European Medicinal and Aromatic Plant (MAP) Farming, Processing and Training Alliance

‘Legislative Analysis on Wild MAP Collection and Production’

Table of Contents

1. Introduction

Plants are organisms belonging to Plantae kingdom and are a fundamental part of ecosystems. Most of the plants during photosynthesis use sunlight to produce organic compounds (i.e., sugars) and oxygen from carbon dioxide (CO_2) and water. There are more than 40, 000 reported useful plant species "documented as fulfilling a particular need for humans, animals, or the wider environment"[1]. However, two out of five plant species across the world are estimated to be at risk of extinction[1,2]. The increased interest about collecting and cultivating wild plants is due to their medicinal, nutraceutical, pharmaceutical, and health benefits[3]. Wild plants are excellent source of phytochemicals (i.e., terpenoids, flavonoids, phenolic acids, fatty acids, etc.) and they are usually noted in the literature as medicinal and aromatic plants (MAPs). MAPs are used to produce herbal medicine products which have become popular over the past decade[3]. To ensure appropriate and consistent quality of herbal medicinal plant substances it is necessary to establish good agricultural and collection practices (GACP) for herbal initial materials[4]. The European committee on herbal medicinal products (HMPC) provides specific guidelines associated with agricultural production and collection of medicinal plants/herbal substances in the wild[4].

Sustainable harvest is the most important conservation strategy for most wild-harvested species. It has been suggested that the plant population, species, and ecosystem diversity will be maintained by non-destructive harvest techniques[5]. The tolerance of wild plants to the harvesting varies and depends on several factors, including i) the lifespan of plant species, ii) the part of the plant that is harvested, iii) the abundance and growth rate of species harvested, and iv) the habitat where harvest takes place. For instance, slow-growing plants are more susceptible to heavy harvesting than those of weedy nature[2]. Globally, the primary source of information about the conservation status of plants and animals is the International Union for Conservation of Nature (IUCN) Red List of threatened species™ (www.iucnredlist.org). The IUCN Red List provides information on the taxonomic, ecological, threat, distribution, and

[1] Kor, L., Homewood, K., Dawson, T.P. et al. Sustainability of wild plant use in the Andean Community of South America. Ambio (2021). https://doi.org/10.1007/s13280-021-01529-7
[2] Papageorgiou, D., Bebeli, P.J., Panitsa, M. et al. Local knowledge about sustainable harvesting and availability of wild medicinal plant species in Lemnos island, Greece. J Ethnobiology Ethnomedicine 16, 36 (2020). https://doi.org/10.1186/s13002-020-00390-4
[3] Shikov, A. N., et al. (2017). "Traditional and Current Food Use of Wild Plants Listed in the Russian Pharmacopoeia." Frontiers in Pharmacology **8**: 841.
[4] European Medicines Agency Evaluation of Medicines for Human Use. London 20 February 2006. Doc. Ref. EMEA/HMPC/246816/2005.
[5] FAO. 2002. Biodiversity and the Ecosystem Approach in Agriculture, Forestry and Fisheries. Satellite event on the occasion of the Ninth Regular Session of the Commission on Genetic Resources for Food and Agriculture. Rome, 12-13 October 2002. Inter-Departmental Working Group on Biological Diversity for Food and Agriculture. Rome

conservation status of taxa that have been evaluated using the IUCN Red List categories and criteria (Figure 1). The aim of the current document is to summarize the legislation regarding the collection and production of wild MAPs in selected countries.

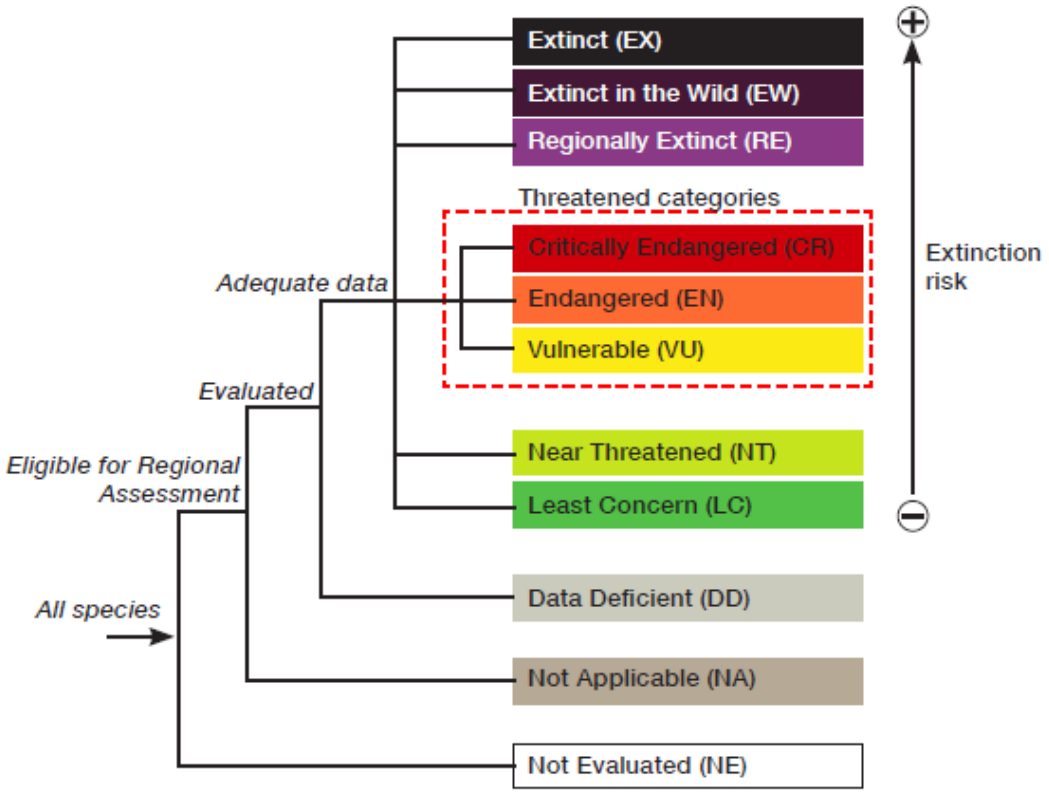

Figure 1. The IUCN Red List Categories at the regional scale (IUCN 2012)[6]. The Figure was obtained by[7].

2. Legislative analysis on wild medicinal and aromatic plants collection and production in selected European countries

2.1. Legislative analysis in Ireland

In the Republic of Ireland, the principal national legislation relevant to biodiversity are Wildlife Act 1976 and the Wildlife (Amendment) Act 2000. Sixty-eight vascular plant taxa are protected in the Republic of Ireland under the Flora (Protection) Order, 2015 (Statutory Instrument No. 365 of 2015) (Table 1, Appendix I)[8]. In the Republic of Ireland, it is illegal to

[6] IUCN. 2012b. Guidelines for Application of IUCN Red List Criteria at Regional and National Levels. Version 4.0. IUCN Species Survival Commission. Gland: IUCN.
[7] Allen, D., Bilz, M., Leaman, D.J., Miller, R.M., Timoshyna, A. and Window, J. 2014. European Red List of Medicinal Plants. Luxembourg: Publications Office of the European Union.
[8] Flora (Protection) Order, 2015.

cut, uproot or damage the listed species in any way, or to sell them. This prohibition extends to the taking or sale of seed. Additionally, it is illegal to alter, damage or interfere in any way with their habitats. This protection applies wherever the plants are found and is not confined to sites designated for nature conservation. The Red List was a commitment in Ireland's National Biodiversity Plan for 2011–2016 (DAHG 2011) and is also one of Ireland's Global Strategy for Plant Conservation targets[9].

Ireland's 3rd National Biodiversity Action Plan (NBAP) 2017-2021, arising from the UN Convention on Biological Diversity (CBD) targets, sets out actions to achieve Ireland's Biodiversity. However, wild MAPs have not been directly included on the agenda. The most important conservation strategy for most wild-harvested plant species is sustainable harvesting. It is suggested that specific legislation and/or guidelines for wild MAP collection are required to be developed and implemented in Ireland as part of the conservation of wild plant species.

Medicinal products that are made from substances contained in plants and may be used to treat diseases, are known as herbal medicinal products. Even though they are natural, they may be dangerous when received without prescription and at the wrong concentration. Therefore, they are covered by pharmaceutical legislation, which aims to protect public health by ensuring the safety, efficacy, and quality of medicinal products. In Ireland, the Health Products Regulatory Authority (HPRA) regulates medicines and devices for the benefit of people and animals. Herbal medicinal products on the Irish market must be either authorized or registered with the HPRA. The HPRA regulates the licensing and sale of medicinal products for human use in Ireland in accordance with the requirements of the Medicinal Products (Control of Placing on the Market) Regulations (S.I. No. 540 of 2007), as amended, and relevant EC Directives, in particular Directive 2001/83/EC as amended by Directive 2004/27/EC and Directive 2004/24/EC. The Directive 2004/24/EC inserted a new chapter (chapter 2a). This chapter contains specific provisions applicable to traditional herbal medicinal products (THMPs) in articles 16a-h. The Traditional Herbal Medicinal Products Directive (2004/24/EC) came into effect in Ireland on the 23 July 2007 (S.I. No. 540 of 2007).[10] According to HPRA, a traditional herbal medicinal product (THMP) must be:

[9] Wyse Jackson, M., FitzPatrick, Ú., Cole, E., Jebb, M., McFerran, D., Sheehy Skeffington, M. & Wright, M. (2016) Ireland Red List No. 10: Vascular Plants. National Parks and Wildlife Service, Department of Arts, Heritage, Regional, Rural and Gaeltacht Affairs, Dublin, Ireland.
[10]http://www.hpra.ie/homepage/medicines/regulatory-information/medicines-authorisation/herbal-medicines/information-for-the-public-thmps

- intended and designed for use without the intervention of a medical practitioner;
- taken orally, for external use or inhalation (not administered by injection);
- administered exclusively at a specified strength and dose;
- on the market for a 'period of traditional use'

Some examples of the herbs used in THMPs include devil's claw, valerian, *Echinacea purpurea* and *Ginkgo biloba*. The botanical name for each herb used in a THMP is stated in the product information, as this is a more exact way of naming and identifying the plant. Traditional herbal medicinal product currently registered by the HPRA can be found in the following link: https://www.hpra.ie/homepage/medicines/medicines-information/herbal-medicines-list.[11]

2.2. Legislative analysis in Italy

In Italy, the production of MAPs is regulated according to different categories: drugs, food supplements, herbal preparation, and cosmetics. The main legislations setting a framework for these categories are:

• **Legislation 6 January 1931 n. 99/1931** defines what the so-called "piante officinali/MAPs" which does not exactly correspond to medicinal plants as this term is an Italian specificity that includes different plant species divided into three categories: medicinal, aromatic, and perfume plants. The "piante officinali" (medicinal plants) can be processed in a laboratory and can be used for their active substances to produce herbal drugs. This law regulates their cultivation, harvesting and commercialization.

• **Legislation 30 October 1940 n. 1724** regulates the harvesting and selling of chamomile.

• **Legislation 9 October 1942 n. 1421** sets the legislative framework for the harvesting and selling of foxglove.

• **DLvo 29 May 1991, n. 178** is the relevant legislation for every medicine including medicinal plants, which means that they are subject to the same rules as the other medicines and necessitate an authorization from the Health Department. It transposes the Directive CEE 65/65 according to which a product should be considered as a medicine as soon as it is recognized to have therapeutic effects.

[11] http://www.hpra.ie/homepage/medicines/regulatory-information/medicines-authorisation/herbal-medicines

• **DLvo 27 January 1992, n. 111** sets the legislative framework for herbal preparation used as food or food supplements and transposes the Directive n. 89/398/CEE. It makes compulsory a notification to the Health Department before commercialization.

• **L. 94/1998** on clinical experimentation in the oncological field and other measures about sanity.

• **D. Lgs. 21 May 2001, n. 169** on dietary supplements.

• **Article 1 of D. Lgs. 24 April 2006, n. 219** about medicines for a human use.

• **D.M. 27 March 2014** on the use of vegetal substances and preparations in food supplements; it also added to the already legal botanicals the BELFRIT list including a lot of new botanicals that can be used in food supplements. It updates the lists established by the following legislation: R.D. 772, 26 May 1932 defining a list of spontaneous medicinal plants subject to the law. 99/1931 and the "Circolare Aniasi" (Circolare 1 of the January 8th 1981, Health Department) that enclosed two lists including examples of plants that can be dispensed only by pharmacists in drugstores or by herbalists in spice shops.

2.3. Legislative analysis in Greece

In General, there is no specific regulation or legislation for the cultivation (production), packaging, certification, and labelling of MAPs in Greece but the corresponding legislation - regulation applied for all food and agricultural products. Additionally, Greece is always trying to comply with the European Regulation, aiming the Greek producers to blend with the Quality certifications for agricultural and other food products, databases, protection and control set by the European Union (such as organic certification, Geographical Indications: Protected Designation of Origin-PDO, Protected geographical indication (PGI).

A) The National (Hellenic) Regulation

1. Ministerial Decision No. 2543/103240 (ΦΕΚ 3529/B/ 09.10.2017) laying down the additional measures necessary for the implementation of the Commission Regulation (EC) No. 834/2007 of the European Council (EE L 189, 20.7.2007,p.1) and of the Regulations 889/2008 (EE L 250 της 18.9.2008, σ. 1) και 1235/2008 (EE L 334 της 12.12.2008, σ.25), in reference to the organic method of production, labelling and control of biological plant, animal and aqua-culture products, as well as the importing regulations from third countries. (In Greek: YA 2543/103240 ΦΕΚ 3529/B/ 09.10.2017/ (Καθορισμός των αναγκαίων συμπληρωματικών μέτρων για την εφαρμογή των διατάξεων του Κανονισμού (ΕΚ) αριθ. 834/2007 του

Συμβουλίου (ΕΕ L 189 της 20.7.2007, σ. 1) και των Κανονισμών 889/2008 (ΕΕ L 250 της 18.9.2008, σ. 1) και 1235/2008 (ΕΕ L 334 της 12.12.2008, σ.25) της Επιτροπής, σχετικά με τον βιολογικό τρόπο παραγωγής, την επισήμανση και τον έλεγχο των βιολογικών προϊόντων φυτικής, ζωικής παραγωγής και υδατοκαλλιέργειας, καθώς και τους όρους εισαγωγής βιολογικών προϊόντων από τρίτες χώρες.

2. Joint Ministerial Decision No. 245090/11/01/2006 Establishing additional measures for the implementation of the Regulation (EOK) 2092/91 of the European Council regarding the organic production and labelling of organic products and nutrition' products (In Greek: ΚΥΑ αριθμ. 245090/ 11.01.2006 (ΦΕΚ 157/Β/2006) Καθορισμός συμπληρωματικών μέτρων για την εφαρμογή του Καν. (ΕΟΚ) 2092/91 του Συμβουλίου «περί του βιολογικού τρόπου παραγωγής γεωργικών προϊόντων και των σχετικών ενδείξεων στα γεωργικά προϊόντα και στα είδη διατροφής» ως έχει τροποποιηθεί και ισχύει».

3. Ministerial Decision No. 336650/22.12.2006 (ΦΕΚ 1927/Β/ 2006) "Details on the implementation of the Joint Ministerial Decision 245090/11/01/2006 (ΦΕΚ157/Β2006) regarding laying down the additional measures for the implementation of the Regulation (EOK) 2092/91 of the European Council regarding the organic production and labelling of organic products and nutrition' products (In Greek: Υ.Α. 336650/22.12.2006 (ΦΕΚ 1927/Β/ 2006) Λεπτομέρειες εφαρμογής της αρ. 245090/11.1.2006 (ΦΕΚ157/Β/2006) Κοινής Υπουργικής Απόφασης «Καθορισμός συμπληρωματικών μέτρων για την εφαρμογή του Καν. (ΕΟΚ) 2092/91 του Συμβουλίου «περί του βιολογικού τρόπου παραγωγής γεωργικών προϊόντων και των σχετικών ενδείξεων στα γεωργικά προϊόντα και στα είδη διατροφής» ως έχει τροποποιηθεί και ισχύει).

4. Ministerial Decision No. 296851/21.06.2017 "Details of the implementation of the Joint Ministerial Decision regarding laying down the additional measures for the implementation of the Regulation (EOK) 2092/91 of the European Council regarding the organic production and labelling of organic products and nutrition' products (In Greek: ΥΑ αριθμ. 296851/21.06.2007 (ΦΕΚ 1114/Β/2007) Λεπτομέρειες εφαρμογής της υπ' αριθμ. 245090/11.1.2006 (ΦΕΚ 157/Β/2006) κοινής υπουργικής απόφασης «Καθορισμός συμπληρωματικών μέτρων για την εφαρμογή του Καν. (ΕΟΚ)2092/91 του Συμβουλίου «περί του βιολογικού τρόπου παραγωγής γεωργικών προϊόντων και των σχετικών ενδείξεων στα γεωργικά προϊόντα και στα είδη διατροφής» ως έχει τροποποιηθεί και ισχύει.

5. Joint Ministerial Decision No. 295194_ 22.04.2009 "Establishing additional measures for the use of propagating material in organic farming pursuant to Regulations (EC) 834/07 and (EC) 889/08 as they apply at any time."(In Greek: ΚΥΑ 295194 αριθμ. 22.04.09 (ΦΕΚ 756/Β/2009) Καθορισμός συμπληρωματικών μέτρων για τη χρήση πολλαπλασιαστικού υλικού στη βιολογική γεωργία σε εφαρμογή των Κανονισμών (ΕΚ)834/07 και (ΕΚ)889/08, όπως αυτοί κάθε φορά ισχύουν.

6. Ministerial Decision No. 2543/103240 "Establishing additional measures for the implementation of the Regulation no 834/2007 of the European Council EE L 189/ 20.7.2007, p. 1 and 1235/2008 (EE L 334/12.12.2008, p.25) of the European Commission regarding the organic production, labelling and control of the biological products of plant, animal and aqua-culture, as well as the terms of biological products imports from third countries. (In Greek: ΥΑ 2543/103240 (ΦΕΚ 3529/Β/ 09.10.2017 Καθορισμός των αναγκαίων συμπληρωματικών μέτρων για την εφαρμογή των διατάξεων του Κανονισμού (ΕΚ) αριθ. 834/2007 του Συμβουλίου (ΕΕ L 189 της 20.7.2007, σ. 1) και των Κανονισμών 889/2008 (ΕΕ L 250 της 18.9.2008, σ. 1) και 1235/2008 (ΕΕ L 334 της 12.12.2008, σ.25) της Επιτροπής, σχετικά με τον βιολογικό τρόπο παραγωγής, την επισήμανση και τον έλεγχο των βιολογικών προϊόντων φυτικής, ζωικής παραγωγής και υδατοκαλλιέργειας, καθώς και τους όρους εισαγωγής βιολογικών προϊόντων από τρίτες χώρες).

Some extra useful regulations and circulars:

ΥΑ number. 7594/115508/12-09-2014 (GG 2663 B): Technical regulation for the marketing of propagating material of aromatic and medicinal plants.

• No. 133581/3471/10-7-2013 Circular of the Special Secretary of Forests (SAA: SEE 410-N1) on the protection of aromatic-apiculture and medicinal herbs of the country

• No. 40332/2014 decision of the Ministry of Environment, Energy and climate Change (issue B, Sheet No. 2383), "Adoption of a national strategy for biodiversity for the years 2014 − 2029 and action plan for the five-year duration"

According to the Joint Ministerial Decision 131759/3479/2015 (GG 2564 B '), the issues of the establishment and operation of forest nurseries (public and private) are regulated to produce and trade forest reproductive material. The provisions of the Joint Ministerial Decision shall apply to propagating material of forest species and hybrids intended for forest and non- forest

purposes and specifying the conditions for the authorization of the establishment and operation of such products.

• P. D 17/2003 (GG) in compliance with Directive 1999/105/EC on the marketing of Forest reproductive material. Its provisions regulate issues of collection, production and marketing of forest reproductive material for forest or non- forest purposes in the country and in dealings with the other MS of the EU (47 types of common interest in the EU). National and European directory and source maps are drafted.

• P. D 100/2014 (GG 167 A') "Hellenic Ministry of Agriculture", in the Department of Forest Nurseries, Forest Genetic Resources and Reforestation, is responsible for the establishment of nurseries, import licenses, seed certification, care for the collection, ginning, control, distribution and disposal.

2.4. Legislative analysis in Spain

In Spain, MAPs are marketed unprocessed (fresh, frozen or dried) as condiments and herbal products, while if processed (essential oils, extracts, essences), they are destined for the food, pharmaceutical or cosmetic industry. The legal framework that regulates medicinal and aromatic plants has had to take into account their traditional consideration, their final destination or the application of the same by the producers. In Spain, there are laws regulating the production of MAPs, however, there are no specific regulation or legislation for the packaging, certification, and labelling of MAPs.

Laws regulating production of MAPs in Spain:

- Order of 3 October 1973 establishing the special register for preparations based on medicinal plant species (BOE 247/1973 of 15 October 1973).
- Law 25/1990 of 20 December 1990 on medicinal products (BOE 306/1990 of 22 December 1990).
- Order SCO/190/2004 of 28 January 2004 establishing the list of plants whose sale to the public is prohibited or restricted on account of their toxicity (BOE 32/2004 of 6 February 2004).

2.5. Legislative analysis in Turkey

In General, there is no specific regulation or legislation for the cultivation (production), packaging, certification, and labelling of MAPs in Turkey. The corresponding legislation - regulation applied for MAPs seed certification and marketing regulation. The regulation on medicinal and aromatic plants was as follows with Official Gazette Date: 17.01.2008 Number of Official Gazette: 26759.

FIRST PART

Purpose, Scope, Basis and Definitions

Purpose and scope

ARTICLE 1 – (1) This Regulation covers the procedures and principles regarding the production and marketing of seeds of oily, fibrous, medicinal and aromatic plants by real or legal persons within the certification system in order to ensure the production of seeds of high quality and in accordance with standards.

Rest

ARTICLE 2 – (1) This Regulation is based on Article 6 of the Seed Law No. 5553 dated 31/10/2006 and Article 3 of the Law No. 969 dated 21/12/1967 on Granting Revolving Funds to Central and Provincial Institutions of the Ministry of Agriculture and Rural Affairs. has been prepared.

Definitions

ARTICLE 3 – (1) In this Regulation;

a) (Amended: OG-18/2/2020-31043) Ministry: The Ministry of Agriculture and Forestry,

b) Application institution: The provincial directorate of the Ministry in the province where the production is made or the institutions authorized by the Ministry for declaration acceptance and field controls,

c) Variety owner: Person or organization responsible for the production, reproduction or preservation of the variety of seeds of the varieties that are eligible for certification and that are registered,

ç) Variety purity: The ratio of varieties different from the genotype of the seed,

d) Elite seed: The seed that is the beginning of the original seed and the source of the seeds in other classes, controlled directly by the breeder or the authorized institution, which has been duly preserved and maintained despite being newly bred or improved in previous years,

e) Raw seed: Final uncertified seeds produced in original and certified seed classes,

f) Raw seed certificate: The document issued for the seeds produced in original and certified seed classes and which are not finally certified,

g) Isolation distance: The minimum distance to prevent pollination between the production of species, genera and varieties that can pollinate and fertilize each other in seed production areas,

ğ) (Amended: OG-14/9/2008-26997) General Directorate: General Directorate of Agricultural Production and Development,

h) Inspector: Public officials or private persons authorized by the Ministry as seed controllers, who carry out checks on seed certification, take samples and conduct market audits and issue documents on these matters,

ı) Original seed: The seed obtained from or from the elite seed, maintaining the purity and health of the variety, grown in research, breeding and testing institutions or under the supervision of these institutions,

i) Pure seed: The generative or vegetative propagation parts of the same plant variety, the foreign materials of which have been removed,

j) Certified seed: Original seed or seed obtained from it, which maintains the purity and health of the variety,

k) Certification body: Organizations authorized by the Ministry with certification,

l) Supplier: Persons or organizations that reprocess or market seeds obtained from seed producers,

m) Seed stage: The production time of the seed in any class in years,

n) Seed sample: Seed in unit weight to be subjected to laboratory analysis and tests specific to the seed type in order to determine the characteristics of the lot and to issue a certificate or report as a result of the seed lot,

o) Seed standard: Quality measures that determine the physical and biological qualities of the seed,

ö) Seed producer: Persons or organizations that produce or contractually produce, process and market seeds,

p) Seed grower: Persons or organizations that contractually produce on behalf of seed producers,

r) Seed lot: In the seed control and certification system, the maximum amount of seed determined according to the type of seed, represented by a certificate or report, which is the basis for taking a sample,

s) TTSM: Seed Registration and Certification Center Directorate,

ş) Production season: The period from 1 July to 30 June of the following year means.

SECOND PART

Certification and Marketing Principles

General conditions

ARTICLE 4 – (1) The general provisions regarding the certification system and marketing are listed below.

a) In order for the seeds belonging to the species in Annex 1 to be produced in the certification system, it is required that the varieties to which the seeds belong are registered.

b) Seeds are produced and marketed by real or legal persons authorized by the Ministry.

c) Elite and original seed productions are produced and marketed by breeders, variety owners or research institutions authorized by them.

ç) It is essential that the seeds are certified within the production season in which they are produced. For seeds that cannot be marketed within the same production season, germination analyzes should be performed before being offered to trade.

d) Traceability in seed production; It is provided with the declaration number before sampling and with the batch number after sampling. Declaration numbers and batch numbers are not repeated even if the type or type changes. The declaration number and the field control report number are given in the form of "Producer organization code number / Sequence number".

Submitting a declaration

ARTICLE 5 – (1) In order for the seeds to be certified, a seed declaration is submitted.

(2) The issuance and acceptance of seed declarations are made by the following method.

a) For seed production, the appropriate declaration in Annex-2 or Annex-3 is filled.

b) A separate seed declaration is prepared for each seed type, each parcel or each field.

c) (Amendment: OG-18/2/2020-31043) In applications with wet signatures, seed declarations are prepared in three copies.

ç) Seed declarations are submitted to the application institution within thirty days from the date of sowing.

d) (Amendment: OG-18/2/2020-31043) The seed declarations, which are signed with wet or electronic signature during the application, are submitted to the application institution electronically or physically, with the attachments consisting of the following documents.

1) The original of the certificate of the sown seed or a certified copy from the official institution where the original of the certificate is located,

2) Trait documents of the variety or parents,

3) Sketches showing the production fields is added.

e) The first copy of the accepted and approved declarations is kept in the institution that accepts the seed declaration. The second copy is given to the controllers for use in field controls. The third copy is given to the manufacturer by stamping "NOT AVAILABLE FOR CERTIFICATION".

Field controls

ARTICLE 6 – (1) Field inspections are carried out in accordance with the following principles.

a) Field control is carried out by controllers authorized by the Ministry. After the completion of the field inspection, the inspector issues the field inspection report in triplicate, taking into account the declaration information and field inspection standards.

b) There is no erasure or scraping in the reports. If the change is mandatory, it is initiated by the controller after the correct one is written by crossing out the mistake.

c) The first copy of the field control report is kept in the application institution to be sent to the certification body and the second copy to be used in case of objection. The third copy is given to the manufacturer by stamping "NOT AVAILABLE FOR CERTIFICATION".

ç) According to the field controls, the class or level of the seed is marked. In case of not being able to enter any class or losing the class, the reasons for this are recorded in the field control report by the controller and the reason for losing the class is circled.

d) If there are reasons that prevent the seed from entering the desired class in field control and if it is technically possible to eliminate these obstacles by the breeder, the farmer is given the field control notification in Annex-4. At the time specified in the notice, field control is carried out by the controller again.

e) As a result of the controls made in the parcels, the seeds are required to comply with the field control standards in Annex-5.

Packaging and labeling

ARTICLE 7 – (1) Seeds are put up for sale after being packaged and labeled in accordance with the officially determined conditions. The conditions to be sought in packaging and labeling are specified in Annex-6.

(2) Labels are obtained from the TTSM or the institution authorized by the Ministry according to the results of the field control report.

Seed samples

ARTICLE 8 – (1) Seed samples are taken in accordance with the seed sampling principles determined by the Ministry and sent to the relevant certification body.

(2) Minimum sample amount, maximum package and lot sizes of seed lots are specified in Annex-7.

Marking of seed lots

ARTICLE 9 – (1) Seed lots are numbered in the format TR.00.KKKK.NNNN. In numbering;

a) TR: Country code,

b) 00: The license plate number of the province where the seed is produced,

c) KKKK: Manufacturer code number given by TTSM,

ç) NNNN: Indicates the lot sequence number of the seed.

2) If a seed sample is to be sent to the laboratory for moisture determination, the samples are taken in accordance with the principles determined by the Ministry and sent to the relevant certification body.

Laboratory controls

ARTICLE 10 – (1) Laboratory analyzes of seeds are carried out by seed certification bodies assigned or authorized by the Ministry.

(2) Seed certification bodies carry out the necessary laboratory analyzes on the seed samples sent to them for the purpose of issuing certificates or issuing an analysis report and issuing a certificate or report.

(3) If the sample amount is below the minimum sample amount, the samples are not subjected to laboratory analysis.

(4) Seeds must comply with the standards in Annex-8 as a result of laboratory controls.

(5) In laboratory analysis of seed production of plant species within the scope of the regulation, Avena fatua, Avena ludoviciana, Avena sterilis, Cuscuta spp. rates must be zero.

Evaluation and documentation of laboratory analysis results

ARTICLE 11 – (1) As a result of the laboratory analyzes carried out by the seed certification bodies, a certificate or report is issued to the seeds.

(2) (Amendment: OG-14/9/2008-26997) Seed certificates and reports are issued by certification bodies in accordance with the format determined by the General Directorate.

(3) At the request of the producer, a raw seed certificate is issued for the harvested, unprocessed seeds.

(4) Samples are taken from the seeds to be certified with a raw seed certificate. If the manufacturer requests, the analysis results are reported to the manufacturer.

(5) Seeds with a raw seed certificate cannot be sold to end users.

(6) Seed certificates and reports are issued in triplicate. The first copy of the certificate or report is given to the producer, the second copy is kept in the certification body, and the third copy is sent to the application body that sent the sample.

(7) A seed analysis report is prepared for the analysis results of the inspection samples taken during the market inspections of the seeds and it is stated that it is an inspection sample.

(8) The results of the analysis are reported to the persons or organizations who want to learn the quality value of their seeds, without seeking the origin of the seed and its compliance with the standards, based on the owner's declaration and by performing the requested tests.

(9) As a result of laboratory analysis, a report of no seeds is issued for the seeds represented by the sample that does not meet the standards of any of the seed classes. The parties represented by the sample, for which the report cannot be seed, are not considered as seeds and are not marketed.

(10) For the certified seeds in stock that are not sold within one year, a germination analysis is performed, a seed analysis report is prepared, and the name of the organization issuing the certificate and the phrase "valid with the certificate dated ….. and numbered …." are written in the considerations section.

Repeating laboratory analyses

ARTICLE 12 – (1) If the class of the seed has dropped or lost due to the laboratory analysis, the rate of inanimate foreign matter, weed and weed seeds, other crop seeds exceeds the standards or the pure seed rate is lower than the standard due to these factors; The seed producer may request that a sample be taken from the seed produced by re-selection and that this sample be subjected to laboratory analysis. This request is made to the applicant institution with the following documents as an attachment to a petition.

a) Field control report,

b) The original of the certificate or report issued by the certification body,

c) Re-analysis form in Annex-9.

(2) The application body takes a seed sample from the seed, which is reselected by the producer, and sends it to the relevant certification body, adding the sample sending protocol and a copy of the above documents.

(3) The relevant certification body makes the necessary analyzes. The first copy of the certificate or reports issued as a result of the analysis is sent to the manufacturer and the second copy to the application institution. The third copy is kept in the certification body. In the comments section of this certificate or report, which certificate or report is valid is written.

Objection to laboratory analyses

ARTICLE 13 – (1) Producers or breeders may object to laboratory analyzes made by seed certification bodies within thirty days at the latest from the date of receipt of the certificate or report.

(2) TTSM, the reference laboratory, is authorized for objections regarding laboratory analysis.

(3) Objection to the laboratory analyzes made by the seed certification bodies is made to the application body with the following documents as an attachment to a petition.

a) Field control report,

b) The original of the certificate or report issued by the certification body,

c) Analysis Objection Form in Annex-10.

(4) The applicant institution sends the witness sample of the seed subject to the objection to TTSM by adding the above documents.

(5) The first copy of the certificate or reports issued as a result of the analysis is given to the producer. The second copy is kept in the certification body. The third copy is sent to the application institution. In the comments section of this certificate or report, which certificate or report is valid is written.

(6) The certificate or report given as a result of laboratory analyzes re-performed by TTSM, which is accepted as the reference laboratory, is final.

Repackaging and labeling of seeds

ARTICLE 14 – (1) Repackaging, labeling and certification of seeds certified with a raw seed certificate is done as follows.

a) Seed owner organization applies to the application institution in the province where the seeds are located, with the raw seed certificate.

b) The labels on the packages belonging to the lot represented by the certificate are removed by the controller and the amount of seeds represented by the removed labels is determined.

c) Producers or suppliers request a sample to the application body after packaging and labeling the seed lots.

ç) Mixing can be made from different seed lots, provided that the type, class and grade are the same. The manufacturer or supplier is obliged to keep the reference numbers of the parties that make up each piece and the records showing the ratio of the parties that make up the pieces in the blend and notify them to the application institution.

d) The controller takes samples from newly created lots. The date and number of the certificate given at the time of application and the batch number or numbers are recorded in the sample sending protocol, and the original of the raw seed certificate is sent to the relevant certification body.

e) Certification bodies carry out the necessary laboratory analyzes on the seed samples sent for the purpose of issuing certificates and issue certificates or reports in accordance with the provisions of Article 11.

(2) Imported seeds can be offered for sale as they are imported without their original packaging intact, or they can be divided into small packages by the importing company and repackaged under the following conditions.

a) The repackaging and labeling of these seeds is carried out by TTSM in accordance with the provisions of the first paragraph.

b) OECD-labeled seeds, written consent is obtained from the authorized certification body of the imported country by the importing company.

c) The quality criteria and all responsibilities related to the certification of these seeds belong to the supplier or seed producer who imports and repackages them.

ç) Packages can be opened and repackaged only by the importing supplier or seed producer.

d) The importer company that opens and packs the packages will put the phrase "This seed was imported by our company and packaged domestically by our company" in addition to the information that should be on the seed labels on the new packages.

e) Seeds that are relabeled and packaged within the framework of these rules are considered certified according to the OECD system.

f) If the batches that make up the balls are formed from seeds produced in different countries, the names of these countries are indicated on the label.

Control trials

ARTICLE 15 – (1) TTSM carries out the final control tests for original and certified seed lots, and the pre and post control tests for elite seed lots. In these trials, the compliance of the samples representing the seed lots with the standards determined in terms of variety purity is tested.

(2) In the preliminary and final control trials, the seed production areas of the parcels that do not comply with the standards in terms of variety purity are inspected by the certification bodies. The registration of varieties that are found to be not in compliance with the standards in terms of variety purity for three consecutive years in the pre-control trials can be canceled by the Field Crops Registration Committee, which is specified in the Regulation on Registration of Plant Varieties, based on the report prepared by TTSM.

Marketing

ARTICLE 16 – (1) Seeds belonging to varieties removed from the registration list can be propagated and traded for a maximum of three years, provided that the stocks are notified to the Ministry.

(2) Imported seeds must meet the minimum certification standards in the Regulation.

(3) Importation of seeds of at least the original class is permitted for reproduction purposes.

(4) Seeds produced and certified according to the provisions of this Regulation can be marketed as organic seeds, provided that they are documented in accordance with the "Regulation on the Principles and Implementation of Organic Agriculture" published in the Official Gazette dated 10/6/2005 and numbered 25841.

THIRD PART

Miscellaneous and Final Provisions

Administrative sanctions

ARTICLE 17 – (1) In the production and marketing of seeds, the provisions of Article 12 of the same Law shall apply to those who act against the Law on Seeds No.

Fees

ARTICLE 18 – (1) Field control, laboratory analysis, certification, and labeling services within the scope of the regulation are subject to a fee. These fees are determined by the Ministry in January each year by increasing the revaluation rate. The fees are paid in cash to the revolving fund account of the institution providing the service, in accordance with the provisions of the "Ministry of Agriculture and Rural Affairs Implementation Regulation on Revolving Funds" published in the Official Gazette dated 28/12/2006 and numbered 26390.

Exceptions

ARTICLE 19 – (1) Certification is not required for seeds used in scientific studies, research and development studies, and studies for the protection of genetic diversity, and for seeds produced by the producer to meet their own needs.

Regulatory authority

ARTICLE 20 – (1) The Ministry is authorized to make all kinds of arrangements to ensure the implementation of this Regulation.

Force

ARTICLE 21 – (1) This Regulation enters into force on the date of its publication.

Executive

ARTICLE 22 – (Amended: OG-18/2/2020-31043)

(1) The provisions of this Regulation are executed by the Minister of Agriculture and Forestry.

3. Guidelines for Good Agricultural and Wild Collection Practice (GACP) of Medicinal and Aromatic Plants in the European Union

The document released in April 2006 by the European Herb Growers Association includes the guidelines for the good agricultural and wild collection practice of medicinal and aromatic (culinary) plants that can be applied to the growing and primary processing practices of all such plants and their derivatives[12]. The document includes information and guidelines about the cultivation, harvesting, primary processing, packaging, and storage and transport among others. Regarding cultivation, MAPs must be grown in non-contaminated soils by sludge, heavy metals and residues of plant protection products (i.e., pesticides) and other not naturally occurring chemicals[12]. The use of fertilizers should be in accordance with efforts to minimize leaching. Irrigation should be applied according to the needs of the cultivated plant/s species. The plants should be harvested when they are of the best possible quality according to the different utilizations and under the best possible conditions. Equipment must be kept both in a clean state and technically perfect working order[12]. The machine parts that have a direct contact with the harvested plant/s should be regularly cleaned and kept free of oil and other contamination (including plant left-overs) [12]. Care should be taken to ensure that no toxic weeds

[12] EUROPAM, the European Herb Growers Association, GACP – Subcommittee. Brussels, 3rd April, 2006; EUROPAM GACP Working Copy no. 7.3

are mixed with the harvested crop. The harvested crop should not be exposed to direct contact with the soil. It must be promptly collected and under dry, clean conditions (e.g. sacks, baskets, trailers and containers, etc.) submitted to transport, with the exception of windrowed and root products prior to washing[12]. Mechanical damage and compacting of the crop must be avoided since that it would result in undesirable quality changes of the crops. More information about the cultivation and harvesting guidelines of MAPs in EU can be found in the EUROPAM, the European Herb Growers Association, GACP – Subcommittee document[12].

4. Conclusions-recommendations

Most of the countries included in the current document do not have specific regulations regarding the cultivation (production), harvesting, packaging, certification, and labelling of MAPs. Italy has two legislations regarding the harvesting of chamomile and foxglove, while Spain has Laws regulating the production of MAPs. To maintain biodiversity and prevent wild plant extinction, sustainable harvesting and GACP should be adopted. Each country should conduct research to detect the plant species that are in danger of extinction and make appropriate regulations and policies. Threatened plants should be reassessed at least every five years and when new information becomes available. Regulation and policies should also be mainly made in a National level regarding cultivation (production), harvesting, packaging, certification, and labelling of MAPs. This requires the engagement and collaboration of various stakeholders, including academia, research institutions, policy makers, processors, collectors, educators.

Appendix I

Table 1[8]. Species, hybrids, or subspecies of flora to be protected throughout Ireland.

No.	Scientific Name	Common Name
1	*Acinos arvensis* (Lam.) Dandy	Basil Thyme
2	*Allium schoenoprasum* L.	Chives
3	*Alopecurus aequalis* Sobol.	Orange Foxtail
4	*Arenaria ciliata* L. (incl. subsp. hibernica Ostenf. & O. C. Dahl)	Fringed Sandwort
5	*Arthrocnemum perenne* (Miller) Moss (syn. *Salicornia perennis* Miller)	Perennial Glasswort
6	*Asparagus officinalis* L	Wild Asparagus
7	*Asplenium obovatum* Viv. subsp. lanceolatum (Fiori) *P. Silva* (syn. *A. billotii* F.W.Schultz)	Lanceolate Spleenwort
8	*Asplenium septentrionale* (L.) Hoffm.	Forked Spleenwort
9	*Astragalus danicus* Retz.	Purple Milk Vetch
10	*Calamagrostis epigejos* (L.) Roth	Wood Small-reed
11	*Callitriche truncata* Guss.	Short-leaved Water-Starwort
12	*Cardamine impatiens* L.	Narrow-leaved Bitter Cress
13	*Cardaminopsis petraea* (L.) Hiitonen	Northern Rockcress
14	*Carex depauperata* Curtis ex With.	Starved Wood Sedge
15	*Carex divisa* Hudson	Divided Sedge
16	*Centaurium pulchellum* (Swartz) Druce	Lesser Centaury
17	*Cephalanthera longifolia* (L.) Fritsch	Narrow-leaved Helleborine
18	*Colchicum autumnale* L.	Autumn Crocus
19	*Cryptogramma crispa* (L.) R. Br. ex Hooker	Parsley Fern
20	*Deschampsia setacea* (Hudson) Hackel	Bog Hair Grass
21	*Epilobium alsinifolium* Vill.	Chickweed Willow Herb
22	*Equisetum* x *moorei* Newman	Moore's Horsetail
23	*Eriophorum gracile* Koch ex Roth	Slender Cotton Grass
24	*Galeopsis angustifolia* Ehrh. ex Hoffm.	Red Hemp Nettle

25	*Groenlandia densa* (L.) Fourr. (syn. *Potamogeton densus* L.)	Opposite-leaved Pondweed
26	*Gymnocarpium robertianum* (Hoffm.) Newman (syn. *Thelypteris robertiana* (Hoffm.) Slosson)	Limestone Fern
27	*Hammarbya paludosa* (L.) O. Kuntze (syn. *Malaxis paludosa* (L.) Swartz)	Bog Orchid
28	*Helianthemum nummularium* (L.) Miller	Common Rockrose
29	*Hordeum secalinum* Schreber	Meadow Barley
30	*Hydrilla verticillata* (L. fil.) Royle	Irish Hydrilla
31	*Hypericum canadense* L.	Canadian St. John's Wort
32	*Hypericum hirsutum* L	Hairy St. John's Wort
33	*Inula salicina* L.	Irish Fleabane
34	*Lathyrus japonicus* Willd.	Sea pea
35	*Limosella aquatica* L.	Mudwort
36	*Logfia minima* (Sm.) Dumort. (syn. *Filago minima* (Sm.) Pers.)	Slender Cudweed
37	*Lotus subbiflorus* Lag. (syn. *L. hispidus* Desf. ex DC. 1815)	Hairy Birdsfoot Trefoil
38	*Lycopodiella inundata* (L.) Holub (syn. *Lycopodium inundatum* L.)	Marsh Clubmoss
39	*Mentha pulegium* L.	Penny Royal
40	*Mertensia maritima* (L.) S.F. Gray	Oyster Plant
41	*Minuartia recurva* (All.) Schinz & Thell.	Recurved Sandwort
42	*Misopates orontium* (L.) Rafin.	Lesser Snapdragon
43	*Najas flexilis* (Willd.) Rostk. & W.L.E. Schmidt	Slender Naiad
44	*Omalotheca sylvatica* (L.) Schultz Bip. & F.W. Schultz (syn. *Gnaphalium sylvaticum* L.)	Wood Cudweed
45	*Otanthus maritimus* (L.) Hoffmanns. & Link (syn. *Diotis maritima* L.) Desf. ex. Cass.	Cottonweed
46	*Papaver hybridum* L.	Round Prickly-headed Poppy
47	*Pilularia globulifera* L.	Pillwort
48	*Polygonum viviparum* L.	Alpine Bistort

49	*Pseudorchis albida* (L.) Á. & D. Löve (syn. Leucorchis albida (L.) E.H.F. Meyer)	Small-white Orchid
50	*Puccinellia fasciculata* (Torrey) E.P. Bicknell	Tufted Salt-marsh Grass
51	*Pyrola rotundifolia* L. subsp. maritima (Kenyon) E.F. Warburg	Round-leaved Wintergreen
52	*Sanguisorba officinalis* L.	Great Burnet
53	*Saxifraga granulata* L.	Meadow Saxifrage
54	*Saxifraga hartii* D.A. Webb	Hart's Saxifrage
55	*Saxifraga hirculus* L.	Yellow Marsh Saxifrage
56	*Saxifraga nivalis* L.	Alpine Saxifrage
57	*Scirpus triqueter* L. (syn. *Schoenoplectus triqueter* (L.) Palla)	Triangular Club Rush
58	*Scleranthus annuus* L.	Annual Knawel
59	*Simethis planifolia* (L.) Gren.	Kerry Lily
60	*Spiranthes romanzoffiana* Cham.	Drooping Lady's Tresses
61	*Stachys officinalis* (L.) Trevisan (syn. *Betonica officinalis* L.)	Betony
62	*Trichomanes speciosum* Willd.	Killarney Fern
63	*Trifolium glomeratum* L.	Clustered Clover
64	*Trifolium subterraneum* L.	Subterranean Clover
65	*Trollius europaeus* L.	Globe Flower
66	*Vicia orobus* DC.	Bitter Vetch
67	*Viola hirta* L.	Hairy Violet
68	*Viola lactea* Sm.	Pale Heath Violet