absinthium L.
	Baccharis illinita DC	Artemisia annua L.
	Baccharis genistelloides Person	Bixa orellana L .
	Baccbaris trimera, Less	Calendula officinalis L.
	Cymbopogon citratus (DC.) Stapf	Cynara scolymus L.
	Maytenus aquifolium Mart.	Hibiscus sabdariffa L.
	Maytenus ilicifolia Mart.	Matricaria recutita L.
	Petiveria alliacea L.	Melissa officinalis L.
	Peumus boldus Molina	Mentha pulegium L.
	Quassia amara L.	Ocimum basilicum L. /
	Quillaja saponaria Molina	Ocimum sanctum L.
	Aspidosperma quebracho-blanco	Rosa rubiginosa L ./ Rosa
	Schltdl.	moschata Desf. ex J. StHil
	Sapindus saponaria L.	Rosmarinus officinalis L
	Psidium guajava L. leaves	Valeriana officinalis L. /
	antibacterial and antifungal,	Valeriana wallichii DC.
	Bauhinia forficata Link, Mikania	Turnera diffusa Willd. ex
	glomerata Spreng., Ocotea odorifera	Schult
	(Vell.) Rohwer and Psychotria	Zingiber officinale Roscoe
	ipecacuanha (Brot.) Stokes	
	mentrasto (Ageratum conyzoides L.),	lemongrass (Cymbopogon
	picão-preto (Bidens pilosa L.) and	citratus (DC.) Stapf) and aloe
	mastruço (Chenopodium	(Aloe spp.),
	ambrosioides L.),	
	Aniba rosaeodora Ducke, Brosimum	Paullinea cupana
	glaziovii Taubert, Caesalpinia	Kunth / HBK
	echinata Lam. and Ocotea pretiosa	
	(Nees) Mez se han clasificado como	
	amenazadas.	
	Fava d'anta (Dimorphandra mollis	
	Benth.) y Jaborandi (Pilocarpus spp.)	
	se exportan aunque está prohibido.	
Jamaica	Juanilama. (Lippia Alba)	Hibiscus sabdariffa
	Cola nitida (Vent.) Schott & Endl.	Ocimum basilicum L Pimenta
	Costus spicatus	dioica (L.) Merr.
	Cymbopogon citratus (DC.) Stapf	Zingiber officinale Roscoe
	Smilax regelii Killip & C. V. Morton	Curcuma longa L.
	Aloe vera (L.) Burm. f.	Rosmarinus officinalis L.
	Morinda citrifolia L.	Azadirachta indica A. Juss.
	Jatropha gossypifolia L.	Arthrostema fragile Lindl.,
	Justicia pectoralis	Bryophyllum pinnatum
	Momordica charantia L.	(Lam.) Oken,
	Psidium guajava L.	Cymbopogon citratus (DC.)
		Stapf,
		Hyptis vertiicillata Jacq.,
		Mikania micrantha Kunth,
		Peperomia hernandifolia





Country	Wild plants	Cultivated plants
		(Vahl) A.Dietr.,
		Blighia sapida K. D. Koenig
		Petiveria alliacea L.;
		Mentha sp
Costa Rica	Juanilama. (Lippia Alba)	Allium sativum
	Menta. (Satureja viminea)	Aloysia triphylla
	Caña Agria. (Costus spicatus)	Ruta graveolens
	Cymbopogon citratus (DC.) Stapf	Ocimum basilicum L Lippia
	Tilo o Tila. (Justicia pectoralis)	alba (Mill.) N. E. Br. ex
	Arrabidaea chica colorant	Britton & P. Wilson and
	Hamelia patens Jacq., antibacterial	Tagetes lucida Cav. are also
	and antifungal,	cultivated
	Psidium guajava L. leaves	Mentha sp
	antibacterial and antifungal,	Matricaria recutita L.
	Quassia amara	Smilax chiriquensis, Smilax
	Jatropha gossypifolia L.	dominguensis,, Bauhinia
	Momordica charantia L.	guianensis; Simarouba
		glauca; Peti v eria alliacea;
		Solanum mammosum;
		Dracontium giigas;
		Uncaria tomentosa/
		guianensis.
		Zingiber officinale Roscoe

Source: Own elaboration





2. Wild collection activity

2.1. Wild collection

Wild collection for household consumption is an activity linked to humans in order to use the plant collected as food or medicine. Although this is still done only for pleasure, there are millions of families around the world who rely on this collection for subsistence or to get some income.

It is almost always a manual collection.

The collector should be familiar with the medicinal species and also know how to distinguish them from other closely related species, to avoid adulterations or falsifications. To be able to collect safely, we must have a great knowledge about identification, no possibility of error, and if in doubt, we should never collect them.

It is not recommended to collect all the available resource as the collection rate is the factor that most affects the maintenance of wild populations. This rate depends on the species, the harvested part and and how much initial density has the resource.

It is not studied in many species the maximum collection to which you can submit a wild plant to not exhaust it and put it in danger of extinction. To make things easier, for wild herbs that appear everywhere: fumitory (Fumaria officinalis), shepherd's purse (Capsella bursa-pastoris), dandelion, plantain, mallow, etc., it is suggested collecting only an average of 50% (that is, of 50% of individuals, take half of each plant and leave a green part that can continue photosynthesis and flowers to make seeds).

There is an organization that studies the useful flora in danger, it is www.floraweb.de. It is worth to follow for those who are interested in the topic and for the ones who realize a harvesting, especially for those plants that do not appear as often.

According FAIRWILD, an organization that certifies sustainable wild collection, recommends the following:

Roots/bulbs: 20% of the population, only every 3 years

Leaves: 30% of them

Flowers: 70% in a plant and 80% of the entire population

Seeds and fruits: 70% of fruits/seeds

In case collection occurred over a wide expanse of land, where environmental conditions are too different from one area to another, the división of large lots into sublots must be done.

To know and to comply with applicable regulations is necessary. A direct collection of nature must be sustainable to maintain and preserve endangered species. There is a fairly comprehensive but not sufficient legislation, which controls the collection of certain endangered species, which require special permits from the administration. In addition, guides and manuals with recommendations on the best way to make the collection are recommended by several conservation organizations. Among them are ISSC-MAP, CITES, TRAFFIC, OMS, WWF, IUCN, etc.





The Non-Timber Forest Products (NTFPs) FAO section has infinite number of documents with tips for picking forest fruits. In turn, at European level, a Guide to Good Practice Cultivation and Collection of Medicinal Plants (GACP from EMEA 2006, OMS, WHO, USA, Argentina, Uruguay, ...) was published. EMEA document is mandatory for companies that manufacture herbal medicines.

(GACP:

http://www.ema.europa.eu/docs/en GB/document library/Scientific guideline/2009/09/WC 500003362.pdf

WHO: http://apps.who.int/medicinedocs/en/d/Js4928e/)

There is also a manual with recommendations for collectors of medicinal plants of GTZ/SIPPO (2003 and 2005). In addition, the International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants was published (Version 1.0 Medicinal Plant Specialist Group, 2007), to determine and ensure the sustainability of wild collection of MAP.

2.2. Good collection practices

2.2.1. Selection of medicinal plants for collection

The species or botanical variety selected for collection should be the same as specified in the pharmacopoeia and also correctly identified.

2.2.2. Botanical identity of medicinal plants for collection

The botanical identity - scientific name (genus, species, subspecies or variety, author and family) it must be checked and recorded for each of medicinal plants harvested. Common names in the local language will be also recorded. If necessary, other information of interest can be also provided, such as the name of the place or the chemotype.

In the case of varieties harvested, propagated, disseminated and grown in a given region, genetic line data must be recorded with local name, including the origin of the seeds, plants or propagation materials.

When there is reasonable doubt about the identity of a species, a reference sample for identification to a regional or national herbarium should be referred.

2.2.3. Collection permit

To collect plants in the wild, obtaining a permit before harvesting and other documents from government authorities and landowners is sometimes required. In the planning phase, sufficient time must be allocated for processing and issuing such permits. The existing national legislation should be consulted and respected.

When necessary, medicinal plants destined for export from the country of collection should be obtained export permits, phytosanitary certificates. Will also be required permits (for export and import) for the International Trade of Endangered Species of Wild Fauna and Flora (CITES) and CITES certificates (for re-export), among other permissions.





The social impact caused by the wild collection in local communities should be examined; likewise monitor the ecological impact of wild collection activities should be considered as well. The stability of natural habitats and the maintenance of sustainable populations of harvested species in the area of collecting must be ensured.

Collection practices must ensure long-term survival of wild populations and habitats that are associated. The population density of the species of interest in the collection sites should be determined, avoiding the collection of species that are scarce or rare.

2.2.4. Technical planning

Before starting the activity of wild collection, geographical distribution and population density of the medicinal plant species must be determined. Factors such as distance to the place of collection and quality of the plant or plants that are expected to collect should be considered and a management plan collection will be performed.

On species being collected, must be collected essential information (taxonomy, distribution, phenology, genetic diversity, reproductive biology and ethnobotany). Photographs and illustrations of the plant or medicinal plants, ethnographic information (common or local names) of species and the parts of plants of interest, are useful tools in the field, especially for inexperienced pickers. In collection sites where can be found species with similar morphological characteristics of the species of interest, whether or not related to it, it is useful to have botanical keys and other support for taxonomic identification.

Fast, safe and reliable transport for moving staff, equipment, supplies and plant material collected for medicinal use must be arranged in advance. Equipment and utensils necessary to cut should be valued, as well as clean containers where to place the material collected. Pruning shears and a knife allow to cut. How to cut will be essential to continue with the normal growth of the species in their environment and get raw material in later years.

It is important have a group of people familiar with the proper techniques, transport, equipment management and manipulation of plant material, including cleaning, drying and storage. Staff should be trained regularly.

Environmental, economic and social impact caused by the collection in local communities should be assessed previously. Collection practices must ensure long-term survival of wild populations and habitats that are associated. The population density of the species of interest in the collection sites should be determined, avoiding the collection of species that are scarce or rare.

2.2.5. Collection

Management plans must refer to:

- species and plant parts (roots, leaves, fruits, etc.) expected to collect, remove plant parts that are not necessary as well as foreign matter,
- the amounts collected must be specified,
- the methods to be used for the collection,
- the time of collection, season or optimal period,
- place, clean areas,
- harvest material (scissors, ...) and necessary equipment (bags, boxes, baskets, ...)





 The time between collection and transportation to the dryer, and the time of sun exposure, it is preferable to be as short as possible.

For example, when species that mainly will use the bark are collected, leave the tree entirely bare should be avoided. Nor a complete ring of bark should be cut, longitudinal strips of bark on one side of the tree but must be cut and collected.

If the underground parts of the plant (as the root) are used the remains of land that have been attached should be removed in the shortest time possible.

In, or near, areas that have high concentrations of pesticides or other possible contaminants should not be collected medicinal plants, as in the roadsides, drainage ditches, the tailings from mines, landfills and industrial plants which can produce toxic emissions. In addition, collect medicinal plants should be avoided in areas of active grazing and its vicinity -including the riverbanks waters of these areas- in order to prevent microbial contamination from animal waste.

The collected plant material should be protected from insects, rodents, birds and other pests, as well as farm animals and pets. If the collection site is located at a considerable distance from processing facilities, it may be necessary to air or sun drying the plant material prior to transport.

If more than one medicinal plant species or more than one portion thereof, the different species should be collected separately and transported in separate containers collected. Cross-contamination it should be avoided at all times.

Collection utensils, such as knives, scissors, saws and mechanical instruments, must be kept clean and in good conditions. The parts that are in direct contact with the plant material should not have excess lubricant or other contaminants.

2.2.6. Medicinal plant collection staff

Practical training is essential, the initial support to gain practical experience in fieldwork. Field staff must know enough about the plant to collect and be able to recognize it by its common name and, if possible, by its scientific name (Latin) and they must be able to distinguish them from other related species botanically or which are similar morphologically. Similarly, collectors should receive instructions on all matters relating to environmental protection and conservation of plant species, as well as on benefits that sustainable harvesting of medicinal plants brings to society.

Whenever necessary, they must wear appropriate clothing and protective elements, for example, gloves, boots, etc.

All workers with open wounds, inflammations or skin diseases should be suspended from work or must wear protective clothing and gloves until full recovery. People with foodborne diseases (FBD), including dysentery and diarrhea, should be suspended from work in all areas of production and processing, in accordance with local and national standards.





Among the conditions that must be reported are include: jaundice, diarrhea, vomiting, fever, sore throat with fever, visibly infected wounds (boils, cuts, etc.) and suppuration of the ear, nose or eyes. Workers with cuts or wounds that are permitted to continue working should cover their injuries with suitable waterproof dressings.

Workers should always wash your hands before handling activities, after using the toilet and after handling medicinal herbs or any contaminated material.

TABLE 3: Method and time of collection depending on which part of the plant to collect

Expoiled part	Recommended collection method	Recommended collection moment	Exemples
Aerial parts (intact	Cut the part that has	The flowering tops	Thyme, rosemary,
leaves and stems, in	grown that year,	are collected right at	lavender, oregano,
bloom or not)	avoiding cutting	the beginning of	yarrow, nettle, St.
	woody part.	flowering.	John's wort, winter
			savory.
Leaves or flowers,	Always leave at least	The leaves of	Fennel, rosehips,
fruits, seeds	half of leaves,	aromatic plants	juniper, hawthorn.
	flowers, fruits or	before flowering and	
	seeds at the plant	early in the day.	
	when cutting.		
Roots	Never pull up more	The roots, in autumn	Ginger, gentian,
	than half. In gentian,	or winter, or once the	Valerian
	pull out the root, cut	plant has borne its	
	the neck and bury it	fruits (for having the	
	in the resulting hole.	seeds).	
Cortezas	Prune part of the		
	branches and peel		
	them.		

Source: Own elaboration

This summary attempts to give some harvesting **recommendations** in the natural environment. The **high quality** of the raw material is the main **objective**.

1. WILD HARVESTING

- Certain species are not easily cultivable, or are economically unsustainable.
- If the amounts of consumption are high or the collection is not carried out correctly, the wild harvest threatens the existence of certain species, and it is advisable to start the crop. Wild collection is becoming more controlled and is protected by local, national and European legislation. For certain plants and in certain areas special permits are required.
- Be cautious with the amount to collect, do not collect all the plants, leave a part of the plant. Do not collect in a state of euphoria
- CITES listed plants (in danger of disappearing) should not be collected without the relevant authorization.
- If the collection is an organic area must be done following the relevant regulations
- Locate areas as clean as possible, away from mines, nuclear, industries, roads, fumigated fields and forests, garbage dumps, etc. Choose areas large enough, with numerous plants of the same species.





- Carry out accurate botanical identification of the plant material (plant), and distinguish similar species, to avoid adulteration or falsification. Find individuals free of diseases and pests.
- Collect at the optimum time of the plant. Latitude and altitude, the vegetative state and the part of the plant used will determine the time of harvest
- There will be a manual collection and the product will be incorporated in sacks or containers, where not to stack too much is recommended.
- Do not pull up plants or flowers, always cut them.
- Collect in favorable weather conditions (without rain or moisture).
- Do not collect diseased plants, or parts of the plant that are sick or are not going to be used.
- Collect by avoiding contamination by ground and/or other plants that may be toxic
- Do not place the product in the sun or on the floor.
- The containers used for the harvested plant must be clean (bags, baskets, trailers).
- Minimize time between picking and drying.
- Protect the product from rain, rodents, birds, pets, etc.
- Indicate sublots when the areas, staff and collection times are very different. The lot must be homogeneous. Only sublots may be mixed if they are guaranteed to be similar, and always indicating such mixture.
- 2. PRIMARY TRANSFORMATION (DRYING, DISTILLING, ETC.)
- Keep equipment and facilities clean and ventilated.
- Drying has to be started quickly and take the shortest time possible
- Protect the product from rain, rodents, birds, pets, etc.
- Avoid direct contact with the ground.
- In hot air dryers to use butane, propane or natural gas is recommended; with gasoline or diesel oil the combustion fumes can not enter the drying room.
- When drying with hot air, temperature, humidity, time, etc. should be monitored and recorded.
- Remove foreign matter and store the material immediately in a container.

3. PACKAGING AND STORAGE

- Do not pack or transport until the product is completely dry.
- The packaging must be new, clean and dry.
- The label must be clear and fixed, and all packages must be identified.
- The store must be clean, dry, ventilated, and no animals are allowed to enter.
- Packages should not be stored on the floor (on pallets), or touching walls or ceilings. They should be ordered by product and lots to avoid confusion.
- To avoid cross contamination transport in a clean or dry truck or container, well ventilated but closed to protect from sun or rain.
- If fumigated, an authorized product must be used, indicating the product.
- If the collection is organic, it must be stored according to the corresponding regulations (national and European Directive 2092/91).

4. STAFF

- Specialization courses are recommended: agricultural, botanical, hygiene, optimum collection time, correct use of fumigations, protection of the environment, etc.
- Sick people with wounds, etc. must not be in direct contact with the plant material or should be protected with gloves, masks, etc





DOCUMENTATION

- The Gatherer must ensure that avoids damage on the existing habitat.
- The entire process must be properly written.
- If the collection is organic, it should be indicated.
- Identification of plant material (species). Part of the plant and lot number. Place of collection (zone/country) and starting date (month/year).
- Type and conditions of equipment, installations, machines, premises, etc.
- The form of drying (natural, in the sun, in the shade, with warm air), place (in store, outdoors, on the floor, on a plastic, on a tray) should be indicated. Temperature, humidity and time should be recorded
- Warehouse conditions (closed, open). Time (1 month, 1 year).
- Type of packaging (bag, box, trailer).
- Time, type (truck, container) and conditions (closed, open, ventilated, with awning, with drying agents) of transport.
- Fumigations applied in the warehouse or transport must also be registered, indicating the authorized product, when, how, etc.
- Indicate the experience and training of the staff. They must know the quality requirements, pharmacopoeias, etc.
- You can receive an inspection visit to be approved as a supplier. A questionnaire must be answered and the collection must be reported using the technical data sheet for each lot.

PART II. CULTIVATION OF MEDICINAL AND AROMATIC PLANTS

3. Production of medicinal and aromatic plants.

The vegetables that we daily use can come from three fundamental ways. One is to buy them. Another is to produce them yourself, on a piece of land owned or rented, on a growing table placed on the balcony. The third way of obtaining is the wild collection, with strict criteria of sustainability, collecting the appropriate amounts, respecting the protected or low abundant species. The path to local self-sufficiency involves a combination of **ecological** cultivation and wild collection of plants with **edible**, **medicinal** or **cosmetic** uses.

Ways of obtaining MAPS:

- 1. Purchased
- 2. Cultivated
- 3. Harvested in the wild

Having close cultivated plants for domestic use or to market is very useful. A pot, an orchard, or the garden can house useful plants. To start planting what is most used is recommended: aloe (*Aloe vera*), lemon verbena (*Aloysia citriodora*) or rosemary (*Rosmarinus officinalis*), and especially the most used herbs for cooking, because they are more aromatic freshly caught

The cultivation of useful plants at the domestic level does not entail any complication, beyond that any other vegetable has. We are interested in knowing the climatic conditions where we have the land. On the other hand, we can distinguish two groups of plants, those that need water and those that endure long periods of drought. With this information, we will decide to plant each species with or without irrigation, sun or shade, etc.





It is usually questioned whether the active principles change when a plant is grown (not wild). Studies have shown that environmental conditions, the climate, irrigation or fertilization, type of soil and planting or harvesting time can affect. Despite this, the proportion of components is one of the parameters of greater qualitative and quantitative variability also in wild plants, depending on the years, age, chemotype or health status of the plant.

If you plant a species that appears around the place where it is cultivated, and we do not intervene and also the environmental conditions, soil, rainwater or sun exposure are identical, in principle, the variability of active principles is equal, the same as in nature.

Most plants are multiannual, some disappear in winter but they can sprout again, such as mint (Mentha sp.) or tarragon (Artemisia dracunculus), others retain a small basal rosette, such as lemon balm (Melissa officinalis) or oregano (Origanum vulgare), and others such as rosemary or sage (Salvia officinalis) endure all year. It is important to know which plants are annuals to collect the seeds to be used the following year, and to change their planting site. Basil (Ocimum basilicum), dill (Anethum graveolens), angelica (Angelica archangelica), calendula (Calendula officinalis), chamomile (Matricaria chamomilla), nasturtium (Tropaeolum majus), cumin (Cuminum cyminum), coriander (Coriandrum sativum), stevia (Stevia rebaudiana), fenugreek (Trigonella foenum-graecum), fennel (Foeniculum vulgare), anise (Pimpinella anisum), White mustard (Sinapis alba), poppy (Papaver rhoeas), bitter melon (Momordica charantia), etc., are considered annual plants. Dill, angelica, borage (Borago officinalis), caraway (Carum carvi), coriander, fennel, mallow (Malva sylvestris), parsley (Petroselinum crispum), clary sage (Salvia sclarea), chicory (Cichorium intybus), etc. are considerd bi-annual plants.

An annual plant sometimes seems not to be because the seeds that fall to the ground germinate with ease: this is the case of arugula (*Eruca sativa*), chamomile, poppy (*Papaver somniferu*m), etc. Although in climates with 300-600 mm and cold winter (often -3°C) and heat in summer (often above 30°C) marigold, fennel, marjoram (*Origanum majorana*), mallow, savory (*Satureja montana*), chicory, Roman sage, etc. are not annual.

Organic farming is an opportunity for quality and safety for people, the environment and marketing, and the drawbacks are low. Adding compost or manure solves fertilization, combining numerous species and adding some plant extract solves pests and diseases, and using straw or vegetable debris to make roofs prevents the adventitious and reduces evaporation of water.

If the plant cultivation or collection is carried out in ecological production or relatively "clean" sites, an absence of contaminants or chemical residues in the product is ensured.

Regarding the utensils, machinery, infrastructure and premises needed, depends on the size of the crop. If we are talking about the cultivation of a garden or an orchard, they will be the same ones that you will use at the domestic level if you have vegetables or fruit trees planted. But if the crop is more than half a hectare, for the production of dry plant, extracts or distillates, the infrastructure and the investment will be significant.

For a good development and growth of aromatic plants it is necessary, therefore, to irrigate those that require it, in the early morning, and at all hours when they are newly transplanted. It is important to avoid the growth of the adventitious, especially those that completely cover the species that require sun exposure; to fertilize especially those that require more water





and/or irrigation; to avoide and control pests and diseases, and water excess or lack of sunshine is one of the main dangers.

In order to grow plants with a cooler environment, shade and protection from sunshine or environmental drying must be combined. Also, those that do not withstand low temperatures has to be sheltered under a dense tree, glued to a wall oriented to the south or protected with a plastic in case the temperatures go down too much.

The majority of MAP are planted by multiplication by alveoli obtained from wild seeds or cuttings of mother plants, also wild ones. Direct sowing involves a high risk. In greenhouses enough roots are obtained to transplant after about 3 months. Outside it can take a year to develop. Starting plant material is one of the key points in MAP. The place of obtaining the seeds, the cuttings or directly the plantation has great importance. The seeds can be obtained from wild plants in autumn, from own seeds saved from the previous year, from exchange with other producers, or from purchase. We will know the origin of the plant material if the plant is ours. If you buy it you have to be sure of the species and its origin is wild. At present, there are numerous varieties of aromatic herbs obtained by improvement of which the chemical composition and its safety are unknown.

With some species it is preferable to make planting from cuttings, for example lavender (Lavandula latifolia), salvia, guava (Psidium guajava), bushy lippia (Lippia alba), linden (Justicia pectoralis), laurel grass, russian tarragon, rosemary or stevia. On the other hand, by means of seeds it is simple with maiteno (Maytenus aquifolium Mart./Maytenus ilicifolia Mart.), balsam, noni (Morinda citrifolia), hibiscus (Hibiscus sabdariffa), camomile, basil, arugula, thyme (Thymus vulgaris), savory Marjoram (Allium schoenoprassum), St. John's wort (Hypericum perforatum), poleo (Mentha pulegium), oregano, parsley, fenugreek, poppy, marigold, nasturtium, dill, fennel, mallow, mustard. With a piece of ginger rhizome (Zingiber officinale), mint or licorice (Glycyrrhiza glabra) is sufficient for regrowth. Aloe is easily reproduced by sprouts, which we can separate and transplant.

The type of substrate is important specially to obtain the plantation and to cultivate in containers. Container size: $40 \text{ cm } \emptyset \times 30 \text{ cm } \updownarrow$.

The soil characteristics that can affect the cultivation of an aromatic plant are the following:

- Texture (sandly, clayey, silty); To large elements better drainage.
- The pH
- Fertility.
- Contaminants.

A mixture of outdoor soil with a pH around 7 and a little compost (5 to 10%) and coconut fiber (5 to 15%) will be sufficient for proper growth. Most aromatic plants grow on any type of soil, between 8 and 5.5, and are a few that do not withstand very acidic or very basic pH. Some plants behave as indicators of acidic pH, for example common foxglove (*Digitalis purpurea*), great yellow gentian (*Gentiana lutea*), strawberries (*Fragaria vesca*), blueberris (*Vaccinium myrtillus*), canulae (*Lavandula stoechas*), or common speedwell (*Veronica officinalis*).

Regarding texture, most who require water need a spongier and fertile soil. It is the case of *Morinda citrifolia*, guava, *Lippia alba*, ginger, aloe, basil, parsley, hop (*Humulus lupulus*), sunflower (*Helianthus annuus*), *Spiraea ulmaria*, coriander, nasturtium, etc.





Plants that have enough with a rainfall of around 500 mm per year, like rosemary, melissa, oregano, thyme, Mahón camomile (*Santolina chamaecyparissus*), evergreen (*Helichrysum italicum*), sage, lavender, etc., do not require fertilization. Add only the compost that the family produces to those planted in the orchard with the vegetables. In addition, we will return to the ground all the vegetables or parts of them that are started, especially in spring and autumn, incorporating them directly or mixing them with straw to make quilts.

There are studies that determine that it is necessary to fertilize when you want to get great productions. Both fertilizer and irrigation do not change the chemical composition in some species (eg thyme), but it can affect the content of active ingredients in other plants.

In the case of plants in containers, fertilization takes place once a year, at the beginning of spring. With about 300 grams per plant is enough, especially those that are irrigated often. It is convenient to remove the plant, move it, add or change soil, or divide it.

The best time to plant on the ground depends on whether the plant is annual, but the rainy seasons are the most appropriate. You can take advantage of a rainy weather forecast to transplant. In this way we will avoid watering and monitoring as they adapt from the wonderful conditions of the seedling tray to the harsh conditions on the ground. When it comes to herbs with high water requirements, such as basil, arugula, capuchin, chives, chilli, parsley, mint, coriander or marjoram, can be planted in the middle of horticultural gardens with drip irrigation during the hot and dry months. In the shade we will plant: hop, common soapwort (Saponaria officinalis), valerian (Valeriana officinalis), catnip (Nepeta cataria), meadowsweet, salicornia (Salicornia sp.), yarrow (Achillea millefolium), absinthe wormwood (Artemisia absinthium), common comfrey (Symphytum officinale), or common tansy (Tanacetum vulgare).

Most do not require irrigation and rainwater is sufficient, knowing that in dry seasons they will be stopped and in rainy seasons they develop. In conditions of 300 to 600 mm per year of rain and some winter day reaching 8°C below zero and occasionally at 37°C some summer has never been necessary to water the following plants: chicory, savory, alfalfa (*Medicago sativa*), fenugreek, poppy, marigold, milk thistle (*Silybum marianum*), chive, whitetop (*Lepidium draba*), dandelion (*Taraxacum officinale*), lemon balm, sages, oreganos, lavender, tarragon, lemon verbena, laurel (*Laurus nobilis*), plantain (*Plantago* sp.), common melilot (*Melilotus officinalis*), mustard, nettle (*Urtica dioica*), *Eryngium*, lime (*Tilia* sp.), walnut (*Juglans regia*), sempervivum, chamomile, rue (*Ruta graveolens*), thyme, fennel, horehound (*Marrubium officinale*), rosemary, elder (*Sambucus nigra*), licorice, hyopericum, malva, safrón (*Crocus sativus*), verbena (*Verbena officinalis*), bladder campion (*Silene vulgaris*), rough star-thistle (*Centaurea aspera*), borage, feverfew (*Chrisanthemum parthenium*), vitex (*Vitex agnus-castus*), etc.

For irrigation, you can group those that have high requirements in summer, for example, basil, chives, mint, parsley, arugula or marjoram that always need moist soil, but beware of abuse as fungi start to appear. In contrast, dill, savory, hyssop (Hyssopus officinalis), tarragon, coriander, oregano, are only irrigated when the ground is dry, and in winter hardly irrigates.

Most aromatic plants need sun. A sage in the shade dies, although some adapt to few hours of sun (mint, oregano). Others live habitually in nature in shady and humid places, for example: eyebright (Euphrasia rostkoviana), lungwort (Pulmonaria officinalis), common violet (Viola odorata), common hepatica (Anemone hepática), caraway. In semi-shade conditions: chervil (Anthriscus cerefolium), wormwood, mint, melissa, oregano, marjoram, tarragon, chives,





hyssop, green oregano (*Origanum virens*), savory. And with direct sunlight, but in cool and humid climate: marshmallow (*Althaea officinalis*), meadowsweet, common soapwort, salicaria, angelica, valerian, inula (*Inula helenium*).

Record everything in a notebook would be ideal, dates and actions; with this registry you can build your own optimal calendar to know when to start planting, transplanting and harvesting. Not to be wrong of species and to be very sure of what you collect is of great importance. The proper part of the plant, whether flowers, fruits or seeds must be collected. To pick the roots in autumn or spring is recommended. Some species have studies of the recommended time for collection with the maximum of active principles. Collecting the leaves before flowering is preferable.

You should choose a proper and clean place, and a sunny day. We will not collect a plant that looks bad, has spots on the leaves or looks sick. The way to collect is by cutting with scissors the part of the plant that is in good condition discarding the rest.

After harvesting it is advisable to do some pruning of the woody plants. From the rest of plants, as autumn arrives, it is necessary to cut the dry parts. In some species, such as basil, flowers should be removed to obtain more leaves, but even this part can be used.

Heat, long day and light are the stevia requirements to develop.

Reasons that make it impossible for a particular species to be cultivated	Conditions of growth: rocks, peaks, rivers, etc.Economic nonviability.
Reasons that favor the crop:	- When the wild collection is unsustainable at the environmental level. Excessive collection of certain species means putting it at risk.
	-Quality requirements by reducing the variables that nature entails, maintaining control aspects: the starting plant material, type of soil, solar exposure, irrigation, fertilization, planting or harvesting time, drying, storage, etc.

Choosing a cultivation of medicinal plants it is conditioned by a number of very important decisions and prior knowledge. The type of crop chosen can condition the amount of hours dedicated, the final quality, as well as the price.

The basic crop models are:

- a. Organic farming (without chemicals).
- b. Conventional farmin (using fertilizers, herbicides, pesticides, provided that the planned safety intervals before collecting are respected, to ensure the absence of residues in the drug, and established residue and contaminant limits are met).

The availability of water:





- a. Irrigation and/or high rainfall (mint, melissa, echinacea, etc.).
- b. Dry conditions and low rainfall (thyme, sage, lavender, etc.).

The **altitude** and **latitude** (closely related to the temperature, and often to the rainfall) condition the species to be cultivated.

Soil and **climate** conditions: soil type, pH, soil orientation, solar exposure, climatology and environmental conditions, habitat, etc.

In the **market** it is important to: choose the plants with less competition or the plants of great consumption or constant consumption, and also look for potential clients, establish contracts of culture, etc.

The **choice of species** depends on whether it will be used domestically or whether it will be produced for commercialization. It will also depend on whether their optimal growth conditions match with what we can give them in our field.

Where to obtain the **plant material**, ie, seeds, cuttings, rhizomes, or bulbs for planting, chemotype, variety, etc.

Regarding the agricultural tasks, it is necessary to decide and to know:

- a. The vegetative cycle (if the plant is annual, biannual or multiannual).
- b. The length of the cultivation cycle of each species (if it lasts a year, or more, and in this case, until when it is profitable).
- c. Plant material: local varieties, seeds, seedling tray, substrates, etc.
- d. Choice of place.
- e. Plantation design: distance between rows and between plants, number of rows per street.
- f. Preparation of the soil.
- g. Nutritional requirements (if it is necessary to fertilize or not), compost.
- h. How to implant.
- i. Crop organization and management: quantities, consumption, rotations, associations.
- j. Rational water management: irrigation, control probes, etc.
- k. How to control the adventitious (padded mesh, manual removal, mechanics, etc.)
- I. Health control: recognition of pests and diseases, vegetable preparations, ...
- m. The necessary equipment, utensils and materials (tractor, planter or seeder, cultivator, milling machine, harvester, etc.) will define, for example, the distance between plants and between rows.
- n. Calendar: planting, maintenance, harvesting, processing, etc.
- o. Locations needed for drying, distilling, cutting, sifting, etc





To successfully implement a new crop of medicinal plants, which meets the optimal quality requirements, it is recommended to follow the following tips:

- Receive information and training on the topic.
- Know and visit farmers who grow medicinal plants, with satisfactory results.
- Consult the aids for the implementation of this new crop.
- Start with little extension of land (half hectare two hectares to obtain essential oils).
- To specialize, test with few species, dominating to the maximum the productive process.
- Organic farming involves more work and hours of manual dedication.
- Follow good agricultural practices (GAP).
- Do not accumulate stock for marketing problems.
- Be well up to date on the market and know the user industry.
- Have contacts in research centers.
- Belong to associations of producers or be part of a cooperative.
- To be mechanized, to study the infrastructure so that the crop does not exceed. Mechanization is almost essential to be competitive economically, because, with a similar quality, the price difference conditions the choice for the least expensive product.

If you decide to plant several species, start with few units of each species is preferable to see the production and adapt it to the rhythm of work, consumption or marketing, which connects with how much planting area. It is better to start with 3 or 4 of each and maximum 100 or 200 m² and check the time required. The rainy season is the worst time for the adventitious and requires more time. Although many of them can be used for their properties or as compost.





4. 4. Medicinal and aromatic plants: cultivation phases

The steps to follow to start a MAPS crop are detailed below. It begins with the choice and preparation of the land, continues with the obtaining of the material and its implementation in the field, it follows with the proper maintenance, to finish with the obtaining of a good production of quality raw material.

4.1. The choice of ground

Not choosing the worst plots to start is advisable. It is preferable to avoid plots with: excess of stones, complicated and difficult access, irregular forms that make difficult the handling, an excessively steep gradient, shallow and saline soils, etc.

The ideal plot: flat surface, free of obstacles, with accesses and with more or less rectangular shape to facilitate planting design, which helps to reduce production costs.

4.2. Machinery and tools

The equipment necessary to carry out the cultivation of MAP (transplanting machines or the adventicious plants control) is not very different from that used in a horticultural crop. At the collection level, the necessary equipment is more specific, but there are machines on the market for this purpose.

4.3. Infrastructure

It depends on the hectares planted, but the needs increase from half a hectare.

A place to prepare the seedling tray and make it grow is necessary. Also a site for the warehouse of machinery, equipment and utensils. A place to dry or distill is required too. In addition, a place where you can separate the parts of the plants (eg the stem of the leaves), and a place to cut or, if necessary, to mix and pack.

The closer we get to the final stage of the production chain, and the closer we are to the final product, the more we need to clean up this infrastructure in order to comply with good practices.

4.4. Land preparation

Mechanical planters need a spongy ground for the seedling plug fits.

- Fertilizer: if manure or slurry is applied, do it a few weeks before planting. It should be kept in mind that rainfed MAPs have few nutrient requirements.
- Cultivator: the cultivator leaves the soil thin and without adventitious. This time can be used to apply the fertilizer.
- Milling machine: if possible, using the milling machine shortly before planting is preferable.





4.5. Plant material

Obtaining the plant material is a very important step in obtaining a quality raw material.

Certain plant drugs can be found in different species, varieties and/or chemotypes (differentiation by composition of active ingredients). The one that is used like medicinal and that is included in the offical books (in the Pharmacopoeias) is the officinal one.

The starting material must be the correct one, otherwise it can not be used because it will not pass the quality controls. This starting material can be obtained by itself or can be purchased at research centers, universities, or seed producers or nurseries specializing in medicinal plants.

There are two fundamental methods for obtaining and multiplying the plant for cultivation:

- By seed (sexual multiplication)
- By cutting (asexual multiplication).

Some species can be obtained by both methods interchangeably. For others, on the contrary, it is recommended to use the seed because it germinates without difficulties (eg oregano), while some have a germination index so low that it is preferable to make cuttings (eg lavender - Lavandula angustifolia-).

The perfect time to do the seedling tray depends on each species, the environmental conditions of the place where it is developed or the availability of adequate infrastructure (greenhouses).

4.5.1. Sexual multiplication. Obtaining the seed

The seed can be obtained by wild collection or by purchase.

Wild collection should be done when the seed is already ripe. Afterwards, it must be dried and stored in a dry and cool environment (between 3 and 5°C).

To contact with companies of wild seeds (specialized in medicinal plants) for the purchase of seeds is preferable. There are a few companies that have varieties selected for their chemical composition (eg. Pharmasaat in Germany).

Not to buy the seeds of use in gardening is advisable, since the varieties for sale are not wild and officinal, but they are selected by ornamental reasons.

Seeds can be planted directly in the field, or do seedbeds. The plants will not be the same between them. There will be some variability, more or less accentuated, depending on the species.





4.5.2. Asexual multiplication. Obtaining the cutting

The harvesting by cutting is usually done with multi-annual plants that can be:

- Wild collection plants.
- Mother plants.

The cuttings are made in seedbeds. The plants obtained will be exactly the same as the mother plant (clones) and will have an initial growth faster than a plant obtained from seed. If a wound is made (a cut in the cortex) in the lower part of the cutting, we will stimulate the formation of roots (acceleration of the cellular division). Another way to favor the rooting is to use certain substrates or substances such as hormones or purine nettles.

To obtain the plant in good conditions (quality of living plant) indispensable care is necessary. Adequate guarantee of water, light, sun exposure, nutrients, temperature, etc. is indispensable.

4.5.3. Obtaining de seedling tray

The seedling tray is the best option in: ecological agriculture (EA); bad soils, with adventitious or weeds; in cases of low seed viability, difficulty in germination, propagation, genetic variability, hybridizations, etc.

There are two types of seedling tray:

- Naked root: it has many drawbacks.
- Seedling plug and miniplug: is the best option.

The bare root is less likely to survive after implantation. It should be done quickly so that the root does not dry out. If the land is dry and there is no rain and there is a rainfed crop (no irrigation), the root can not stand in an initial environment so dry, since the type of substrate is totally modified.

On the other hand, with a seedling tray (of seed or cutting) not all these disadvantages are found. Moistening well the seedling plug, the root has enough water to survive, the same substrate is maintained close to the root. It is not necessary to go so fast since the seedling is removed from the alveoli and buried in the ground.





How to make our seedling tray

To make our own seedling tray a container, the material and the size is required. They can be the typical individual alveolos, trays of porexpan, egg cups or recycled bottles, whatever is available. The substrate can be outdoor soil, being optional some compost and coconut fiber. The plant material used is the most important thing. For growth success a place with lots of light and little direct sunlight is required, sheltered from the wind. If a greenhouse is done it has to be irrigated every day and the container has to have a good amount of soil so that it does not dry out.

A hole in all the containers is necessary so that the irrigation water does not accumulate or rot the roots. Fill the container with the substrate without tightening it or just slightly. Lay 2-4 seeds in the center of the container and cover with a pinch of substrate. Lay 2-4 seeds in the center of the container and cover with a pinch of substrate. In the case of cuttings, cut the tenderest top of a plant, remove most leaves leaving only the 2 or 3 younger and insert the stem into the substrate by squeezing the soil to be in direct contact with it. Water gently so that the seeds and the cutting do not jump and keep the establishment always wet, but never soaked. Ensure that it has enough light, but the plant stretches and ends up prostrate. At least 3 months or more are needed to transplant, because enough roots must have formed.

To make a sketch of the seedling tray to know what we have in each place is recommended.

4.6. Installing the crop in the field

The time to place a seed or a plant on the ground is very important, especially for annual species. For example, the essential oil yield of coriander leaves is higher the earlier it has been placed in the field, it will be much better during the rainy season than in the dry season.

The implantation can be done in two ways:

- Implantation with direct sowing.
- Implementation with seedling plugs.

4.6.1. Direct seeding

For direct sowing, a sowing machine is used. After sowing press the earth lightly is recommended, to improve seed - soil contact.

Direct sowing is normally used for species with large seed and / or vigorous plants (eg thistle or fennel) and on land without stones or surface crust.





Drawbacks:

- If the species is not very vigorous and if it is sown in the rainy season and is produced in Ecological Agriculture (EA), it is very possible that the adventitious weeds will win the game.
- The facilities for direct planting are cheaper than a seedling tray, but it is much more insecure, since germination also depends on the rain or the irrigation. Often, it is necessary to replant the field.
- More kilograms of seed per hectare are needed and may be very expensive or of low availability.
- Difficulties may also arise in the sower graduation.

4.6.2. Plantation with seedlings

We start from seedlings developed in nursery. The plantation size depends on the size of the species and the field and crop conditions.

Implantation is a very important stage. The ground, which must be previously worked, must be fluffy and then we pass the milling machine with the aim that the planter could work well and leave seedling plug well fixed. Just before planting, we must water the plant, to ensure that the seedling plug is well wet.

A plantation is rarely homogenic. Is better to choose the most growth seedlings and to despreciate the small ones. The homogenic growth in plants in the field is essential to achieve that the adult plants come together in a row and facilitate their collection.

If the crop is conventional, it is usually applied preemergence herbicide, or a false planting (watering to encourage the germination of field seeds and pass the grower below) if possible, any procedure will prevent the proliferation of adventitious weeds after planting. If the crop is environmentally friendly, no chemicals or herbicides (no chemical fertilizers or pesticides) are added.

A typical orchard planter can be used. As for the planter, always try it before you start, adjust the distance between plants and between rows and check that the cue is well buried and the plant well erected. These clamp planters, typical of orchards, work quite well, except when there are stones, lumps and slopes. You must know that in a terrain with slope the planter of two rows will not work very well, since while the tacos are sunk in a row, in the other they are not sufficiently buried.

4.7. Cultivation maintenance

The maintenance of the crop is undestood like the tasks of fertilization, irrigation and control of adventitious plants (or weeds). Depending on whether the crop is organic or conventional, the way of performing this maintenance will vary.

The most important maintenance activities of the crop are: fertilizer, weeding and irrigation, as well as the control of diseases and pests, contaminants and residues.





4.7.1. The fertiliser

If the crop is ecological, manure or manure from ecologically-produced farms is used, whereas, if conventional, chemical products may be used.

It is usually fertilized before planting (at the time of preparation) and during cultivation. But above all, it will depend on the nutritional requirements of the plant.

Aromatic plants (eg thyme, sage, etc.) do not have great nutritional requirements and it is not necessary to fertilize too much; On the other hand, the more the field is fertilized, the more adventitious plants grow.

There are many plants that need to be watered, like mint, which increase yields in biomass per hectare as a function of fertilization. Some, like the artichoke, a nitrogenous fertilizer increases the yield of leaves per hectare, but decreases the quantity of caffeilquinic acids of the leaf.

4.7.2. Weeding

The weeding takes place between lines and between plants of the same line, the necessary time until the plants, when growing, join together.

In ecological cultivation mechanical methods are used to weed, such as tillers, cultivators, milling machines, etc. In addition, there is the possibility of burning (thermal weeding) for weeds that grow between the crop lines. In contrast, herbicides are used in conventional cultivation.

One way to prevent the adventitious occurrence is to use straw quilts or other vegetable remains, as well as paper, plastic or biodegradable materials, which also prevent the evaporation of irrigation water or rain. They are also used anti-weeds meshes that last longer and allow to take advantage of rainwater, although its cost is higher.

In the case of thyme, the yield in essence oil (kg / ha) is indirectly proportional to the presence of adventitious that reduce the sun exposure.

4.7.3. Irrigation

Irrigation depends on the water needs of the species, the rainfall of the area, and/or the possibility of watering.

Irrigation in the cultivation of certain species does not affect the composition of active ingredients, on the contrary, improves yield. For example, watering in *Melissa officinalis* or in *Satureja montana* increases the essential oil content, as well as the amount of leaves per hectare; On the contrary, irrigation in *Origanum vulgare* does not increase production and worsens cultivation by increasing the risk of fungal diseases.

With tarragon, production increases more if it is watered only at critical stages (such as the branching period or the formation of flower buds) than if it is watered every 2 or 4 days.

4.7.4. Pest and disease control





The state of health of plants and crops is essential to obtain a quality vegetable drug.

In conventional agriculture they can be treated with chemical pesticides. On the other hand, in organic agriculture pests can be avoided in a variety of ways: through a selection of tolerant varieties, site choice (altitude), crop rotation, date of introduction, mechanical protection (nets or meshes), the use integrated wrestling and plant extracts, and frequency and harvest status.

Natural pesticides preparations with herbs

Any crop has associated a set of living things that grow linked to it, vegetables and animals. Some are harmful and others are beneficial. Plants may be susceptible to disease or pests. The presence of animals that feed, attack or use the crop for their benefit and therefore decrease production (ie, snails, ants, birds, insects: aphids, whiteflies, cochineals, caterpillars, mites, etc.) are considered pests. A disease is usually caused by fungi (such as mildew or mildew), bacteria or viruses.

The presence of beneficial wildlife such as ladybugs, certain birds, frogs, wasps, praying mantis, earwigs, dragons and lizards are often very interesting, as they feed on harmful animals such as aphids or cochineal. Likewise, it is advisable the presence of useful flora that increases biodiversity and protects against pests and diseases.

To achieve a healthy plant or crop it is recommended to apply some good practices that are detailed below. It is advisable to control certain adventicies, follow cultural practices that allow favorable environmental conditions for plant health, work on surface soil, fertilize compost, manure or green manure, invest in planting adapted local varieties, to control the irrigation and to manage the humidity, to favor the presence of beneficial living beings, to mix crops and to correctly rotate the crops.

Some aromatic plants, when planted together, play an interesting role in the health of the orchard. For example, peppermint is a good ant repellent and cabbage insect; the draba is considered repellent of the white fly, aphid of the apple tree and attracts the black fly of the tomatoes; Tagetes (*Tagetes erecta*) controls nematodes; Rosemary and sage avoy carrot and cabbage insects; the nasturtium repels aphids and the savory helps the beans.

Prevention is preferable to treatment, but if necessary, once we have the pest or disease we have different options to fight and reduce or entirely eliminate it. We can eliminate unwanted beings manually or by means of traps, use other living beings that are enemies of pests (eg microorganisms: bacteria, fungi, etc.), and if necessary, treatments can be carried out with plant extracts (comfrey, yarrow, nettle, dandelion, valerian, burdock, chamomile, marigold).

To prevent a vegetable from being infested by fungi, water must not be flooded near the plant and it is preferable to leave space between plants. On the other hand, it is recommended to use the decoction of horsetail (*Equisetum* sp.) to have a healthy vegetable, and sulfur treatments to eliminate or prevent the fungus spores.

The most versatile and effective plants in various pests and diseases are garlic extract (*Allium sativum*), as well as other garlic species (*Allium ampeloprasum* and *Allium ramosum*), neem oil (*Azadirachta indica*), and essential oils of mint (*Mentha piperita*) and thyme (*Thymus vulgaris* and *T. zygis*). Microorganisms may be a good choice, *Trichoderma harzianum* and *Beauveria bassiana*. A relative is the melia (Melia azedarach) that adorns many parks and streets and whose fruits are used crushed for the same purpose as neem.





Melia: crush a quarter of a kilo of fruit and put them to macerate with a liter of water for a day, filter, add 2 liters of water and spray about 30 m2.

Other extracts that appear to be effective in certain cases are clove essential oil (*Syzygium aromaticum*) and cinnamon (*Cinnamomum cassia*, *C. verum*), with cinnamaldehyde; (*Citrus sinensis*) and grapefruit (*Citrus paradisi*) rich in α -tocopherol, methyl paraben, triclosan, hesperidin and naringin; of cypress (*Cymbopogon citratus*), of roman sage (*Salvia sclarea* extract), of turmeric (*Curcuma longa*), of wormwood (*Artemisia absinthium*), of cressa (*Cupressus sempervirens*), patchouli (*Pogostemon cablin*), ruda (*Ruta graveolens*) or savory (*Satureja hortensis*), being good fungicides and bactericides.

Other useful plants with pungent principles are paprika (*Capsicum annusum*, *Capsicum frutescens*), plants rich in saponins such as soapbark (*Quillaja saponaria*), common soapwort (*Saponaria officinalis*), cassava (*Yucca schidigera*), (*Lysimachia foenum-graecum*) or tich in tannins such as walnut (*Juglans nigra*) and pomegranate (*Punica granatum*).

With the maceration, decoction and/or fermentation of plants and four preparations we can achieve good health of the crops.

Chamomile is a great asset for mildew, about 50 grams of dried flowers per liter of water and 10% dilution by spraying every 2 weeks.

Horsetail for fungi, in general will enough 15 grams of dry plant per liter (boiled and left to rest for 24 hours, filtered and diluted 1 liter in 4 liters of water)

The Ortiga manure is fantastic for the aphid, about 80 g of fresh plant per liter and 5% dilution.

But the great choice is neem and garlic. A garlic clove halved in a 5-liter bottle of rainwater (about 50g / I) for a few days and diluted to 20% by spraying the plant and soil for three days in a row to combat bacteria, fungi, Aphids and mites and repel nematodes.

Dyeing of propolis diluted to 1-5% is another good option, although it is preferable not to abuse.

To make these preparations correctly it is advisable to use rainwater, the spring is a good temperature moment and the indicated one (15-25°C), preferably between new moon and half moon, stirring once a day for 5 and 30 days until the bubbles of the fermentation do not appear (depends on the temperature). It is advisable to filter with a cotton cloth and to pack in plastic bottles in a cool place and sheltered from the light, labeled with the name and date of the preparation because it is not recommended to use beyond one year, nor two months once opened. Apply once diluted between 5 and 20%, maximum two after a week, and observe the result and the condition of the pest or disease and the crop. It is advisable not to mix extracts, so you can check if they work and calculate the doses and number of applications.

To prepare a liquid formulation at home with essential oils we need natural emulsifiers: soy lecithin, about 15% to help us mix the oil with water. Another form is by 0.1% polysorbate 80





in water, and to 9.95 ml of this solution is added 0.050 ml of essential oil shaking for about 10 seconds.

This is a market with great potential because the tendency is to use preparations as natural as possible, although the way of commercialization is an important barrier for small companies.

4.8. Harvesting

Harvesting is the process by which you get the part of the plant that will be used (vegetable drug). The drug is separated directly from the plant at the time of harvesting (root, flower), or a part of the plant is cut and then the officinal part is separated (for example, stems are collected with leaves that are later separated). The method of harvesting depends on the species and the part of the plant to be harvested.

The time of harvesting is fundamental to obtain a quality vegetable drug. The qualitative and quantitative composition of the active principles varies according to different parameters, the variability of the species, the climate and environmental conditions, the vegetative state of the plant, the age of the plant. It also depends on the place of the planet where it is found, time of year, time of day, altitude and latitude, type of drug or part of the plant, health status of the plant, etc.

There are two types of harvesting, wild collection and agricultural harvesting

The agricultural harvesting is simpler to mechanize, by means of special machines and / or adaptations. For example, an alfalfa mower adapted to a rototiller, cereal harvesters or forage mowers, or potato harvesters can be used.

Harvesting can be started in the first or second year of implantation and can be carried out for three to five years, for certain species (thyme, savory, etc.) and from eight to nine years for others (rosemary, lavender, etc.).

The farmer must know what part of the plant is used and when to collect it, using the necessary means to separate the drug from the rest of the plant.





5. Good farming practices

This summary presents management and production recommendations. Raw material of high quality is the main objective.

1. CULTIVATION

- Accurate botanical identification of plant material (seeds and/or cuttings), and disease and pest free. In the case of seeds or cuttings derived from genetically modified organisms (GMOs) they must be under current European regulations.
- Use of healthy soils without contaminants or residues (without sewage sludge, heavy metals, without frequent fumigations, pesticide residues, chemical fertilizers, fertilizers that produce leachate, human excrement, etc.).
- Irrigation water clean and free of organic and chemical contamination (standard of quality set by regulation), and only the necessary one.
- Soil and weather needs (water, sun, nutrients) must be covered.
- Avoid herbicides and pesticides as much as possible. Apply the lowest effective dose.
 Respect the security period. Communicate the products used, the quantity and date of application to the buyer.
- If the crop is organic, it must be carried out according to the corresponding regulations.

2. COLLECTION

- Collect at the optimum time of the plant.
- Collect in favorable atmospheric conditions (without rain or moisture).
- Do not collect diseased plants, or diseased or unused parts of the plant.
- Keep collecting machines and their warehouses clean.
- Control contamination by land and / or other (toxic) plants.
- Do not place the product in the sun or on the floor.
- The containers used for the harvested plant must be clean (bags, baskets, trailers).
- Minimum time between picking and drying.
- Protect the product from rain, rodents, birds, pets, etc.

3. PRIMARY TRANSFORMATION (DRYING, DISTILLING, ETC.)

- Keep equipment and facilities clean and airy.
- Start drying quickly and last as long as possible.
- Protect the product from insects, rodents, birds, pets, etc.
- Avoid direct contact with the floor.
- In hot air dryers it is recommended to use butane, propane or natural gas, with gasoline or diesel oil the combustion fumes can not enter the drying room. Highly recommended solar dryers.
- When drying with hot air, temperature, humidity, time, etc. should be monitored and recorded.
- Remove foreign matter and immediately store the dried material in a container.

4. PACKAGING AND STORAGE

- Do not pack or transport until the product is completely dry.
- The packaging must be new, clean and dry.
- The label must be clear and fixed, and all packages must be identified.
- The warehouse must be clean, dry, ventilated, protected from entry of animals, etc.





- Packages should not be stored on the floor (better on pallets), or touching walls or ceilings.
 They should be ordered by product and lots to avoid confusion.
- Transport avoiding cross contamination in truck or container. They have to be clean, dry, well ventilated but closed protecting from the sun or rain.
- If fumigated, an authorized product must be used, indicating the product.
- If the crop is organic, it must be stored according to the corresponding regulations.

5. HUMAN RESOURCES

- Specialization courses are recommended: agricultural, specific techniques of MAPS cultivation, botany, hygiene, optimum harvesting time, production and processing, correct use of chemical fertilizers, herbicides and pesticides, etc.
- Sick people with wounds, etc. Must not be in direct contact with the plant material or should be protected with gloves, masks, etc.

6. DOCUMENTATION

- The entire process must be properly written.
- Identification of plant material (seeds and/or cuttings), species and variety. Specify seeds
 or cuttings from genetically modified organisms (GMOs). Part of the plant and lot number.
 Place of cultivation (zone/country) and start date (month/year). Type of soil and irrigation
 water (no heavy metal residues, no pesticides, no chemical fertilizers, no microbial
 contamination, etc.). Indicate herbicides and pesticides: product, when, how, etc.
- If the crop is organic, it should be indicated.
- Moment (day/month/year), form (manual, machine) and collection time (2 days, 1 week).
 State of the plant at the time of collection (flower, fruit, etc.).
- Type and conditions of equipment and installations, machines, premises, etc.
- Indicate the form of drying (natural, in the sun, in the shade, with warm air), place (in store, outdoors, on the floor, on a plastic, on tray) and note the temperature, humidity, etc.
- Warehouse conditions (closed, open). Period (1 month, 1 year).
- Type of packaging (bag, box, and trailer).
- Period, type (truck, container) and conditions (closed, open, ventilated, with awning, with drying agents) of transport.
- Fumigations applied in the warehouse or transport, indicating authorized product.
- Indicate the personnel experience and training. They must know the quality requirements, pharmacopoeias, etc.
- They can receive an inspection visit to be approved as suppliers. Answer a questionnaire and inform about the cultivation by means of the datasheet of each lot.





PART III. PROCESSING AND SALE OF MEDICINAL AND AROMATIC PLANTS

6. Transformation of medicinal and aromatic plants: preservation, drying, distillation, extraction.

The preservation and transformation of an aromatic and medicinal plant is started after harvesting. With a freshly harvested plant you can do everything: an infusion, use as food or condiment by adding it to food, drying, macerating in oil, wine or alcohol for internal or topical use, crushing or liquefying to take or make a poultice, add a fat, or other preparations for the skin.

There are numerous forms of transformation used at the industrial and domestic level.

Industrial	1. extraction by percolation (solvent and heat),
	2. microwave,
	3. supercritical fluids,
	4. other.
Domestic	1. direct use freshly harvested,
	2. drying,
	3. freezing,
	4. macerations in vegetable oil, alcohol and/or vegetable glycerin, and
	5. steam extraction (distillation of essential oils).

If we are not sure about what we are going to do with a plant it is preferable to dry. Refrigeration can be useful for a few days, but another domestic option is to put the freshly plant in a jug with water near the kitchen to season or decorate. Freezing is fantastic, especially for the seasoning plants, because in this way they do not lose the aroma, although (except for the marjoram or savory) most lose their texture. Macerations are possible with both fresh and dried plants, although when fresh they retain all their energy properties. In spite of this, in some, including marigold, it is advisable to partially dry before macerate in oil, as the flowers may have more than 90% water when they are freshly harvested and fungi generated risk is very high.

6.1. Main systems of primary transformation

6.1.1. Drying

The drying process can be done naturally in the sun, in the shade or forced by heat. It should always be done in clean places, with no possible access by rodents, domestic animals or birds. The temperature and drying time, the relative humidity of the air and the water content, the composition and the structure of the material to be dried are the factors that condition the drying process. It is essential that the drying process be started as soon as possible once it has been collected. The yield of the dried plants is usually around 20% of the starting fresh material.





To dry properly is sufficient to arrange the plant in the shade, in small layers, in a dry and ventilated place. In some cases, such as elderberry, melissa or marigold, the best way is to leave them in the sun on the first day, pick them up first thing in the morning, turn them in at noon and, before the evening humidity begins. Deposit them in cardboard boxes, arranged in small layers, and leave them in inside to finish drying them. To dry naturally in the shade, you must take advantage to collect when the weather forecasts are favorable, without rains, if possible, for a week.

There are other drying systems that use energy to produce heat, although in this case it is essential to control the temperature in order not to degrade active principles, evaporation of essential oils or modification of organoleptic characteristics (darkening of drugs, decreased odor, etc.). It is recommended not to exceed 40°C. Solar energy is the most economical option without a doubt compared to biomass, gas or electricity.

When the plant crunches means it is dry and it is time to pack in glass jars, paper bags tightly closed, cardboard boxes protected with paper, etc. It is recommended to store them in a room or in a closet, protected from rodents, light, moisture and heat. Expiration date depends on each plant, if it is preserved under correct conditions the active principles take time to degrade, two or even three years. However, one of the major drawbacks is the appearance of insects in some plants, including coriander, camomile, angelica, horse chestnut (*Aesculus hippocastanum*), thistle marmoset, mallow, etc. The ideal, therefore, is to produce for the consumption of a year.

With the drying we obtain a dry drug that will be able to be well conserved and maintain the active principles, besides avoiding processes of degradation, microbial growth, aflatoxins, etc. The reduction of the humidity is usually done until having a moisture content (loss of mass by desiccation) of 8-12%.

When it's dry, select the part that is used and remove any remains of the plant that are not used, or foreign elements that may have been incorporated during collection (soil, stones, etc.). Yo can do it manually with sieves, but there are special machines with sieves, or air columns separating different densities by air stream. By adding magnets can be separated remains of irons.

Then, depending on the use, you can do:

- Grinding (powder for capsules or tablets, condiments, etc.).
- Crushing (cans, infusion bags, etc.).

And finally, packaging and storing quickly, to avoid any kind of contamination.

6.1.2 Freezing

To freeze it is enough to collect the part of the plant, to clean it and to drain it. It is very practical to use a Zip type bag with the name of the plant and the date. It is then quickly deposited in a freezer. Frozen plants of more than one year can be used without problem, as long as the cold chain has not been broken.

6.1.3. Maceration





To macerate in virgin vegetable oil, olive oil, sesame or almonds, it is sufficient to soak the fresh or dried part of the plant at room temperature in a proportion that can range from 5 to 30% or even more. This is also done if the solvent is pure alcohol or any other grade (spirits, rum, vodka, or wine). The amount of plant and solvent is important for the final concentration of active ingredients.

So the procedure to be followed is to weigh the plant and the solvent that we are going to leave macerating in a closed container. It is recommended to close well, especially the alcohol due to the risk of evaporation, in a covered place and never directly to the sun so as not to degrade ingredients or oils. You can improve the active ingredients extraction by shaking from time to time. After a time, which can vary from days to six months, most components have already been extracted, having two options: leave well closed if not to be used at the moment, or instead strain it and pack it in small containers, 50-100 ml. If this last option is chosen, do not open a container until the end of other one, which allows the shelf life to be extended. Opening and closing is how most degrade the preparations.

In extracts, when weighing the plant and solvent, we are performing a weight/weight (w/w) dilution, ie gram/gram, although the volume of the liquid can also be calculated and will be w/v (g of plant and ml of solvent). The important thing is to know the exact amount of active ingredients in the extract, but at the home level this option is not possible, so will be useful to make a ratio of added plant quantity to the amount of extract obtained at the end. With these data we can define formulations and calculate medicinal doses and dosages. A 10% liquid extract means that in order to have the same active ingredients as in the plant it is necessary to multiply by 10 the amount of extract.

In an alcohol, degrees is the percentage of pure alcohol found. For example, alcohol of 70 degrees means that there is 70% alcohol (ethanol), that is, 700 ml of ethanol per liter, and the rest is water.

The alcohol content of fermented drinks: wine or beer is less than 15°. Distillates such as vodka or rum contains about 40 degrees alcohol, and cazalla, aguardiente or marc, and dry anise about 45°

6.1.4. Essential oils distillation

To carry out a correct distillation and to obtain essential oils, a special alembic is needed, called column, where the plant is placed. It is not the same one that is used to get pomace or alcohol.

A distiller is composed of:

- Boiler (steam generator).
- Distillation vessel.
- Cooling coil.
- Separation vessel (Florentine vase).

The distillation vessel contains the vegetable drug. The water boiler is heated by a heat generator (fuel or biomass), to produce steam that goes through to the distillation vessel and allows the essential oil to be drawn into the refrigerant coil. Then the gas passes to liquid and the water is separated from the essential oil in the Florentine vessel.









To measure the distiller, you must take into account:

- The amount of drug to be distilled during the years of maximum productivity.
- The period of collection of each species to be distilled.

Depending on the amount to be distilled, one size or another is required. At the domestic level, is sufficient with a still of 5-10 liters. In some plants the essential oil obtained is so little that the hydrolate must be used. For a medium distillation frequency and quantity, a still of 50 liters is well, although at professional level there are of 2,000 liters and more.

One of the most frequent questions is what material the alembic should be. It is frequent to use copper without column, but it is not the most suitable. The best material without doubt is stainless steel, because the oil obtained has better quality.

The production of essential oils depends on:

- Variety.
- Part of the plant used.
- Environmental, climatic and crop conditions (dry or irrigated).
- Time of collection.
- Type of distillation.

The part of the plant and its vegetative state are important parameters to control when we extract the essential oil. For example, rosemary is better if it is distilled in a state of flowering. The climatic conditions, the chemotype, the age of the plant, the time of day and place where it is collected, etc. also affect.

The alembic should be placed in a ventilated place and with a water faucet nearby for reflux. Fill the bottom with water by calculating the exact amount, place a grid or some material that will let water vapor through and prevent the plant from coming into contact with water. So that nothing evaporates, all the parts are put together by putting flour in the joints, and it is placed on a source of heat that can be firewood, a stove or a renewable energy. An important point is the reflux (cooling coil), where the cold water will cool the water vapor to convert it into floral water (hydrolyzate) and essential oil. A trick used is to place bottles of liter and a half of frozen water as they help reduce the consumption of reflux water, and of course, water can always be recycled.

At the end of the reflux there is a faucet through which water and oil comes out. Since most oils weigh less than water (except those of bitter almonds, mustard, cinnamon, parsley, or clove) and do not mix, they can be separated easily with a decanter: on the one hand the essential oil, which remains in the top and on the other the hydrolate.

6.2. Packing

Plant drugs packaging must ensure that it isolates them from the outside.

In some pharmacopoeias, relevant details are defined, such as the Austrian Pharmacopoeia (OAB): "in tightly closed containers" (adequate protection against contamination with other substances), "in hermetically sealed containers" (additional protection against the effects of





the ambient humidity). In some drugs it may be indicated "with a suitable desiccant" (mullein flowers), or also "protected from insect attack".

Once the vegetable drug is dry, the right kind of material is as follows: bags or sacks of paper or paperboard; Cellophane bags; Kraft bags; Cans of plastic, polypropylene or polyamide (aluminum is not sustainable).

Essential oils and liquid extracts should be packed in suitable containers (topaz glass or galvanized drums) and store under conditions of darkness and constant temperature (12-15 $^{\circ}$ C). Polyethylene, polypropylene and polyvinyl chloride are not suitable as they absorb the essential oil from the drug and the environment.

6.3. Labelling

Once packaged, raw materials must be identified.

Labels should contain minimal information:

- Popular name of the plant.
- Latin name.
- Part used.
- Presentation (powder, crushed, ...)
- Lot Number.
- Zone and date (month and year) of harvest.
- Expiration date
- Provider's name.
- Net weight.Nombre popular de la planta.

The delivery note, it is the documentation that accompanies a product, identifies and defines it and allows to confirm the delivery of the product to the customer:

- Provider's name.
- Address.
- Product name.
- Lot.
- Total weight of the game.
- Number of containers.
- Order number.
- Delivery note number.
- Date.

6.4. Storage

A number of factors can affect the quality of the product during storage, among them we can highlight the following: conservation measures, type of protection against light, temperature, humidity, and size of the crushed:





- Conservation measures are not specified in any pharmacopoeia, but should be taken into account (the how, where, how long they should be stored) in storage and transport, as well as the packaging material of medicinal plant products. Almost all drugs need protection in the light, especially if it is direct sunlight. This is because most drugs, but especially the leaves, flowers and plants, lose color, which gives an incorrect appearance. In addition, the degradation processes of active ingredients are accelerated.
- Temperature is another of the parameters that maintains the quality of a drug. There are not many studies on plant drugs and temperature, but the colder the environment, the better the drugs will be kept. Heat causes changes in the constituents of drugs and decreases the content of essential (volatile) oils with a temperature increase. Also, heat is a factor that favors insect and microbiological contamination (especially if there is moisture in the raw material or in the environment)
- Moisture has two unfavorable effects on drugs conservation. Certain enzymes, especially glycosidases, will begin to degrade the constituents. In addition, there is a growth of fungi and yeasts, or other microorganisms.
- The crushed size of the dry plant plays an important role in keeping the drug in the
 best conditions. The smaller the particle size (dust) the larger the surface. This causes
 unfavorable factors to act more quickly. This should be taken into account, particularly
 in drugs containing essential oils (mint, camomile, green anise, etc.), tannins
 (Hammamelis, walnut, etc.) and bitter principles (Centaurea, gentian, etc.)
- The best for the conservation of the vegetal drugs would be a dry chamber, with temperature less than 10 degrees and in conditions of relative humidity less than 60%.

6.5. Contaminants and residues

A plant, whether wild or cultivated, it is exposed to a multitude of environmental factors during its growth: land, air and water, which can carry certain pollutants:

- Microorganisms and insects.
- Aflatoxins.
- Heavy metals.
- Phytosanitary, herbicides. An ecological product does not contain them.
- Radioactivity.Microorganismos e insectos.

When drying the drugs these contaminants become waste and require special attention, from a hygienic and toxicological point of view. The number of microorganisms can increase greatly, under slow and wet drying conditions. No less important is the formation of fungal toxins (aflatoxins).

Storage and transportation is also critical. Certain storage and transport conditions and temperature and high relative humidity, favor the growth of insects and microorganisms, especially in badly dried drugs. If the packaging is not correct, cross contamination, uptake of environmental humidity, roasting or oxidation of oils or extracts may occur. A warehouse, with a preventive program of disinsecting the facilities, must ensure that the drugs are properly packed. A truck without awning can cause a dry matter to become wet and to lose quality (darkening, degradation of active principles, growth of microorganisms, etc.).





The way to carry out all the processes that have been explained previously (from the choice and preparation of the land to the maintenance of the crop) will affect the quality of the final product.

That is, for the quality of the final product to be optimal, the following observations must be considered:

- An incorrect choice of plant material will condition the procurement of a non-officinal drug. It can also affect, due to the difficulty of mechanization, the presence of foreign elements and other plants. Soils too acidic or basic, will not allow a correct growth of the species and the production of active principles. An incorrect choice of altitude, latitude, rainfall, sunshine, etc., can also affect this incorrect growth.
- Not controlling the possible contaminants or residues, will involve the absorption of these by the plant: heavy metals and microorganisms found in soil and water; Herbicides and fumigations (pesticides) of the soil (old remnants), water (irrigated) or air (a field or neighboring forest). An incorrect application of herbicides and pesticides in the crop, favors the presence of residues if the established times are not respected. Immediate collection will lead to the accumulation of residues of heavy metals, pesticides, and/or microorganisms during the drying process. It is preferable to prevent and avoid the presence of pests or diseases, to avoid having to deal with chemicals.
- Proper weeding, fertilization and irrigation will ensure the growth of plants and a
 homogeneous presence of the active ingredients, as well as the absence of
 adventitious weeds, and the rate of foreign elements will be below that marked by the
 pharmacopoeia.
- Organic farming favors better quality.

6.6. Documentation that must accompany a raw material

It is advisable to provide information on the raw material that is marketed. Collection and cultivation data, method of transformation, characteristics of the plant, warehouse and transport should appear. In addition to this information, it is preferable that the raw material has an analysis bulletin.

DATA SHEET

- Name of the plant in Latin and variety.
- Part of the plant
- Origin

Production

- Type: wild collection or cultivation.





- Time of harvest and vegetative phase of the plant at this time

Transformation: drying, extraction, distillation

- Method employed, indicating what, how, when, where, conditions (temperature and exposure time).

Storage:

- Conditions and time of storage.
- Packing material.

Transport:

- Type, time and conditions of transport

Treatments

- Phytosanitary treatments carried out (with what products, concentration, how, when, where).

Certificates:

- Green product certificate (if available).
- Certificate of homogeneous lot.
- Certificate of absence of adulterations and / or falsifications or cross contaminations (gluten, lactose, etc.).
- Certificate of absence of foreign elements (stones, earth, irons, insects, etc.) and humidity.
- Certificate of absence of transgenics and allergens.

QUALITY CONTROL ANALYSIS BULLETIN

- Macroscopic and microscopic characteristics.
- Tests (loss of mass by drying, ash, foreign elements, index of swelling, bitterness, stomata, saponification, etc.).
- Identification (CCF).
- Assessment of active substances, residues (heavy metals, aflatoxins, pesticides, radioactive activity) and microbial contamination.

6.7. Supplier audit or approval





The manufacturer customer may request to respond to a questionnaire to obtain more information from the supplier and even make a visit to check how the facilities and staff meet the quality requirements.

This questionnaire asks about:

- The organization.
- The staff.
- The installations.
- Equipment.
- Documentation.
- Work system.
- Material flow.
- QA.
- Production.
- Warehouse.

This information will be essential to establish a quality assurance, to classify the raw material and the supplier as reliable, as well as to have total traceability.

7. Manufacture of herbal products. Good manufacturing practices.

The production of plant-based products differs considerably if it is carried out domestically or artisanal to those manufactured at industrial level. The ingredients, methods, equipment, technology and requirements vary enormously. Even so, simple formulations and preparations can be made for food, cosmetic, medicinal or agricultural use. The person responsible for placing the product on the market must ensure durable stability and preservation, as well as quality, efficiency and safety of its products.

The steps to define a new product are as follows:

First of all, we must know the use we will give, whether it will be a food, medicine or cosmetic.

Once we know this we must know what activities we expect from the plants in order to choose which of these we are interested in.

Once we know which vegetable drug we can use we must check if it has some other unwanted effect or some toxicity to rule it out. For this there are bibliography or websites to consult.

Once we have decided which plant(s) we will use, we will choose the most suitable preparation (infusion, oil maceration, etc.) and how we will use it (drops, spray, scrubs, etc.)

Then decide the amounts of each ingredient and the preparation, as well as the quantities to be taken and the number of times a day.

We have to start on a minimum and if it does not work we have to increase amounts. Keep in mind that each person can respond differently.

As for children there are different ways of calculating amounts, the best is the weight. If we consider that the usual doses are 60-70 kg for adults, we can make a relation depending on the weight of the child.

While the product is developed it is necessary to see what are the quality compliance requirements, what specifications the manufacturer or the product must comply with, what is the mandatory text of the label, etc.





In turn, you should think about the type of packaging, price, way of marketing, define logo, trademark registration, dissemination form, social networks, marketing plan, etc.





7.1. Types of preparations according to extraction solvent

7.1.1. Without solvent

There is a case in which nothing is used to extract and it is the own plant that is used, is the case of the juices (*Sonchus asper*), exudates (turpentine), chopped (cabbage leaf), the internal pulp of the leaf (Aloe), part of the dry powder plant (tepecohuite), or decorative or aromatic use.

7.1.2. Water

Water is used in one of the most known and usual forms of preparation at home level, such as **infusions** and **decoctions** of plant, fresh or dried, whole or crushed. In infusions, when the water boils it is thrown on the plant and allowed to infuse a few minutes while it is covered. On the contrary, in the decoction, the plant boils with the water for a few minutes to get a better extraction of active principles (it is done with roots, barks and hard materials that require heat).

Therefore, for a chamomile flower or mint leaves an infusion is sufficient. In addition, boiling them evaporate the essential oils.

Maceration with water is recommended when heat is not required for the dissolution of the active ingredients in water. For example, bearberry leaves (Arctostaphylos uva-ursi) are urinary antiseptic thanks to ubiquinone (arbutin), which is soluble in water, but in these leaves also tannins are found that make an infusion very astringent; On the other hand, in the maceration at room temperature, few tannins pass into the water, so leaving the leaves to soak in water overnight is sufficient. Another example is the rose hips (the fruit of *Rosa canina*), which contains a lot of vitamin C that can be degraded by heat, so it is recommended to macerate.

These three preparations with water can be taken orally, but they can also become part of a bath or poultice, as well as we can make a syrup, gargle or steam. The amount of plant per liter or per cup is indicated in specific monographs and depends on each use, on the plant, on the frequency of intake, etc.

7.1.3. Vegetable oil

The vegetable oil, which is better virgin and first pressed, is the basis for other preparations. The ideal is to macerate at room temperature and without heat that can degrade active ingredients, but sometimes, you need an oleate that can be obtained in a few hours thanks to the water bath. Although to obtain a magnificent maceration of basil in olive oil for food use is sufficient with one day.

The oil is used so that the active or aromatic components can be extracted and remain in it for therapeutic use, internal or external, or to flavor food. It usually uses about 100 to 300 grams of dry plant per liter of vegetable oil. For example, almond oil with marigold flowers is preferably used externally for its anti-inflammatory, antiseptic and healing properties conferred by the active principles of flowers. Instead, the marjoram in olive oil is a delicious ingredient that garnishes any legume.





This vegetable oil may be the basis of another preparation. For example, marigold oil as a major ingredient may form part of a cerate (now called ointment) or marjoram oil is used to make mayonnaise.

7.1.4. Glycerin, propylene glycol

Other preparations consist of using glycerin or propylene glycol to make the extract. A cosmetic for topical use which is composed of an active which confers properties, will only be extracted by means of an optimum solvent for the skin: vegetable oil, glycerin or propylene glycol, although the first two components are preferable. To improve the extraction of the active principles, a mixture of the last two is usually made with water and even with alcohol. Thus, the hydroalco-glycerinates give us better extractive power and improve the storage capacity, although the alcohol can finally be evaporated (mixture= water:alcohol 98°C:glycerol - 30:20:25; plant:solvent - 1: 4, minimum maceration time 12 days). It is recommended that cosmetic products in contact with the skin do not contain more than 1 to 5% glycerol or hydroalco-glycerin extract.

There are a number of semi-solid preparations where the base ingredient is a vegetable oil macerated (fat). An ointment is the mixture of a fat with a resin, and because of the latter the consistency is sticky. A kerato is to add a small proportion of wax (10-20%) to a fat. A **balsam** is a plant exudate soluble in alcohol, different from a resin or rubber containing acids, aromatic substances or turpentine, which is applied on the outside and is mainly used for the respiratory system (Eg Balsam of Peru, Tolú, Peru, Storax, and Liquidambar).

A **liniment** is a liquid preparation in solution or emulsion form. It is mixing of extracts, tinctures, and/or essential oils, with water, vegetable oil and/or alcohol, to achieve rubefacient action when rubbing the skin. This intense vasodilatation and analgesic action is ideal in muscular, rheumatic and neuralgic conditions (eg menthol, turpentine, camphor).

An ointment with a soft, oily consistency consists of fat (vegetable oil, glycerin) or beeswax, and incorporates a liquid or powdered extract. Three types of ointments are distinguished depending on the type of ingredients and the way of preparation:

- Solutions (= lotions): the active substance: it is soluble liquid or solid in the excipient. They are mixed in cold or hot.
- Emulsions (= creams): the active liquid is insoluble in the excipient. An emulsifier (wax, lecithin, white clay) is needed. The phase Aqueous (hydrolyzate) + oily (oil or wax) are joined in hot and cold in two ways: A/O (water in oil) and O/A (oil in water) according to the proportions of each phase that make up the cream. If the proportion of the oil phase is higher than the aqueous phase, the aqueous is added to the oil and it will be A/O (eg 15% beeswax and 45% oleate, 39% aqueous extract and 1% borax, essential oil).
- Suspensions (= pastes (clays)): the molten excipient is added to the powdered active.

The gels are semi-solid preparations consisting of an emulsion of methylcellulose, agar, gelatin, propylene glycol or linseed seed mucilages in water. That is, it is an O/A emulsion to which is added a gelling agent and wetting and hygroscopic agents, which collect water.

7.1.5. Alcohol





Alcohol is another of the useful solvents that we usually have at home. A maceration with wine (white, red or rosé) can be the basis for preparing a medicinal wine or aperitif and also a vinegar, depending on which plant is used (eg thyme and red wine for medicinal wine, gentian and white wine for aperitif, tarragon and any wine for vinegar).

A macerated in alcohol will be the basis of oral or topical preparations, medicinal or nutritional. Of medicinal use internally (olive or passionflower) or external route for frictions (rosemary or lavender). A liquid extract of wine or alcohol is rarely used for a cosmetic preparation, although dry extracts are sometimes used in very little proportion (less than 5%).

A mother tincture is defined when a fresh plant and alcohol of 70 or 90 °, 01:10 (10 ml of solvent and 1 gram of dry drug) are macerated for homeopathic use. A tincture is a liquid solution with dry drug and alcohol of 70 or 90 °, 1:5 or 1:10, by maceration or percolation. For example: Tincture of cinnamon bark: 1g of vegetal drug + 5 g of alcohol 70° (1: 5 = 20%). An alcohol is the mixture of the plant and alcohol $80-96^{\circ}$, 1:1 or 1:2, for 8 to 10 days.

A preparation that also uses alcohol in its preparation is the elixir. These are hydroalcoholic sweetened solutions. Most herbal digestive liqueurs are. To dissolve soluble substances in water and alcohol (alcohol from 18% up to 45%), we can add essential oil, dyes or fluid extract (20-25%), which we sweeten with 64% simple syrup (64 g sugar in 100 ml of water) and at least 45%.

7.1.6. With other ingredients

Cataplasm: Semi-solid preparations of flours of seeds (flax, mustard, fenugreek), fresh leaves chopped (cabbage, onion), fruit (figs or strawberries), roots (burdock, comfrey), clays, olive oil or water. They are mixed in a mortar, until obtaining a consistent uniform paste by means of heat. It is spread with a thickness of 1 cm between two cloths or gauze of linen or cotton, previously heated and applied on the area to be treated. It is applied hot and left until it loses heat. Take into account the temperature and the time of application. For example, calendula cataplasm (*Calendula officinalis*) is healing, anti-inflammatory, analgesic and pectoral.

Patch: are semi-solid preparations. Vegetables minced in a mortar are mixed with fats or resins, virgin vegetable oil or lard, or an infusion of a plant with clay until it has a pasty consistency. Apply directly on the skin and fix with a bandage, or put between two cotton fabrics and apply in the area. Rubefacient substances, which irritate the skin such as alfalfa (*Medicago sativa*) or verbena (*Verbena officinalis*) are used. Indicated for sore knees, but should not be left too long, as they could cause injury.

They can be prepared with juices, chopped leaves, vegetable powder, clays, oils or infusions, or to prepare a beauty mask without therapeutic utilities.

Compresses: With an infusion or decoction of 50 to 100 g of plant per liter of water, it is filtered, to soak the compress or gauze and apply.

Poultices: hey are the same as the compresses, but very hot. Impregnate the gauze and, if essential oils are used, add 5 or 10 drops per liter of water, and this will impregnate the gauze. Apply directly, as hot as you can withstand, for 15-20 minutes. Afterwards, it is convenient to rub the area with cold water, to produce a circulatory change. It is indicated for rheumatism, abdominal spasmodic pain and for otorhinolaryngological problems. You can use spruce (*Abies*





alba), eucalyptus (Eucalyptus globulus), thyme (Thymus sp.), Pine (Pinus sp.) or tusilago (Tussilago farfara).

Even for use in food, it depends on where the plant is added (in a liquor, stew, mayonnaise, etc.) and how it is actually used, an extraction solvent is involved.

7.2. How to recognize the quality of a plant and its preparations

One of the reasons that affect the quality of a product is the error of identification and, therefore, the use of a different plant than we should use.

To recognize the quality of a plant or its preparations are essential the organoleptic characteristics, that is to say, the color, smell and flavor. At different points in the process, these characteristics can be affected: cultivation, harvesting, drying, processing or storage. Another quality criterion is that it only contains the part of the plant that is used, and not includes other parts of the plant, or animal or mineral remains.

An analytical laboratory ensures the quality of the plant, especially in reference to the absence of contaminants and residues, as well as the level of content in active principles. One way to eliminate the risk of chemical residues is by producing and consuming organic plants.

It can be affirmed that we have a quality product if the processes of obtaining and processing have been carried out correctly, and the plant complies with the date of preferential consumption. Reducing the risk of microbial contamination is achieved by applying heat (infusion), removing water (drying), or adding substances that lower water activity, such as salt, sugar, vinegar or glycerin (products).

7.3. Good Manufacturing Practices

Almost all countries have Good Manufacturing Practices; usually the approach is general, intended for food or medicines.

For the manufacture of Medicines based on Plants, the following are mandatory in Europe:

- Guideline on good agricultural and Collection Practices (GACP) for starting materials of herbal origin. EMEA, 1/8/06
- 2. Good Manufacturing Practice (HUMAN & VETERINARY). Part I and/or II and Annex 7: Manufacture of Herbal Medicines

The WHO, EMEA, FDA, etc., have good practices and guidelines for herbal products. Here are a few:

GMP: Updated Supplementary Guidelines for the Manufacture of <u>Herbal Medicines</u> Department of Technical Cooperation for Essential Drugs and Traditional Medicine July 2005 WHO

Good manufacturing practices and inspection. Quality assurance of pharmaceuticals A compendium of guidelines and related materials. Volume 2, WHO, Geneva, 2004





Good manufacturing practices: supplementary guidelines for the manufacture of <u>herbal</u> <u>medicinal products</u> WHO Annex 08 1996. Guidelines for the *assessment* of herbal medicines are provided in Annex 11.

Good agricultural and collection practice for herbal raw materials. Prepared by the Botanical Raw Materials Committee of the American Herbal Products Association in cooperation with the American Herbal Pharmacopoeia. December 2006

Guidance for Industry. <u>Botanical Drug Products.</u> Junio 2004 FDA http://www.fda.gov/cder/guidance/4592fnl.htm

Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for <u>Dietary Supplements</u>. FDA. June 25, 2007. Compliance: June 25, 2008; o 2009 o 2010

Good Manufacturing Practices Guidelines" Canadian, 2007 http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui_0001_tc-tm_e.html.

Cuba: Good Practices of Manufacture of Herbal Products, Annex Nº 3 CECMED, 6/7/2004. From 16-2000 Guidelines on Good Practices for the Manufacture of Pharmaceutical Products.

7.3.1. Good Manufacturing Standards

In Europe is used the Good Manufacturing Practice (HUMAN & VETERINARY). You can read the documentation regarding Good Manufacturing Practices Part I or II in the following link: http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm

We detail below the Annex 7 on Manufacture of Herbal Medicines:

Activity	Good Agricultural and Collection Practice (GACP)44	Part II of the GMP Guide†	Part I of the GMP Guide†
Cultivation, collection and harvesting of			
plants, algae, fungi and lichens, and			
collection of exudates			
Cutting, and drying of plants, algae, fungi,			
lichens and exudates *			
Expression from plants and distillation **			
Comminution, processing of exudates,			
extraction from plants, fractionation,			
purification, concentration or			
fermentation of herbal substances			
Further processing into a dosage form			
including packaging as a medicinal			
product			

[†]Explanatory Note.





The GMP classification of the herbal material is dependent upon the use made of it by the manufacturing authorisation holder. The material may be classified as an active substance, an intermediate or a finished product. It is the responsibility of the manufacturer of the medicinal product to ensure that the appropriate GMP classification is applied.

- * Manufacturers should ensure that these steps are carried out in accordance with the marketing authorisation/registration. For those initial steps that take place in the field, as justified in the marketing authorisation/registration, the standards of Good Agricultural and Collection Practice for starting materials of herbal origin (GACP) is applicable. GMP is applicable to further cutting and drying steps.
- ** Regarding the expression from plants and distillation, if it is necessary for these activities to be an integral part of harvesting to maintain the quality of the product within the approved specifications, it is acceptable that they are performed in the field, provided that the cultivation is in compliance with GACP. These circumstances should be regarded as exceptional and justified in the relevant marketing authorisation/ registration documentation. For activities carried out in the field, appropriate documentation, control, and validation according to the GMP principles should be assured. Regulatory authorities may carry out GMP inspections of these activities in order to assess compliance.

Premises & Equipment

Storage areas

- Herbal substances should be stored in separate areas. The storage area should be
 equipped in such a way as to give protection against the entry of insects or other animals,
 especially rodents. Effective measures should be taken to prevent the spread of any such
 animals and micro-organisms brought in with the herbal substance, to prevent
 fermentation or mould growth and to prevent cross-contamination. Different enclosed
 areas should be used to quarantine incoming herbal substances and for the approved
 herbal substances.
- The storage area should be well aerated and the containers should be located in such a way so as to allow free circulation of air.
- Special attention should be paid to the cleanliness and maintenance of the storage areas particularly when dust is generated.
- Storage of herbal substances and herbal preparations may require special conditions of humidity, temperature or light protection; these conditions should be provided and monitored.

Production area

 Specific provisions should be made during sampling, weighing, mixing and processing operations of herbal substances and herbal preparations whenever dust is generated, to facilitate cleaning and to avoid cross-contamination, as for example, dust extraction, dedicated premises, etc.

Equipment

 The equipment, filtering materials etc. used in the manufacturing process must be compatible with the extraction solvent, in order to prevent any release or undesirable absorption of substance that could affect the product.





Documentation

Specifications for starting materials

- Herbal medicinal product manufacturers must ensure that they use only herbal starting
 materials manufactured in accordance with GMP and the Marketing Authorisation
 dossier. Comprehensive documentation on audits of the herbal starting material
 suppliers carried out by, or on behalf of the herbal medicinal product manufacturer
 should be made available. Audit trails for the active substance are fundamental to the
 quality of the starting material. The manufacturer should ensure that the suppliers of the
 herbal substance/preparation are in compliance with Good Agricultural and Collection
 Practice.
- To fulfil the specification requirements described in the basic requirements of the Guide (chapter 4), documentation for herbal substances/preparations should include:
 - a. the binomial scientific name of plant (genus, species, subspecies/variety and author (e.g. Linnaeus); other relevant information such as the cultivar name and the chemotype should also be provided, as appropriate;
 - details of the source of the plant (country or region of origin, and where applicable, cultivation, time of harvesting, collection procedures, possible pesticides used, possible radioactive contamination etc.);
 - c. which part(s) of the plant is/are used;
 - d. when a dried plant is used, the drying system should be specified;
 - e. a description of the herbal substance and its macro and microscopic examination;
 - f. suitable identification tests including, where appropriate, identification tests for constituents with known therapeutic activity, or markers. Specific distinctive tests are required where an herbal substance is liable to be adulterated/ substituted. A reference authentic specimen should be available for identification purposes;
 - g. the water content for herbal substances, determined in accordance with the European Pharmacopoeia;
 - assay of constituents of known therapeutic activity or, where appropriate, of markers; the methods suitable to determine possible pesticide contamination and limits accepted, in accordance with European Pharmacopoeia methods or, in absence thereof, with an appropriate validated method, unless otherwise justified;
 - tests to determine fungal and/or microbial contamination, including aflatoxins, other mycotoxins, pest-infestations and limits accepted, as appropriate;
 - j. tests for toxic metals and for likely contaminants and adulterants, as appropriate;
 - k. tests for foreign materials, as appropriate;
 - any other additional test according to the European Pharmacopoeia general monograph on herbal substances or to the specific monograph of the herbal substance, as appropriate.





Any treatment used to reduce fungal/microbial contamination or other infestation should be documented. Specifications and procedures should be available and should include details of process, tests and limits for residues.





Processing instructions

- The processing instructions should describe the different operations carried out upon the herbal substance such as cleaning, drying, crushing and sifting, and include drying time and temperatures, and methods used to control cut size or particle size.
- In particular, there should be written instructions and records, which ensure that each container of herbal substance is carefully examined to detect any adulteration/substitution or presence of foreign matter, such as metal or glass pieces, animal parts or excrement, stones, sand, etc., or rot and signs of decay.
- The processing instructions should also describe security sieving or other methods of removing foreign materials and appropriate procedures for cleaning/selection of plant material before the storage of the approved herbal substance or before the start of manufacturing.
- For the production of an herbal preparation, instructions should include details of solvent, time and temperature of extraction, details of any concentration stages and methods used.

Quality control

Sampling

- Due to the fact that medicinal plant/herbal substances are heterogeneous in nature, their sampling should be carried out with special care by personnel with particular expertise. Each batch should be identified by its own documentation.
- A reference sample of the plant material is necessary, especially in those cases where the herbal substance is not described in the European Pharmacopoeia or in another 6 Pharmacopoeia of a Member State. Samples of unmilled plant material are required if powders are used.
- Quality Control personnel should have particular expertise and experience in herbal substances, herbal preparations and/or herbal medicinal products in order to be able to carry out identification tests and recognise adulteration, the presence of fungal growth, infestations, non-uniformity within a delivery of crude material, etc.
- The identity and quality of herbal substances, herbal preparations and of herbal medicinal products should be determined in accordance with the relevant current European guidance on quality and specifications of herbal medicinal products and traditional herbal medicinal products and, where relevant, to the specific Ph. Eur. Monographs.





8. Market and commercialization. Legislation, standards and certification

8.1. Organization of medicinal and aromatic plants sector

The market is the set of acts of purchase and sale (marketing), influenced by the environment (socio-economic, legal, political, conjunctural, cultural, demographic, technological, etc.). In other words, depending on the market and the environment characteristics, special conditions can be created to be able to buy and sell. Freedom to enter or leave the market may be subject to strict rules.

The market covers groups of people, who buy and sell, with different functions and interactions:

- producers,
- manufacturers,
- distributors (wholesalers, retailers, points of sale, etc.),
- prescribers (influence on consumption),
- buyers and consumers.

The **agents** involved in the production and marketing of herbal products are the following:

PRODUCERS

- Collection (drying)
- Cultivation (drying)

RAW DRY PLANT TRANSFORMERS AND COLLECTORS

- Plant wholesalers (dry plant)
- Extractor industry (extracts)
- Distillers (essential oils)

INDUSTRIES USING RAW MATERIAL (dry plant, extracts, essential oils):

- Conditioning industry (packers)
- Manufacturers of foodstuffs, tea, infusions, spices and condiments, food supplements, additives.
- Manufacturers of medicines.
- Manufacturers of cosmetics.
- Manufacturers of flavorings
- Perfumery-detergency industry
- Manufacturers of fertilizers or phytosanitary products.
- Manufacturers of fodder, premixtures or additives for animal feed.

WHOLESALE DISTRIBUTION:

- Importers Exporters
- Dealers

RETAIL DISTRIBUTION:

- Controlled trade (pharmacies, herbalists)
- Uncontrolled trade (supermarkets, shops, direct sale)





And the aromatic and medicinal herbal **products** on the market are:

MEDICINAL

- Non-prescription medicines
- Traditional herbal medicines.
- Homeopathy

PERFUMERÍA Y COSMÉTICA

- Cosmets
- Essential oils
- Perfumery: detergents and air fresheners

FOOD

- Tea and infusions.
- Spices and condiments.
- Fourth range (fresh condiment grass).
- Food Complements.
- Additives.
- Drinks.

OTHERS

- Extracts for agricultura.
- Animal fodder.
- Feed suplements for pets.
- Construction materials.
- Textile materials or utensils.
- Dyes.
- Extracts to tan skins.
- Gardening.

8.2. World market of medicinal and aromatic plants

The world market for medicinal and aromatic plants in all segments (excluding soybean and algae) contributes about 83,000 million dollars in all segments (Gruenwald, 2010). Depending on the segment, growth is constant, ranging from 3% to 12% per year.





The distribution of the world market is as follows (Graph 1):

GRAPH 1: World market distribution



Source: The Global Herbs & Botanicals Market; Dr. Joer Gruenwald, 2010.

The different areas of consumption in the world market are composed of four major sectors:

- Herbs and spices.
- Essential oils.
- Extracts (active principles, medicine and supplements).
- Fresh vegetable products.

8.2.1. Herbs and spices

Plants or parts of plants intended for the preparation of food and drink are called **spice** or **aromatic seasoning**, because of their characteristic color, aroma or taste. They may be fresh or dried, whole, chopped or milled. By incorporating them, food and drinks become more desirable and tasty and, as a result, better use is made of them (eg thyme leaves and flowers or the clove floral button). Herbaceous species that come from temperate zones are often called "herbs", while seeds of tropical species are known as "spices".

A **prepared condiment** is the product obtained by mixing several species or condiments with each other, and/or with other food substances (eg natural seasonings are salt and vinegar).

Their commercialization is usually dry, sliced or powdered. Spices can come from different parts of the plant: bark, buds, flowers, leaves, rhizomes, roots, seeds, stigma and style, and tops of the plant.





During the period 2005 to 2009, the production of herbs and spices has increased by 2.1% per year, and growing volume by 6.2%

TABLE 4: World spice production data

YEAR	TONS	SURFACE	
	Production (t)	(ha)	
2005	7.053.671	5.246.666	_
2006	7.228.567	5.185.576	
2007	7.519.948	5.348.744	
2008	7.604.213	5.336.041	
2009	7.800.779	5.538.012	

Source: Own elaboration based on FAOSTAT, 2010.

The biggest markets in world spice trade are the United States, European Union, Japan, Singapore, Saudi Arabia and Malaysia. The most important supplier countries are China, India, Madagascar, Indonesia, Vietnam, Brazil, Spain, Guatemala and Sri Lanka.

TABLE 5: The evolution of spice production worldwide.

SPICE (t)	2005	2006	2007	2008	2009
Anise, star anise, fennel, coriander.	392.032	418.197	408.196	415.027	425.068
Chillies and peppers	2.692.085	2.818.093	2.993.417	2.942.521	2.959.283
Clove	105.103	89.287	108.894	110.364	110.239
Ginger	1.321.245	1.490.510	1.555.707	1.605.444	1.618.627
Mustard, seed	562.611	452.283	403.846	512.847	661.326
Pepper (Piper spp.)	436.280	442.112	425.810	414.849	414.075
Peppermint	69.340	91.625	73.865	72.335	72.335
Other species	1.466.999	1.418.187	1.541.203	1.521.761	1.530.761
Vanilla	7.976	8.273	9.010	9.065	9.065
TOTAL	7.053.671	7.228.567	7.519.948	7.604.213	7.800.779

Source: Own elaboration based on FAOSTAT, 2010.

Among the species most produced worldwide are chili, dried peppers and ginger. As for the annual evolution of the production of spices, mustard is the one that has increased the area and the quantity produced in 2009.





TABLE 6: Area of the most important spices worldwide.

SURFACE (ha)	2005	2006	2007	2008	2009
Anise, star anise, fennel, coriander.	567.067	597.514	618.943	634.715	625.217
Chillies and peppers	1.763.261	1.830.518	1.909.589	1.830.597	1.832.471
Clove	467.501	368.384	376.520	385.030	384.950
Ginger	364.696	417.598	416.872	421.3 3 6	427.423
Mustard, seed	720.195	617.296	616.408	683.606	845.442
Black Pepper (Piper spp.)	5.52.440	566.956	548.237	505.768	547.200
Peppermint	3.150	3.380	2.960	2.970	2.970
Other species	7.31.931	707.130	777.167	789.9 2 1	790.241
Vanilla	76.425	76.800	82.048	82.098	82.098
TOTAL	5.246.666	5.185.576	5.348.744	5.336.041	5.538.012

Source: Own elaboration based on FAOSTAT, 2010.

8.2.2. Essential oils

Essential oils are chemicals synthesized by plants. These substances are extracted by steam distillation and its components are used by the industries of natural products, aromatherapy, etc.

The amount of essential oil in the plants varies according to species, ranging from 0.01 to 2%, calculated on the weight of fresh distilled grass.

More than 200,000 tons of essential oils are produced worldwide.

It is shown below that there is a significant increase in recent years reaching 2500 million dollars in 2007 (last recorded data).

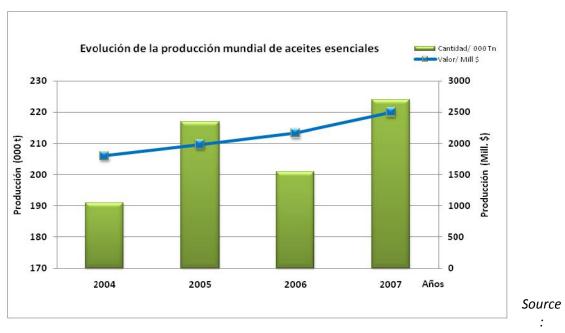
The 12 most important essences, with a production of over 1000 tons, represent 95% of the volume of essential oils produced, including orange, *Mentha arvensis* and lemon.

The 18 most important essential oils represent almost 75% of the world's total value. Almost 90% of the world's consumption of essential and absolute oils occurs in only 13 countries, led by the USA and China, which together hold 44% of world consumption.





FIGURE 2: Evolution of world production of essential oils



FAOSTAT, 2010

TABLE 7: World production of the main essential oils in 2008.

ESSENTIAL OIL	PRODUCTION (t)	ESSENTIAL OIL	PRODUCTION (t)
Orange	35000	Other mints	1000
Mentha arvensis	32000	Eucalyptus Citriodora	1000
Lemon	9200	Sassafras	1000
Eucayptus (Globulus)	4000	Chinese cedar	800
Peppermint	3300	Litsea cubeba	7 60
Lemon verbena	1800	Native mint	7 50
Clove	1800	Texas cedar	550
Lime	1800	Star anise	500
Lavandin	1100	Mandarin	460
Patchouli	1000	Virginia cedar	300

Source: CIEFH- CEPPARM, 2010

8.2.3. Extracts (active ingredients, medicine and supplements)

The plant extract is defined as the dry or liquid product obtained from plants or part of them with various procedures and with various solvents. Extracts of medicinal plants are widely used as dietary supplements and in the treatment of diseases. For example, valerian, echinacea root, ginseng, peppermint, feverfew, etc.





In geographical terms, the world market for herbal drug supplements is led by Germany (26%), Asia (19%), Japan (17%), France (13%), rest of Europe (12%) and North America (11%).

Principales productores de extractos a nivel mundial

Norte America Otros
11% 2% Alemania
26%

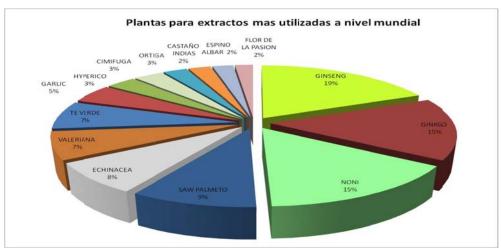
Japon
17%

Resto Europa
12%

GRAPH 3: Main producers of extracts worldwide

Source: Dr. Joerg Gruenwald, 2010.

Ginseng, Ginkgo and Noni, are the plants for extracts most used worldwide, reaching 49% of the total among the three. In turn, the exporting countries for extractive plants are led by China, the US and Germany. The US is the country with the highest unit value reaching 8000 \$/ton.



GRAPHIC 4. Plants for extracts most used worldwide

Source: Dr. Joerg Gruenwald, 2010





SUMMARY TABLEWORLD PRODUCTION

HERRS AND SPICES

- √ World production in 2009 was 7800779 t and 5538012 ha

- ✓ Main markets: IIS FIJ Janan
 ✓ Main sunnliers: China India Madagascar
 ✓ Most produced spices worldwide dried papers and ginger

FSSFNTIAL OILS

- ✓ World production in 2007 was 224000 t and 2500 million dollars ✓ Main essential oils: oranges, mentha arvensis and lemon.

FXTRACTS

- ✓ Main nroducers: Germany (20%) Asia (19 %) and lanan (17%)
- ✓ Main medicinal extracts. Ginseng Ginkgo and Noni





8.3. European market of medicinal and aromatic plants

8.3.1. Herbs and spices

The EU market for spices and herbs increased from 265 thousand tonnes in 2003 to 336 thousand tonnes in 2008. The EU's main consumer country is Germany, which accounts for 19% of total EU spice consumption, followed by UK (16%), Romania (14%) and Hungary (12%).

The EU countries show a very different evolution in the market of herbs and spices. In some, their consumption declines, while others, as Spain, have been one of the countries with the greatest evolution in consumption in recent years.

TABLE 8: Consumption of herbs and spices in Europe, Years 2004-2008 in thousands of tons.

COUNTRIES	2004	2005	2006	2007	2008	Annual change average %
UK	42,4	45,5	48,1	52,6	58,8	8,7
Germany	53,7	53,2	53,1	63,1	53,1	-0,3
Romania	40,9	41,2	40,1	37,8	43,1	1,3
Hungary	56,4	55,1	38,2	38,2	40,6	-7,9
France	14,7	17,2	15,5	20,2	22,1	3,0
Holland	17,8	19,1	14,3	22,6	20,8	-1,3
Spain	4,8	16,4	12,4	13,2	20,5	31
Belgium	11,7	10,6	10,1	10,8	10,3	-3,0
Poland	9	9,6	8,9	10,5	9,4	-0,7
Sweden	5,1	5,9	6,8	7,6	7,7	9,8
Austria	1,5	5,7	5,7	7,1	6,8	2,3
Italy	8,2	7,9	6,9	6,6	6,4	-5,9
Czech Republic	8,4	8,4	8,2	7,1	5,8	-8,0
Denmark	5,3	4,2	5,1	4,3	5,1	-2,3
Greece	4,4	4,0	4,5	4,4	4,6	1,6
EU 27	320,6	338,2	314,1	332,6	336,1	1,2

Source: FAOSTAT, 2010.

Production

Traditionally, the most of the herbs and spices production is concentrated in the of moderate and semitropical climate regions.

According to the ITC (International Trade Center), herbs and spices are mainly produced in developing countries, supplying approximately 55% of the world market. A few herbs and spices are produced in Europe.





The production of herbs and spices reached 154 thousand tons as we can see in Graphic 5. According to FAOSTAT, most of the spices produced in Europe are concentrated in Eastern European countries such as Romania, Hungary and Bulgaria. Although Spain also plays an important role, these three countries of Eastern Europe are responsible for 88% of EU production.



Graphic 5. Surface evolution and European production of spices.

Source: FAOSTAT, 2010

Of the total EU production, 62% are peppers (different Capsicum genera), 33% are spice seeds and 5% are other spices that have not been classified. The production of vanilla is almost insignificant, with small productions in Portugal.

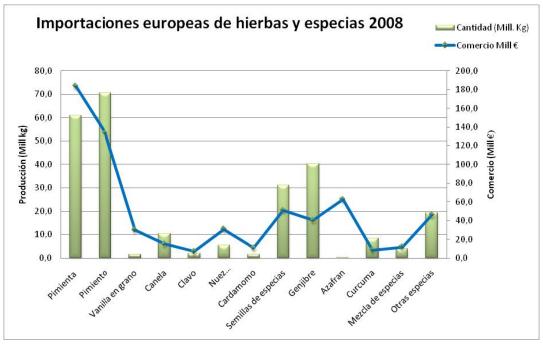
Comercio exterior

With approximately 28% of the EU's total imports of herbs and spices, whole or crushed pepper is the largest imported product, with Germany accounting for 32% of the largest importer.





Graph 6. European imports of herbs and spices in 2008



Source: FAOSTAT, 2010.

TABLE 9. European imports of herbs and spices in 2008

PRODUCT	COMERCIO (Mill. €)	PRODUCTION (Mill. kg)	UNIT VALUE (€/kg)
Black pepper	183,7	60,9	3,0
Pepper	133,5	70,5	1,9
Vanilla beans	30,1	1,6	18,8
Cinnamon	15	10,5	1,4
Clove	7	2,0	3,5
Nutmeg/Mace	30,8	5,4	5,7
Cardamom	11	1,6	6,9
Seeds of spices	51	31,0	1,6
Ginger	40,4	40,3	1,0
Saffron	62,6	0,141	444,0
Turmeric	8,7	8,5	1,0
Mixture of spices	11,7	3,9	3,0
Other spices	45,8	19,3	2,4
TOTAL	631,3	255,6	2,5

Source: FAOSTAT, 2010





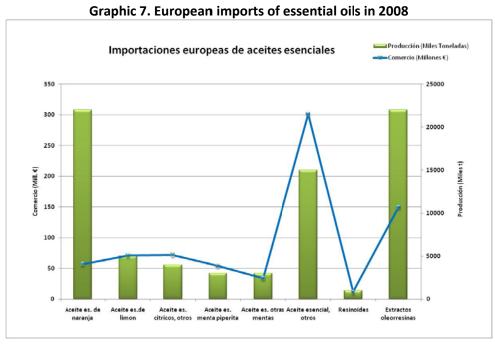
8.3.2. Essencial oils

The main market for essential oils is aimed at perfumery and fragrances, skin care, hair care and aromatherapy.

In 2008 the cosmetics market reached 68 billion € in retail sales, with France, Germany, UK, Spain and Italy being the market leaders with a 72% market share.

Accurate data on the consumption of essential oils are not available, since more than 3,000 plants are used to extract them, but we only find about 300 in the world market.

Foreign trade



Source: EUROSTAT 2010.

European imports increased between 2004 and 2008 by 6.3% in terms of value and by 0.9% in terms of volume imports, indicating an overall increase in prices.

The main importers of essential oils and oleoresins in the EU are France (26% of total EU imports), the United Kingdom (19%), Germany (19%), the Netherlands (9.2%), Spain (6.8%) and Italy (4.3%).





TABLE 10: Essential oils imports from Europe in 2009.

PRODUCT	(Thousands of t)	(Millions €)
Orange essential oil	22000	57
Lemon Essential Oil	5000	71
Citrus essential oil, others	4000	72
Peppermint essential oil	3000	54
Essential oil, other mints	3000	34
Essential oil, others	15000	301
Resin	1000	11
Oleoresin extracts	22000	149
TOTAL	75000	749

Source: EUROSTAT 2010.

Graphic 8. European exports of essential oils in 2008

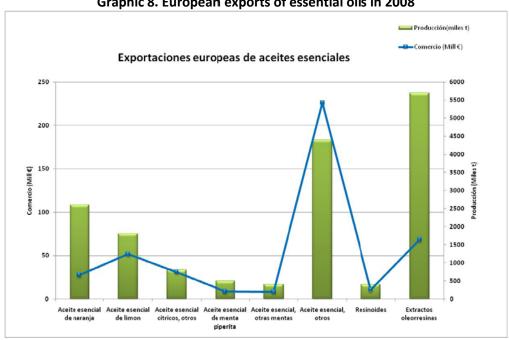






TABLE 11: Essential oils exports from Europe in 2009.

PRODUCT	(Thousands of t)	(Millions €)	
Orange essential oil	2600	27,5	_
Lemon Essential Oil	1800	51,5	
Citrus essential oil, others	800	31,1	
Peppermint essential oil	500	8,5	
Essential oil, other mints	400	8,2	
Essential oil, others	4400	226	
Resin	400	10,5	
Oleoresin extracts	5700	68,2	
TOTAL	16600	431,5	

Source: FAOSTAT 2010.

The EU's main exporter was France, representing 33% of EU exports. Other major exporters are the United Kingdom (16%), Germany (14%), Italy (10%), Spain (8.2%) and The Netherlands (8.1%).

Germany continues to grow in importance, but also Italy and Bulgaria show a strong increase. The main destinations were USA, Germany, Switzerland, France, Japan, the United Kingdom and Ireland.

Business chanels

In the business of exporting essential oils there are four different channels: agents or brokers, importers or traders, the processing industry (importer of processing), and the final product manufacturers. The trade structure illustrated in the following figure is constantly changing. The distribution channels and specific functions mentioned are not as clear as they appear.

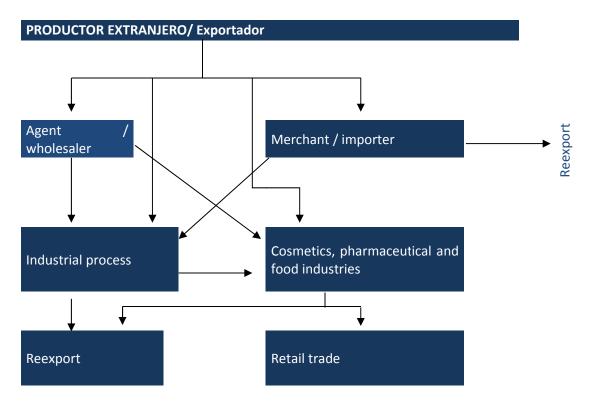
However, between sixty and eighty percent of the essential oil trade goes directly from producers or exporters to processing importers, such as multinational fragrances and flavors.

The essential oil market is fragmented among the following market sectors: aromatherapy, natural personal care cosmetics, pharmaceuticals products, perfumes and fragrances, and beverages.





Graphic 6. Distribution channels for essential oils



Price development

It is very difficult to note the overall price evolution of essential oils, due to the large number of essential oils marketed.

Nevertheless, it can be said that the price level of essential oils is influenced by:

- Quality factors: determined by origin country, climate, harvest, ingredients concentration and extraction method. The quantities produced have a great influence on the prices of essential oils.
- Factores económicos: Based on supply and demand. Supply depends on the size and yields of current harvests, stocks of traders, processors and end users, and the existence of synthetic substitutes.

On the other hand, in crops organically produced, fair trade certification and (for some products) wild collection, raw materials have a great influence on the price. These products are sold at higher prices than those produced conventionally.





SUMMARY TABLE – EUROPEAN MARKET

HERBS and SPICES

- Demand/import:
 - ✓ Main products: Pepper, black pepper, saffron, ginger, nutmeg
 - ✓ Main importing countries: Germany, Netherlands, United Kingdom
- Supply/export:
 - ✓ Main products: spices mixture, seeds, capsicum and saffron
 - ✓ Main exporting countries: Holland, Germany, Spain,

ESSENTIAL OILS

- Demand/import:
 - ✓ Main products: Oleoresin extracts, orange essential oil, lemon essential oil.
 - ✓ Main importing countries: France, United Kingdom, Germany
- Supply/export:
 - ✓ Main products: Oleoresin extracts, orange essential oil, lemon essential oil.
 - ✓ Main exporting countries: France, United Kingdom, Germany

EXTRACTS

- Demand/import:
 - ✓ Main products: Ginkgo, Hyperico, Valerian
 - ✓ Main importing countries: Germany, France, Italy
- Supply/export:
 - ✓ Main products: Ginkgo, Hyperico, Valerian
 - ✓ Main exporting countries: Germany, Bulgaria, Polland





8.4. Legislation and responsible administrations

8.4.1. Center and South America

Agriculture

Websites of the Ministries of Agriculture:

- Brazil http://www.agricultura.gov.br/
- Costa Rica http://www.mag.go.cr/
- Jamaica http://www.moa.gov.jm/

Medicines

Pan American Health Organisation (PAHO)

• http://www.paho.org/hq/?lang=es

Serie PARF network - Technical Document № 10. Pan American Network for Drug Regulatory Harmonization Working Group on Drug Registration. Medicines registration requirements of in the Americas. 2013

Brazil

National HealthSurveillance Agency http://portal.anvisa.gov.br/

Costa Rica

Regulation of Registration, Control, Import and Publicity of Medicines, Executive Decree No. 28.466-S Version 18 of the standard.

https://www.ministeriodesalud.go.cr/index.php/regulacion-de-la-salud/autoridad-reguladora-de-medicamentos

Jamaica

- Food and Drugs Regulation, 1975
- Pharmacy Regulations, 1975

Health and Food

Websites of the Ministries of Health and Food:

Brasil

- http://www.saude.gov.br/
- http://bvsms.saude.gov.br/

Costa Rica

https://www.ministeriodesalud.go.cr/

Jamaica

- http://moh.gov.jm/
- http://plataformacelac.org/es/pais/jam





Food protection:

Brazil

- Law No. 986 de 1969, Basic Food Standards http://www.anvisa.gov.br Portaria No. 1.428/MS de 1993, Technical Regulation for the Sanitary Inspection of Foods. Portaria No. 326/SVS/MS de 1997, Aprueba el Reglamento Técnico de Condiciones Higiénico-sanitarias y Buenas Prácticas de Fabricación para Establecimientos Productores/Industrializadores de Alimentos Agencia Nacional de Vigilancia Sanitaria (ANVISA)
- Ministry of Agriculture and Supply

Costa Rica

• Technical Regulation No. 100 de 1997 On Prepackaged Food Labeling. General Health Law, articles 196 to 238 Decree No. 26556-S, authorizes the use of synthetic and natural colorants in foods, provided that it complies with what is established in the Codex Alimentarius Decree No. 26559-MAG-S, companies or Food processing plants, products and by-products of animal origin, which establish the Risk Analysis and Critical Control Point (SARCPC) System, are subject to audit, inspection and control by the Ministry of Agriculture and Livestock.

Jamaica

Food and Drugs regulations, 1975 Public Health (Food Handling Regulations), 1998
 Standards (Labelling of Processed Food) regulations, 1974 Food Storage and
 Prevention of Infestation Act, 1973 Food Storage and Prevention of Infestation
 Regulations, 1973

8.4.2. Europe

Medicines

- http://www.ema.europa.eu/ema/
- http://www.emcdda.europa.eu/

Food and Agriculture

- http://ec.europa.eu/food/index en.htm
- http://www.efsa.europa.eu/

Species conservation

- CITES Agreement Reglamento 338/97 de 9 diciembre 1996, Reglamento 865/2006 de 4 mayo 2006 y otros.
- Convention on the Conservation of European Wildlife and Natural Habitats (Bern, 1982)
- CE Habitats Directive, Nature Conservation and Species Conservation law





8.4.3. International

Species conservation

- CITES: International trade in endangered species convention http://www.cites.org
- Agreement: Berna 1979, Rio Janeiro 1992, Johanesburg 2002
- Nagoya Protocol. 29th October, 2010
- Guidelines on the Conservation of Medicinal Plants, 1993, 2003 (WHO, IUCN, WWF)

8.5. Certifications

8.5.1. Production (wild collection and cultivation)

Environment:

 ISO 14000 (an international environmental management standard published in 1996). http://www.iso.org/iso/iso14000

Wild collection certification:

- http://www.ceres-cert.com/sp_recoleccion_sylvestre.html
- In ecological terms:
 http://www.imo.ch/imo_services_wildcollection_es,29115,22157.html

Cultivation:

- GLOBAL G.A.P.: http://www.globalgap.org
- Medicinal plants: GACP (Good Agricultural and Collection Practices). In Spanish: WHO
 Guidelines on Good Agricultural Practices and Collection (BPAR) for Medicinal Plants
 http://apps.who.int/medicinedocs/es/d/Js5527s/

Organic production:

- ECOCERT: http://www.ecocert.com/es/agricultura-ecologica
- DEMETER (Biodynamic agriculture):
 http://www.demeter.net/certification/standards/production
- Associazione Italiana per l'Agricoltura Biologica (ITALIA): http://www.aiab.it/
- Soil Association (REINO UNIDO): https://www.soilassociation.org/what-we-do/organic-standards/soil-association-organic-standards/farming-growing-standards/
- BIOSUISSE (Suiza): http://www.bio-suisse.ch/
- JAS (Japanese agricultural standard of ecological agriculture)
 http://www.ecocert.com/es/reglamento-japaneso-jas
- MAFRA Corea del Sur: http://english.mafra.go.kr/
- ACO Australia (Australia Certified Organic): http://english.mafra.go.kr/





8.5.2. Product manufacturing

Medicines:

- GMP (Good Manufacturing practices) for herbal products: WHO Guidelines on good manufacturing Practices (GMP) for Herbal Medicines (2007; 92 pages) http://apps.who.int/medicinedocs/en/d/Js14215e/
- GACP (BPAR).
- ICH (International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use): http://www.ich.org/products/guidelines.html

Food:

- HACCP (Hazard Analysis and Critical Control Points).
- The ISO 22000 international standard specifies the requirements for a food safety management system.

Veterinary:

GMP+ (Certification Scheme Animal Feed Sector). Approved by "Animal Feed Sector Central College of Experts 20/5/2005. Adopted by "Product Board Animal Feed" 7/6/2005. Effective date 1/1/2006. It offers an integrated quality assurance system based on ISO 9001:2000, HACCP e ISO 22000.

Cosmetics:

- COSMOS standard. Natural and ecological cosmetic certification. https://cosmosstandard.org/
- ECOCERT. Natural and ecological cosmetic certification. http://www.ecocert.com/es/cosmeticos-naturales-y-ecologicos
- Control IMO (ECOCERT / COSMOS)
 http://www.imo.ch/logicio/pmws/indexDOM.php?client_id=imo&page_id=cosmetic&l
 ang_iso639=en
- Soil association (REINO UNIDO): https://www.soilassociation.org/what-we-do/organic-standards/soil-association-organic-standards/health-beauty-standards/
- NATRUE True friends of natural and organic cosmetics: http://www.natrue.org/
- COSMEBIO (Francia). Natural and ecological cosmetic certification: http://www.cosmebio.org/
- BDIH (Alemania). Natural cosmetic certification. http://www.kontrollierte-naturkosmetik.de/e/index e.htm

Quality:

• ISO 9001:2000 (Quality management system)

Ecologic:

 EU EcoLabel. EU label that helps identify products and services that have a reduced environmental impact throughout their life cycle, from the extraction of raw materials through production, to their use and disposal. Recognized throughout Europe, EU





Ecolabel is a voluntary label for the promotion of environmental excellence that can be trusted. http://ec.europa.eu/environment/ecolabel/

- USDA Organic: http://www.usda.gov/wps/portal/usda/usdahome?navid=organic-agriculture
- DEMETER (biodynamic production): http://www.demeter.net/certification/standards/processing
- Natural Products Association (U.S.): http://www.npainfo.org/

8.6. Business opportunities for young people

Medicinal plants production is profitable when added value is given to primary production, that is a final product or service is marketed.

Unmet needs or market niches can be detected if a previous market study is carried out. For example, very specific products with extra quality, ecological, difficult to find or high consumption, etc.

But it is also possible to provide a service related to plants and education, including training, dissemination, advice, etc., addressed to an audience interested in the subject and using different methodologies. An example would be the recognition and identification of botanical species along with the explanation of uses through nature outings, conducting talks, as well as workshops. Create an aromatic garden is another option, as well as the research of ethnobotanical knowledge of the area and development of related products.

Peaple are a highly valuable intangible asset in a bussines and it is precisely these people who push projects with energy. One of the most complex areas is marketing and for this, training and being a good communicator is important.

Potential development activities are described below for:

- urban youth (herbal culture for health);
- rural youth (collection and cultivation of herbs for consumption and the local market);
- Youth social organization (a cooperative producing grass for sale in bulk or for products for the final consumer).

	Costa Rica	Brazil	Jamaica
Organización	Costa Rica Rainforest Outward Bound School	Go Brazil	Jamaica 4H Club
Topic	Adventure sports	They receive Young people from all around the world who come to study the language and culture.	School of agriculture and domestic economics for young people with economic difficulties.
Training	Young people from the	They have a social	Professional training.





	city who go camping	responsibility program	
	and do activities in	with local communities to	
	nature. Learn to know	develop an economic,	
	the herbs and their uses	local, regional or national	
	and preparations, as	activity.	
	well as do domestic		
	cultivation or a garden.		
Potential	Trip of medicinal and	Identification of local	Identification of local
activities	food flora recognition:	flora.	flora.
	identification and uses.		
		Recovery of	Recovery of
	Workshop of	ethnobotanical and	ethno botanical and
	preparations with herbs	scientific knowledge.	scientific knowledge.
	for food, medicinal and		
	cosmetic use.	Development of	Development of
		preparations.	preparations.
	Garden of useful plants.		
		Sustainable harvesting	Sustainable
		and ecological cultivation	harvesting and
		on a larger scale.	ecological cultivation
			on a larger scale.

8.6.1. Potential activities

Recognition trip of medicinal and food plants: Identification and uses.

This activity consists of trips following a route that can be marked or not. The route of about 2 kilometers, circular, must be very close to the facilities. In this tour, students must identify wild plants that grow mostly in the area. Each plant with medicinal uses can be identified in situ, or a written document of support for the educator and for the assistants can be elaborated, where the plants, their Latin and popular names, the part used and properties can be described.

It is necessary to take into account that each season of the year will be different regarding the flowering, landscape, etc. It can be used to work other subjects of nature, or to make cross training, with brushstrokes about customs, popular architecture, etc.

Calculate the time required to take the trip with ease. For a good teaching quality, the number of attendees should be around 15 people.

The main objective is to share knowledge, raise awareness and educate, to strengthen the link with nature.

It must be established if there will be a price or it will be free. Often, it is recommended to have some type of insurance that covers accidents or to explain in advance if there is any risk.

Indicate how the participants should be dressed and worn, if they should carry a camera, notebook, scissors or any other utensil.





Another fundamental aspect is the calendar of exits, the diffusion of the same, the management of the inscriptions. It is important to have ready the support documentation that will be given to the students, the issuance of attendance certificates and the educators training.

Once everything is organized and it is time to go out, it is better to make an initial presentation explaining the purpose of the trip, placing the attendees in the geographical area where they are, summarizing what is going to be visited, presenting the guide, etc.

Then, as the species are found, it is necessary to stop and wait for all the participants to arrive to begin the explanations about the plant species, the morphological description, anecdotes, names, uses, preparations, etc. Once the explanation is finished, to leave time for questions and to take the pictures calmly is advisable. You can then continue to the next plant.

When we know the route deeply, we can study another, with other plants.

Workshop of preparations with herbs for food, medicinal, cosmetic use

The steps to organize a workshop are: choose the topic, define the necessary time and set day and time.

To give this kind workshop it is necessary to define the objective, in order to be able to propose the training and methodology. The workshops are one of the very practical ways of imparting knowledge, as students observe and participate in making the preparations. It is preferable to start the training with a theoretical part that allows you to understand the "what and why", then perform the "how".

It is preferable to define the level of training, according it is aimed at beginners, people with a certain level or professionals.

The price of the workshop should be set, mainly because of the materials, because a practical workshop can involve little investment if it is demonstrative (the educator performs the preparations and the people observe), or greater investment if it is participatory and all the students do the workshop.

Dissemination is essential to complete attendance. Broadcasting, social networks and databases are an asset.

Of equal importance is the teacher, who should know widely the plants to be used, the ingredients, the methods of elaboration, understanding the reason of each step, and above all, the advice and utilities, conservation and rational and safe use.





Garden of useful plants

A garden is a creation that represents the author, is his footprint, his writing. It is an idea that conditions and modulates a landscape, whose main intention is to beautify a place. This garden, if it is also built with useful plants and adapted to the place, its maintenance will be low. Thus, it will fulfill sustainability, biodiversity and territorial integration parameters, including elements for the environment knowledge.

To organize a garden with useful plants, it is essential to know which species to start with. We recommend starting the experiment with few. The ideal is to make a list with the favorites, classifying those that require water on one side and on the other those that endure the drought.

Also mark the plants that are annual, and how will the family rotations be performed every year (the order would be the following: if we start with umbelliferous and liliaceae, are followed by solanaceae, then legumes and cruciferous are planted, and we end with quenopodiaceae and cucurbitaceae).

To start the design, you must take measurements of the space you are going to occupy. The ideal is to make a sketch specifying what type of sun exposure is available, orientation and slope, if it is a place exposed to the wind or a transit point, if water is available, ... Know the situation of faucets or organization of the irrigation system, type of soil and substrate necessary, composting and seedling trays place, where to store the utensils, etc.

This garden can be organized very simply or very complex, by themes, by colors, by shapes, in rows, flower beds or spirals, supported by geography and drawings of the land, taking advantage of different strata, combined with other structures, etc.

When defining a flower bed, we should consider leaving enough space around a plant, taking into account the size of the adult plant, as well as the height so that they all get sunlight. Most aromatic plants like the sun and withstand drought and little fertilization.

In addition, some plant useful by its own form can be used as a hedge, as a tapestry, as a climber or flower beds.

Aromatic plants with great ornamental beauty: Salvia sclarea, lilac (Syringa sp.), Violet, yarrow, bladder campion, wormwood, sagebrush, common heather (Calluna vulgaris), wild garlic (Allium sp.), Sunflower, marigold, cotton lavender (Santolina chamaecyparissus), lavender (Lavandula latifolia), lemon verbana, oregano, rosemary, rose, rue, elderberry, laurel, linden, olive, cypress, myrtle (Mirtus communis), juniper (Juniperus sp.), vitex (Vitex agnus-castus), Saponaria officinalis, Celtis australis, Amaranthus sp., basil, common snapdragon (Antirrhinum majus), Begonia gracilis (Begonia x tuberhybrida), borage, Cucurbita maxima, chive, carnation (Dianthus sp), wild mallow (Malva sylvestris) and common hollyhock (Alcea rosea), marshmallow (Althaea officinalis), rockroses (Cistus sp.), hawthorn (Crataegus sp.), honeysuckle (Lonicera sp.), thistles and many others.

Calendar in temperate zones:

 Spring: sowing of the plant with seeds or cuttings. Prepare the soil. Review of the irrigation system. Add compost. Plan and transplant taking into account plant requirements and planting framework. Control of adventitious and padded.





- Summer: irrigation, sun protection, harvesting and transformation. Control of pests and diseases. Control of adventitious and padded. Collect seeds.
- Fall: arvesting and transformation. Cuttings. Arrange the area of annual plants. Compost. Collect seeds.
- Winter: keep the seeds well. Look for new plants. Plan space, rotation and species association.

In tropical areas, it will be necessary to take into account the rainy season to start the plantations and to know adequately the vegetative cycle of native species.

Local flora identification

It is essential for any of the activities, whether the trips of recognition or the activities in botanical gardens.

It is recommended to consult flora books or botany websites about the local flora.

Recovery of ethnobotanical knowledge.

Ethnobotany studies the relationship between human societies and plants. It is evident the importance of ethnobotany for its recovery of local knowledge, a popular knowledge that is necessary to preserve and return to society disconnected from the natural world, acquiring awareness of the preservation and conservation of the natural environment and landscapes, as well as traditional knowledge.

Ethnobotany uses the knowledge of people with plant culture, elaborates a herbarium of the plant material and analyzes the results. All this complemented with a bibliographical investigation of the plants species of the zone.

<u>Development of traditional preparations.</u>

Based on ethnobotanical knowledge, contrasted with bibliography, information sheets, workshops or develop products can be developed for later commercialization.

Sustainable collection and ecological cultivation at small and/or medium scale

See PART I y II.





8.6.2. How to convert the idea into a professional reality: legal requirements

A profession aimed at producing plant products for the final consumer requires training, experience and knowledge. The latter must be of a technical, commercial and legal nature.

Herbal products on the market are distributed by many sectors, most of them very legislated.

The simplest way to start is by producing raw material, as it has lower requirements. Subsequently, or simultaneously, the elaboration of a foodstuff or a cosmetic is a possibility. The choice of a drug, a biocide or a pesticide means a very high investment. But if resources, personnel and facilities are available, it is obviously possible.

To be able to market, a sanitary authorization of facilities that distribute, store, pack, manufacture and/or import a food, medicine or cosmetic, must be requested, indicating what type of products are intended to be sold. The distribution and subcontracting of activities is the simplest way to obtain authorization. The other options complicate the contents of the request memory, drawings, quality assurance system, etc.

Professional dedication options are diverse; some ideas are shown below:

- Cultivation
- Sale of seeds
- Specialized nursery
- Gardener
- Development of equipment
- Irrigation installer
- Wild collection
- Essential oils distillation and active ingredients extraction
- Sale of fresh products: Fourth range
- Sale of dried plants
- Packaging and labeling.
- Production of food products
- Manufacturers of tea, tea, spices and seasonings, food supplements, others.
- Manufacturers of feed, premixes or feed additives.
- Manufacture of cosmetics
- Making extracts for agriculture: fertilizers.
- Distributor of raw materials: dried plant extracts, essential oils
- Product Distributor
- Trade, Sale





INFORMATION SOURCES

BIBLIOGRAPHY

A.Holfmann, C.Farga, J.Lastra, E.Vechazi. Plantas Medicinales de uso comun en Chile. Ediciones Fundación Claudio Gay. 1992

Alice L. Perez. Compendium of Medicinal and Aromatic

Alonso Quesada Hernandez. Plantas al Servicio de la salud. Costa Rica y entroamerica. 2008

Armando Caceres. Plantas de Uso Medicinal en Guatemala. Ed Universitaria San Carlos de Guatemala, 1999

Blanca Arrillaga de Maffei. Plantas usadas en medicina Natural. Hemisferio Sur, Montevideo, 1997.

Blumenthal M, Goldberg A, Brinckmann J. Herbal Medicine. Expanded Commision E Monographs. American Botanical Council, 2000.

BURILLO ALQUÉZAR, J. (2003) Investigación y experimentación de plantas aromáticas y medicinales en Aragón. Gobierno de Aragón.

CARBONNEL, F. (1998) Introducción a la Aromaterapia. Barcelona: Martorell. Pers- pectiva histórica de los aceites esenciales en España, situación actual y fichas de los aceites con gráficas de cromatografía de gases.

Caribbean Herbal Pharmacopoeia, 2 ed. 2007 Tramil

CYTED, CONAPLAMED, CONCYT. Memoria del I curso Iberoamericano de Fitoterapia Clinica y III Reunión RIPROFITO. 2000

Dominguez X.A. Métodos de investigación fitoquímica. Ed.Limusa. México. 1973.

Eduardo Alonso Paz, Maria Julia Bassagoda, Fernando Ferrerira. Uso racional de las plantas medicinales. Yuyos. Ed Fin de siglo, 2008.

ESCOP Monographs. The Scientific Foundation for Herbal Medicinal Products. 2ª ed. Thieme, 2003.

FANLO, M., MELERO, R., MORÉ, E., CRISTOBAL, R. (2009) Cultivo de plantas aromáticas, medicinales y condimentarías en Cataluña. 6 años de campos de demostración. CTFC, APSB.

Federico Varela Nieto, Joaquin Lopez Gonzalez. Las plantas aromáticas y medicinales. Potencialidad y retos de futuro. Conferencia Portugal. 2012

FERNANDEZ-POLA, J. (1996) Cultivos de plantas medicinales, aromáticas y condimenticias Ediciones Omega S.A Barcelona.





FERRER ALEGRE, F. (2002) Apuntes. Acppam. Cardedeu: Museu Arxiu Tomas Balvey.

Fichas populares sobre plantas medicinales. Tomo I y II. CEMAT y FARMAYA. Guatemala, 2000

FUNDACIÓN ALONSO MARTÍN ESCUDERO. Las Plantas de extractos. Bases para un plan de desarrollo del Sector. Melissa. SA Ed. Mundi Prensa. Trabajo amplísimo de los extractos.

G. F. Asprey, M.Sc., and Phyllis Thornton, Medicinal plants of Jamaica. PARTS I & II. Reprinted from the West Indian Medical Journal. Vol. 2 No. 4. Vol. 3 No. 1.

Héctor B. Lahitte, Julio A. Hurrell. Plantas Medicinales Riopltenses. LOLA 2004

I Jornadas Ibéricas de plantas medicinales, aromáticas y de aceites esenciales. (1989) INIA.

ICMAP: News

ITEIPMAI Le séchage. Chemille: Iteipmai.

ITEIPMAI. (1995) Le séchage. ITEIPMAI.

ITEIPMAI: Herbalia

Jorge Alonso. Tratado de Fitomedicina. ISIS, 1998

José Caribé / José Maria Campos. Plantas Que Ajudam o Homem. Cultrix / Pensamento

José Caribé, José Maria Campos. Plantas que ajudam a homem. Cultrix/Pensamento. 1997

Juan Tomás Roig. Plantas Medicinales aromáticas o venenosas de Cuba A-J. Editorial Científica-Técnica La Habana. 1991

Juan Tomás Roig. Plantas. Medicinales aromáticas o venenosas de Cuba L -Z. Editorial Científica-Técnica La Habana. 1989

Laerte Dall/Agnol Renê Bergel. Manual de Qualificação de Fornecedores de Plantas Medicinais e Aromáticas. Herbarium 2002

Les plantes de l'Arc Alpin: ressources pour le développment regional. (2003) Mediplant et Agroscope.

Les rendez-vous d'herbalia (2008) ITEIPMAI.

Luiz Claudio Distasi, Clélia Akiko Hiruma-Limo. Plantas medicinales Na Amazônia E na mata Atlântica Editorial Unesp 2002

Memento terapêutico programa de fitoterapia. edição 2002

MORÉ, E., FANLO, M., MELERO, R., CRISTOBAL, R. (2010) Guía para la producción sostenible de plantas aromáticas y medicinales. CTFC, APSB.





MUÑOZ, F. (1987) Plantas medicinales y aromáticas, estudio, cultivo y procesa- do. Mundi-Prensa. Muy interesantes los capítulos sobre cultivo, secado y destilación.

Plantas Medicinales caribeñas para la atención primaria. Manual práctico. Tramil, 2008

Plantas Medicinales Volumen II CIMED 2002

Plantas Medicinales. Fitomed. Ministerio de salud publica. Ecimed, 1993

plants-THE AMERICAS-Costa Rica. January 2014. University of Costa Rica

Prefeitura da Cidade do Rio de Janeiro, Secretaria Municipal de Saúde, Sub gerência de Programas de Fitoterapia

Projecto Plantas Medicinais. Itaipu Binacional. 2012

Proyecto de asistencia sanitaria de base con remedios a partir de plantas medicinales en las provincias de santa fe, misiones y buenos aires guia de buenas practicas de recolección y manufactura de plantas medicinales.

Revista de la FAO: Non-wood forest products

Rodolfo Barriga Ruiz. Plantas útiles de la Amazonia peruana: características, usos y posibilidades. CONCYTEC 1994

Semillas y plantel en agricultura ecológica (1998) Escola agraria de Manresa

Sérgio Franceschini Filho. Plantas Terapêuticas. Andrei 2004

Trease and Evans. Farmacognosia. 13 Edición. Bailliere Tindall. Mexico. 1989.

VAN GINKEL, A. (2008) Apuntes del Master y diplomatura de postgrado (acreditado por la UAB). "Plantas medicinales y fitoterapia. Módulo 2. Cultivo de plantas medicinales. Tecnologia y producción".

Vilda Figueroa, José Lama. El cultivo de las plantas condimentosas y su empleo en la cocina. La Hababa, 1999.

Vilda Figueroa, José Lama. Guia para conocer y ampliar el uso de las plantas de condimento en Cuba. La Hababa, 1997.

WHO monographs on selected medicinal plants. Volume 1 y volume 2. World Health Organization, Geneva, 1999, 2002.

WIJESEKERA, R.O.B. (1991) The medicinal plant industry. Washington: CRC Press.

Yedo Alquini, Nathieli Keila Takemori. Organização Estructural de Espécies Vegetais de interesse Farmacológico. Herbarium 2000





INTERNET

Legislación Europea

http://ec.europa.eu/health/documents/eudralex/index_en.htm

GMP - EudraLex - Volumen 4

http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm

European Medicines Agency

http://www.ema.europa.eu

http://www.fitoterapia.net

Botánica:

www.kew.org/plants-fungi/ http://www.theplantlist.org/

Cosmética:

http://ec.europa.eu/consumers/sectors/cosmetics/index_es.htm

http://ec.europa.eu/consumers/sectors/cosmetics/

Alimentos: Europa:

http://www.efsa.europa.eu/

http://ec.europa.eu/food/food/index_en.htm

http://www.efsa.europa.eu/

http://ec.europa.eu/food/food/foodlaw/index_en.htm

DG SANCO Seguretat alimentària (http://ec.europa.eu/food/index_en.htm)

Medicamentos: Europa:

http://www.ema.europa.eu/ema/

http://ec.europa.eu/health/documents/eudralex/index_en.htm

Public Health Europe - European Commission - http://ec.europa.eu/health/index_en.htm

Alimentación animal:

http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm_register_feed_additives 1831-03.pdf

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)

http://www.efsa.europa.eu/en/panels/feedap.htm

Guia de l'EFSA

http://www.efsa.europa.eu/en/feedapguidance/feedaptechguidance.htm

http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm_register_feed_additives _1831-03.pdf

http://www.feedmaterialsregister.eu/index.php?page=Presentation

EUROPAM www.europam.net

European producers association. GAP and GCP could be found.

CPPARM http://www.cpparm.org/la-filiere/les-organismes

French Committee on MAPs organisations.

ITEIPMAI http://www.iteipmai.fr/





French reseach institute on MAPs. Documentation, cultivation brochure.

APSB-CTFC http://apsb.ctfc.cat/
Research área on cultivation and wild collection of MAPs.

Agroscope http://www.agroscope.admin.ch/org/index.html?lang=en Swiss public agriculture reseach

MEDIPLANT http://www.mediplant.ch/en/welcome Swiss research institute on MAPs

F.I.P.P.O http://www.fippo.org/
Italian Federation of Medicinal Plants producers

http://www.pianteofficinali.org Consiglio per la Ricerca e la esperimentazione in Agricoltura

IFOAM www.ecoweb.dk/ifIFoam

HERBOTECNIA www.herbotecnia.com.ar Information on cultivation of medicinal, aromatic and dye plants. Very interesting the information technology in production, drying and cultivation of medicinal, aromatic and dye plants.

WWF-Adena www.wwf.es http://wwf.panda.org/

CITES http://www.unep-wcmc.org/cites

TRAFFIC http://www.wwf.org.uk/wildlifetrade/ www.traffic.org

International Standard for Sustainable Wild Collection of Medicinal and Aromatic Plants (ISSC-MAP) Version 1.0, 2007 http://www.floraweb.de/map-pro/

IUCN www.iucn.org

FAO www.fao.org

http://www.sld.cu/fitomed/index.htm

http://www.tramil.net/Tramil.html

www.orasconhu.org

http://www.noni.com.pa/