

New 2018 Legislation for MAP in Italy

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ABSTRACT

National laws governing the Medicinal and Aromatic Plants (MAP) sector in Italy were first established in 1931 and other legislative actions followed in the years immediately thereafter. In 2018, a revision of the early legislation was finally released after many years and input from all involved in the sector. This work, a part of other MAP research in the Piedmont Region of northwest Italy, describes the 2018 legislation, compares and contrasts it with the 1931 law, and considers its potential to impact and create opportunities in the sector. Although products named botanicals are not regulated by the 2018 MAP law in Italy, the legislation governing the category is discussed in order to provide a comprehensive review of regulatory intervention for officinal plants. The goal of this work is to educate Italian MAP sector researchers and public/private operators of the legislative changes and its implications. The analysis highlights that the 2018 legislation embraces continued expansion of the sector by providing goals and oversight for the process.

Keywords: Herb; Law; Botanical; Regulatory framework; Medicinal and Aromatic Plants (MAP)

INTRODUCTION

The 2018 national legislation regulating the MAP sector in Italy, 'Consolidated law on the cultivation, collection, and first transformation of medicinal plants pursuant to article 5 from the law of July 28, 2016 N° 154 [Testo Unico in materia di coltivazione, raccolta e prima trasformazione delle piante officinali ai sensi dell'articolo 5 della legge 28 luglio 2016 N° 154]', was released 87 years after the initial regulations. The term 'officinal plants' used only in Italy, derives from the Medieval Latin *officina* or *opificina*. Throughout the world, officinal plants are named medicinal plants or botanicals. Botanical plants or their parts are also called 'drugs'. The term refers to a pharmaceutical laboratory and is understood to be the place where they are processed. In other words, officinal plants, excluding aromatic plants for fresh consumption, are raw materials that require transformation and/or processing before use [1-3].

LITERATURE REVIEW

The MAP sector includes three plant categories: 'aromatic, medicinal, and perfumery'. While officinal and medicinal plants are similar, they are not synonymous. Currently, the term 'officinal plants' refers to plants containing substances that confer particular odours or flavours and that are used in the preparation of beverages, perfumes, cosmetics, foods (including functional foods and foods

supplements) for healthy uses in general. Several definitions exist for 'medicinal plant'. One is simply "a plant (wild or cultivated) used for medicinal purposes" [4]. The World Health Organization (WHO) [2] defined a medicinal plant in 1980 as "a vegetable organism that contains in one of its organs substances that can be used for therapeutic purposes, or which are the precursors of semi-synthetic drugs". Similarly, Catizone et al. [5] defined medicinal plants as "plants contain [sic] substances that can be used for therapeutic purposes or that represent the precursors of chemo-pharmaceutical synthesis". Related to this discussion other functional plants are known by two different names in Europe—botanicals and herbals. These "plants, their parts, substances and preparations derived from them" are "used as they are or in processed form as ingredients for the production of foods and food supplements, but also cosmetics, medical devices, drugs and other ..." [6]. Used mostly in the preparation of medicinal products or specific food supplements [2] the term botanical has traditionally referred to the complex of aromatic, medicinal, and perfumery plants as discussed in the next section. The European Food Safety Authority (EFSA) has reported that "botanicals and the derived preparations made from plants, algae, fungi or lichens have become widely available on the EU market in the form of food supplements", and that "some botanicals are considered as traditional herbal medicinal plants and are used both in medicinal products and in food supplements" [7].

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The MAP sector has a long history of culture and tradition, and is well known for its primary production niche. Until the 1930s, Italy was a net exporter of high-quality MAP products (herbs and their derivatives), most of which were obtained through wild collection. Since then, internal production has shifted to the cultivation of many species in small quantities, while imports are used primarily to meet the needs of processors and final consumers. Italian demand for herbs and their derivatives has grown for years, as research and interest in natural and healthy products, foods, cosmetics, and other uses has remained high.

The MAP sector in Italy

Statistical data on MAP products in Italy is aggregated in list form alongside other 'industrial plants', such as tobacco and soya. The category is defined broadly as 'aromatic, medicinal, spices and culinary plants' [8,9]. The plants listed within the 'aromatic, medicinal, spices and culinary plant' category are reported in the 'Istruzioni per la rilevazione 24 Ottobre 2010. 6° Censimento Generale dell'Agricoltura [Survey Instructions, 24 October 2010. 6° for the General Agricultural Census]' and is under development in the 'Manuale di rilevazione. Aspetti generali. 7° Censimento Generale dell'Agricoltura [Survey Handbook. General Aspects. 7° General Agricultural Census]' [10,11]. Another source of information on the consistency of the sector, although not used in this work, is contained within the 'Classification of economic activities' (ATECO codes), in which code 10.28.00 refers to the activity 'Cultivation of spices, aromatic plants and pharmaceutical' that includes: cultivation of spices and aromatic plants perennial and non-perennial (e.g. anise, badian, ..., basil, chervil, sage, etc.), cultivation of plants mainly used for pharmaceutical products or for insecticides, fungicides and similar products, and cultivation of crops for drugs and narcotics' [12].

At the primary production level of MAP, Italy ranks second among EU countries in total number of MAP farms after Poland, but before Bulgaria and France. In terms of MAP cultivated surface area, Italy ranks fourth behind Poland, Bulgaria, and France [13]. The surface area in Italy under cultivation with MAP in 2010 was about 7,000 ha, a value that grew to 24,163 ha in 2016 [3,8,9,13]. A 2018 breakdown of the data indicated that about 5,400 ha were farmed organically, of which more than 80% was 'converted' organic [13,14]. The total number of farms (specialized or not) in 2016 numbered slightly fewer than 6,200. Its average size rose from 2.5 ha in 2010 to 3.9 ha in 2016. In fact, during these years, all key farm measures showed growth: surface area (227%), number of farms (110%), and average farm size (56%) [9,13]. The count of utilised species was fewer than 300 during 2016, of which 120 were national products (54% cultivated, 25% from wild, and the remainder were a combination [2,3,15]. Four regions of Italy account for 58.2% (2016) of the surface area under cultivation with MAP: Marche, Puglia, Emilia-Romagna, and Toscana. In terms of count, 49.6% of MAP farms are also spread across four regions: Marche, Puglia, Liguria, and Sardegna [9,13]. The surfaces used for MAP farming in all these locations are generally marginal hilly or mountainous areas.

Between 1,000 and 3,000 operators participate in the Italian MAP sector, which includes processors, farmers, importers and exporters, brokers, wholesalers, small artisans, and commercial companies [15]. Women are well-represented in the sector as they cultivate many of the non-specialised MAP farms. Today, roughly 2,000

or more commercial brands fall under the MAP product heading [15]. Despite the two decades of uptrends in consumption, brands, and operators as touted by sector associations and operators, the economics of MAP products in Italy is highly variable. The actual value of Italy's national consumption of herbs and their derivatives is difficult to estimate because these products, most of which are produced in very small quantities, are often counted as a portion of other productions (pharmaceutical, cosmetics, food, beverages, supplements, feed, etc.) [2,3,15]. With these issues, the overall Italian market for officinal plants has an estimated value of €750 million, including imports [16].

The national production is known for its high quality, it is often certified organic and typical (e.g. *Mentha × piperita* Luds. *Officinalis Sole Rubescens* Camus (aka Italo-Mitcham or black mint), or *Mentha × piperita* Luds. *Officinalis Sole Pallescens* Camus (aka white mint or Piedmontese). Nevertheless, the Italian products become so scarce and costly that about 70% of herbs and their derivatives must be imported from countries with labor costs below those in Italy. Now, approximately 25% of these herbs and their derivatives come from China [15]. Indeed, in 2018, Italy had a net negative trade balance of €362,000 across all officinal plants and their derivatives that resulted from the net of imports valued at €1,000 million and exports valued at €662,000 million [13].

Not all categories within the MAP sector result in negative imbalances. For example, the 2018 quantity of essential oils, resinoids, odoriferous substances, essences, and their mixtures produced and sold in Italy represented more than 21,800 tonnes and €348 million, with imports valued at just €1 million and exports totalling €546 million [17]. The contrast in these examples relate in part to the role that product supports play. In particular, at the level of primary production, the sector received no European Union (EU) supports, as no specific Common Market Organization (CMO) exists to lobby for it. In fact, only since the 2000s has the sector been able to obtain grants or loan financing through the Common Agricultural Policy (CAP) Reform within the context of rural area policies. Currently, EU policy for rural areas is legislated by Regulation (EU) N° 1035/2013 [18]. Its expansive objective is "to ensure the sustainable development of rural areas", which is attained through interventions focused on selected priorities that range from the transfer of knowledge and innovation to farms to organization of the supply chain.

The responsibility for implementation of the regulation rests with the Rural Development Programme (RDP) [19]. As follow-on work to the 2007-2013 programming period, the RDP developed national and/or regional interventions for each Member State were also applicable to MAP farms (specialized or not) for its 2014-2020 programming. The following captures some of the many targets of the measures: young farmers (e.g. investments in physical assets, business start-up aid for small farm development); small farms (e.g. quality schemes for agricultural products and foodstuffs, including compulsory/voluntary certifications); non-agricultural activity investment (e.g. LEADER Programme); mountain areas (e.g. rural area farm and business development); short supply chains (producer group set-up); rural area women (e.g. farm and business development, LEADER); climate change mitigation, adaptation and biodiversity (e.g. organic farming, direct payments to natural and constrained areas, biodiversity). LEADER refers to programmes developed by local action groups (LAG) with "particular relevance to fostering knowledge transfer and innovation in agriculture, forestry, and rural areas" [18,19].

The 2018 Italian legislation

Official plants in Italy had long been regulated primarily by National Law, January the 6th 1931, N° 99 ‘Medicinal plant disciplines of growing, harvesting, and trade [National Law of January 6, 1931, n. 99 Rules for growing, harvesting, and marketing medicinal plants] and by some other rules [20,21]. The sector had also been subjected to regional laws [21]. Despite countless legislative proposals to the Italian Parliament from sector associations over many years, a new national legislation was not enacted until 2018. The Legislative Decree of May 21, 2018, N° 75 ‘Testo Unico in materia di coltivazione, raccolta e prima trasformazione delle piante officinali ai sensi dell’articolo 5 della legge 28 luglio 2016 N° 154 [Consolidated law on the cultivation, collection, and first transformation of medicinal plants pursuant to article 5 from the law of July 28, 2016 N° 154]’ contained ten articles that supplanted all previous national officinal plant laws [22]. This legislative simplification affected only national laws; regional regulations remained in force. Regional laws (of the Administrative regions) apply not only to officinal plants, but are often aimed at the agricultural sector to protect the natural environment. Law focus on several aspects: natural heritage preservation interventions, such as development of forbidden-to-collect officinal species lists; organic officinal plant production incentives; botanical gardens established to promote knowledge of these plants; recommendations (non-specific) for plants in hilly/mountainous areas. The 2018 law came from recommendations of the ‘Supply Chain Panel, established by the Ministry of Agricultural, Forest and Food for planning years 2013-2016 [23]. The new legislation began by expanding the definition of officinal plants to include not only medicinal, aromatic, and perfumery plants, but also algae, fungi, and lichens. It called for a list of cultivated species to be established. The legislation also delineated its scope of activities: cultivation, wild collection, and primary processing of plants on farms. Primary processing functions were precisely enumerated to include washing, defoliation, sorting, peeling, cutting and selection, as well as pulverisation and distillation or other means used to obtain essential oils. Activities related to plant drying, stabilising, and preserving were also specified.

One sizeable change with the new law was that it recognised all of the abovementioned activities as ‘agricultural activities’ in article 21, 35 of the Italian Civil Code [24]. Legislation outside the purview of the 2018 legislation is used to regulate activities related to plants that produce narcotics or psychotropic drugs. Moreover, only pharmacists and herbalists can prepare officinal plants and their derivatives for direct consumer use or for use in dry or liquid preparation of extracts for human food processing and production.

In terms of MAP legislation oversight, no specific authorisation is required to practice the activities described in the cultivation and production of officinal plants. Nevertheless, production must occur in accordance with the rules of the European Medicines Agency (EMA), Good Agricultural and Collection Practices (GACP) for herbal material start-up, and the Good Manufacturing Practices (GMP), in particular the Annex 7 ‘Manufacture of Herbal Medicinal Products’ (Article 2) [25]. Wild collection of officinal plants is permitted (Article 3). Administrative regions, as well as the Autonomous Provinces of Trento and Bolzano, have to adhere to the same rules for “officinal plants species that grow spontaneously on their respective territories” according to

several requirements: 1) “conservation needs of local biodiversity” [20]. The Administrative Regions and Autonomous Provinces of Trento and Bolzano always prepare their own plant or parts of plant lists, for which wild collection is allowed, as well as precise rules for collection prohibition for certain species; 2) prescription of the EU on the protection of species and wild fauna and flora ... (Council Regulation (EC) 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein); 3) Italian law on protected and endangered species and varieties; 4) EU legislation on biodiversity from the GACP for officinal plants from wild, algae, macroscopic fungi and lichens used for medicinal purposes. Furthermore, a three-year plan called ‘Plan for the sector of the officinal plants supply chain’ (Article 4) must be developed to comply with the regional RDP programme to link the sector RDP and overall EU rural policy. The Plan is developed by ‘Technical Panel’ experts (Article 5) [26-29], which is comprised of representatives from universities and Ministry of Agricultural, Food and Forest Policies, associations of farmers, processors, brokers, unions, and research institutions. The Italian Ministry of Agricultural, Food and Forest Policies organized Technical Panel to direct several working groups: 1) Research and training, 2) List of plants and Registry of Varietal, 3) Wild plants and criteria for their collection, 4) Sector Plan, and 5) Economics and statistical data monitoring [26]. In an

action similar to the one that established the Technical Panel, the legislation also formed an ‘Economic and Market Observer Panel’ to analyse sector economic and market data, with a focus on price and market trends. There is some membership overlap between the technology and economic panels. To value sector products, the legislation called on the Ministry to decree that a Registry of Varieties (Article 6) will be established. The document defined procedures to certify and guarantee the technological characteristics and traceability of seeds or propagative materials from cultivation to market. With an eye to enhancing national products, the law allows to the Regional Administrations to create their own brands –in accordance to national and EU laws-that meets specific standards of high quality and are useful to certify them (Article 7), and the Ministry of Agricultural, Food and Forestry Policies can establish a national brand of quality that could be adopted at the regional, inter-regional, or district level. Full implementation of the new law for officinal plants will take place only after implementation of the decrees [26-29]. In this regard, it can be noted that currently the inter-ministerial decree provided for in article 1 and article 3 of the 2018 law for officinal plants is still in process; the acquisition of the consent of the Ministries of Health and the Environment is nearing completion. After passage to the State-Regions Conference, it can be signed by the Minister of Agriculture and published. Following this, the Sector Plan will have to be approved, but above all, the working group in charge will have to decide on which species to start developing experiments for the Register of Varieties. To complete the framework of the Italian legislation on officinal plants, please note that botanicals used in food supplements, are governed by specific Decrees of the Ministry of Health, 2018 and Managerial Decrees of 2019 [30-32] (before the legislations of 2018 and 2019, botanicals, were regulated by the Decree Ministry of Health 9 July 2012). Botanical extracts are often used in food supplements as well as herbal medicine products (HMPs). In the EU, HMPs are regulated as medicinal products. The definitions for both HMPs and THMPs (Traditional Herbal Medicine Products) have been

introduced under Directive 2004/24/EC (European Commission 2004) [33]. Moreover, botanicals are also considered as novel foods (Regulation [EC] N° 258/97, Regulation [EC] 2015/2283, European Commission 2008), food, and food ingredients not used to a significant degree for human consumption. The 2018 decree for botanicals replaced not only the previous one from 2012, but also the list attached to it, already amended by attachment 1-bis / Decree of 17 July 2014, the so-called 'BELFRIT list', while the 2019 decree for botanicals is specific for *Curcuma longa* L. "In the EU, food supplements are defined and regulated as a specific category of foodstuffs under Directive 2002/46/EC (European Commission 2002a)" [31]. However, this directive currently only establishes rules applicable to vitamins and minerals used in food supplements, but does not include rules on the use of botanicals.

Therefore, the national legislation, while respecting the EU General Food Law (Regulation [EC] No 178/2002), regulates botanicals for food supplements as detailed in the next section. The 2018 decree delineated the plants, in addition to the substances and preparations permitted for food supplement use (Annex 1). It laid out the notifications necessary to place a product on the market and "to evaluate the products in relation to the complex of constituents, the daily intake [sic] and the indications given on the label". It elucidated protocols related to the marketing of supplements and products that

do not comply with the Decree, but that are obtained in EU states or Turkey or by the EFSA and are mutually. Additional important information on documentation was put forth in Annex 2. Specifically, this portion of the law specifies the plant, production process, and finished product information that food business operators must maintain for inquiries [30]. If Annex 1 is an early indicator, then it is reasonable to anticipate that these lists will become active documents. Indeed, in 2019, Annex 1 was updated twice [31] and it contained several elements for each plant species: useable plant parts, advertisement-approved functional properties, and label warnings and limitations (e.g. dosage). Updates to these lists can occur at any time depending on supplement use and consumption. Such an instance occurred with *Curcuma longa* L., which required an update to its warning label when it became known that the product was not recommended for use by persons with liver and/or biliary problems [31].

A comparison of the 1931 and 2018 legislations

Comparison of the 2018 and 1931 legislations, summarized in Table 1, is useful to highlight sector potential effects and opportunities. The new legislation was significant in that its purview centered on officinal plants alone and that the sector would be guided by the 2018 law and three decrees (the Legislative Decree 21th May 2018 is sometimes called 'new law' or '2018 law', while the National Law of January 6, 1931, n. 99

Table 1: Comparison between the 1931 and 2018 officinal plants legislation of Italy.

Article	1931 Law Article title and/or content	2018 Legislative Decree Article title and/or content
Art.1	Cultivation, collection and trade stipulations.	Definition and scope.
Art. 2	Authorisation card to cultivate and collect from wild. Herbalist diploma is compulsory to use officinal plants.	Cultivation, collecting and first transformation stipulations.
Art. 3	Authorisation card: it is issued by Podestà, with the positive opinion of the Fascist Trade Association.	Withdrawal, collection, and first transformational stipulation.
Art.4	Sanctions if collectors violate art. 2.	Sector Supply Chain Plan.
Art. 5	Sanctions for officinal plants damages.	Sector Technical Plan.
Art. 6	Release of the Herbalist Diploma.	Medicinal and aromatic plants Varietal Registry.
Art. 7	Herbalist diploma permits: to cultivate, collect and trasformazione industriale of officinal plants. Only Pharmacists	Medicinal and aromatic plant quality branding.
Art. 8	Sanctions related to art. 6 and 7 violations.	Sanctions. Financial neutrality. Final transitional stipulations.
Art. 9	It is not considered herbalist or collector who distills or possesses for personal or family use officinals, without making trade, in an amount not higher than that stated in the list approved by Royal Decree on the proposal of the Ministry of Agriculture and Forest.	
Art. 10	Consultative Commission.	
Art. 11	Composition of the Consultative Commission.	
Art. 12	Consortia and Federations.	
Artt. 13-15	Other regulations.	
Art. 16	Funds intended for: functioning of the Consultative Commission and other activities.	
Artt. 17-18	Other regulations.	

Source: Designed by the Author

is called ‘old law’ or ‘1931 law’) [20,27- 29]. The new legislation lent direction for cultivation versus wild collection as did the old law, but the 2018 Legislative Decree also provided rules for officinal plant primary processing and marketing activities. Key law differences are highlighted below.

Definitional differences

The 2018 law precisely defined officinal plants, as well as the scope and disciplines of not only officinal plants (medicinal, aromatic and perfumery plants), but also algae, macroscopic fungi, and lichens for the same uses. These last three plant types were not considered in the 1931 law. The 1931 law also established that medicinal plants would be included in a special list jointly defined by the Ministry of Agriculture and the Advisory Commission (Regio Decreto del 19 Novembre 1932, n. 772 [Regio Decreto of 19 November 1932, No. 772, List of plants deemed medicinal] and Circolare Ministeriale del 8 gennaio 1981, n. 81, Prodotti a base di piante medicinali [Circolare Ministeriale of 8 January 1981, No. 81, Products based on medicinal plants]). Medicinal drugs and psychotropic drugs were clearly excluded in the new law, but not in the old law.

Worker certification differences

The old law permitted only herbalists with a diploma to participate in the cultivation, collection, and industrial preparation of medicinal plants and only pharmacists to participate in their retail sale. In 1931 law wild collection requires an authorisation card that specifies the species and quantities for which the collection is allowed, their quantity and the time of collection [21]; the card was issued by the Podestà and Fascist Trade Association, suppressed in the 1944. As of 2018, require neither certification nor authorization.

‘Agricultural activity’ recognition differences

The 2018 law took a significant step by recognizing cultivation and collection and primary processing activities as ‘agricultural activities’. Acknowledgement of these activities as agricultural moved sector farmers to a higher level of access to public support grants and other fiscal benefits. While much was granted to officinal farms through this change, some non-primary activities and products normally processed on officinal farms remained outside the ‘agricultural’ designation.

Innovations differences

Plants for medicinal purposes, including active ingredient production, are subjected to specific cultivation and processing standards (GACP) that were not part of the 1931 law. In addition, wild plant protections and preservation principles were aligned with EU biodiversity regulations and there was a call to establish a Varietal Register, whereas the 1931 rules simply contained a list of species prohibited from harvest.

Sector development differences

In the 1931 law, interventions to develop the sector were delegated to an Advisory Commission (Ministry of Agriculture), however, these efforts were limited to “studying and proposing interventions to advance and better use the herbal and essence heritage” [21]. Similarly, the constitution of Consortia prescribed only specific areas for cultivation, collection, primary processing, and uses of the officinal plants.

The 2018 law expanded the tools to monitor and enhance the sector by establishing a Technical Panel and an Economic and Market Oversight Panel. The former is tasked to develop a formal ‘Plan’ of organized sector-specific interventions and the latter must monitor markets and pricing to meet the informational needs of operator. The Sector Plan is a programmatic and strategic tool for identifying priority interventions to improve the conditions of production and initial transformation of officinal plants. It also promotes aggregation and association among farmers and operators to integrate the supply chain.

Regional differences

The 2018 law provides, as the 1931 law did not, Regional Governments to define their own regulations for wild collection within the framework of meeting their territorial biodiversity needs. The new law also provided for product promotion and protection through brand creation at the regional (Administrative Regions) or state level for possible regional adoption.

Botanicals

Even if not regulated by the 2018 law, as recalled several times, the regulatory framework for officinal plants must also refer to the Italian rules for botanicals. The standards for botanicals in Italy are described in regulations outside the 2018 law. In Decrees issued by the Ministry of Health on December 10, 2018 and January 9, 2019, the level of consumer protection was raised by extending regulations to cover all plants involved in food supplement production. Furthermore, these orders facilitated the free circulation of food supplements through application of the principle of ‘mutual recognition’. These standards also promoted adoption of the new list of plants to be used in food supplements, and for substances and preparations. Information based on scientific data approved by the National Committee for Nutrition and Food Safety of Italy, plus data integrated from the 2012 Decree and 2014 BELFRIT, was compiled. It describes the physiological effects of each botanical included on the list and provides specific information on safety, quality control, and documentation for the use of botanicals as food supplements.

DISCUSSION AND CONCLUSION

The Italian MAP sector waited more than 80 years for revisions to its governing legislation. During the interim, interest and consumption (herbs, derivatives) in sector products has grown so much that more than two-thirds of the raw materials it produces require import today. The continued success of the niche hinges on its unique set of factors: cultivation is possible in marginal areas, where it contributes to conservation of those lands; biodiversity is preserved, which meets a societal desire; additional/alternative income is possible for farms.

The 2018 legislation modernizes the goals of the sector through expert panels tasked to organize plans and monitor markets, while the old law that relied on consortiums and federations to organize and manage a vague supply chain. Another opportunity created by the new regulation is linked to the Sector Plan because it will define the priority of interventions for the sector and promote association amongst farmers (or between farmers and operators) to overcome supply fragmentation. The new legislation also expanded sector qualified growers by recognizing cultivation, wild collection, and

initial processing as agricultural activities that no longer require a diploma-certified herbalist. In addition, recognition of many activities in the sector as agricultural should move some production incomes from being only supplementary to substitutive, if not in line with those derived from traditional crops. Sector products are also viewed as well suited, for example, to agro-tourism and educational farms. Two additional critical factors to the sector in the legislation were that a Varietal Registry (not yet issued) be established and that an ability to create collective branding to protect and enhance medicinal plants be designed. These steps, as well as official plant supply chain planning and market oversight resulted in legislation that demonstrated a desire to promote and develop a long-term future for the sector. Finally, the new law 2018 reiterates the right for Administrative Regions and the Autonomous Provinces of Trento and Bolzano to create specific legislation to regulate the collection and cultivation or other aspects aimed to improve the sector. Given the positive and innovative aspects presented by the 2018 law, delay in its full implementation due to incomplete decrees is noteworthy.

To complete the regulatory framework for MAP in Italy, specific interventions for botanicals used in food supplements must be fully described. The national legislation through decrees of the Ministry of Health will suffice for a lack of EU rules (e.g. authorization procedure, defined and updated list of plants admitted) for botanicals used in food supplements.

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CONFLICTS OF INTEREST

The author declares that no conflicts of interest exist.

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