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(Article begins on next page)
Medicinal and Aromatic Plant Legislation in the European Union, in Italy, and in several of its Regions*

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This work analyzed particular regulations on the cultivation and collection of medicinal and aromatic plants (MAPs) in the European Union (EU) and in several regions of Italy: Piedmont and Valle d’Aosta (Northwest), Tuscany (Central), and Sicily (South). The analysis should emphasize to private and/or public institutions the information to further develop and improve MAP cultivation, both in the considered context and beyond it.

Keywords: MAP, law, regulation, cultivation, collection

1. Introduction

Europe is a major importer of medicinal and aromatic plant material. Germany ranks fourth as importer and third as exporter while Italy ranks eighth as importer in the world (Bogers et al., 2006). According to differing data sources that are not always recent, the cultivated area for MAPs in the European Union (EU) covers 69,640 hectares (Crescimanno, 2007) distributed among 11,490 farms (2005). Total Italian production is approximately 2,000-2,500 tons/year (fresh), 3,000-4,000 tons/year (dry), and 70 tons/year (essential oils) (Primavera, 2009). Across the European continent, MAPs are mainly cultivated in France, and in the East (Romania, Bulgaria). In Italy, the Piedmont Region accounts for about one-third of the national MAP cultivated area (Barbieri & Ferrazzi, 2011).

This paper reviewed EU, Italian, and regional regulations and laws aimed directly or indirectly at MAPs. The analysis included legal regulations or voluntary standards that affect MAP cultivation and collection most because they hold potential for rural areas, especially for those at the margin. MAPs could enhance such areas by protecting natural resources and contributing to farm income diversification. The regulations regarding organic product are examined because MAPs fall within organic agriculture—a highly popular product category considered “natural” and of high quality (Carruba & Sutera, 2006).

The legislation scrutinized in this work must be considered within the general context of international conventions regarding MAP collection and trade: the
Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the Convention on Biological Diversity (CBD), and the Convention on the Conservation of European Wildlife and Natural Habitats (Bern Convention) (Khate et al., 2003). Table 1 enumerates the various regulations and laws that were analysed.

This work involved the identification and analysis of MAP collection and cultivation rules on several levels: EU, country (Italy), and regions (Piedmont, Valle d’Aosta, Tuscany, and Sicily). The regions considered in this work were chosen for their importance to Italian MAP production, approximately 31% Piedmont and 15% Tuscany, (Marzi & De Mastro, 2008), and for their varied geographic locations: Piedmont and Valle d’Aosta (north), Tuscany (central), and Sicily (south). The quantities produced in Sicily (bergamot and manna ash trees excluded), and especially in the Valle d'Aosta, are of less interest; however, the public in these areas have recently re-valued MAPs and made them important for marginal and mountainous land recovery and agricultural production diversification.

The second stage of work will utilize personal interviews of professionals and public servants from the examined regions to obtain information on the effects of the laws under consideration, and to quantify the size of subsidies to MAPs.

2. European Union, Italian, and several Italian regional legislation

2.1 European Union

The MAP-related legislation at the EU level involves the following Directives/Regulations (Bogers et al., 2006; http://eur-lex.europa.eu):


(2) Directive 92/43EEC Conservation of natural habitats, and wild fauna and flora;

(3) Regulation (EC) No 101/2012 amending the Council Regulation 338/1997 on the protection of species of wild fauna and flora by regulating trade therein. This Regulation lists animal and plant species for which trade is restricted or controlled, including the list included in the Allegates of CITIES;

good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use;

(5) Regulation (EC) No 834/2007 on organic production and labelling of organic products. It defines organic production principles, prohibits GMO use for EU organic production, requires use of the EU organic product label (for processed food, at least 95% by weight of its ingredients of agricultural origin are organic), and sets strict private standards;

(6) Regulation (EC) No 1698/2005 on rural development. This regulation provides for creation of Rural Development Programs at the national or regional level (as in Italy) with specific measures and financial aid for farms in less favoured areas, and of interest for MAPs.

Listed above, Rural Development Regulation (EC) 1698/2005 promotes the Leader+ Programs and INTERREGIVC initiatives, both of which have MAP cultivation interests (Khate et al., 2003; http://eur-lex.europa.eu). Known as ‘European Community Initiatives’, they are managed at the national and regional levels; INTERREGIVC is specifically addresses cross-border, transnational, and inter-regional cooperation. Market research, training courses, dried plant equipment purchasing, and ‘quality indicators’ to enhance production are several of the initiatives supported by these EU programs.

At the EU level, the ‘Guidelines for Agricultural and Wild Collection’ (GACP) from the European Herbs Growers Association (EUROPAM) “are intended to apply to the growing and primary processing practices of all such plants and their derivatives traded and used in the EU,” and to “provide additional standards for the production and processing of raw materials. In this respect, they will be aimed at minimizing insufficient quality by prevention” (http://www.europam.net).


2.2 Italy
In Italy, the medicinal plant sector (Vender & Fusani, 2011) is still modelled on a Legge Nazionale 6 gennaio 1931, n. 99 ‘Disciplina della coltivazione, raccolta e
commercio delle piante officinali.’ The law defines such plants as medicinal, aromatic and used in perfume, and contains two mandates (http://www.pianteofficinali.org/main/leggi):

1. herb gatherers must obtain an authorization card;
2. medicinal plant users must obtain an undergraduate herbalist diploma (since 1999).

Medicinal plants, declared as such, are distinguished into two tables according to the source of their sale, within or outside the pharmacy. The two groups are named/identified as ‘medicinal plants’ and as ‘medicinal, aromatic, and perfume plants’ in Regio Decreto 19 Novembre 1932, n.772 ‘Elenco delle piante dichiarate officinali’ and Circolare Ministeriale 8 gennaio 1981, n. 8 ‘Prodotti a base di piante medicinali’ (http://www.pianteofficinali.org/main/leggi). In this case, the law specifies that anyone can collect and hold medicinal plants without prior authorization, but only for personal or family use.


The most recent attempt to legislate MAP activities was in 2011 with the introduction of further restrictions and product certification. Finally, although not compulsory, farms that produce for the processing industry are expected to comply with Good Agricultural Practices (GAP) and Good Wildcraft Practices (GWP) (http://www.europam.net).

The wait has been long for legislation to regulate the entire field of medicinals and herbs. Despite the introduction of numerous bills, no new law has yet to pass. However, since 1972, agricultural law-making power has been transferred from the state to the Italian regions per DPR 15 gennaio 1972, n.11, ‘Trasferimento alle Regioni a statuto ordinario delle funzioni amministrative statali in materia di agricoltura e foreste, di caccia e di pesca nelle acque interne e dei relative personali e uffici’ (http://www.respanm.it/normative). Therefore, regional laws have increasingly regulated MAP cultivation, collection, and trade; such directives are usually contained in laws relating to agro-forestry.
Finally, of interest to MAPS, is the ‘National Strategy for Biodiversity by the year 2010’. While executed in 2010, the document refers to the 2011-2020 period and contains specific objectives and priority measures for its implementation. Contained within the strategy document is a ‘health’, which is specifically germane to MAPs, for which protection and sustainable management of plant and animal species for food production, nutritional safety, therapeutic purposes, and biomedical research is important (http://www.minambiente.it/home_it).

2.3 Specific Italian regions

Piedmont Region legislation highlights the importance of MAPs for marginally-profitable farms and mountain area environmental defense. In this region, two laws govern this topic (http://arianna.consiglioregionale.piemonte.it):

1. Legge Regionale 2 novembre 1982, n. 32 ‘Norme per la conservazione del patrimonio naturale e dell’assetto ambientale’ names those species for which collection is not allowed (Arnica Montana L., Achillea moschata Wulfen) and promotes MAP cultivation with ad hoc financial aid;

2. Legge Regionale 1993, n. 38 ‘Norme relative alla coltivazione e commercializzazione delle piante officinali peculiari della Regione Piemonte’ promotes organic cultivation, operator training, and the establishment of botanical gardens for seed dissemination. This law also includes description of an herbal species protection and enhancement program and identifies the local species suited for cultivation.

In the nearly entirely mountainous Valle d’Aosta Region, MAP legislation is very recent. Legge Regionale 16 febbraio 2011, n. 2 ‘Disciplina della coltivazione, raccolta e commercio delle piante officinali,’ created less than two years ago (http://www.consiglio.regione.vda.it/banche_dati/leggi_regolamenti), defines three categories of herbs:

1. foods for herbal use;
2. medicinal plants for food and household use;
3. medicinal plants for medical use.

While cultivation and collection are freely practiced throughout the region, the law requires that qualified and formally trained persons perform the first phase of processing. Furthermore, the industry requires the use of a logo to indicate origin and
quality as it recognizes that regional production is enhanced through such promotion (http://www.consiglio.regione.vda.it/banche_dati/leggi_regolamenti).

_Tuscan Region_ has no laws dedicated to MAPs. _Legge Regionale 6 aprile 2000, n. 56_ ‘Norme per la conservazione e la tutela degli habitat naturali e seminaturali, delle flora e della fauna selvatiche. Modified from _Legge Regionale 11 aprile 1995, n. 49_,’ this regional law, when applied to medicinal plants, lays down rules for the protection of biodiversity through flora and fauna habitat protection. Table C contains the list of protected species of which many are medicinal. The law also integrates and provides financial assistance to farmers who adopt organic practices (http://www.regione.toscana.it/regione/multimedia/RT/documents).

_Legge Regionale 8 marzo 2000, n. 23_ ‘Istituzione dell’anagrafe regionale delle aziende agricole, norme per la semplificazione dei procedimenti amministrativi ed altre norme in materia di agricoltura’, enumerates the agricultural rules for specific plants. Article 26 within the law is devoted to herbs and specifies municipal reporting requirements for beginning cultivation and collection activities. The rules apply to those who cultivate, process, manufacture, and/or sell herbs; the law further requires that those who perform processing activities possess an undergraduate Herbalist Diploma (since 1999).

In the _Sicily Region_, _Legge Regionale 6 maggio 1981, n. 98 and 9 agosto 1988, n.14_ ‘Norme per l’istituzione nella regione siciliana di parchi e riserve naturali’ regulates parks and protected areas, and expands protections to specific endangered plants. _Legge Regionale 1994, n. 9_ ‘Norme per l’esercizio dell’attività di erboristeria’ (modified by _Legge Regionale 22 dicembre 2005, n. 19_), regulates herbalist activities (http://www.gurs.regione.sicilia.it/Indicep1.htm). In addition, it outlines specific training courses for growers and herbalists, which promotes the profession through national standards. The law also defines the field of herbal medicine, and provides grants to aid individual farmers and groups to pursue several goals:

(1) develop plant cultivation;
(2) improve the first stages of processing, especially collection, drying, and storage;
(3) promote research activities, such as seed selection and propagation material.
3. Conclusions
Phase one of this work has elucidated two major concepts. First, that some public institutions (EU, regions) show interest in the MAP sector as demonstrated by new laws governing the field. Second, initiatives covered by EU programs were not always effective in Italy at improving production quality or the marketing/concentration of farmer supply. In fact, farmers frequently failed to understand the legislative interventions, especially those cultivating small areas.

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References
Foreste, Dipartimento Interventi Infrastrutturali, Servizio XI Servizio allo Sviluppo, Palermo, 3-16.


DPR 15 gennaio 1972, n. 11 Trasferimento alle Regioni a statuto ordinario delle funzioni amministrative statali in materia di agricoltura e foreste, di caccia e di pesca nelle acque interne e dei relativi personali e uffici (DPR January 15, 1972 No. 11 Agricultural, forestry, hunting, and inland water fishing statute transfer to the regions from the state administration). Retrieved from http://www.respamm.it/normative, accessed 30/07/2012.


Legge Regionale 6 maggio 1981, n. 98 e 9 agosto 1988, n. 14 Norme per l’istituzione nella regione siciliana di parchi e riserve naturali (Regional Law May 6, 1981 No. 98 and August 9, 1988 No. 14 Standards for the institution of parks


<table>
<thead>
<tr>
<th>Regulation/Law</th>
<th>Content description</th>
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<tbody>
<tr>
<td><strong>EU</strong></td>
<td></td>
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<tr>
<td>COM (2006) 216</td>
<td>Reverse the decline of biodiversity by 2010</td>
</tr>
<tr>
<td>Council Regulation (EC) 101/2012</td>
<td>Protection of wild fauna and flora by regulating trade</td>
</tr>
<tr>
<td>Council Regulation (EC) 1698/2005</td>
<td>Rural Development</td>
</tr>
<tr>
<td><strong>Italy</strong></td>
<td></td>
</tr>
<tr>
<td>Legge Nazionale 99/1931</td>
<td>list of plants deemed medicinal</td>
</tr>
<tr>
<td>Regio Decreto 772/1932</td>
<td>List of plants deemed medicinal</td>
</tr>
<tr>
<td>Circolare Ministeriale 8/71</td>
<td>List of plants deemed medicinal</td>
</tr>
<tr>
<td>Legge Nazionale 1421/1942</td>
<td>Collection and sale of Digitalis purpurea L.</td>
</tr>
<tr>
<td>Legge Nazionale 1724/1940</td>
<td>Collection and sale of Camomille</td>
</tr>
<tr>
<td><strong>Piedmont Region</strong></td>
<td></td>
</tr>
<tr>
<td>Legge Regionale 32/82</td>
<td>Conservation of plant natural descendance and habitat</td>
</tr>
<tr>
<td>Legge Regionale 38/93</td>
<td>Cultivation and commercialization</td>
</tr>
<tr>
<td><strong>Valle d’Aosta Region</strong></td>
<td></td>
</tr>
<tr>
<td>Legge Regionale 2/2012</td>
<td>Cultivation, harvest, first processing, processing and commercialization</td>
</tr>
<tr>
<td><strong>Tuscany Region</strong></td>
<td></td>
</tr>
<tr>
<td>Legge Regionale 56/2000</td>
<td>Rules for the protection of biodiversity</td>
</tr>
<tr>
<td>Legge Regionale 23/2000</td>
<td>Enumerates agricultural rules for specific plants, including herb plant details</td>
</tr>
<tr>
<td><strong>Sicily Region</strong></td>
<td></td>
</tr>
<tr>
<td>Legge Regionale 98/81 e 14/88</td>
<td>Rules for parks and natural protected areas</td>
</tr>
<tr>
<td>Legge Regionale 9/1994</td>
<td>Regulates herbalist activities</td>
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<td>E Legge Regionale 19/2005</td>
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