

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER



# **FINAL REPORT**

Analysis of the value chain of Medicinal and Aromatic Plants in Albania with a focus on quality, environmental, social and sustainable requirements and its compliance infrastructure

The study was developed under the Global Quality and Standards Programme (GQSP) Albania: Strengthening quality and standards compliance capacity for selected value chains

Funded by Switzerland through its State Secretariat for Economic Affairs (SECO)

Implemented by the United Nations Industrial Development Organization (UNIDO)



# **EXECUTIVE SUMMARY**

This report presents the results of the medicinal and aromatic plants (MAPs) value chain assessment conducted within the framework of the assignment "Analysis of the value chain of aromatic and medical plants, fruits and vegetables in Albania", mandated by UNIDO as part of the Global Quality and Standards Programme (GQSP), which is a global programme supported by Switzerland through its State Secretariat for Economic Affairs SECO. A Twin report has been produced for fruits and vegetables (F&V).

The purpose of the GQSP in Albania is to sustainably enhance the market access of SMEs in the MAPs and F&V value chains through strengthening quality and standards compliance capacity and placing the focus on quality and compliance infrastructure and economic, social and sustainability requirements.

The study was conducted between September 2022 and April 2023. It is based on extensive field research, literature review and similar studies employing the GQSP framework.

The MAPs sector is one of the leading export-oriented agrifood sectors in Albania. The export of dried wildgrown MAPs has traditionally been a significant business in Albania also during the planned economy. Albania mostly exports semi-processed dried MAPs and essential oils. The main markets for dried MAPs (as well as for essential oils) are in the US and the EU (mainly Germany). For some MAPs, such as sage, Albania is a key global player (about 3/4 of the sage imported by US is sourced from Albania). During the last decade, Albanian exports of dried MAPs increased by three times in value, reflecting a significant increase both in volume and prices. During the same period, the export of MAP essential oils increased eightfold. However, the value of exported essential oil is far lower compared to that of dried MAPs. The added value in processing is limited, as distillation is the only process Albanian exporters use to produce this product.

Standards play an essential role in this global value chain. The Albanian MAPs sector still needs to improve its performance regarding compliance with requirements (e.g. food safety), which has increased the attention of exporters to quality, investments in technologies and, last but not least, the demand for lab tests and analyses. Large foreign importing companies usually require such tests to be performed or occasionally repeated in accredited laboratories of their choice. Furthermore, the standards required for refined, higher-added-value products are usually higher and the required investment in fixed assets is quite substantial. These entry barriers prevent Albanian processors/exporters from accessing higher-added-value market segments, such as cosmetics.

There are severe quality-related challenges along the MAPs value chain, especially upstream, i.e. among wild MAPs collectors, cultivators and small consolidators. The most critical issues include a lack of traceability, food safety, high levels of foreign materials within the

product, and a lack of marketing standards. In addition to insufficient capital investments in technologies and facilities, the need for a proper legal framework and enforcement, fierce competition between buyers, informality and other market dynamics have contributed to quality issues. In response to these challenges, numerous international development projects and government agencies, to a certain extent, have allocated substantial resources to the upstream segment, including farmers and consolidators.

The main recommendations are grouped into the three following key areas:



**1.** Creating an enabling environment and a policy framework primarily focused on the need to draft a comprehensive National Quality Policy (NQP) and establishing a governing body capable of coordinating the national quality infrastructure system.



2. Enhancing the Quality Infrastructure with an emphasis on bolstering capacities related to certification (GDA and TIC), as well as testing and inspection (including laboratories and other state inspection institutions). Recommendations on other key QIS institutions are elaborated in the main sections.



**3.** Promoting private sector compliance through the engagement of MAPs value chain operators and their associations in the development and management of the Quality Infrastructure and fostering a culture of quality along the entire value chain, as well as among consumers, through capacity building and awareness raising.

Outlined below are the key challenges and issues concerning QIS, specifically with a focus on MAPs. Additionally, included are recommendations on how these challenges can be addressed by UNIDO and other stakeholders/donors.

**QIS gap**: The National Quality Policy (NQP) serves as the fundamental governmental instrument for establishing and supervising the QIS. In Albania, there is a need to ensure fine-tuning, coherence and compliance concerning the NQP, as well as to establish a competent national body for the coordination of the Quality Infrastructure System, which could serve as a technical secretariat to formulate and support the implementation of the National Quality Infrastructure.

**Recommended Action**: Support the fine-tuning, compliance and coordination related to the National Quality Policy

QIS gap: There is limited awareness among MAPs operators on the role and importance of QI institutions. Lack of trust in local service providers such as laboratories (as also mentioned below) is partially caused by a lack of awareness about the role of QI institutions, such as GDA. The involvement of sector stakeholders is limited or non-existent. For example, GDS Technical Committees do not include stakeholders/experts from the MAPs sector. Moreover, GDM has a limited scope of services relevant to the MAPs sector, and its legal base is only partially aligned with EU regulations.

**Recommended Action:** Increase awareness among MAPs sector stakeholders about QI institutions. Assist GDS in increasing the engagement of stakeholders from the MAPs sector within the technical committee, so as to enable MAPs operators to actively participate in the process of drafting, approving and adopting Albanian standards where relevant; provide support to both GDS and GDM in capacity building related to legislative alignment, implementation of the existing legislation, internationalization, accreditation and better catering to MAPs needs (translating standards, preparing guidelines, and creating manuals on legal requirements and measures).

**QIS gap**: There is a limited use of services rendered by local laboratories among value chain stakeholders and a lack of trust in some local laboratories, which can be partially attributed to capacity deficiencies and also the accreditation process. On the other hand, there is a lack of locally accredited certification bodies for some types of certifications (most notably GlobalGAP). The lack of locally accredited operators increases the cost/prices of services and reduces monitoring.

**Recommended Action**: Capacity building for the GDA, with a focus on laboratory testing service providers and TIC/certification bodies.

QIS gap: Testing capacities in Albania fall short of the needs, due to the inadequate number and accessibility of certified laboratories, a limited range of accredited tests/analyses, high service costs and a poor reputation. Another issue arises from inadequate sampling for the analyses. Not all major stakeholders in the value chain possess in-house (mini)laboratories, and among those who do, there are deficiencies in terms of equipment and human resource capacities. In addition to the support through capacity building for the GDA (as highlighted above), direct support to laboratory operators to enhance their capacities is crucial.

**Recommended Action:** Support the increase and improvement of laboratory testing services. Strong cooperation with FSVI, leading private laboratories and Albanian certification bodies/TIC.

**QIS gap**: Local consumers' lack of awareness about safety and quality standards. Moreover, most farmers lack awareness about GACP / food safety and plant health standards. On the other hand, weak value chain coordination leads to a lack of traceability, while there is an increasing demand (both mandatory and voluntary) in export markets.

**Recommended Action:** Promote a culture of quality along the entire value chain and among consumers. Promote and support the application of GAP; develop and introduce new protocols to address emerging challenges in production and harvesting. In this regard, it is essential to highlight the potential for adopting indigenous or new varieties, aligned with the market demand.





# TABLE OF CONTENT

AC	KNOWLEDGEMENT	8
1	INTRODUCTION	15
2	METHODOLOGY	16
	2.1 METHODOLOGICAL APPROACH	17
	2.2 TYPOLOGY OF DATA	17
	2.3 PRODUCT PRIORITIZATION	17
	2.4 PESTEL AND QI PERFORMANCE ASSESSMENT	17
	2.5 CULTURE FOR QUALITY AND SWOT ANALYSIS	17
3	VALUE CHAIN TRENDS	19
	3.1 GLOBAL TRENDS	19
	3.2 MARKET TRENDS IN MAIN MARKETS	19
	3.3 ALBANIAN PRODUCTION TRENDS	20
	3.4 ALBANIAN INTERNATIONAL TRADE TRENDS	21
	3.5 ALBANIAN MAPS VALUE CHAIN STRUCTURE AND STAKEHOLDERS	22
	3.6 ENGAGEMENT OF WOMEN AND YOUNG PEOPLE IN THE MAPS SECTOR	22
	3.7 THE IMPACT OF CLIMATE CHANGE ON MEDICINAL AND AROMATIC PLANTS	22
4	MAIN MARKET REQUIREMENTS	25
	4.1 GENERAL ASPECTS	25
	4.2 OVERVIEW OF PRODUCT CATEGORIES AND SCOPE OF THE STUDY FOR THE MAI MARKETS.	
	4.3 REQUIREMENTS FOR EXPORT TO EU COUNTRIES	26
	4.4 EXPORTING MAPS TO THE USA	28
	4.5 EU PROVISIONS FOR ORGANIC PRODUCTION AND MOST REQUIRED STANDAR IN GLOBAL MARKETS	
5	THE ALBANIAN QUALITY INFRASTRUCTURE SYSTEM	36
	5.1 BACKGROUND	36
	5.2 REGULATORS AND THE GOVERNMENT	39
	5.3 QUALITY INFRASTRUCTURE INSTITUTIONS	40
	5.4 QUALITY INFRASTRUCTURE SERVICES	43
	5.5. CONFORMITY ASSESSMENT AND TESTING	44

	5.6 CERTIFICATION BODIES	44
	5.7 QUALITY PROMOTION STAKEHOLDERS	44
	5.8 CULTURE FOR QUALITY AMONG CONSUMERS AND VALUE CHAIN STAKEHOLDERS	44
	5.9 A SYNTHESIS OF QIS EVALUATION IN ALBANIA	44
6	PAST AND ONGOING INITIATIVES AND SUPPORT SCHEMES	53
	6.1 MAIN STRATEGIC DOCUMENTS AND POLICY FRAMEWORK	53
	6.2 FISCAL AND TRADE POLICIES	60
	6.3 BUDGETARY SUPPORT POLICIES	66
	6.4 OTHER DONOR SUPPORT INITIATIVES	72
7	MAIN FINDINGS, RECOMMENDATIONS AND CONCLUSIONS	81
	7.1 MAIN FINDINGS, KEY GAPS AND RELEVANT RECOMMENDED ACTION	82
	7.2 RECOMMENDATIONS	84
	7.3 DEVELOPING A PARTNERSHIP STRATEGY FOR QI IMPROVEMENT	86
8	REFERENCES	10
	8.1 CONCLUSION AND GAP ANALYSIS	105
	8.2 RECOMMENDATIONS	110
AN	NEX	
	 MAIN STANDARDS ADOPTED IN MAPS IN WESTERN BALKANS AND RELEVANT CONTENTS	5 127
A.2	PRIVATE STANDARDS MOST ADOPTED IN MAPS SUPPLY CHAINS IN ALBANIA	128
LIS	T OF TABLES	
Table	2.1: Criteria and indicators used for the selection of products in the Medicinal and Aromatic Plants value chain	16
Table	e 2.2: Assessment of the elements of PESTEL (in relation to QI) with a focus on the selected va	
Table	e 3.1: Import trends of MAPs in the EU and US (HS 1211)	22
Table	e 3.2: Import trends of essential oils in the EU and US (HS 3301)	22
Table	e 3.3: Production of MAPs in Albania (period 2012-2021)	22
Table	e 3.4: Production of wild MAPs in Albania (2019-2021)	23
Table	e 3.5: US sage imports from Albania by year	25
Table	e 4.1: Products/markets matrix	32
Table	e 4.2: Priority MAPs, main processing for export and final users	33

Table 4.3: MAPs export to the EU: requirement categories, key issues and legislation	38
Table 4.4: Stakeholders, responsibilities and actions for traceability implementation in the  EU legal framework	40
Table 4.5: Contaminant limits in selected MAPs: metals and chemicals	43
Table 4.6: Contaminants limits: selected dried MAPs	44
Table 4.7: Legal requirements and supply chain stages	52
Table 4.8: ISO standards of prioritized essential oils	53
Table 4.9: Compliance of essential oils with EU legal provisions and product category	54
Table 4.10: Substances generally recognized as safe – CFR Title 21, Vol. 3, Part 182	60
Table 4.11: Synoptic table of the main relevant ISO and private standards by scope and developer	63
Table 4.12: Share of sampled enterprises holding different certifications	65
Table 5.1: The components of the quality infrastructure in Albania	68
Table 5.2: The main gaps and possible interventions for improving quality infrastructure for the policy-making framework	73
Table 5.3: The main gaps, challenges, needs and possible interventions for improving accreditation for the MAPs sector	
Table 5.4: The main gaps, challenges and needs and possible interventions for improving standardization for the MAPs sector	76
Table 5.5: The main gaps and recommendations for improving metrology for the MAPs sector	78
Table 5.6: Main gaps, challenges and needs and possible interventions for improving inspection	81
Table 5.7: Main challenges and needs for the NAVPP in Albania	82
Table 5.8: Main challenges and needs for the laboratory network in Albania, with a focus on the MA sector	
Table 5.9: Main challenges and needs for certification in Albania	88
Table 5.10: The main challenges and needs of institutional stakeholders for the promotion of culture for quality in Albania	
Table 5.11: Non-institutional actors: main challenges and needs for the sector advocacy towards a better QIS in Albania	92
Table 5.12: Main certifications implemented by companies by type	95
Table 5.13: Summary of challenges and recommendations for each value chain node/segment	97
Table 5.14: Main factors presently affecting QI development, trends and impact	100
Table 5.15: Synopsis of main weakness factors and threats to MAPs sector development	100
Table 6.1: Criteria of support measures for the sector of MAPs by year	105
Table 7.4: Partners and partnership actions of the stakeholders with regard to their efforts for an improved QIS in Albania	129
Table A.1: below shows the different GlobalG.A.P standards and the good practices to which they a referred. Those standards which are particularly suitable for the fresh plants sector and for the EU market are highlighted in the following table	
	-70

Table A.2: Synopsis of GlobalG.A.P. standards and main tools	140
Table A.3: BRCGS standards and main features	144
Table A.4: Main VSS adopted for fresh fruits and vegetables and fresh and processed MAP	147
LIST OF FIGURES	
Figure 3.1: Global trade (import) of MAPs	20
Figure 3.2: Global import of essential oils (HS 3301) (million USD)	21
Figure 3.3: Geographical distribution of MAPs cultivation and production in Albania by region (2021).	23
Figure 3.4: Albanian export of MAPs (HS code 1211)	24
Figure 3.5: Distribution of Albanian export of MAPs (HS code 1211) during 2021	24
Figure 3.6: Albanian export of essential oils (HS code 3301)	24
Figure 3.7: Distribution of exports of essential oils (HS code 3301) in 2020	25
Figure 3.8: Distribution of cultivated MAPs farms by size (2020)	26
Figure 3.9: Women's position in the MAPs value chain	27
Figure 4.1: Export requirements within the EU based on the supply chain stage	52
Figure 4.2: Example of a label of essential oil for further processing: export to the EU	56
Figure 4.3:COA Template- Sage	61
Figure 4.4: The official Organic label for organic products in Europe	63
Figure 5.1: Involvement of staff in quality management among the MAPs exporters	96
Figure 5.2: Results of the PESTEL analyses according to the main components	98
Figure 5.3: Results of the PESTEL analyses scoring according to subcomponents	99
Figure 5.4: The relational diagram of the QIS in Albania	101
Figure 7.1: Stakeholder attitude and influence in orientation toward QI	129
Figure A.1 GlobalG.A.P. family of products	140
LIST OF BOXES	
Box 1: Object of NAVPP inspections	80
Box 2: NFA inspection planning and implementation	80
Box 3: NOVAL (Tenuis) laboratory	
Box 4: List of certification bodies	87
Box 5: Level of engagement of business associations in raising awareness on quality	90
Box 6: Main measures of relevance for MAPs for the year 2023	106



# **ACKNOWLEDGMENTS**

The preparation of the Value Chain Analysis for the Medicinal and Aromatic Plants (MAPs) sector in Albania has been supported by the Global Quality and Standards Programme (GQSP), funded by the Swiss State Secretariat for Economic Affairs (SECO) and implemented by the United Nations Industrial Development Organization (UNIDO), in coordination with the Ministry of Agriculture and Rural Development (MARD) and the Ministry of Finance and Economy (MFE) of Albania. The development of this Analysis has benefited significantly from the valuable views, inputs and constructive feedback gathered through interviews, meetings and workshops involving various public and private stakeholders engaged in the MAPs sector and in Quality Infrastructure (QI) development in Albania, particularly the General Directorate of Standardization (GDS), the General Directorate of Metrology (GDM) and the General Directorate of Accreditation (GDA).

The Value Chain Analysis has been prepared with the overarching guidance of the UNIDO project team and has built on on the work of the Development Solutions Associates (DSA). The report was drafted by Luciano Leonetti, Edvin Zhllima and Drini Imami. Special

gratitude is extended to Alban Ibraliu, Tokli Thomai and Xhevahire Dulja, Irena Gjika and Alba Tema for their support in the implementation of the study. The report has greatly benefited from the feedback provided by Dorina Nati, Elvana Zhezha, Cong Wu, Rebeca Gallardo and Gerta Alimadhi from UNIDO.

Publication design and layout were developed by Radhika Nathwani at UNIDO.

#### **Disclaimer**

This document has been produced without formal United Nations editing. The designations employed and the presentation of the material in this document do not imply the expression of any opinion whatsoever on the part of the Secretariat of the United Nations Industrial Development Organization (UNIDO) concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries, or its economic system or degree of development. Designations such as "developed", "industrialized" and "developing" are intended for statistical convenience and do not necessarily express a judgment about the stage reached by a particular country or area in the development process. Mention of firm names or commercial products does not constitute an endorsement by UNIDO.







Albania is currently in the process of EU integration and has actively participated in trade liberalization agreements with other countries in the region, as well as with the EU. While trade liberalization expands market access, technical barriers to trade and sanitary and phytosanitary measures have become increasingly significant in regulating trade activities. These barriers can pose significant challenges, especially for developing or emerging economies like Albania, as exporters must prove compliance with market entry requirements, such as standards and technical regulations related to Quality Infrastructure

(QI), including (lack of) relevant technical or human capacities.

The production and trade of medicinal and aromatic plants (MAPs) is a strategic sector for Albanian agricultural and rural development, in terms of contribution to agri-food production, employment and particularly exports (AGT-DSA, 2021). Albania has a long-standing tradition in the production and export of MAPs.

The foundation of the entire MAPS supply chain in Albania is rooted in agro-forestry activities in

mountainous regions. The main driver of development in the sector is export, as more than 90% of the total MAPs output is exported. The MAPs value chain encompasses multiple stages and associated businesses and is labour-intensive. As a whole, it is estimated that the MAPs value chain in Albania contributes to the income of about 20,000 households (AASF, 2019). On the other hand, the Albanian MAPs sector's international trade balance yields a substantial trade surplus, accounting for over a tenth of all agrifood exports (surpassing 40 million USD).

In the last two decades, all performance indicators in the MAPs sector show a positive trend in terms of output growth and trade balance (imports decline or exports increase), as well as in terms of investments. The latter has primarily addressed the following necessities: i) Consolidating the upstream part of the supply chain and transitioning from wild MAPs to cultivated varieties, and ii) Expanding, diversifying and aligning production and product range with the market trends and demand, increasing essential oils extraction and expanding organic certification (AGT-DSA, 2021).

The gradual transition from a predominant reliance on wild MAPs collection to cultivating MAPs has yielded several significant outcomes in terms of quality and sustainability: i) increasing the primary production of certain MAPs became a necessity in order to meet the rising demand for MAPs processing for essential oil, but also to partially replace wild MAPs collection with MAPs cultivation; ii) after two decades of reorganisation and consolidation of the MAPs sector, it became clear that the unresolved issues related to quality standardisation and control in the upstream segment of the supply chain required a substantial change in the traditional structure of this segment of the supply chain; iii) the poor governance of natural resources and the high levels of migration resulted in an intensive harvesting of wild MAPs in some areas, leading to genetic deterioration and weakening of the diversity of MAPs in the existing habitat.

Despite the progress achieved in the agrifood sector in Albania, compliance with food safety and quality standards remains a challenge in terms of both EU approximation and export market requirements. The slow process of consolidation and improvement of the Quality Infrastructure (QI), partially attributed to inadequate public investments, has also played a role in impeding the growth of the MAPs sector, fuelled in part by the mutual distrust or scarce cooperation between public institutions, independent service providers and leading value chain operators.

There have been repeated instances of Albanian MAPs export rejections, mainly due to non-compliance with safety standards, leading to significant financial losses for the traders and frequently impacting primary producers (i.e., farmers) as well. On the other hand, consumers in both export markets and the domestic market are becoming increasingly aware of the

importance of ensuring high food safety and quality standards. This growing awareness is evident in the rising adoption of international or private standards. Products intended for foreign markets must adhere not only to health and safety regulations, but also to the escalating number of additional requirements from international buyers. In many instances, this translates into the necessity to apply voluntary international standards (UNIDO, 2016).

To avoid the above-mentioned needs and to integrate into global markets, Albanian exporters need to ensure compliance with legal and additional requirements, including the adoption of voluntary standards. Therefore, quality infrastructure services (inspection, compliance, and certification) must be available and have sufficient capacity to support every stage of the value chain. On the other hand, the lack of reliable and affordable market information services has had a more significant impact than inadequate QI in generating risks for all agri-food sectors, including MAPs. SMEs, which proved profitable in the short term, are facing factors and market-related challenges in the long-term.

Based on the above, the Global Quality and Standards Programme (GQSP)<sup>1</sup>, an initiative led by the United Nations Industrial Development Organization (UNIDO), has conducted a "Value chain analysis of the medicinal and aromatic sector and fruit and vegetable sector in Albania, focusing on quality, environmental, social, sustainability standards and regulations (market requirements, in particular the EU market requirements) and the capacity to comply".

A quality-related diagnosis of the selected value chains was performed to identify gaps and provide recommendations that tackle the quality infrastructure bottlenecks and constraints that prevent the MAPs value chain from increasing exports and competitiveness. The methodological approach was based on the Quality Along the Value Chain Methodology (QI4VC).

This report is structured into **seven** chapters: The first two chapters present the introduction and methodology, followed by the value chain analysis, including production trends and market trends. The fourth chapter consists of a diagnosis of legal requirements for exports in main countries, including an in-depth analysis of the main provisions for fresh and dried MAPs and essential oils in EEA and US, followed by a description of gaps in the quality infrastructure system in Albania, highlighting features, performance and culture for quality. The sixth chapter provides a description of past and ongoing initiatives. The final chapter consists of conclusions and recommendations.

<sup>1</sup>The Global Quality and Standards Programme (GQSP), supported by Switzerland through its State Secretariat for Economic Affairs (SECO), is a global initiative aiming to assist more than 12 countries worldwide to boost their competitiveness in 16 specific sectors. The objective of the country project in Albania is to sustainably increase market access in the Medicinal and Aromatic Plants (MAP) and Fruit and Vegetable (F&V) value chains by strengthening the capacities for compliance with quality and standards, with a focus on fostering stronger international trade relations, particularly with EU markets,



#### 2.1 METHODOLOGICAL APPROACH

This study is based on the UNIDO Quality Along the Value Chain (QI4VC) approach (UNIDO, 2023). The analysis of selected value chains with a focus on quality infrastructure systems constitutes the conceptual base of this approach.

The value chain (VC) approach is increasingly employed by policy-makers and donors/development agencies to identify suitable entry points to enable the upgrade of the value chain (FAO, 2014). A value chain can be understood as a set of businesses, activities and relationships engaged in creating a final product or service (FAO, 2006). The value chain analysis describes how producers, processors, buyers, sellers, and consumers gradually add value to products as they pass from one link in the chain to the next (UNIDO, 2011).

The dynamics and complexity of a value chain could also represent a challenge for national quality institutions. Hence, it is crucial to highlight the importance of having a fit-for-purpose Quality Infrastructure (QI) that addresses the needs of a specific value chain. Having the proper QI is a crucial element for the development of a sector, increasing exports and competitiveness. Moreover, developing countries with a robust quality system are more likely to gain the trust of importers and investors. By strengthening the institutions, structures and relationships within the QI, an intervention could improve the quality of the products and processes and thereby contribute to the value chain's competitiveness (UNIDO, 2023).

However, there is no ready-made Quality Infrastructure System (QIS) model that will suit all countries and value chains. For this purpose, a tailored-made approach is necessary. Identifying the bottlenecks and gaps at each of the stages of the value chain is crucial to create interventions that tackle the main issues and strengthen not only the institutions, but also the private sector.

The overall objective of this methodology is to perform a quality-related diagnosis of the selected value chain to gain a full understanding of its functioning and better identify and design project interventions that tackle the quality infrastructure bottlenecks that prevent the value chain from increasing exports and competitiveness.

The Quality Along the Value Chain Methodology (QI4VC) is a reliable way to ensure that support to Quality Infrastructure is precisely tailored according to the needs of each value chain, and thereby, interventions can become more effective (UNIDO, 2023). It also ensures stakeholders' participation in developing a shared vision that identifies how the chain should perform and the improvements needed. The outcome of this exercise is the identification, prioritization and attainability of the QI deficiencies of the selected value chain to be strengthened. QI4VC also serves as a tool for policy development as it provides governments, donors and development agencies with an assessment of the quality-related gaps and investment opportunities that need to be addressed to increase exports and competitiveness (UNIDO, 2022).

## 2.2 TYPOLOGY OF DATA

## Secondary data

To ensure comparability between global and Albanian trends, secondary data were retrieved mainly from international databases such as UNSTAT COMTRADE (for international trade), FAOSTAT and EUROSTAT (e.g., international trade). For some indicators, data from the Albanian Institute of Statistics (INSTAT) or the Ministry of Agriculture and Rural Development (MARD) were used. In addition, a thorough review of other relevant studies and reports was carried out.

The focus of the analyses was on priority products, selected on the basis of a prioritisation matrix, as described in sub-chapter **2.3** below. The constraint faced when conducting analyses at the product level is that for some products (e.g., some specific MAPs) there are no available statistics, while for some others the statistics are outdated. Only USDA has HS10 data which are reported and available (relevant only for MAPs that are massively exported to the US

from Albania). It should be noted that in some cases, classifications across different databases do not fully correspond, thus leading to (minor) discrepancies.

#### Primary data

The primary data collection consisted of semistructured in-depth interviews carried out with key informants. More than 50 value chain actors, mainly processors/exporters (with most of the value chain operators of this category included in the sample), as well as experts/stakeholders, were interviewed using two distinct types of questionnaires – the semi-structured survey questionnaire which targeted exporters was based on the QI4VC approach.

A SWOT analysis and a PESTEL analysis (focused on quality infrastructure) were carried out, using a participatory approach. The relevant outcomes are respectively presented in chapter 5 and chapter 7.

## Data analysis

Secondary statistical data and structured questions from the survey have been subjected to a standard descriptive analysis, including tables and graphs depicting statistics and historical trends. The information/notes from the interviews were analysed using a content-summarizing approach and qualitative

content analysis techniques, with the aim of condensing the most relevant and interesting topics that surfaced during the interviews.

The methodology used for the data analysis related to SWOT and PESTEL is described in detail in sub-chapter 2.4 and 2.5 below.

#### 2.3 PRODUCT PRIORITIZATION

A product prioritization process was conducted, which consists of a ranking system based on the cumulative ranking of the performance criteria selected by experts, using a simple formula where each criterion (indicator) is assigned a specific weight. The result is a Product Prioritisation Matrix (PPM) which is generated based on a multi-indicator ranking index. This index combines the scored ranking of several criteria.

The data collected during the inception period and a review of the guiding methodologies from UNIDO (QI4VC tool from UNIDO, 2023) were used to define and calculate the criteria. QI4VC is an innovative assessment tool developed by UNIDO. The QI4VC typically employs a range of performance criteria for selecting or prioritising specific value chains. We

used this approach for selecting the products. The groups of criteria used in QI4VC are categorized into outward performance criteria (export potential and competitiveness, international trade environment) and inward performance criteria (economic, social and environmental) as well as externalities like national development strategies, donor priority sectors, and spill-over effects that influence the development of the selected value chain.

Indicators were selected based on a review of the literature, secondary statistics and semi-structured interviews carried out with experts. In this study, the inward indicators are assigned a weight of 60%, whereas the outward indicators are assigned a weight of 40% (Table 2.1).

**TABLE 2.1:** CRITERIA AND INDICATORS USED FOR THE SELECTION OF PRODUCTS IN THE MEDICINAL AND AROMATIC PLANTS VALUE CHAIN

Туре	Criteria	Indicators	Resources
Export and competitiveness	Market trend	Export value trend in the international market	Secondary statistics/ interviews
	Production/export potential	Area of cultivated MAPs measured in ha	Secondary statistics/ interviews
Environmental, poverty reduction and pragmatic	Impact of product production on the environment	MAPs are capable of being cultivated and replacing the wild stock	Secondary statistics/ interviews
	Contribution to women empowerment and gender equality	Scoring of the engagement of women in self-employment	Interviews
	Extent of value-adding potential	Current inclusion in the distillation industry	Secondary statistics/ interviews
	Project spillover effect	Extent to which the intervention in terms of quality infrastructure will enhance the outcome of other relevant projects	Assessment based on other ongoing initiatives involving SDC or UNIDO

Source: Own elaboration based on QI4VC tool.

The PPM tool was initially designed by defining the criteria and assigning individual weights to each of them. The assignment of the weights and the selection of the criteria were based on consultations with experts. The weight assigned to some criteria depends on the current situation: for instance, the weight assigned to 'future performance' can be lower than the weight assigned to 'recent performance'; this is due to limited

data and lack of reliable forecast estimates.

Each criterion selected was ranked to prepare the ranking table.

The products selected are lavender, sage, helichrysum, oregano and thyme. In addition, distilled oil was selected as a cross-cutting added-value product derived from the most competitive MAP.

# 2.4 PESTEL AND QI PERFORMANCE ASSESSMENT

In order to examine the macro-environmental (external environment) and the relevant factors influencing the quality infrastructure (QI) a PESTEL (Political, Economic, Social, Technological, Environmental and Legal) analysis was used. The outcomes of this exercise are provided in **Chapter 5**.

The analysis enables the identification, tracking and assessment of the key factors that might influence the QI. The analysis is conducted in two steps: i) Selection of the relevant PESTEL components from a list determined through brainstorming sessions, expert assessment and literature. ii) The relevant components were further broken down into sub-factors, forming the metrics used to assess the QI.

The advantage of the PESTEL analysis lies in its ability to provide an understanding of the broader business

environment, fostering the cultivation of strategic thinking. However, it is crucial to engage highly qualified expertise in compiling the PESTEL analysis. The PESTEL template was provided to participants during the workshop held for the presentation of the preliminary results<sup>2</sup>. Participants were familiarized with the methodology and received guidance on how to assess each PESTEL component, assigning a score ranging from o to 6 ("o" indicating "no influence" and "6" indicating "maximum influence"). During the workshop, a total of 31 templates were completed by participants, and the information from these templates was subsequently entered into an Excel database form. Each component underwent descriptive analyses, with the aim of calculating the average scores and the standard deviation. The template used for the PESTEL analyses is provided in table 2.2 below.



<sup>&</sup>lt;sup>2</sup> Workshop "UNIDO PROJECT ID 200309 Global Quality and Standards Programme Albania: Strengthening quality and standards compliance capacity for selected value chains" performed on February 17th, 2023 in Tirana

**TABLE 2.2.** ASSESSMENT OF THE ELEMENTS OF PESTEL (IN RELATION TO QI) WITH A FOCUS ON THE SELECTED VALUE CHAIN

Political - The regulatory role of the government in relation to business, labor legislation, commercial legislation, consumer protection legislation, environmental protection legislation, etc.	0	1	2	3	4	5	6
	No influence	£	£	£	£	£	Maximum influence
	No influence	£	£	£	£	£	Maximum influence
	No influence	£	£	£	£	£	Maximum influence
	No influence	£	£	£	£	£	Maximum influence
,	No influence	£	£	£	£	£	Maximum influence
Economic - Economic situation (macro indicators), market openness, ownership, competition, etc.	0	1	2	3	4	5	6
1 1 7	No influence	£	£	£	£	£	Maximum influence
, ,	No influence	£	£	£	£	£	Maximum influence
	No influence	£	£	£	£	£	Maximum influence
	No influence	£	£	£	£	£	Maximum influence
5 1	No influence	£	£	£	£	£	Maximum influence
Socio-demographic trend, education, culture for QI, etc.	0	1	2	3	4	5	6
	No influence	£	£	£	£	£	Maximum influence
Does immigration encourage/cause the improvement of the	No	£	£	£	£		Maximum
QI?	influence	_		_	_	£	influence
Is the local educational level sufficient to encourage/cause	No influence	£	£	£	£	£	
Is the local educational level sufficient to encourage/cause the improvement of quality standards?  Does the development of society's consumption culture	No						influence Maximum
Is the local educational level sufficient to encourage/cause the improvement of quality standards?  Does the development of society's consumption culture encourage/cause the improvement of quality standards?  Does the behavior of foreign consumers affect the	No influence No	£	£	f	£	£	influence Maximum influence Maximum
Is the local educational level sufficient to encourage/cause the improvement of quality standards?  Does the development of society's consumption culture encourage/cause the improvement of quality standards?  Does the behavior of foreign consumers affect the improvement of quality standards?  Technological - Innovation and technology transfer,	No influence No influence No	£	£	£	£	£	influence Maximum influence Maximum influence Maximum
Is the local educational level sufficient to encourage/cause the improvement of quality standards?  Does the development of society's consumption culture encourage/cause the improvement of quality standards?  Does the behavior of foreign consumers affect the improvement of quality standards?  Technological - Innovation and technology transfer, intellectual property rights, availability and access to the services of research institutes.  Do the capacities of national laboratories suffice to enhance	No influence No influence No influence	££	f f f	f f f	f f	f f	influence Maximum influence Maximum influence Maximum influence
Is the local educational level sufficient to encourage/cause the improvement of quality standards?  Does the development of society's consumption culture encourage/cause the improvement of quality standards?  Does the behavior of foreign consumers affect the improvement of quality standards?  Technological - Innovation and technology transfer, intellectual property rights, availability and access to the services of research institutes.  Do the capacities of national laboratories suffice to enhance quality standards?  Has product certification brought about the fulfilment of	No influence No influence No influence o	f f f	f f f	f f f	f f f	f f f	influence Maximum influence Maximum influence Maximum influence  6 Maximum
Is the local educational level sufficient to encourage/cause the improvement of quality standards?  Does the development of society's consumption culture encourage/cause the improvement of quality standards?  Does the behavior of foreign consumers affect the improvement of quality standards?  Technological - Innovation and technology transfer, intellectual property rights, availability and access to the services of research institutes.  Do the capacities of national laboratories suffice to enhance quality standards?  Has product certification brought about the fulfilment of quality standards?	No influence No influence o No influence No influence	f f f	f f f	f f f	f f f	f f f	influence Maximum influence Maximum influence Maximum influence  6 Maximum influence Maximum
Is the local educational level sufficient to encourage/cause the improvement of quality standards?  Does the development of society's consumption culture encourage/cause the improvement of quality standards?  Does the behavior of foreign consumers affect the improvement of quality standards?  Technological - Innovation and technology transfer, intellectual property rights, availability and access to the services of research institutes.  Do the capacities of national laboratories suffice to enhance quality standards?  Has product certification brought about the fulfilment of quality standards?  Is innovation in farm production protocols promoting QI?  Have advisory services (extension) contributed to the	No influence No influence O No influence No influence No influence No influence	f f f f f f	f f f f	f f f f f f f f f f f f f f f f f f f	f f f f f f	f f f f f	influence Maximum influence Maximum influence Maximum influence  6 Maximum influence Maximum influence Maximum

Environmental technological solutions and policies, particularly related to climate change, with the goal of preserving the potential of natural resources	0	1	2	3	4	5	6
Are climate change adaptation interventions influencing the improvement of the QI?	No influence	£	£	£	£	£	Maximum influence
Is environmental legislation enforcement driving the improvement of the QI?	No influence	£	£	£	£	£	Maximum influence
Do policies and regulations for sustainable land and water use promote better QI?	No influence	£	£	£	£	£	Maximum influence
Does the level of infrastructure (electricity, roads, telephone, internet, logistics) influence the development of the QI?	No influence	£	£	£	£	£	Maximum influence
Do developments in renewable energy drive the improvement of the QI?	No influence	£	£	£	£	£	Maximum influence
Legal - European, national, sectoral legislation forming an institutional framework for fostering development within the business environment	0	1	2	3	4	5	6
Is legal alignment with the EU sufficient to promote the improvement of the QI?	No influence	£	£	£	£	£	Maximum influence
Is political attention to quality institutions sufficient to promote the development of the QI?	No influence	£	£	£	£	£	Maximum influence
Is sector-level legislation useful for promoting the development of the QI?	No influence	£	£	£	£	£	Maximum influence
Are Albanian institutions promoting quality and safety contributing to the development of the QI?	No influence	£	£	£	£	£	Maximum influence
Are Albanian inspection institutions for food safety and quality standards helping the development of the QI?	No influence	£	£	£	£	£	Maximum influence

Source: Author's adaptation from Marmol et al. (2015)

# 2.5 CULTURE FOR QUALITY AND SWOT ANALYSIS

It is crucial to assess culture for quality in the context of the selected sector/value chain, by emphasizing the relevant important aspects such as food safety and quality awareness and how they are addressed. Culture for quality, as aligned with ISO 9000:2015, encompasses customer focus, leadership, people engagement, process approach, improvement, evidence-based decision-making and relationship management.

We have drafted a subsection (5.8) which addresses the key elements of culture for quality in the context of the stakeholders of the selected value chain. After providing an overview of the consumer / customer perceptions and expectations, we delve into leadership, guided by the relevant literature, with a specific focus on forms of value chain governance, such as contract farming (see 5.8.3). Forms of value chain governance / leadership are crucial to improve value chain performance, including standards compliance. In this context, we also highlight the nature of relations between stakeholders of the value chain. The following subsection (see 5.8.3), focuses on the process approach, evidence-based decision making and improvement. Here, there is a special emphasis on the use of laboratory analysis as a basis for making decisions (evidence-based decision making) and improving performance / compliance with standards.

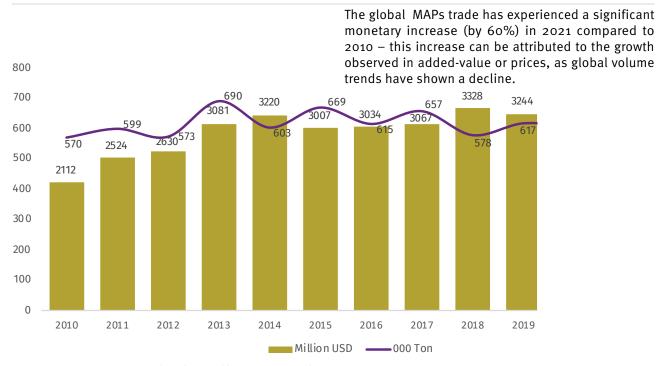
On the other hand, a comprehensive SWOT exercise was conducted in order to identify potential intervention priorities, with a focus on selected priority products. The outcomes of this exercise are provided in **Chapter 7**. The primary emphasis was placed on weaknesses and threats within the policy, regulatory and institutional efforts aimed at achieving quality standards and identifying lucrative markets for the priority MAPs products. The SWOT template was provided to participants in the workshop held in the context of the presentation of the preliminary results. Participants were introduced to the SWOT components and discussions were held with participants on the main strengths, weaknesses, opportunities and threats related to quality infrastructure in the selected value chains. Participants were provided with guidance to rank the 5 most significant weaknesses and 5 most critical threats. Participants were further encouraged to describe any additional significant weaknesses or threats influencing the advancement of quality in the targeted value chains, which have not been identified in the template. During the appraisal, a total of 31 templates were completed and subsequently entered into a spreadsheet form. Each component underwent descriptive analyses, which involved estimating the frequency of selected options for each weakness and threat based on the indicated level of importance.



# 3.1 GLOBAL TRENDS

The worldwide production of medicinal and aromatic plants (MAPs) is estimated to be 330 million tons from a total area of 77 million ha. However, it is not easy to accurately assess how many MAPs are commercially traded on an international or even national level (Argyropoulos, 2019). Considering the limited availability of data on MAPs in international databases, especially in relation to production, this sub-chapter focuses on trade.

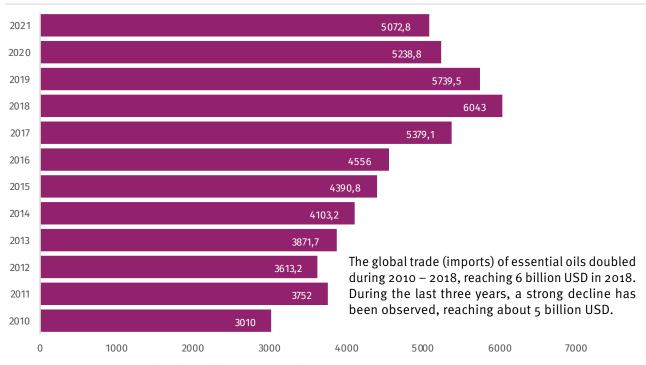
FIGURE 3.1: GLOBAL TRADE (IMPORT) OF MAPS



Source: UN Comtradedatabase (2023) https://comtrade.un.org/data

The main MAPs exporting countries are China and India, followed by Germany and the US. The main markets (importing countries) are the US (15%), Germany (12%), Japan (8%) and China (6%). Countries such as France, India and Spain import less than 4% of the global imported MAPs (UN Comtrade, 2022).

FIGURE 3.2: GLOBAL IMPORT OF ESSENTIAL OILS (HS 3301) (MILLION USD)



Source: UN Comtradedatabase (2023) <a href="https://comtrade.un.org/data">https://comtrade.un.org/data</a>

The leading exporting countries of essential oils are India (976 million USD), the US (866 million USD), France (501 million USD), China (349.3 million USD) and Brazil (279 million USD). The main markets (top importing countries) of essential oils in 2021, in terms of import values, were the US (23%), France (9%), Germany (8%) and China (7%) (UN Comtrade, 2023).

#### 3.2 MARKET TRENDS IN MAIN MARKETS

The main markets for MAPs globally and for Albanian exports in particular are the EU and US markets. The import of MAPs in the EU has increased by 71 percent since 2010 in monetary value. The share of Albanian MAPs in the basket of EU imports has shown a growth from 2 to 4 percent during the same period – thus, the increase in the import of MAPs from Albania is outpacing the overall import trends within the EU.

The import of MAPs in the US has increased by 82 percent since 2010 in monetary value. The share of Albanian MAPs in the basket of US imports has been similar to the EU one shown above, namely increasing from 2 to 4 percent during the same period – thus the increase in the import of MAPs from Albania is outpacing the overall import trends also in the case of the US.

**TABLE 3.1:** IMPORT TRENDS OF MAPS IN THE EU AND US (HS 1211)

Year	EU		US			
rear	Mill USD	Albanian share	Mill USD	Albanian share		
2010	365	2%	268	2%		
2015	452	3%	394	4%		
2016	490	3%	413	3%		
2017	526	3%	410	2%		
2018	575	3%	453	2%		
2019	563	4%	403	3%		
2020	569	4%	434	4%		
2021	627	4%	490	4%		

Source: UN Comtradedatabase (2023) <a href="https://comtrade.un.org/data">https://comtrade.un.org/data</a>

The import of essential oils in the EU follows a similar pattern to the import of MAPs — it has increased by 71 percent since 2010 in monetary value. The share of Albanian essential oil in total EU imports is insignificant, averaging around 0.1 percent.

The import of essential oils in the US has increased significantly since 2010 – it has more than doubled. Similarly to the EU, even in the case of the US, the share of Albanian essential oils in total imports remains negligible, despite of the strong upward trends.

**TABLE 3.2:** IMPORT TRENDS OF ESSENTIAL OILS IN THE EU AND US (HS 3301)

Year	EU		US			
	Mill USD	Albanian share	Mill USD	Albanian share		
2010	724	0.1%	571	0.0%		
2015	986	0.0%	988	0.0%		
2016	1022	0.1%	1064	0.0%		
2017	1159	0.1%	1269	0.2%		
2018	1259	0.1%	1376	0.4%		
2019	1125	0.1%	1096	0.4%		
2020	1025	0.1%	1060	0.3%		
2021	1244	0.2%	1179	0.5%		

Source: UN Comtradedatabase (2023) <a href="https://comtrade.un.org/data">https://comtrade.un.org/data</a>

The main Albanian MAP in terms of production (both cultivated and wild) and export is sage (for more details see sub-chapter 3.4).

## 3.3 ALBANIAN PRODUCTION TRENDS

The cultivation of Albanian MAPs reached a value of 16 thousand tons in 2021, marking an increase of nearly three times when compared to 2012. The primary factor driving this growth is the expansion of the cultivation

area. The expansion of the cultivation area has been stimulated by subsidies (with a particular focus on supporting investments in cultivation in the case of MAPs) (Gecaj et al, 2020).

TABLE 3.3: PRODUCTION OF MAPS IN ALBANIA (PERIOD 2012-2021)

Category	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Area (ooo ha)	-	-	5.0	5.0	5.0	5.4	5.6	5.6	6.3	7.0
Production (ooo ton)	5.3	7.0	17.4	10.8	10.6	12.8	12.5	12.9	14.4	16.0
Yield (Ton/ha)	-	-	-	0.21	0.20	0.23	0.22	0.22	0.22	0.22
Annual growth of production	-	-	-	-	-	8.3%	2.8%	0.6%	12.5%	11.8%
Annual growth of cultivation	-	-	-	-	-	20.7%	-2.5%	3.1%	11.5%	10.8%

Source: INSTAT (2022). The 2021 statistical yearbook. http://instat.gov.al/al/temat/bujq%C3%ABsia-dhe-peshkimi/bujq%C3%ABsia/#tab2

Data on the trends of wild MAPs are limited (3 years). Interviews suggest that due to demographic transition (migration and aging, hence fewer people who can

collect wild MAPs), as well as improper harvesting of wild MAPs, the overall wild MAPs collection has almost halved in some areas when compared to 10 years ago.

TABLE 3.4: PRODUCTION OF WILD MAPS IN ALBANIA (2019-2021)

Category	2019	2020	2021	
Area of wild MAPs (ha)	633,466	662,790	537,513	
Production of wild MAPs (ton)	4,615	3,781	7,608	
No. of organic MAPs farms	40	49	-	
Percentage in total organic farms	49%	43%	-	

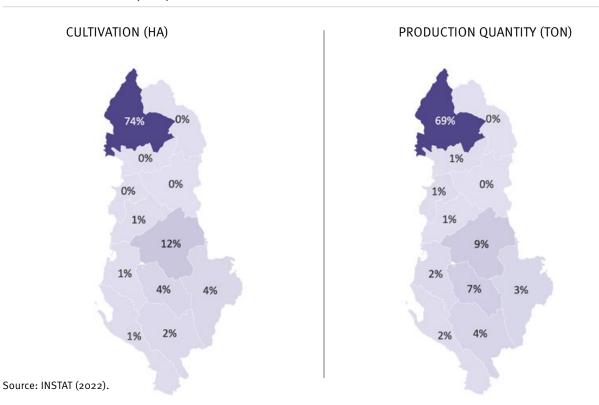
 $Source: INSTAT \ (2022). The 2021 \ statistical \ yearbook. \ \underline{http://instat.gov.al/al/temat/bujq\%C3\%ABsia-dhe-peshkimi/bujq\%C3\%ABsia/\#tab2}$ 

Regionally, MAPs cultivation is mainly concentrated in northern Albania, specifically in the Shkodra region (with a significant production in Malësia e Madhe), accounting for 70%-74% of the total MAPs production and cultivation of in the country. Another important

region is Elbasan, accounting for 9%-12% of the total MAPs cultivation and production in the country. Other areas of relatively high production are Berat (mainly Skrapar area) and Gjirokastër (mainly Përmet area), as well as Kukës and Dibër.



FIGURE 3.3: GEOGRAPHICAL DISTRIBUTION OF MAPS CULTIVATION AND PRODUCTION IN ALBANIA BY REGION (2021)



## 3.4 ALBANIAN INTERNATIONAL TRADE TRENDS

MAPs exports have been increasing in both quantity and value. That increase has been fueled both by an increase in global demand and by an increase in production capacity in Albania, due to growing cultivation trends, as shown in the previous version.

## FIGURE 3.4: ALBANIAN EXPORT OF MAPS (HS CODE 1211)

Albanian exports of MAPs reached EUR 41.5 million or 14 thousand tons in 2021, showing a notable growth rate since 2012, when only around 5 thousand tons were exported. The increase from 2010 to 2021 amounts to nearly 160% in volume and 307% in value, implying a concurrent increase in prices.



FIGURE 3.5: DISTRIBUTION OF ALBANIAN EXPORT OF MAPS (HS CODE 1211) DURING 2021

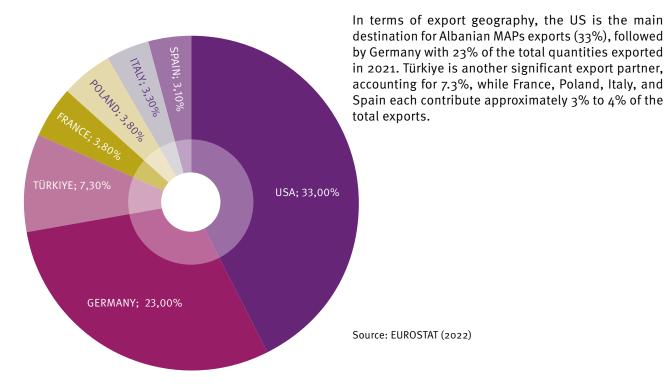
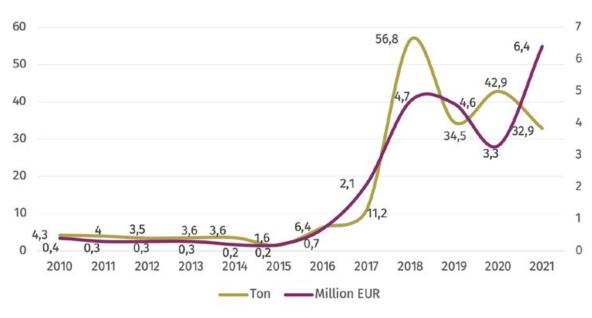


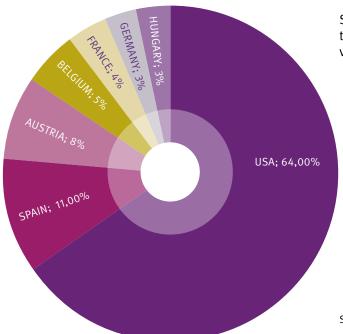
FIGURE 3.6: ALBANIAN EXPORT OF ESSENTIAL OILS (HS CODE 3301)



Source: EUROSTAT (2022)

In 2021, Albania exported around 33 tons of essential oils, equivalent to roughly 6 million euros in value. The trend of essential oil exports has shown significant improvement over the past years, compared to a very low level in 2010, with only around 4 tons exported.

FIGURE 3.7: DISTRIBUTION OF EXPORTS OF ESSENTIAL OILS (HS CODE 3301) IN 2020



Similarly to dried MAPs, essential oils are also directed towards the US and EU markets. Almost 2/3 of the total value of exported essential oils is exported to the US.

Source: EUROSTAT (2022)

As highlighted earlier, sage is the main MAP produced and exported. Albania is a key global player – for example, the majority of sage imports in the US (more than  $\frac{3}{4}$ ) is sourced from Albania. Exports to the US (main market for Albanian sage) have been increasing from year to year. In 2020, Albanian exports of sage to the US reached a record value of nearly USD 12 million, corresponding to a quantity of 3,227 tons. The price of exported sage has been fluctuating within the range of 2.9 USD/kg to 4.1 USD/kg.

TABLE 3.5: US SAGE IMPORTS FROM ALBANIA BY YEAR

Year	Imported value oooUSD	Share to total import (value)	Imported Quantity (tonnes)	Share to total import (quantity)	Price (USD/kg)
2010	4,120	52%	1,223	54%	3.4
2015	10,554	75%	3,259	83%	3.2
2016	10,031	68%	3,447	80%	2.9
2017	6,106	58%	2,024	71%	3.0
2018	8,078	54%	3,097	73%	2.6
2019	10,260	64%	2,944	75%	3.5
2020	11,793	67%	3,277	78%	3.6

Source: USDA (2022). <a href="https://apps.fas.usda.gov/gats/ExpressQuery1.aspx">https://apps.fas.usda.gov/gats/ExpressQuery1.aspx</a>

# 3.5 ALBANIAN MAPS VALUE CHAIN STRUCTURE AND STAKEHOLDERS

# 3.5.1. Input suppliers

Input suppliers represent a major source of information and advice for MAPs farmers, similarly to the case of fruits and vegetables. At times, processors have distributed to farmers inputs such as seeds or seedlings, either for free or at reduced prices, in order to enhance the production of specific varieties of MAPs and maintain quality control.

With the exception of a few MAPs (e.g., sage) which are partially developed using locally collected propagules,

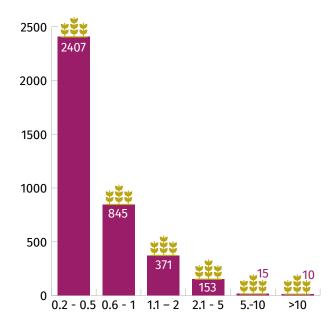
the expansion of cultivated plots primarily relies on imported seeds (AGT-DSA, 2021). There is increasing attention to producing certified indigenous seeds from local genotypes or commercial production of MAPs seedlings from certified local seeds. Experiments have been carried out by the ATTC (Agriculture Technology Transfer Center) of Shkoder, which has the capacity to boost indigenous seedling production and to test the introduction of new MAPs varieties. There are also cases of exporters / processors who are engaged in the testing of new varieties to assess their performance before distributing the relevant seedlings to supplying farmers.

# 3.5.2. Harvesters and cultivators

Harvesters are primarily rural households/farmers/people living in the rural and mountainous areas of the country. They harvest wild MAPs, dry them, and store them in their houses until they sell them to collectors or directly to processors. There are up to an estimated 20,000 farming households engaged in wild MAPs collection (Skreli and Imami, 2019). In addition to silvo-pastoral communities (i.e. those who typically have livestock too, especially small ruminants), it is also common for households in urban areas to engage in seasonal wild MAPs collection.

# **FIGURE 3.8:** DISTRIBUTION OF CULTIVATED MAPS FARMS BY SIZE (2020)

During the past decade, there has been an increase in the production of cultivated MAPs (as highlighted earlier). Estimates indicated that there are currently around four thousand farmers that cultivate MAPs. Most of them are small, below one Ha.



Source: AGT-DSA, 2021

# 3.5.3. Individual Collectors

There is a significant number (around 150-200) of **individual collectors** at the municipal and village level. They supply various aggregators or directly to processors. Individual collectors usually collect wildgrown MAPs from local harvesters and sell them to district-level aggregators or even directly to processing companies. The markup / profit margins depend on the plant type and the value added through their operations (other factors like humidity, colour, plant origin and the quantities available in the market also influence the markup).

# 3.5.4. Aggregators

There are around 30 **regional/district level collectors/ aggregators**. They serve as intermediaries between farmers and small individual collectors and processing companies. They provide expertise and technologies related to cultivation protocols and harvesting practices. This is driven by their desire to maintain control over the quality of MAPs. Although they do not have any significant processing capacities, they often perform some simple but rather essential value-added operations such as drying, cleaning, and sorting. Some of them use old buildings as warehousing storage facilities.

# 3.4.5. Processors/exporters

These are divided into small and large exporters. There are nearly two dozen small processors, each contributing value to the raw product through processes like cleaning, grinding, and packaging. Their typical capacity varies between 150 to 500 MT of MAPs per year. They sell directly to foreign customers or via specialised exporters. On the other hand, there are nearly a dozen larger operators (exporters/processors) that both process and store large inventories of various types of MAPs with volumes reaching up to 2000 tons per year in some cases. The largest exporters are Filipi Co Herbs & Spices, Albkalustyan Relikaj, Herba Fructus Natural, Agroherbal, Gjedra, Albania Herb SHA, Cibuku and MEIA. Both groups produce essential oils via distillation processes. The market is export-driven - only a small share is oriented towards the supply of domestic supermarkets, green markets and HoReCA. There are a few companies and several producer groups that sell a wide range of packed herbs (e.g. Natyral and ATC), tea infusions (e.g. Craco) and a limited variety of essential oils (mostly the larger exporters, but also small processors).

## 3.4.6. Retail

While export markets are the primary destination for MAPs, there is also an increasing demand within the local market. Processed or fresh MAPs, used mainly as tea infusions and flavouring agents, are sold via different **retail outlets**. As the retail sector is consolidating, supermarket chains are also becoming an important outlet for these products. Several supermarkets sell MAPs supplied by local processors. However, groceries, drug stores, restaurants, pharmaceutical shops and specialised shops remain

relevant outlets for food processing companies. In this respect, it is worth mentioning Neranxi and Merja, which operate a specialised retail chain - Neranxi is also a prominent importer of spices and dried fruits. Some varieties of MAPs are sold in the fresh fruit and vegetable markets (AGT-DSA 2021).

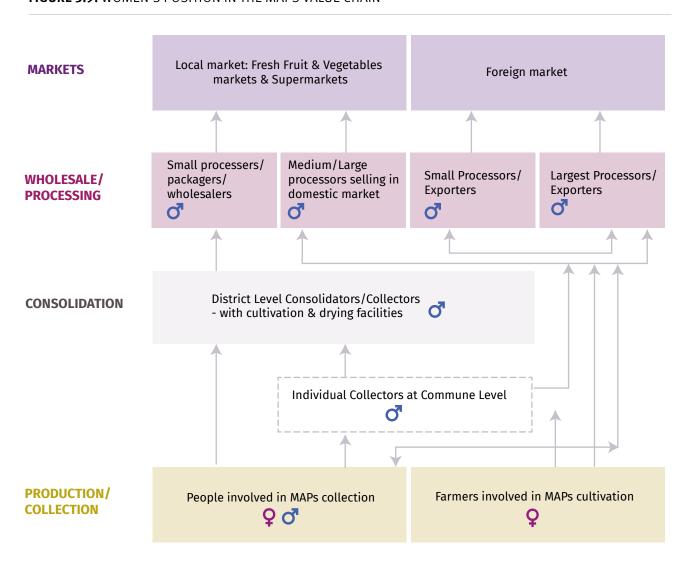
## 3.6 ENGAGEMENT OF WOMEN AND YOUNG PEOPLE IN THE MAPS SECTOR

Previous studies have shown that, despite of the immense contribution of women to the agricultural sector, the established cultural norms impede ownership rights and limit the types of roles (where and what) that women are able to play within the sector. However, women often play critical roles in

rural households and farming. This is particularly due to the fact that men often migrate (on a seasonal or permanent basis) or may be employed in non-farming activities.

The following diagram illustrates the engagement of women and men in each stage/link of the value chain.

FIGURE 3.9: WOMEN'S POSITION IN THE MAPS VALUE CHAIN



Note.  $\mathbf{Q}$ -female-dominated  $\mathbf{Q}_{\mathbf{C}}$ -joint participation of females and males

Source: GIZ, 2021

The MAPs activities are based on wild harvest and cultivation. Both men and women are engaged in the collection of wild MAPs.

In the cultivation process, the majority of the activity is based on small and medium-sized farms. The presence of hired labour dominated by women is quite frequent. Women are involved in the cultivation of plants, while men handle the tasks of loading and transporting the produce. Most hired employees are women. In family farming, the division of labour is less evident. However, according to estimates made by IDRA/ISETN (2018), it was observed that the share of women engaged in labour is significantly higher compared to men. Cultivation at a small level enhances the opportunities for women to work and generate income under more comfortable conditions compared to the collection of wild MAPs. Furthermore, engagement in the cultivation of MAPs allows women to effectively manage their household tasks, as the majority of the work takes place in plots that are conveniently close to their homes. At the farm level, women are more extensively involved in labour-intensive tasks, such as weeding, harvesting, and post-harvesting processes, in comparison to men. Women are responsible for the vast majority of farm operations, while men usually focus on managerial tasks such as sales (this is similar to the findings of FAO, 2018 and GIZ, 2021).

Export enterprises are mostly managed by men. However, they often engage younger and more highly educated members (both male and female) of their extended families for a range of management- and administration-related tasks, such as handling relations with buyers and managing the inventory, for example. At the processing level, women constitute the most significant portion of the hired labour force.

Women frequently carry out extensive and labourintensive sorting and cleaning operations for MAPs at the processing level. Considering their involvement in both types of processes, it is obvious that their contribution to the farming/harvesting level is higher.

Findings from a survey conducted among MAPs household farms (GIZ, 2021) indicate that the majority of women in MAPs family-run farms are never or rarely engaged in activities such as applying for credit or learning new technologies. In addition, approximately 80% of the respondents stated that men are responsible for representing the farm in administrative units and participating in capacity-building activities (GIZ, 2021).

Access to services and inputs is limited, particularly for women. Women are less likely to attend trainings in rural areas and interact with input suppliers, who are often the main source of information about production technologies.

When it comes to young people, the greatest challenge lies not so much in the demand for their labour or engagement, but rather in their (comparatively limited) interest in participating in the agricultural sector and residing in rural areas. Depopulation of rural areas, especially the more remote ones, is now common and is being particularly driven by the movement of young people. Interviewed exporters provided evidence indicating that the average age of workers in cultivation farms and companies is around 50 years old. There is a lack of interest among young people to engage in the agricultural sector, especially when it comes to demanding tasks such as harvesting wild MAPs and cultivating them. In the case of harvesting, the labour is inherently strenuous, and in the case of cultivation, lack of mechanization makes certain work processes difficult.

## 3.7 THE IMPACT OF CLIMATE CHANGE ON MEDICINAL AND AROMATIC PLANTS

In Albania, the implications of climate change on Albanian agriculture could be substantial. While there are no clear indications of the effect of climate change, recent literature suggests that Albania is one of the most sensitive areas in South Europe. As stated by Sutton et al. (2013), temperature rises are more significant and precipitation declines are more noticeable in July and August, relative to current conditions. In the northern mountains of Albania, the rise in summer temperatures can be as much as 4 to 5 degrees Celsius. Forecast precipitation declines are more pronounced during the crucial period of May-September, when precipitation is already at its lowest levels, particularly in the southern and northern mountains. Also, Mueller and Hoffman (2022) provide evidence of a rapid surge in summer temperatures, a reduction in precipitation and an increase of consecutive dry days during the period 1992-2020. Despite the demonstrated resilience of both wild and cultivated MAPs, areas with limited irrigation could

become highly vulnerable and experience losses in terms of yield and quality. Studies on the impact of climate change on MAPs are scarce and relatively shallow (Skreli and Imami, 2019; Zhllima et al, 2022). Extreme weather events are already affecting the availability and supply of MAPs on the global market, and projected future rises in extreme weather are likely to have a further adverse impact on MAPs yields.

Based on expert assessments, the impact of climate change on MAPs includes the following:

- » Heightened population dynamics of insects
- » Emergence of new pests
- » Shifting patterns in pest and disease development and evolution of new pest strains.
- » The quality of MAPs seed production is also being affected by crop/weed interactions, loss of <u>pollinator</u> biodiversity, and <u>genetic diversity</u>.

According to experts, climate change is expected to have the following impacts on MAPs:

- » Alteration of MAPs' phenology, seed reproduction, flowering, anthesis/pollen viability, pollination/ fertilization, seed dormancy, seed yield, and ultimately seed quality.
- Decreased productivity and quality due to high temperatures. Temperature-related stress can affect the production of secondary metabolites and other compounds that typically form the foundation of medicinal properties of plants. As a result of higher temperatures, the MAPs will begin to produce less of these compounds, which could lead to a partial reduction in their capacity to act as antioxidants for human health benefits.
- Several threats are posed to MAPs species.
   Different plant species can respond differently
   to climate change, and this divergence applies
   to medicinal species as well. Some species can
   move to higher latitudes or altitudes, whereas
   other species face the threat of extinction.

To mitigate the future vulnerabilities of MAPs to climate change, it is crucial to conserve endangered wild flora. This will include the cultivation of MAPs by adapting the selection of varieties and cropping cycles. Agroforestry practices and other nature-based solutions are recommended to integrate species that are well adapted to the local habitat and capable of thriving under the new climatic conditions. The recommendations are provided in the last chapter of the report.







As described in the QI4VC methodology (UNIDO, 2022), market operators and exporters must ensure the highest product quality to comply with market requirements (mandatory and voluntary standards) in order to avoid potential rejections and better integrate into global markets. In order to achieve this, the availability and accessibility of QI services

for the private sector are of primary importance. This chapter outlines the mandatory legal requirements and the voluntary requirements (standards and certification programmes) related to quality and provides recommendations for the Albania QI system with relevance to the MAPs value chain.

# 4.1 GENERAL ASPECTS

#### **GENERAL ASPECTS**

The first distinction to be made within these quality requirements involves distinguishing between; i) requirements, which are related to mandatory legal provisions and, ii) voluntary standards and certification programmes, which are related to quality requirements or schemes introduced by the trading counterparts

The most relevant *requirements* for marketing any product in any given market generally fall into two categories:

- **1. Documentation related to Quality Infrastructure QI,** which includes all requirements related to:
  - 1. Consumer safety along the supply chain, including handling, transport and storage;
  - 2. Marketing and market access;
  - 3. Labelling and provision of information to consumers or users
  - 4. Items in contact with the product, including packaging;
  - 5. Phytosanitary controls (for plant products).

#### 2. Administrative documentation not related to QI,

mostly consisting of rules related to fiscal issues and trade-related fiscal barriers.

The categories of requirements related and not related to QI are the same across all markets; however, the specific requirements can significantly vary based on the destination market. Even within the EU market, Member States may establish additional and stricter requirements for their respective market jurisdictions. Such additional requirements cannot be less stringent that the already established ones. Other countries with legislation aligned to the EU *acquis*, like Switzerland, have specific and EU-harmonized requirements, yet operate under an independent legal framework.

Voluntary standards are intended to adopt stricter or additional features as compared to legal requirements. Certification programmes can be used to certify the compliance of a given product with a set of requirements and/or with voluntary standards. Certification programmes involve a protocol which is usually based on control points and accredited/

licensed auditors that regularly verify the compliance of certification subjects with the protocol.

# **CATEGORIES OF QI-RELATED REQUIREMENTS**

- 1. Consumer safety (EC, 2023a) covers various aspects of food and non-food products. With regard to the products covered in this document, the distinction is detailed below.
- » Food safety for fresh and dried MAPs and MAPs essential oils when sold as a food product or flavouring for food products;
- » Safety related to chemical products and compounds when dealing with MAPs essential oils utilized in various applications such as cosmetics, novel products (e.g., pharmaceuticals), or non-food purposes.
  - 2. Traceability (EC, 2023b) includes the tools to trace a product along the entire supply chain, based on the "one step back one step forward" recording approach; it includes the TRACES platform (EC, 2021) to facilitate trading while standardizing and sharing documents and information.
  - Marketing requirements refer to the quality attributes of a product that must be met to ensure compliance with market access criteria.
  - 4. Labelling(EC, 2023c), including elements for traceability; these regulations are relevant to the information to be provided to the buyer.
  - 5. Items and materials in contact with the product(EC, 2023d), including packaging refer to the characteristics of materials and items used along food supply chains, such as transport containers, processing machinery and packaging materials. Those items and materials or the contact between those materials and the product stored, handled, or processed must not cause harm to consumers and shall minimise the impact on the environment.
  - 6. Phytosanitary or veterinary controls(EC, 2023e), for live plants and animals and food products, are aimed at managing pathogens that affect plants and animals; pathogens associated with food-borne diseases are regulated as part of food safety.

The most important distinction when dealing with food products is between food safety and food quality requirements.

Only the first three components are pertinent to QI. Even though certain documents such as the proof of origin (certificate of origin) have the primary function of satisfying administrative requirements, they also contribute to the functionality of the traceability system.

In addition to regulations, which are translated into mandatory requirements to be complied with, almost all buyers top up the legal requirements with additional requirements, which can be translated into formalized standards or contractual agreements.

An increasing number of producers are also voluntarily adopting different standards related to the adoption of good practices associated with the value chain (e.g. GlobalGAP IFA), production regimes (e.g. BioSuisse) or good practices related to a specific topic (e.g.VeganOk).

Compliance with the requirements related to QI is only partially associated with the mandatory documentation; in the EU, the Swiss Confederation and the US, only the phytosanitary requirements are associated with a mandatory certification. Although most requirements, especially those dealing with food safety, must be complied with, there is no need for documentary evidence.

# 4.2 OVERVIEW OF PRODUCT CATEGORIES AND SCOPE OF THE STUDY FOR THE MAIN MARKETS

# 4.2.1 Products/markets selection

As illustrated in the methodology chapter, the prioritization process led to the selection of five medicinal and aromatic plants. Based on actual and potentially realistic export flows of the selected products, a product/destination market matrix was produced, as presented in **Table 4.1** below. The analysis of legal requirements and the most common additional requirements and certifications required by the buyers will be focused on the products/markets highlighted in the matrix.

**TABLE 4.1: PRODUCTS/MARKETS MATRIX** 

Product	Fresh/ processed	Market			
Medicinal Aromatic Plants					
Oregano, sage, thyme	Dried for food use <sup>3</sup> , essential oil for food and cosmetics	EU, US			
Helichrysum, Lavender	Dried for fragrance; essential oil for cosmetics and pharmaceutical industry	EU, US			

# **Product specifics**

Some dried MAPs, such as **lavender and helichrysum**, are mainly used for essential oil production, lavender flowers and are also used as dried fragrances; the

quantity of these two dried MAPs used as a fragrance is small and there are no direct exports for this destination of use from Albania; however, dried lavender and helichrysum exported from Albania could be eventually used for this purpose.

# 4.2.2 Export modalities for the selected MAPs products

# Overall export structure and requirements

Albanian MAPs are exported dried or in the form of essential oils. At present, most of the exported Albanian MAPs are intermediate products; dried Albanian MAPs are mostly sold as food products; essential oils are exported only as initial intermediate products for supply chains that involve several further processing steps. **Table 4.2** below shows the final destination of the priority MAPs analysed in this document.

- » Dried MAPs are exported in bulk and can be further processed either as food flavourings in retail packaging or as ingredients in the food processing industry;
- » Essential oils are exported as an intermediate product for further processing. In most cases, the same essential oil is required by different industries (food, detergents, cosmetics etc.) with different minimum requirements, depending on the use. Albanian essential oils production and export are not segmented depending on the user. Importers are trading companies that sell to different industries according to the demand and characteristics of the imported essential oil, in most cases making additional controls and analyses;

When exporting essential oils, the product category (food, cosmetics) must be specified and cannot be multiple even if the product is the same: different uses translate into different requirements, segregated

<sup>&</sup>lt;sup>3</sup> Only lavender flowers are used as a food product; herbal teas are food products.

traceability, and different labelling. Currently, these requirements are communicated to Albanian exporters through written rules, whenever necessary.

**Dried MAPs**, including herbal teas and dietary supplements, are considered in most cases as food products, **not** as medicinal products. However, all

dried MAPs exported from Albania are declared and classified as food products.

There is a growing interest in the Albanian industry for the introduction of simple products with higher added value, such as dried MAPs in retail packaging or some types of cosmetics (essential oils used in massage oils) and various kinds of detergents, including soaps.

TABLE 4.2: PRIORITY MAPS, MAIN PROCESSING FOR EXPORT AND FINAL USERS

MAPs	Main export item	Main final use	Secondary final uses
Sage	Dried, Essential Oil	Dried: Food industry – flavouring  Further processing for dietary supplements	Dried: Food industry: herbal infusions
		Essential oil: Fragrances, Medicinal industries	Essential oil: Food industry, flavouring
Oregano	Dried	Food industry – flavouring	Essential oil: Food industry
Thyme	Dried	Food industry - spices 4	Essential oil: Food industry
Lavender	Essential Oil	Fragrance in cosmetics <sup>5</sup> and detergents industries <sup>6</sup>	Dried: fragrances  Essential oil: food industry
Helichrysum	Essential Oil	Cosmetics and Medicinal industries	Dried: herbal infusions

## **Dried MAPs export modalities**

At present, dried MAPs are almost exclusively exported as products for the food industry, including herbal teas and dietary supplements. Herbal infusions claiming to have also therapeutic functions are sold in the domestic market (e.g. herbal tea for diabetic patients) and could be exported as herbal infusions (a food product category), but not as pharmaceutical products. A label claiming therapeutic properties could even be considered as misleading for the consumer and can therefore be forbidden.

Exported dried MAPs fall into different customs categories, but, at present, are subject to the same import regime and customs rules.

## MAP Essential oils export modalities

Essential oils have a wide range of applications and are used as a component in several categories of products, including the food industry (as flavouring, additives), as fragrances and perfumes, detergents and personal cleaning products, cosmetics and, pharmaceuticals.

Different essential oils have also a different range of uses: for example, lavender essential oil can be used as a fragrance and for the production of detergents and cosmetics, whereas Helichrysum essential oil is almost

exclusively used for cosmetics and pharmaceutical products.

In international markets, the largest volumes are exported as "flavouring" for food processing, but the largest variety of essential oils is exported as "fragrances", used in cosmetics, detergent industries and processing activities dealing with ambient fragrances and aromatherapy. Several types of essential oils are also exported for pharmaceutical processing.

Since essential oil can be sold as a generic intermediate product or a more valuable specific product for a certain industry, various buyers or even the same buyer may require that different lots of the same product comply with different requirements and standards, depending on their intended use of the product; regardless of the applicable requirements, the label will remain the same.

When essential oils are sold as a product for further processing, a more limited range of requirements is applied, as compared to the sale of more complex products for final consumption, such as food products having essential oils as ingredients, various cosmetics, detergents, fragrances, etc.

When essential oils are sold as end products (e.g. flavourings for the food industry or fragrances for

<sup>&</sup>lt;sup>4</sup> HS code 09109931 (wild), 091099313,9)

<sup>&</sup>lt;sup>5</sup>Products for aromatherapy are classified as cosmetics

<sup>6</sup> HS code 33030040

aromatherapy) or as components used for a specific industry, the requirements for the specific product category should also be applied, in return for higher prices and wider market opportunities.

As a result, when targeting higher added-value market segments, the intended use of the essential oil is a key factor in establishing the requirements to be complied with. This is due to the fact that requirements for food products and their relevant components, such as flavourings, differ from those applied to fragrances. Even among various fragrances, the requirements vary depending on their end use (detergent, cosmetics, deodorants etc.). Moreover, the value of essential oils varies according to their geographical destination (EU countries, USA etc.).

## Essential oils as components in consumer products

When the essential oil is not sold as an intermediary product or raw material, but rather as a finished product or is incorporated into a product intended for end consumption, the following criteria are applied:

- Pure essential oils intended for a specific use (e.g. as food additives to be used in food preparation or as fragrances for burning), are required to feature on their labels their specific intended use, and therefore comply with the relevant standards and rules (that apply to food or fragrances); it is prohibited to specify multiple uses for a single product sold in the market, even if the product is the same; however, EU rules allow the use of a more generic classification, such as "consumer product". The specific rules of the three most common product categories for selected MAPs are described below;
- » Different products using essential oils as a component. In the case of products comprising several components, including essential oils, or obtained from essential oils following further processing, e.g. detergents or soaps containing one or more essential oils or commercial massage oils, the end product is the one that should be taken into account in order to establish the applicable requirements and standards; in the example, the end product must comply with the standards that apply to detergents or cosmetics, depending on the product;

Products for aromatherapy, soaps, perfumes, massage oils and body lotions are all subject to the same regulations that apply to cosmetics.

In the case of products for end users (i.e. not for intermediate consumption), the labels and the applicable standards vary according to the use. In most markets and particularly in the EU and Swiss markets, products intended for end consumption with potential multiple uses must be sold as distinct products, with different requirements and labels for each use; for example, quality requirements and expiration terms for limonene will be different if the product is sold as

a food additive as opposed to a fragrance used in air freshening devices, such as diffusers.

The label and the description of the product written on the packaging or in the leaflet included in the package can be a decisive factor for its classification and therefore for the applicable standards that the product should comply with, especially for products for end consumption; for example, massage oil is classified as a cosmetic product and herbal tea is classified as a food product; however, if the packaging claims that the product has a specific therapeutic benefit, the product must comply with the standards (and the approval process) required for pharmaceutical products; otherwise, the label or the indications will be considered as misleading for the customer and therefore be rejected.

There are groups of commonly traded products bearing seemingly misleading names which are accepted and formally classified as such, even if they fall under a different category. The most popular groups of products in this category making use of essential oils are listed below:

» Products for aromatherapy. Aromatherapy products are fragrances classified as cosmetics, even if used for air freshening (e.g. released through a dispenser or a diffuser). As such, essential oils used for aromatherapy must comply with the requirements for cosmetics.

When used as a *component in a detergent or soap*, the classification of the end product prevails, so they should comply with the basic requirements of essential oils used for further processing.

Perfumes and deodorants are also treated as cosmetics, hence the essential oils included in perfumes must comply with the same rules as those that apply to cosmetics.

» Essential oils used for massages. These products are classified as cosmetics. Commercial massage oils for end users are made of carrier oils and essential oils. Carrier oils are vegetable oils constituting the majority of the product and are the base to which essential oils are added. As cosmetic products, they are intended for external use (i.e. on the skin) and the end product must comply with the relevant requirements for cosmetics, rather than those applicable to ingestible products like food or pharmaceuticals.

## 4.3 REQUIREMENTS FOR EXPORT TO EU COUNTRIES 7

## 4.3.1 Key features and trends

The analysis is divided into *four* parts: i) an introductory part, outlining the key issues of the legal and additional requirements for exporting food products to EU countries and the trends in the evolution of legal and additional requirements and voluntary certifications; ii) an overview of the legal requirements for exporting fresh and dried MAPs to EU countries, divided by category of requirement (food safety, phytosanitary, labelling, marketing etc.), iii) requirements for MAPs essential oils and, iv) provisions and requirements for organic production and most common voluntary certifications used by Albanian MAPs and MAPs essential oils processors/exporters.

With regard to this analysis, two final disclaimers should be also taken into account:

- It is crucial to review and update the information regularly, as regulations may become stricter based on new insights and periodic re-evaluations. The information presented in this document reflects the situation as of the beginning of 2023.
- 2. This report mainly covers the EU requirements at the Community level. For many aspects, there are differences depending on the country of destination.

# EU legal requirements and additional requirements from buyers as an international benchmark

EU requirements on quality are considered a benchmark: full compliance with these requirements generally allows export to most other markets. Legal requirements for contaminants and residuals are particularly strict and, in many cases, buyers demand even stricter parameters.

In other cases, production practices that are legally permitted, such as irradiation, are not preferred by consumers, so buyers do not accept products manufactured by using such practices.

Generally speaking, on the exporters' side, the most difficult requirements to comply with are those established by the actual buyer, which are frequently stricter than the legal standards. In some cases, certain certifications, though inherently voluntary, have gained such widespread acceptance that they are practically becoming obligatory for assuring buyers in terms of quality standards.

The EU has established a complex QI and several tools to control the enforcement of legal requirements. Repeated non-compliance with the European food legislation by a particular country may lead to stricter import conditions or even suspension of imports from that country. These stricter conditions usually include a requirement for a health certificate and an analytical test report for a certain share of shipments from specific countries. Products originating from countries that have shown repeated non-compliance are enlisted on a list included in the Regulation on the increased level of official controls on imports.

Only a small number of the products imported and marketed in Europe are subject to official (physical) controls, as the primary responsibility for their safety lies with commercial operators (e.g. importers). Therefore, importers conduct most of the checks required to ensure that the products are safe, and they may also demand certification and other proof of quality and safety(CBI, 2023).

In addition to border inspections, official food controls include regular inspections that can be carried out at all stages, from import to retail sales. In case of non-compliance with the European food legislation, individual cases are reported through the Rapid Alert System for Food and Feeds RASFF (see below).

# Evolution and trends in EU legal requirements for food products and voluntary standards for the import of fresh and dried MAPs.

Farm to Fork principles within the framework of the EU Green Deal

The legal requirements for the import of all food products into the EU are frequently modified and are becoming increasingly strict, in line with EU policies on food safety. In particular, the rules on contaminants (mainly metals) and residues (mainly PPP) are expected to become more stringent as a result of the application of the "Farm to Fork" component of the EU Green Deal policy.

The Farm to Fork Strategy aims to increase the whole supply chain sustainability in terms of environment, food safety, food security and fair distribution of revenues along the food chain, while ensuring food affordability.

The farm to fork strategy aims at a significant reduction of the environmental impact of EU agriculture by 2030.

The reduced use of pesticides and antimicrobials, the increase of soil fertility and the reduction of nutrient losses in soil, as well as the establishment of a clear target for organic farming, are the milestones of the farm-to-fork strategy.

<sup>&</sup>lt;sup>7</sup> The information contained in this chapter is mainly based on the International Trade Centre MAPs Export Guideline (Export Guide. Medicinal and aromatic plant ingredients and products, Geneva, February 2023), the website of the Center for the Promotion of Imports from developing countries (CBI), the Access2Markets, the chapter on food safety of the European Commission (http//food.ec.europa.eu), the EU relevant legislation on food, food safety, labelling, phytosanitary requirements and traceability, as well as its summaries, and the UNIDO GQSP report "Georgia. Strengthening conformity assessment for fruits and vegetables. Value Chain Study".

The Farm to Fork principles set a clear and restrictive trend for the evolution of the legal requirements to access the EU markets.

Exporters to the EU are not obliged to immediately adopt the farm-to-fork principles; however, the adoption of this approach will help in the approximation to the EU market in the near future.

# The EC Code of Conduct and the voluntary introduction of environmentally and socially sustainable practices.

In addition to the gradual restrictions that will be introduced in the legal requirements, the European Commission has launched a Code of Conduct to encourage environmentally and socially sustainable practices among food manufacturers and retailers. It comes as one of the first deliverables of the Farm to Fork Strategy which aims to improve the overall sustainability of the European food system. The EU Code of Conduct consists of 7 aspirational objectives, aiming for more sustainable and healthier food choices:

- 1. Healthy, balanced and sustainable diets for all European consumers.
- 2. Prevention and reduction of food loss and waste.
- 3. A climate-neutral food chain in Europe by 2050 by reducing energy use and applying sustainable bioeconomy-based solutions while contributing to a circular economy.
- 4. An optimized circular and resource-efficient food chain in Europe by improving resource efficiency and enhancing the sustainability of food and drink packaging.
- 5. Sustained, inclusive and sustainable economic growth, employment, and decent work for all.
- 6. Sustainable value creation in the European food supply chain.
- 7. Sustainable sourcing in food supply chains.

Every company (regardless of its size) involved in food activities or related to food processes can adhere to the EU Code of Conduct. Stakeholders wishing to endorse the Code are required to make a long-term commitment to it (at least until 2025) and to provide an annual report in April. Endorsement information will be made available to the public and each stakeholder will present their progress at least once a year on a specific and dedicated platform.

# Increasing number of voluntary standards and supermarkets' private standards.

A trend that has been growing since the end of the last century, in parallel with the growth of supermarket chains in the market, is the request of these latter outlets for additional requirements included in their own quality standards, which are used in addition to other international certifications. Whilst several of these standards are for internal use only in the trading relations between the supermarket chains and the suppliers, others, such as Tesco Nurture, are released for certification and included in existing international certification schemes.

These standards have evolved over time in line with the evolution of the concept of sustainability, thus increasing their scope from the production side (GAP/ IPM, GMP, HACCP) to a wider set of rules covering environmental and social issues. The main aim of these schemes is to provide a guarantee to customers that the food products from the supermarket chain suppliers are grown in an environmentally responsible way. For this purpose, these schemes are often based on the implementation of more restrictive requirements than those established in the relevant legislation, i.e. regarding the use of plant protection products and the upper residue limits of plant protection products in food products. For example, these protocols may establish a maximum percentage of MRL with reference to those stipulated by the law, and may also define a maximum count of pesticide residues, although within the MRL, as it is common among German supermarket chains (for instance: maximum five residues).

The most common voluntary standards and supermarket private standards applicable to the MAPs subject to this study are presented in sub-chapter **4.3.5** and **Annex**.

## 4.3.2 Requirements for fresh and dried MAPs

## 4.3.2.1 Overall requirements

**Table 4.3** below provides a synopsis of the topics related to requirements for export to the EU of fresh and dried MAPs, the relevant key issues and the reference legal provisions.

TABLE 4.3: MAPS EXPORT TO THE EU: REQUIREMENT CATEGORIES, KEY ISSUES AND LEGISLATION

Requirement category	Key issues	Reference norms
Traceability	» One step back, one step forward principle;	Reg. EC/178/2002 8
	» Labelling with an indication of the origin and production lot;	Commission Implementing Reg. (EU) 931/2011
	» Proof of origin for non-EU producers	
Food safety		
Food Hygiene	» HACCP application	Reg. (EC) 852/2004 (EC, 2004)
Contaminants	» Metals;	Reg. (EC) 1881/2006 (EC, 2006)
	» Chemicals;	
	» Toxins;	
Residuals	» PPP, other chemicals	Reg. (EC) 396/2005(EC, 2005)
Microbiological	» Selected microbiological contaminations dangerous for human health;	Reg. (EC) 2073/2005.
Foreign bodies	» Soil, insects, dirt.	No specific regulation, buyers' standards apply.
Labelling	» Information about product, origin, traceability, marketing standard;	Reg. EU 1169/2011 (EC, 2011a).
Phytosanitary	<pre>» Certificate*;</pre>	Reg. (EU) 2019/2072.
	» Additional documentation for specific products and origin;	Additional regulations for specific contingencies.
Marketing	» Application of EU and/or UNECE quality standards;	Reg. (EU) 543/2011.
Other aspects	» Irradiated food: "Irradiated food" indication on the label.	Directives 1999/2/CE and 1999/3/CE.
	» Novel food: applicable to products not commonly in commerce before 1997.	Reg. (EU) 2015/2283.
	» Products contaminated by radioactivity.	

Source:Own elaboration

## 4.3.2.2 Traceability 9

## Reference Legislation

Base regulation	Regulation (EC) No 178/2002 — General Food Law.
Application	Commission Regulation (EU) $931/2011$ on the traceability requirements set by Regulation (EC) No $178/2002$ .

<sup>\*</sup>Specific and additional rules are foreseen for products of animal origin, animal feed and live plants

Additional information provided at the General Food Law factsheet on traceability. Tracing food through the production and distribution chain to identify and address risks and protect public health. In <a href="https://food.ec.europa.eu/system/files/2016-10/gfl">https://food.ec.europa.eu/system/files/2016-10/gfl</a> req\_factsheet\_traceability 2007 en.pdf

## Description

"Under EU law, "traceability" means the ability to track any food, feed, food-producing animal or substance that will be used for consumption, through all stages of production, processing and distribution. Traceability is a way of responding to potential risks that can arise in food and feed, to ensure that all food products in the EU are safe for European citizens to eat" (EC, 2023a). The Commission Implementing Reg. (EU) 931/2011 details how traceability is implemented.

Traceability is very important for the protection of consumers, especially when food is found to be faulty. To ensure traceability:

- » Food businesses need a comprehensive system of traceability so that information can be easily accessed and targeted withdrawals can happen, if needed, without wider disruption of the system;
- » Food businesses, including importers, must be able to identify at least the immediate supplier of a product or lot of products and the immediate subsequent consignee (one step back - one step forward principle). Records must be kept showing the correspondence between the exported lot and the sources of the supply (companies or individuals) of the products included in that lot;
- » Traceability is also embedded in labels, which must provide adequate traceability information, including the lot and origin;

» As part of the administrative documentation required for imported products, a "proof of origin" (a certificate released by the Chamber of Commerce) must be provided. This document serves the purpose of custom and rules of origin implementation, and it also contributes to traceability.

The EU has published guidelines that require business operators to document the names and addresses of the supplier and customer in each case, as well as the nature of the product and date of delivery. Operators are also encouraged to record information on the volume or quantity of a product, its batch number, if any, and a more detailed description of the product, such as whether it is raw or processed.

Nowadays, the majority of traceability information, transformed into optical codes (such as barcodes or QR codes), is provided on the packaging of the product. This is not a legal requirement, but a common business practice.

In addition to the general requirements, there are specific provisions for certain categories of food products, so that consumers can identify their origin and authenticity. Special traceability rules are also provided for Genetically Modified Organisms (GMO).

With reference to traceability, it is crucial to clarify the relation between QI stakeholders, their relevant responsibilities and the actions to be taken when a risk is identified.

**TABLE 4.4:** STAKEHOLDERS, RESPONSIBILITIES AND ACTIONS FOR TRACEABILITY IMPLEMENTATION IN THE EU LEGAL FRAMEWORK

Stakeholder	Overall responsibilities	Actions when a risk is identified
Food and feed businesses	» Identify and document information on products "one step forward and one step back" in the food chain.	<ul> <li>Immediately withdraw the affected products from the market and, if necessary, recall them from consumers;</li> <li>Destroy any batch, lot or consignment of feed that does not satisfy food safety</li> </ul>
		requirements;  » Inform the competent authorities of the risk and of the actions it has taken;
Member State authorities	<ul> <li>Monitor production, processing and distribution of food and feed products to ensure that operators have traceability systems in place;</li> <li>Fix and enforce appropriate penalties for operators that do not meet EU requirements on traceability;</li> </ul>	<ul> <li>Ensure that operators are fulfilling their obligations;</li> <li>Take appropriate measures to secure food safety;</li> <li>Trace the risk both upstream and downstream along the food chain. Notify the Rapid Alert System for Food and Feed (see box);</li> </ul>

## The EU

- » Establish sector-specific legislation on traceability, as appropriate;
- » The Food and Veterinary Office of the European Commission carries out regular inspections to ensure that food and feed operators are meeting food safety standards – including the implementation of traceability systems;
- » The European Commission alerts members of the Rapid Alert System for Food and Feed of the risk;
- » Requests information from operators to enable traceability and coordinates the intervention of national authorities;
- May impose import/export restrictions;

Source: Own elaboration based on EC - Traceability factsheet

For a practical implementation of traceability in relation also to food safety functions, two important tools were established: i) the TRACES platform, described herein below, which serves for enhancing traceability and facilitating international trade and ii) the RASFF alert system, which utilises traceability when food safety hazards are identified. The RASFF alert system as part of food safety tools is described below.

## THE TRACES PLATFORM (EC, 2023F)

TRACES – Trade Control and Expert System – is the European Commission's online platform for sanitary and phytosanitary certification required for the import of animals, animal products, food and feed of non-animal origin and plants into the European Union, and the intra-EU trade and EU exports of animals and certain animal products. The platform has a tool to ensure:

- » Traceability (monitoring movements of consignments, both within the EU and from non-EU countries);
- » Information exchange (enabling trade partners and competent authorities to easily exchange information on the movements of their consignments and significantly speeding up administrative procedures);
- » Risk management (rapidly responding to health threats by tracing the movements of consignments and facilitating the risk management of rejected consignments).

When products are imported into the EU or traded within the EU single market, TRACES supports the issuance of official certificates, records official controls, and manages route planning swiftly and efficiently through an online platform. The complete digitalisation of the TRACE platform rendered the traditional phytosanitary certificate obsolete: the electronic certification capability of TRACES NT enables both EU and non-EU authorities to digitally stamp official documents and certificates. National competent authorities and economic operators use TRACES to complete official certificates online, while control authorities at the EU border or at the final destination check the consignments and their accompanying documents to permit their entry into and/or transit through the EU. In this way, the control authorities at the EU border or at the destination are pre-notified of the arrival of a consignment and can plan their controls accordingly.

Registration on the TRACES platform is obligatory for EU entities involved in handling relevant food products, whereas it is optional for non-EU entities. However, registration on the platform provides continuous access to the most up-to-date formats of phytosanitary certificates and other export documents and greatly facilitates the process of border inspections.

# 4.3.2.2 Food safety OVERALL ASPECTS

Food safety issues are the most complex and articulated component of the legal requirements for food exports in the EU. They include prescriptions, controls and information tools related to the following aspects: i) Food hygiene, ii) contaminants, iii) residuals, iv) microbiological factors and, v) control of foreign bodies, which also falls under quality and phytosanitary control.

A complex QI and quality control architecture is established for the implementation of controls related to food safety. The main QI at the EU level is EFSA, the European Food Safety Agency. To fulfil its mission, EFSA has developed, inter alia, two significant tools that will be addressed throughout this chapter: i) *The coordinated EU multi-annual control programme*. for controlling, in all member states, the various food safety parameters along the entire supply chain and, ii) *the Rapid Alert System for Food and Feed – RASFF* for taking prompt action in case of detection of any food safety hazards or breach of EU food safety rules.

# Rapid Alert System for Food and Feed (RASFF) (EC, 2023g)

To make use of traceability and as part of the food safety tools, **the Rapid Alert System for Food and Feed** (RASFF) was established to ensure the exchange of information between member states, enabling rapid responses by food safety authorities in the event of public health risks arising from the food chain.

RASFF was established to enable food safety authorities to rapidly exchange information on health risks arising from food or feed so that they can take immediate action. Information exchanged through RASFF can lead to products being promptly recalled from the market. While access to RASFF is restricted solely to the authorities of member states and the European Commission, summarized information is made available to the general public through the RASFF Window, an interactive and searchable online database.

## **FOOD HYGIENE**

## **Reference Legislation**

Base regulation	Regulation (EC) No 178/2002 – General Law on Food.
Implementation	Regulation (EC) 852/2004 on the hygiene of foodstuff.

## Description

Regulation (EC) No 852/2004 defines food hygiene as "the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff, considering its intended use". This regulation applies across the entire food chain (from farm to fork) and assigns the main responsibility for compliance to food business operators.

The leading concept is that, to avoid food contamination from unwanted substances, it is necessary to maintain excellent hygiene practices along the entire supply chain. The regulation is structured around six key topics:

- General obligations of food business operators, including: 1.1) general and specific hygiene requirements, 1.2) Hazard Analysis and Critical Control Point (HACCP) implementation for primary producers and processors, 1.3) Food business registration and approval.
- 2. *Guide to good practices*, including personal hygiene and training.

All imports must comply with the provisions related to the general obligations. The most relevant aspect for exporters is the implementation of HACCP principles; this provision, which is also in line with the Albanian Law on Food is a pre-requisite for exporters and can be verified through a range of controls such as analyses for microbiological contamination, presence of foreign bodies in the product, etc.

Both the EU regulation and the Albanian law set the implementation of HACCP as a requirement to be complied with, but do not require a compliance certification, which is voluntary.

Part A of Annex I of the above regulation lists the general hygiene provisions for primary production (and associated operations) which — in terms of plant production — include the maximum avoidance of contamination by means of clean facilities and equipment, hygienic production, clean water, healthy and trained staff, prevention of contamination by animals and pests, appropriate storage and handling of

waste and hazardous substances, correct use of plant protection products and biocide and consideration of the analyses performed on plants or other samples with importance to human health.

Primary producers have to keep records, particularly on the use of plant protection products and biocide, the occurrence of pests and diseases that may affect food safety, and the results of any relevant analyses carried out.

Annex II lists the general hygiene requirements for all food business operators.

## **CONTAMINANTS (EC, 2006)**

## **Reference Legislation**

Base regulation	Regulation (EC) No 178/2002  – General Law on Food.  Council Regulation 315/93 EEC.
Application	Commission Regulation (EC) 1881/06 setting maximum levels for certain contaminants in foodstuffs <sup>10</sup> , as amended.
	Commission Regulation (EC) 2020/2040 (amending Reg. (EC) 1881/06 introduces a particularly relevant innovation for dried MAPs.

## Description

The basic principles of the EU legislation on contaminants in food are laid down in Council Regulation 315/93/EEC and specified in Reg. EC 1881/06

Contaminant levels should be kept as low as can reasonably be achieved, applying good practices for primary production and manufacturing (GAP and GMP).

Maximum levels are established for certain contaminants (EC, 2006). These limits vary among different fresh MAPs (classified as "herbs" in Reg. (EC) 1881/06).

There are also different limits for fresh and dried MAPs, described below in two separate chapters.

## Herbs (fresh MAPs)

The legal requirements for contaminants that are pertinent to the MAPs included in this study are as follows:

<sup>10</sup> Text with EEA relevance

TABLE 4.5: CONTAMINANT LIMITS IN SELECTED MAPS: METALS AND CHEMICALS

Contaminant / Product	Metals		Chemicals
	Lead mg/kg	Cadmium mg/kg	Perchlorate mg/kg
Fresh MAPs			
Oregano	0.10	0.20	n.a.
Thyme	0.10	0.20	n.a.
Sage	0.10	0.20	n.a.
All other MAPs	0.10	0.20	n.a.

Source:EC, 2006

The permitted maximum levels are frequently updated; moreover, buyers often require lower levels of both contaminants and PPP residues as compared to legal requirements.

There are no specific maximum levels of contaminants set for Helichrysum and Lavender when used as food products; however, their use is quite limited. In Reg. (EC) 1881/06, they are included in "herbs".

There is no maximum level of contaminants established for nitrates in the products under consideration; however, a limit has been set for lettuce and various other leafy vegetables.

There is no maximum level of contaminants established for mycotoxins in the products under consideration; however, such a limit is set for MAPs and dried fruits.

## **Dried MAPs**

Dried MAPs mainly include products used for food flavouring and herbal teas.

The limits established for metals and chemical contaminants are mostly the same, with the exception of perchlorate in dried herbs, when applied to fresh MAPs; however, such limits are more difficult to comply with, because of the higher concentration of dry matter in dried MAPs.

In certain instances, the limits established for toxins differ between dried and fresh herbs, mainly because contaminants and toxins are more concentrated in dried MAPs and microbiological hazards are also higher.

Particular attention has been given to establishing maximum toxin levels in dried herbs, spices and herbal infusions. In Reg. (EC) 1881/06, all MAPs relevant to this study are classified as herbs, including sage, helichrysum and lavender, which for other purposes have a different classification.

The table below shows the limits established for certain toxins in dried MAPs and *herbal teas*.

**TABLE 4.6:** CONTAMINANTS LIMITS: SELECTED DRIED MAPS

Contaminants	Chemicals	Toxins		
Products	Perchlorate	Ochratoxin A	Tropane alkaloids	Pyrrolizidine alkaloids
Dried herbs	0.75	10.0		400 1,000 for 100% dried oregano
Dried spices		15.0		
Herbal infusions			25.0	200, 400 for 100% thyme herbal infusion
Food supplements including MAP				400

A specific and recent issue is related to the introduction in 2020 of a maximum level of *pyrrolizidine alkaloids*, due to the short-term toxicity and long-term carcinogenicity potential among herbal tea users.

*Pyrrolizidine alkaloids* are naturally produced by several plants as a pest defense<sup>11</sup>; These plants can contaminate the most commonly used MAPs by contact; they are discarded during the selection/cleaning process for dried MAPs production, but at that point, alkaloids contact contamination has already occurred; as a consequence, this contact contamination should be prevented during cultivation, which is proving particularly difficult.

With the introduction of Reg. 2020/2040, a maximum level of pyrrolizidine alkaloids in herbal infusions is established. With reference to the dried MAPs subject to the study, the *limits are established at* 200  $\mu$ g/kg for oregano and sage and mixed herbs, and 400  $\mu$ g/kg for 100% thyme herbal tea.

## **RESIDUALS**

## **Reference Legislation**

Base	Regulation (EC) No 178/2002 –
regulation	General Law on Food
Application	Regulation (EC) 825/2004  Regulation (EC) 396/2005 on maximum residue levels of pesticides in food and feed of plant and animal origin

## Description

Regulation (EC) 396/2005, also known as "MRL regulation", sets the Maximum Residue Levels – MRL in food products for some chemicals which are harmful to human health. For this purpose, the European Food Safety Authority (EFSA) assesses the safety for consumers based on pesticide toxicity, the maximum levels anticipated in food and the diverse diets of Europeans.

The regulation harmonizes and rationalizes the previous rules set at EU and national level.

MRLs apply to 315 fresh products and also to these same products after processing, with adjustments made to account for dilution or concentration that may occur during the process. The legislation covers pesticides currently or formerly used in agriculture in or outside the EU (around 1,100) and other kinds of chemicals used for other purposes, e.g. in food product sterilization.

A general default **MRL** of **o.o1** mg/kg is applicable in cases where a specific pesticide is not explicitly mentioned. However, there are many substances for which MRLs are established.

"Some of these plants are MAPs themselves, such as Borago Officinalis, but are used with care because their toxicity is known.

Due to the very large number of MRLs applied to any category of products (in the order of tens of thousands), an **EU pesticide database** was established.

Farmers, traders and importers are responsible for food safety, which includes compliance with MRLs. Member State authorities are responsible for the control and enforcement of the MRLs. In order to ensure that this is done in an adequate and uniform way, the Commission has three instruments in place:

- The co-ordinated EU multi-annual control programme sets out for each Member State the main pesticide-crop combinations to be monitored and the minimum number of samples to be taken. Member States are obliged to report the results, which are published in an annual report.
- 2. EU Reference Laboratories provide coordination, staff training, development of analytical methods and preparation of tests to evaluate the skills of various national control laboratories.
- 3. The Food and Veterinary Office of the Commission carries out inspections in the Member States to assess and audit their control activities.

If pesticide residues are found at a level of concern for consumers, the Rapid Alert System for Food and Feed (RASFF) disseminates this information and measures are taken to protect the consumer.

## The EU Pesticide database

The database is available online (EC, 2023h) and is open to the public. It allows users to search for information on active substances used in plant protection products, Maximum Residue Levels (MRLs) in food products, and emergency authorisations of plant protection products in Member States. Searches can be made in accordance with the following categories:

- 1. Active substances. The database contains information on active substances (including those that are low-risk or candidates for substitution) and basic substances, whether approved or not approved in the EU. Additionally, the database incorporates certain safeners and synergists that have not yet undergone assessment at the EU level.
- Food products. Users can search for a particular food product (e.g. tomatoes) and retrieve the MRLs for all pesticide residues that apply to that product.
- 3. Pesticide residues and the MRLs that apply to such residues in food products. Users can select a particular pesticide residue in specific food products and find the current or historical MRLs that legally apply. Users can also download data on MRLs.
- 4. PPP Emergency Authorisations in EU Member States. Member States are fully responsible

for granting emergency authorizations, so the database only includes information provided by the Member States.

## **MICROBIOLOGICAL**

## **Reference Legislation**

Base regulation	Regulation (EC) No 178/2002 – General Law on Food. Regulation (EC) No 825/2004.
Application	Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

## **Description**

The regulation sets out two types of microbiological criteria that food businesses should comply with, as listed in its Annex I, namely: i) food safety criteria, and ii) process hygiene criteria.

As part of their procedures based on the HACCP principles and using good hygiene practices, food businesses at each stage of food production, processing and distribution, including retail, should ensure that:

- » the supply, handling and processing of raw materials and foodstuffs under their control is carried out in compliance with the process hygiene criteria;
- » the food safety criteria that apply throughout the entire shelf-life of the products should be attainable under reasonably foreseeable conditions of distribution, storage and use.

For each food category, the regulation and its annex specify:

- » Micro-organisms for which it should be tested.
- » Sampling plan (the number of units to be tested, frequency, etc.);
- » Limits for each sample unit tested;
- » Analytical reference method to be used;
- » The stage in the manufacturing process at which the criterion applies, (e.g. at the conclusion of the manufacturing process or at the point in the process when the count of a particular microorganism is expected to be at its highest);
- » Actions to be taken in case of unsatisfactory results.

All fresh and dried MAPs are at risk of microbiological contamination, particularly in post-harvest and transportation segments of the supply chain. These risks are controlled through appropriate post-harvest practices. Certain practices such as fumigation are permitted for exports in the USA, but not in the EU.

However, the dried MAPs segment is the one with elevated risks associated with microbiological aspects

of food safety. This is primarily due to the potential emergence of a few hazardous pathogens during various stages, including collection, preparation, processing (such as cutting, selecting, and drying), handling, storage, and transportation. Furthermore, the proliferation of microorganisms can lead to the accumulation of residues in the product. For instance, bacteria thriving in MAPs can generate nitrates as a by-product.

In order to deal with these risks, specific treatments and relevant equipment should be used.

For example, high levels of Salmonella have already impeded the export of dried MAPs to both the USA and EU countries. In certain years, Albanian sage needed to be exported to a third country for steam treatment before it could be sold in the USA.

The primary methods for sterilizing dried MAPs are: i) steam, ii) irradiation, iii) fumigation.

For export to EU countries, the primary method adopted is steam sterilization or pasteurization 12.

Although irradiation is legally allowed under the EU legislation, it is generally not favoured by buyers and consumers due to the requirement that the product label must indicate if the product has been irradiated.

Fumigation with methyl bromide and ethylene oxides is banned (since 1991) and fumigation with propylene oxide is allowed, but its use is not a preferred pasteurization practice.

The use of ethylene oxide is considered particularly dangerous, to the extent that it is included among the substances for which Regulation (EC) 396/2005 establishes a Maximum Level of Residues (MLR).

## 4.3.2.3 Foreign bodies and matters

Foreign matter is defined as any kind of external contaminant introduced to a food product at any stage of its production or distribution. It includes dead and live pests and larvae (e.g. flies, mice etc.), soil, excreta, stones, hair, fingernails, band-aids, bits of cleaning cloth, fragments of plastic or metal, cardboard, glass, metal shards, etc.

The presence of foreign matter in fresh or dried MAPs can pose risks to both human health and phytosanitary concerns (e.g. the presence of certain live pests). Even in situations where there are no hazards to consumers, the presence of foreign bodies can impact the quality to such an extent that the product may become untradeable or, if traded, subject to rejection.

The most common and serious problem related to foreign bodies in the MAPs subject to this study *is related to the presence of foreign bodies in dried MAPs*, such as dirt, stones, insects, excreta, metal or glass scraps. The difficulty to reduce the presence of foreign bodies in collected wild MAPs has been one of the

<sup>&</sup>lt;sup>12</sup> Steam sterilisation of dried MAPs is obtained through a brief contact (20-40 seconds) with high pressure steam at a temperature that may vary between 102°C and 122°C

initial drivers which led Albanian exporters to focus on cultivated MAPs.

There is no official limit for foreign bodies in spice and herb shipments to the European market. In contrast, the FDA (2015) and the American Spice Trade Association (ASTA) have established formalized rules in this regard. Consequently, most European buyers define their own specification requirements or adhere to the cleanliness specifications outlined by ASTA, which define the maximum allowable presence of dead insects, excreta, mold and other foreign matter. The Quality Minima Document of the European Spices Association does not allow the presence of any foreign objects greater than 2mm in diameter.

In order to prevent contamination with insects, non-EU suppliers should implement preventive measures, such as heat treatment or fumigation, using only those fumigants approved in the destination market. Using optical, metal and similar detectors is also recommended to prevent contamination with foreign bodies. However, physical sorting and manual inspection are always recommended, even if detectors are installed.

## 4.3.2.4 Phytosanitary

## **Reference Legislation**

General rules:	Reg. (EU) 2016/2031 on protective measures against pests in plants
Implementation:	Implementing Reg. (EU) 2019/2072 (EC, 2019)
	Reg. (EU) 2016/2031 (EC, 2016)

## **Description**

The legislation is continuously updated and new versions of the regulation are released every three to six months<sup>13</sup>.

Phytosanitary certification<sup>14</sup> is required for the import of all plants, with few exceptions<sup>15</sup>. Specific provisions are outlined for propagation material, wood and seeds.

The regulation also contains a list of all plants/foods of plant origin that are banned in the EU (Annex VI) and specifies those plants or parts of plants for which additional indications in the phytosanitary certificate (Annex VII) are required. At present (Feb 2023), no MAPs from Albania are banned. Phytosanitary certificates should provide indications that the product is: i) properly inspected, ii) free from pests<sup>16</sup> and iii) in

<sup>13</sup> The last version of Reg. (EU) 2019/2072 is dated 14 July 2022 <sup>14</sup> The reference legislation for phytosanitary certificates is based on Article 72(1) of Reg. (EU) 2016/2031. A certificate template is provided in Annex 4 of the Regulation.

line with the provisions included in Reg. (EU) 2019/72

Additional declarations to be indicated in the phytosanitary certificates for exports to the European Union are required by Article 71.2 of the Plant Health Regulation (EU) 2016/2031.

## 4.3.2.5 Marketing requirements

## **Reference Legislation**

General rules:

Reg. (EU) 1308/2013 (EC, 2013)

Implementation:
Implementing Reg. (EU) 543/2011 (EC, 2011b).

While the United Nations Economic Commission for Europe (UNECE) does not have a distinct marketing standard for fresh herbs, the General Marketing Standards outlined in Regulation (EC) No. 543/2011 (Annex 1 Part A) are applicable.

The general marketing standards require fresh herbs to be:

- » intact, sound and clean;
- » free from any visible foreign matter;
- » free from pests;
- » free from external moisture, foreign smells or tastes.

For fresh herbs, the quality of the leaf is the most important factor, including its colour and the balance between the stem and leaves. It is imperative to prevent decay, bruising, blackening, yellowing, pesticide residue, uneven coloring, and the absence of leaves in fresh herbs. Product uniformity is another important factor. The condition of the fresh herbs must be such that they can endure transportation and handling.

Some countries exporting fresh MAPs to Europe, such as Israel, have developed specific quality inspection procedures and national standards for fresh herbs intended for export, based on their trading experience <sup>17</sup>.

Sample conformity checks are made at the border, before the products enter the customs territory of the EU. However, "In certain third countries which provide satisfactory guarantees of conformity, preexport checks may be carried out by the inspection bodies of those third countries. Where this option is applied, Member States should regularly verify the effectiveness and quality of the pre-export checks carried out by third-country inspection bodies (EC, 2011). At present, conformity checks for MAPs imported from Albania are performed by the importing country and cannot be performed in Albania.

Conformity checks are carried out selectively by control bodies to ensure compliance with the marketing <sup>17</sup> A comprehensive presentation on quality inspection for fresh herbs intended for export from Israel is available at: https://unece.org/fileadmin/DAM/trade/agr/meetings/capacity-building/2007\_slovakia/FreshHerbs\_IL.pdf

<sup>&</sup>lt;sup>15</sup> Those listed in Part C of Annex XI to Reg. (EU) 2019/2072

<sup>&</sup>lt;sup>16</sup> Including all quarantine and non-quarantine regulated pests. In practice, the certificate must indicate that the product is free from all pests

standards. These checks are based on risk analysis and concentrate on traders who are more likely to have goods that do not meet the standards.

## 4.3.2.6 Labelling

## **Reference Legislation**

General rules:	Regulation (EC) No 178/2002  - General Law on Food  Directive 2000/13/EC
Implementation:	Implementing Reg. (EU) 1169/2011(EC, 2011)Reg. (EU) 543/2011

## **Description**

In fresh and dried MAPs labelling, a major distinction should be made between: i) products packaged for wholesale trading, also defined as botanical raw materials bulk shipment and, ii) products prepackaged in sealed retail packaging 18. Products prepackaged in sealed retail packaging must fully comply with Reg. (EU) 1179/2011, as any other food product, while products packaged for wholesale trading are subject to different and less complex labelling rules.

However, many products have their own labelling specifications.. For this purpose, the EU has established a database on labelling requirements, detailing the relevant requirements for each product or category of products (EC, 2023i).

## Fresh and dried MAPs for food use in bulk packaging

*Dried MAPs* in bulk packaging should include the following information:

- » Name and address of the packer or dispatcher;
- » Name and variety (only if applicable)<sup>19</sup> of the product;
- » Country of origin;
- » Class and size, if applicable (which is not the case for the selected MAPs);
- » Official control mark to replace the name and address of the packer (optional);
- » Certain post-harvest treatments, such as the use of anti-moulding agents, should be disclosed on the product's packaging. However, for the selected
- <sup>18</sup> These products are intended for direct sale in retail outlets and cannot be touched or consumed without breaking the sealed packaging. For instance, strawberries sold in trays and enclosed in sealed plastic wrapping are pre-packaged for retail sale, while strawberries in the same trays, but not sealed (allowing them to be touched and for the contents of each tray to be altered) are considered as packaged for wholesale trade.
- <sup>19</sup> Name of product in case of closed boxes, where the content is not visible. Name of variety, only for specific produce: none of the six selected kinds of produce subject to this study fall into this specific category.

products, there are no authorized post-harvest treatments that need to be indicated on the label.

If applicable, information on voluntary certification should be provided in addition to the certification logo, such as the name of the inspection body and the certification number for organic certification or GGN if the product is certified under GLOBALG.A.P. standards.

As regards *MAPs*, according to the International Trade Centre, labels accompanying bulk shipments of botanical raw materials destined for the EU should generally include the following basic information:

- » Common name of the botanical material;
- » Net weight (only if pre-packaged);
- » Lot marking with the marking preceded by the letter 'L';
- » Country of origin or place of provenance;
- » Name and address of the exporter;
- » If certified (e.g. Organic, Biodynamic, Fair for Life, Fairtrade or FairWild), information on the certification and certifying control body.

# Fresh and dried MAPs pre-packaged in sealed retail packaging

If the product is provided pre-packaged in sealed packaging for final consumption, more complete information should be provided in accordance with Reg.1169/2011; moreover, the information should be provided in the official language of the country where the product is sold or in a language that is understood by the customer. The following information should be provided:

- » Common name of the product;
- » Full name of the country of origin;
- Name and address of the producer, packager, importer, brand owner or seller (retailer) in the EU who places the product on the market, and the wording "Packed for:", if applicable;
- » Net content in weight;
- » Minimum durability a best-before date;
- » Lot number;
- Declaration of nutritional value (when mixed with other foodstuffs);
- » The indication "Protective atmosphere packaging", if applicable;
- Additional information about the size, variety or commercial type and post-harvest treatment can be provided on the product labelling for products with specific marketing standards (CBI, 2022b). The regulation specifies some specific post-harvest treatments that should be indicated on the label; however, for the products subject to this study, there are no admitted post-harvest

treatments that, if applied, should be indicated in the label.

Dried MAPs (including herbal teas) are considered as processed products; the relevant packaging should provide the following information:

- » The name of the food;
- » The list of ingredients (if there is more than one single ingredient);
- » An indication of any ingredients that can cause allergies or intolerances, if applicable;
- » The quantity of certain ingredients or categories of ingredients, if made evident in the commercial denomination or claims on the label (QUID);
- » The net quantity;
- » The minimum durability indicated by the 'best before' or 'use by' date;
- » Any special storage conditions and/or conditions of use;
- » The name or business name and address of the responsible food business operator;
- » The country of origin or place of provenance;
- » Instructions for use;
- » The nutrition declaration;
- » Lot indication.

# 4.3.3 Requirements for essential oils export in the European Union

## Key concepts

Essential oils are defined as "steam-distilled extract from twigs, leaves, woods, seeds, exudates (e.g. frankincense), fruits, flowers, barks and root";

» Essential oils are considered in the EU as an inherently dangerous product category; as a consequence, in addition to other regulations specific to the intended use of the essential oil, the products traded in EU countries should comply with: i) CLP regulation<sup>20</sup>, version 4 (CLP4) on the packaging and labelling of hazardous chemicals and, ii) REACH Regulation (Regulation (EC) No 1907/2006) on the Registration, Evaluation, Authorisation and Restriction of Chemicals if essential oils are sold for purposes other than flavouring (i.e. food);

- Essential oils are considered chemical compounds, i.e. including a mix of various chemical substances. Depending on the intended use, labelling rules may require the disclosure of the main chemical substances present in the compound;
- » The intended use should always be specified: essential oils cannot be imported without specifying their intended use, e.g. as food products or cosmetics; consequently, the same essential oil may need to comply with different legal provisions, depending on its intended use;
  - In the EU, only authorized entities are permitted to trade essential oils, and they are required to submit a substance registration dossier (SID) for each chemical compound and each intended use of that compound. Any entities trading essential oils are responsible for the compliance of their products with the relevant legal provisions (whether the essential oil is interned for use in the cosmetic industry or food industry etc.). Non-EU companies can export essential oils only to authorized traders or should establish a legal entity within the EU that will be authorized as an essential oil trader;
- » The quantity and complexity of compliance rules significantly increase depending on the stage of the supply chain. Essential oils produced as raw materials for further processing are subject to relatively simple rules and controls. If essential oils are included in products intended for final consumption, the complexity of rules and controls significantly increases;
- In addition to safety considerations, essential oils are typically examined for potential adulteration.

  Analysing the purity of essential oils and assessing their chemical characteristics, which are characteristic of the product, is necessary.
- » Marketing standards: most essential oils have an ISO standard. Buyers will require that the characteristics and contents of the exported essential oil align with the relevant ISO standard. The ISO standards for the prioritized essential oils are listed below.

Legal requirements according to the supply chain stage

The legal requirements for importing essential oils in relation to the supply chain stage are as follows:

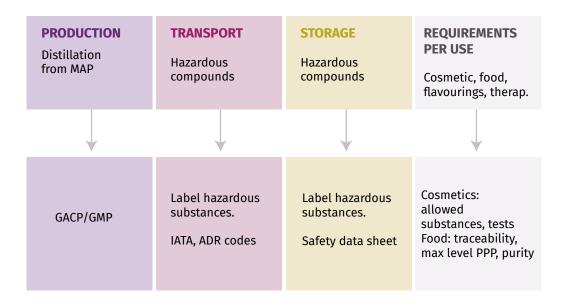
 $<sup>^{20}\</sup>mbox{The CLP}$  regulation is the consolidated version of Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures

TABLE 4.7: LEGAL REQUIREMENTS AND SUPPLY CHAIN STAGES

Supply chain stage	Applicable rules	Conformity check	
MAPs production and collection	GACP	Chemical and physical controls and analyses.	
Essential oil extraction	GMP		
Essential oil packaging/transport	REACH and CLP Regulations	Packaging, labels, technical dossie	
Essential oil storage/ handling	REACH and CLP Regulations.		
Specific uses	Regulations related to final use (cosmetics, food, medicinal).	Specific for each use (see below).	

The correlation between supply chain stages and legal requirements is illustrated in Figure 4.1 below.

Figure 4.1: Export requirements within the EU based on the supply chain stage



The applicable GACP and GMP for MAPs collection (wild MAPs) and cultivation (cultivated MAPs) and essential oil extraction are internationally standardised and not specific to particular destination markets (EMA, 2022; WHO, 2007).

The application of GAPC and GMP ensures the quality and safety of extracted essential oils. The essential oil produced should meet the specific characteristics typical of that product, which for the most common essential oils are formalised in ISO standards. In some cases, there may be multiple ISO standards associated with various characteristics of essential oils extracted from different cultivars or hybrids of the same species. This is the case, for example, of essential oils extracted from plants of the *Lavandula* genus, which even have

different commercial names ("Lavender oil" and "Lavandin oil"), depending on the species from which the essential oil is extracted<sup>21</sup>.

An ISO standard for Helichrysum essential oil has not yet been developed.

The table below shows the ISO standards related to the products discussed in this document.

<sup>&</sup>lt;sup>21</sup> Lavender oil is extracted from Lavendula angustifolia, while Lavandin oil is extracted from a hybrid of two Lavendula species

**TABLE 4.8:** ISO STANDARDS OF PRIORITIZED ESSENTIAL OILS

Sage essential oil	S. officinalis: ISO 9909: 1997 S. Lavandulifolia ISO 3526:2005	Helichrysumess. oil	Not developed
Oregano essential oil	ISO 13171:2016	Lavender essential oil Lavendula angustifolia	ISO 3515:2002
Thyme essential oil	ISO 198w17:2017	Lavandin essential oil <i>Hybrid angst. x lat.</i>	Abrialis ISO 3054:1987 Grosso ISO 8902:2009

The compliance of the essential oil with the relevant ISO standard or with the reference characteristics commonly used in international markets (where a specific ISO standard has not yet been established) is confirmed through physical and chemical analyses. A range of such analyses is commonly required by buyers.

In particular, EU buyers require compliance in terms of:

- Chemical substances present in the essential oil. Essential oils are classified as NCS – a category of chemical compounds (see below). Consequently, the analysed essential oil should contain only the chemical substances characteristic of that NCS. Moreover, the presence of chemicals not allowed by REACH Regulation should be avoided.
- 2. *Physical characteristics*. The analysis of physical characteristics focuses on:
- » Colour;
- » Flavour,
- » Density;
- » Optical rotation;
- » Refractive index;
- » Solubility in water and oil (how easily the essential oil dissolves).

In addition to legal requirements, many buyers have additional requirements.

## Market segmentation

The European market for essential oils is divided into three segments, providing different channels for import. In this document, we will only consider the requirements for the export of essential oils intended for food or cosmetic use; the requirements of essential oils used for detergents and pharmaceuticals will be not considered.

Oregano, Sage and Thyme essential oils are mostly used in the food industry, while lavender and helichrysum

essential oils are widely used in the cosmetics and detergent industries.

From a legal standpoint, essential oils used for flavourings (i.e. a category of food products) are not subject to the same documentation requirements as essential oils for other applications, such as fragrances (a category of cosmetics). The REACH regulation requires suppliers of essential oils used for these alternative applications to provide a more extensive documentation. Essential oils for flavourings are exempted from REACH.

Nonetheless, in practice, European buyers of essential oils used for flavourings often have the same documentation requirements as buyers of essential oils used for other purposes. Since suppliers are not aware of how their customers will use the essential oil, they need to possess all the documentation required for various potential applications, including flavourings and fragrances.

Regardless of their intended use, essential oils to be traded in the EU should comply with Reg. (EC) 1272/2008 ("CLP4" regulation on the labelling of hazardous chemicals), as described below.

It is possible that the buyer will require that the exported essential oil complies with requirements related to various categories (e.g. cosmetics and food), in order to re-sell the essential oil to a wider range of customers.

## Compliance with EU regulations

Suppliers of natural ingredients from non-EU countries should adopt recognised extraction practices (in this case, steam extraction), and use labelling that adheres to the CLP Regulation. Moreover, information on potentially hazardous substances should be included in the Safety Data Sheets (SDS), as specified in the REACH regulation. Failure to comply with the CLP and REACH Regulations will render it impossible to sell the products in EU markets.

TABLE 4.9: COMPLIANCE OF ESSENTIAL OILS WITH EU LEGAL PROVISIONS AND PRODUCT CATEGORY

Requirement category	Key issues	Reference norms
Common for all uses – essentia	loils as raw material	
Packaging and Labelling - CLP4	<ul> <li>Labels include basic information, pictograms on hazards and codes of chemical substances;</li> <li>UFI and EINECS codes indicated in labels;</li> </ul>	Reg. (EC) 1272/2008
REACH	<ul> <li>Only authorised and registered entities established in the EU are allowed to engage in the trading of hazardous chemicals;</li> <li>For trades exceeding 1 Ton, the importer should be registered in REACH<sup>22</sup>;</li> </ul>	Reg. (EC) 1907/2006
	» All products should be accompanied by a safety data sheet;	
Essential oils for cosmetics		
EU Cosmetic regulation	» Manufacturers of cosmetic ingredients need to provide information on the properties and attributes of ingredients;	Reg. (EC) 1223/09
Essential oils for food use		
EU Food law	HACCP application	Reg. (EC) 852/2004
Traceability	General norms on traceability	Reg. (EU) 931/2011
Contaminants and residuals	<pre>» Metals (contaminants);</pre>	Reg. (EC) 1881/2006
	» PPP residuals;	Reg. (EC) 396/2005
	» Foreign bodies (plastic, metals, other foreign bodies); includes analysis of essential oil purity;	Reg. (EC) 2073/2005
Regulations on food additives, flavourings and enzymes		<ul> <li>» Reg. (EC) 1333/2008 (food additives);</li> <li>» Reg. (EC) 1334/2008;</li> <li>» (flavourings); flavourings list in Reg.</li> </ul>
		(EC) 872/2012; » Reg. (EC) 1332/2008 (food enzymes);

## Labelling – the CLP Regulation

The Classification, Labelling and Packaging (CLP) Regulation (CE 1272/2008) aligns the previous EU legislation with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The CLP regulation aims to ensure regulatory efficiency and harmonize the communication of hazard-related information.

The CLP Regulation supplements the REACH Regulation. It regulates the notification of classifications, the establishment of a list of harmonized classifications and the establishment of a classification and labelling inventory.

The CLP does not apply to substances and compounds for end users, such as drugs, cosmetics, food, and animal feed, even when they are used as food additives or food flavourings.

<sup>&</sup>lt;sup>22</sup> It can also be an entity owned by the exporter, provided that the company branch is established in EU as a separate entity and registered in REACH

Under the CLP regulation, natural ingredients should be labelled and packaged in a manner that ensures the protection of workers, consumers and the environment. The label should include the following information:

- » The name, address and telephone number of the supplier;
- » The quantity of the substance or mixture, unless specified elsewhere on the packaging;
- » Product identifiers; In the case of chemicals, an UFI (unique formula identifier) code should be provided on the label, to ensure prompt and appropriate action in case of poisoning; various other codes can also be added, such as the EINECS (European Inventory of Existing Chemical Substances), a registry number given to each chemical substance commercially available in Europe or the CAS identification number (used also for export in the US)<sup>23</sup>;
- » Hazard pictograms, signal words, hazard statements, precautionary statements and supplemental information. Since essential oils are considered a hazardous compound, a number of hazard pictograms and precautionary statements are required.

An example of a lavender oil label used in essential oil wholesaling is provided below.

## **REACH Regulation**

Registration, Evaluation, Authorisation and Restriction of Chemicals - REACH regulation (Reg. (EC) 1907/2006) addresses the production and use of chemical

substances<sup>24</sup>, and their potential impacts on both human health and the environment.

The basic principles of REACH are that: i) all chemical substances should be registered in order to be sold in EU markets25 and, ii) only authorised entities can trade registered substances.

In the classification of chemicals under REACH, essential oils are classified as "Natural Complex Substances"- NCS, meaning that they are composed of several chemical substances. Compositions of NCS vary widely in complexity, ranging from simple (with only a few constituents) to very complex (more than 100 constituents). Their chemical characterisation varies according to that complexity.

The distinctive feature of NCS is that, being botanical products, they display natural variations in chemical composition, even when derived from a single genus and species. These variations can be attributed to factors such as origin, climatic fluctuations, or the specific part of the plant that is processed. Processing methodologies will also affect variations in chemical composition.

All essential oils produced in Albania are already registered, so this is not an issue for exports. However, the requirement that these essential oils should be traded by an authorised entity can create a bottleneck in the trading process.

FIGURE 4.2: EXAMPLE OF A LABEL OF ESSENTIAL OIL FOR FURTHER PROCESSING: EXPORT TO THE EU

# Label example Identification by a) Trade name b) International name c) CAS no. d) EINECS N° Warning Exercises since ordinates. May sake are since ordinates or sake since ordinates ordina

<sup>&</sup>lt;sup>23</sup> For food flavourings, Reg. (EC) 872/2012 also provides a table of correspondence between substance unique identification number (FL.n.), the name of the substance, the CAS (Chemical Abstract Services) number adopted in the US, the JEFCA number (FAO/WHO Expert Committee on Food Additives) and the Council of Europe Number.

<sup>&</sup>lt;sup>24</sup>A "chemical substance" is defined in REACH (Article 3.1) and in CLP (Article 2.7) as: "a chemical element and its compounds in their natural state or obtained by any manufacturing process, including any additives requires to preserve their stability and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition"

<sup>&</sup>lt;sup>25</sup> The identification of a substance in a registration dossier should address the requirements specified in chapter 2 of Annex VI of REACH, which specifies that "For each substance, the information given (...) shall be sufficient to enable the identification of each substance".

All exported lots should be accompanied by a safety data sheet (SDS). SDS are complex documents, articulated in 16 chapters26, covering all safety aspects. Specific guidelines for SDS preparation are provided by ECHA-the EU Chemical Agency (ECHA, 2020).

The identification and denomination of substances used in the SDS should follow the indications provided in the REACH regulation.

Should a new compound or substance be registered, a registration dossier should be submitted to ECHA, the European Chemical Agency. However, should the traded amount be smaller than 1 Ton per year, registration is not required.

# Essential oils exported as raw material for further processing

Essential oils can be exported as an intermediate product for further processing; in this case, the product should comply with REACH (if sales exceed 1 Ton per year) and CLP regulations, namely with the following provisions:

- » It should be sold to an entity registered and authorized to deal with that specific NCS (in the case of the particular essential oil);
- » A Safety Data Sheet SDS should be provided (see above for SDS contents);
- » An indication of the NCS codes (UFI and EINECS) should be included;
- » The label should comply with the rules of the CLP on hazardous substances;
- » Packaging and transport should be suitable for NCS.

Both the exporter and the importer are responsible for the compliance of labels and SDS with the legal requirements.

## **Essential oils exported for cosmetics**

These products should adhere to the provisions included in Reg.(EC) 1229/2009 (the so-called "Cosmetic Regulation"). This regulation is constantly updated with new substances which are either allowed or allowed in limited quantities<sup>27</sup>.

<sup>26</sup>i) Identification of the company/undertaking, ii) Hazards, iii) Composition/information on ingredients, iv) First aid measures, v) Firefighting measures, vi) Accidental release measures, vii) Handling and storage, viii) Exposure controls/personal protection, ix) Physical and chemical properties, x) Stability and Reactivity, xi) Toxicological information, xii) Ecological information, xiii) Disposal considerations, xiv) Transport information, xv) Regulatory information, xvi) Other information

<sup>27</sup> For example, the new Reg. (EU) 2022/1181 states that products that contain preservatives releasing more than 0,001% (10 ppm) of formaldehyde (formaldehyde releasers) should bear the warning "releases formaldehyde". This provision is not relevant for essential oils.

There are seven categories of cosmetic products: i) oral care; ii) skin care; iii) sun care; iv) hair care; v) cosmetic decoration; vi) body care; and vii) perfumes.

Essential oils for cosmetics can be used in each of these product categories. Essential oils are used in cosmetics mostly as body lotions or essential oils for massages, either mixed with carrier oils (as in most commercial products for end users) or used in their pure form; some essential oils, like lavender, are also widely used as air fresheners.

A considerable quantity of essential oils is used for aromatherapy products. In the EU legal framework, aromatherapy products are classified as cosmetics, including air fresheners<sup>28</sup>.

In addition to compliance with REACH and CLP regulations, essential oils exported for cosmetics should also comply with Reg. (EC) 1223/09 ("Cosmetic regulation").

Reg.(EC) 1229/2009 provides a list of substances that cannot be present in cosmetic products and a list of substances which can be present in limited quantities<sup>29</sup>.

Should a product be exported as a product for final consumption, including simple products such as air fresheners for aromatherapy, the exporter should provide the buyer with a complete technical dossier, including the following information and documents:

- » The Safety Data Sheet SDS (see above for the provisions of the REACH regulation on SDS contents);
- » The Technical Data Sheet TDS;
- » Certificates of analysis including, inter alia, information on product purity. Most essential oils have an ISO standard to adhere to;
- » Allergen declaration;
- » Traceability information;
- Responsible sourcing policies and practices, including the statement that the product has not been tested on animals;
- » Record of certifications obtained and standards applied.

# Essential oils exported as products for aromatherapy or ambience fragrance

Products for aromatherapy, including those that will be used for ambience freshening, are classified as cosmetics, as the active substances will be inhaled by the customer and will eventually have effects comparable

<sup>&</sup>lt;sup>28</sup> The logic of this classification is that the active substances will be inhaled by the customer and will eventually have effects comparable to those of massage oils, cosmetic creams etc.

<sup>&</sup>lt;sup>29</sup> Annex II to Reg.(EC) 1229/2009 indicates 1,328 substances not allowed in cosmetics; Annex III indicates the substances allowed in limited quantities in cosmetics

to those of massage oils, cosmetic creams, etc.

The products and their labelling should comply with CLP4

## **Essential oils exported as food products**

Essential oils exported as food products can serve as food additives, flavourings or enzymes.

They should comply with all rules relevant to food products, including the following:

- Traceability: at a minimum, the "one step back-one step forward" concept should be implemented. The exporter should make individual batches traceable with markings on each container. These batches, whether produced by blending or not, should also be registered in an administrative system.
- » Hygiene: the HACCP and GMP practices should be applied;
- » Compliance with rules on contaminants: PPP residues, foreign bodies;
- » Labelling: the CLP regulation and the rules on food labelling should be observed. In addition to the CLP provisions (chemical substance codes, hazard pictograms, warnings, etc.), the following information should also be provided:
  - » product name;
  - » batch code;
  - » whether the product is intended for use in food products;
  - » country of origin;
  - » name and address of the exporter;
  - » date of manufacturing;
  - » "best-before" date;
  - » net weight;
  - » recommended storage conditions.

- Packaging. European buyers generally base their packaging requirements on ISO standard 210:2014. This standard provides general rules for the packaging, conditioning and storage of essential oils. Unless otherwise specified by the buyer, the following packaging instructions should be followed:
  - » Use United Nations approved packaging. This packaging is suitable for the transport of dangerous goods, including essential oils;
  - » For details on packaging materials, see the guidelines of the European Federation of Essential Oils on the transport of dangerous goods;
  - » Preserve the quality of essential oils by using containers made from a material that does not react with the constituents of the oil (e.g. lacquered or lined steel, aluminium);
  - » Use new packaging materials;
  - » Do not use detergents to clean containers of working materials. They may contaminate the oil because of residues. Use only water or alcohol and let it dry carefully;
  - » Fill headspace in containers with a gas that does not react with the constituents of the oil (e.g. nitrogen or carbon dioxide). If the essential oil reacts with air in the container, this process may result in quality deterioration;
  - » Facilitate the recycling of packaging materials by European buyers. For example, use containers of recyclable material (e.g. metal);
  - » Store containers in a dry, cool place to prevent quality deterioration;
  - » Keep Organic certified essential oils physically separated from conventional essential oils.

## 4.4 EXPORTING MAPS TO THE USA

# 4.4.1 US MAPs categorization for food safety purposes

With reference to the selected MAPs, all of them are considered as "Substances generally recognized as safe" in the Code of Federal Regulations – CFR (CFR, 2023). The limits that apply to the use of a substance to be included in this category are provided for in CFR Title 21(CFR, 2023). These substances, if used in accordance with the indications provided in the CFR, are considered safe and are therefore not subject to any specific authorizations other than those foreseen for food products (dried MAPs used as spices) or by the GMP required for all essential oils.

The same varieties of marjoram are included in the list annexed to sub-categories 182.10 (spices and other natural seasonings and flavorings) and 182.20 (essential oils). However, these lists do not include *Oreganum Majorana*, which is the MAP commonly known as marjoram in Europe. It is not clear whether *Oreganum Majorana*, if exported to the US, would automatically classify as "Substances generally recognized as safe".

While all the essential oils extracted from the selected MAPs are included in this category, not all the dried MAPs are, as detailed in the table below.

TABLE 4.10: SUBSTANCES GENERALLY RECOGNIZED AS SAFE - CFR TITLE 21, VOL. 3, PART 182

182.10 Spices and other natural seasonings and flavorings.		182.20 Essential oils, oleoresins (solvent-free), and natural extractives (including distillates)		
Commercial name	Botanical name	Commercial name	Botanical name	
Not included		Immortelle	Helichrysumaugustifolium DC	
Lavender	Lavandula officinalis Chaix.	Lavender	Lavandula officinalis	
Not included		Lavender, spike	Lavandula latifoliaVill.	
Not included		Lavandin	Hybrids between Lavandula officinalis Chaix and Lavandula latifolinVill.	
Oregano (oreganum, Mexicanoregano, Mexicansage, origan)	Lippia spp.	Origanum	Origanumspp	
Marjoram, sweet	Majorana hortensisMoench.	Marjoram, sweet	Majorana hortensisMoench.	
Marjoram, pot	Majorana onites (L.) Benth.	Not included		
Clary	Salvia sclarea L.	Clary	Salvia sclarea L.	
Sage	Salvia officinalis L.	Sage	Salvia officinalis L.	
		Sage, Greek	Salvia triloba L.	
		Sage, Spanish	Salvia lavandulaefoliaVahl.	
Thyme	Thymus Vulgaris	Thyme	Thymus Vulgaris and Thymus zygis var. gracilisBoiss.	
		Thyme, white	Do.	
		Thyme, wild or creeping	Thymus serpyllum L.	

# 4.4.2 Requirements for exporting dried MAPs to the US

Albania is a major exporter of dried sage to the US. In the previous decade, almost 50% of dried sage imported into the US came from Albania; however, recurrent issues were faced in relation to the presence of microbial contamination (in particular Salmonella) and foreign bodies. At a certain stage, it became necessary to either treat the imported lot for microbial control directly in the US or to initially export it to a third country where steam treatment was performed (and added value retained) and then re-export the treated lot to the US.

Considering the above, the assessment of export requirements will be focused on microbial controls and foreign bodies.

## Controls for microbiological contamination

To control pathogens, companies follow various methods including irradiation and steam treatments. According to the United States Environmental Agency (EPA), the method used "...depends on the pathogen of concern, particular characteristics of the spice, and whether the spice can withstand a particular treatment without significant degradation in quality".

For instance, irradiation eliminates organisms and bacteria that cause foodborne illnesses and food spoilage. Benefits include improved food safety and extended shelf life without the use of chemicals or toxic substances and without affecting nutrient levels. Irradiation is approved for use on spices and seasonings, but treated foods should be clearly labelled as "treated by radiation" or "treated by irradiation" on the packaging.

Another method employed is Ethylene Oxide (ETO), which is a flammable, colourless gas used as a sterilant for spices as well as for sterilizing cosmetics and medical devices. Testing for ETO residue on spices is necessary, as it is toxic to humans.

A common way to control Salmonella, a microbial contaminant often present in dried MAPs, is by using steam treatment.

Maximum Residue Levels (MRLs) for ETO set by Health Canada's Pest Management Regulatory Agency (PMRA) amount to 7 ppm for ETO and 940 ppm for Ethylene Chlorohydrin (a degradation by-product of ETO) in specific herbs, spices and fruits and vegetables. These levels are consistent with the US ranges.

## **Foreign bodies**

In contrast with the EU, there are limits and indications on limits regarding the presence of foreign bodies, set by the FDA (2005) and ASTA - American Spice Trade Association.

## 4.4.3 Essential oils

The export of MAPs essential oils in the US is easier than in the EU: MAPs essential oils are considered inherently safe and the declaration on the intended use of the product provided by the exporter defines the applicable rules (i.e. whether it is a cosmetic or food product). It is up to the importer to verify the compliance of the received product with the declared category.

In the US, the term "aromatherapy" is not recognized (contrary to the EU, where it is classified as a cosmetic product), so this indication would be not accepted. In principle, essential oils are either cosmetics, drugs or food products.

Essential oil imports can be subject to controls by the Animal and Plant Health Inspection Service - APHIS and the Food and Drug Administration - FDA. The FDA regulates essential oils according to their intended use by a company under the "Federal Food, Drug, and Cosmetic Act".

In addition to the administrative and customs documentation (CBP<sup>30</sup> form 301, import summary, bill of lading, commercial invoice and packing list), only two documents are required:

- Certificate of origin.
- Certificate of analysis sheet COA, providing the key physical and chemical parameters of the essential oil. A COA template is provided in Figure 4.3 below

FIGURE 4.3: COA TEMPLATE- SAGE



## Certificate Of Analysis Sheet Organic Sage Essential Oil Common/Strong (Salvia officinalis)

	Sage C	Sage Oil Organic			
Customer	-	•			
Batch -	Pi	roduct Code	92	Date	08/10/2015
EST RESULTS					
ANALYTICAL TEST		SPECIFICATION RAI	NGE	RESULT	
Appearance		Clear liquid pale to slightly yellow		Conforms	
Odour		Characteristic		Conforms	
Relative Density @ 20°C (g/ml)		0.910 - 0.925		0.915	
Refractive Index @ 20°C		1.458 - 1.472		1.466	
Optical Rotation @ 20°C (Degrees)		+2.0 to +15.0		+8.60	
TORAGE					
Shelf life of this product is int major factors. Material store reflects a minimum period in its continued shelf life may be commercial expiry date as sh failure would be changes in o	d in adverse cond which we would every much long own below. The e rganoleptic prop	litions may deteriorate in expect product to remain or and we advise re-test at expiry date is subjective as	uch faster. Our sugge- in good usable condi- t the indicated date as ad should be controll- ediment / baze / off o	sted "Re-test" data tions if stored as a and then every 3-6 ed by QC/QA. Typ dour etc) Such ch	e shown on this certificate ecommended. Thereaft months up to a suggeste ical indicators of re-test anges may be gradual an
slight and the commercial ex		act to renect a vinoic min	amum proposas subje	crto carner re-te	st approvals
TABILITY			imum proposai subje	et to carrier re-te	st approvals
TABILITY Date of packing:		10/15	imum proposai suoje		st approvals
TABILITY Date of packing: Re-test date: Commercial expiry date			amum proposas suoje		st approvals

<sup>&</sup>lt;sup>30</sup>Customs Border Protection

# 4.5 EU PROVISIONS FOR ORGANIC PRODUCTION AND MOST REQUIRED STANDARDS IN GLOBAL MARKETS

## 4.5.1 EU provisions for organic production

Demand for organic productions represents a significant and growing share of the total demand for agrifood products in EEA countries<sup>31</sup>. The market share varies from around 1% to 6% in most eastern and southern European countries, and from 11% to 27% in Denmark, Switzerland, Sweden and Austria.

Organic production in most countries is regulated by law, i.e. a product should comply with the relevant legal requirements to be considered as organic; consequently, the choice to produce under an organic regime is voluntary, but production is subject to legal requirements. A product that does not comply with organic production legal requirements can still be exported to EEA countries, provided that it complies with the requirements for non-organic productions as detailed above.

The legal ground for organic produce in the EU is Reg. (EU) 2018/848, which came into force in January 2022. Several other delegated and implementing regulations are regulating the trade of organic products.

Third country producers should comply with the same set of rules as those applied in the European Union, in order to be allowed to export organic produce to EU countries. The main provisions include:

- » Before a product can be certified as organic, producers are required to have used these production methods for at least 2 years throughout a conversion period;
- » Producers should maintain soil fertility and water retention, avoid cross-contamination and use organic inputs and organic propagation materials (i.e. seeds and seedlings);
- » In order to be certified as an organic farmer or exporter, it is necessary to be registered and certified through a recognised control body or an accredited certifier, for verifying compliance with the organic rules. Annual inspections and checks are carried out to verify continuous compliance with the legal requirements of the organic production regime;

After being audited by an accredited certifier, the producer or the exporter can use the EU organic logo (see **Figure 4.4** below) on its products, along with the logo of the standard holder.

For many years, the challenge of having accredited certifiers has hindered the growth of Albanian organic production for export. The solution that was adopted involved establishing branches of recognized control bodies in EU countries, which conducted the processes of auditing, control, and certification.

**FIGURE 4.4:** THE OFFICIAL ORGANIC LABEL FOR ORGANIC PRODUCTS IN EUROPE



All organic products imported into the EU should have the appropriate electronic certificate of inspection (e-COI). These certificates are managed through TRACES (see subchapter 4.3.1.2 above). Without an electronic certificate of inspection, products will not be released from their port of arrival in the European Union.

# 4.5.2 Standards and certifications most required in EEA MAPs markets

# 4.5.2.1 Categories of standards and certifications

Main standard categorization criteria relevant to this study are related to: i) scope and, ii) developer/ property. The table below shows a simplified structure of the main relevant standards presently in use, according to those two categories.

<sup>31</sup> EEA — European Economic Area is composed of EU Member States, plus Switzerland, Norway and Iceland

TABLE 4.11: SYNOPTIC TABLE OF THE MAIN RELEVANT ISO AND PRIVATE STANDARDS BY SCOPE AND DEVELOPER

Developer/property Scope	ISO	Private entities
Management	ISO 9000 family (5 st.), quality management system	
Food safety	ISO 22000 family (4 st.)	Main ones: FSSC 22000
Overall supply chain		
Supply chain segments		Main ones:
		» GlobalG.A.P. family and adds-on (production and post-harvest);
		<pre>» LCG-BRCGS (processed food);</pre>
		» GFSI-IFS (food processing);
Companies and value chains functions	<ul> <li>» ISO 27001 (Information security management system);</li> <li>» ISO 28001 (Security management system);</li> <li>» ISO 37001 (anti-bribery management system);</li> <li>» ISO 10002 (customer satisfaction);</li> <li>» ISO 22301 (business continuity, resilience);</li> </ul>	
Sustainability	<ul> <li>ISO 45001 (Occupational Health &amp;Safety);</li> <li>ISO 14001 (Environmental management system);</li> <li>ISO 50001 (Energy management);</li> </ul>	Over 300 VSS; main ones: SMETA, Fairtrade, Rainforest, SA 8000, some GlobalG.A.P. adds-on, fair for Life, BSCI
Cultural values		<pre>» Halal (different by country and TIC);</pre>
		» Kosher (different by TIC);

The adoption of a standard by a company follows a complex process, which includes auditing, inspection and certification by an accredited independent and specialised subject, collectively known as TIC (Testing, Inspection, Certification) bodies. TIC bodies also issue certifications for compliance with legal requirements, such as the mandatory implementation of HACCP in most countries, but not certificates of compliance.

In some cases, private standards are developed by interest groups, such as GFSI (Global Food Safety Alliance), sometimes having the status of NGO (as Rainforest).

In other cases, large buyers, such as supermarket chains or retailers groups or associations have formalised their requirements into proprietary standards, typically developed in collaboration with the TICs.

In many cases, the TICs themselves have also developed proprietary standards.

A relatively recent trend is related to the proliferation of proprietary sustainability standards, i.e. standards aimed at the accomplishment of indicators related to UN Sustainable Development Goals, such as workers safety, fair treatment of workers and suppliers, sustainable use of environmental values, and gender issues. These proprietary standards are collectively known as Voluntary Sustainability Standards. According to UNCTAD's definition, "Voluntary Sustainability Standards (VSS) are private standards that require products to meet specific economic, social and environmental sustainability metrics. The requirements can refer to product quality or attributes, but also to production and processing methods, as well as transportation".

VVS usually include several sustainability indicators related to different SDGs (e.g. Fairtrade). Over time, their development has aligned with the creation of ISO sustainability standards, usually focused on the management of a single sustainability aspect (e.g. ISO 450001 on occupational health and safety or ISO 50001 on energy management).

# **4.5.2.2 Demand for standards introduction and TIC services**

## Outcomes of field survey

The outcomes of the field survey proved that, even if international buyers of Albanian MAPs and MAPs essential oils often request additional or stringent parameters (e.g. MRL) as compared to legal requirements, there is a relatively small demand for certified implementation of proprietary standards.

However, there is good demand for organic products, so 28% of the sampled entrepreneurs are certified as organic producers (EU-Bio, BioSuisse, USDA Organic).

Moreover, several operators, particularly in the MAPs sector, hold ISO 9001:2015 certification (14% of the sample), as a means to establish credibility as reliable partners. Quality system certification is less common: 6% of the sample holds FSSC22000 certification, a private standard based on ISO 22000, with additional features.

The most commonly adopted food safety standard for processed products is BRCGS (10% of the total sample), but it is adopted only by MAPs processors/exporters.

Finally, there is a significant demand for TIC services for HACCP certification, with 20% of the sampled companies holding this certification.<sup>32</sup>

**Table 4.12** below summarizes the frequency of certified enterprises within the sample object of the field survey. It is important to underline that a single company may hold more than one certification.

<sup>32</sup>HACCP is a management system that is integrated into most food legislation worldwide. Its implementation is mandatory in the EU, US and Albanian legislations. However, certification for compliance is not mandatory.

**TABLE 4.12:** SHARE OF SAMPLED ENTERPRISES HOLDING DIFFERENT CERTIFICATIONS

Certification	Share of sample
Organic (BiO) USDA Organic or BioSUISSE Organic	28%
HACCP	20%
ISO 9001:2015	14%
BRCGS	10%
Kosher	10%
FSSC 22000	6%
Rainforest Alliance	2%
FairTrade	2%
Sedex Members Ethical Trade Audit (SMETA)	2%
Others	6%

Source: UNIDO/GQSP 2023 Survey

# Standards and certifications related to quality management and food safety management systems

The most known and adopted standards for quality management and food safety management systems are ISO 9001:2015 and ISO 22000:2018, respectively. However, since ISO 22000:2018 is not recognized by GFSI, many enterprises and buyers prefer the private FSSC 22000 standard, which is GFSI recognized and embeds ISO 22000:18, plus some of the technical standards (TS) of the ISO 22000 family and additional features specific to FSSC 22000.

Among the sampled enterprises, HACCP certification is rather common (20% of total). HACCP is not a standard, but a food safety management system which finds mandatory application in most food legal frameworks (including those in Albania and all countries targeted for export worldwide), but for which certification for compliance is not mandatory. HACCP principles and steps are embedded in ISO 22000:2018, along with several other features and components.

No enterprises among those included in the sample hold ISO 22000:2018 certification. However, 6% of the sampled enterprises hold FSSC 22000 certification, which is a private standard integrating ISO 22000:2018 as described below. The advantage of FSSC 22000 over ISO 22000:2018 is that FSSC 22000 is recognized by GFSI, while ISO 22000:2018 is not.

Another relatively popular private standard for food safety *and* quality is BRCGS: 10% of the sampled enterprises hold BRCGS certification.

A short description of the above-mentioned four standards (ISO 9001 family, ISO 22000 family, FSSC 22000 and BRCGS) is provided in the **Annex**.

## VSS categories and overall EU buyers demand for VSS

The Voluntary Sustainability Standards – VSS are standards linked to the Sustainable Development Goals; these VSS are commonly divided into nine subcategories, namely: i) Due diligence, ii) Credibility, iii) Traceability, iv) Food safety, v) Quality, vi) Sustainable business, vii) Human and Labour rights viii) Environment and climate change and, ix) Gender. Each VSS can be included in one or more categories, depending on its scope.

Some ISO standards, such as ISO 45001 (Occupational health & Safety), ISO 14001 (Environmental management system) and ISO 50001 (Energy management) are also linked to SDG, but cannot be classified as VVS according to the UNCTAD definition.

There is a large number of VSS. The ITC *Standards Map database* (Standard Map, 2022) considers over 300 VSS<sup>33</sup>, many of which are part of VSS families, such as GlobalG.A.P., which is made of core standards, production-oriented specific modules (which generate a separate standard) and add-on modules. Some large buyers, such as supermarket chains, collaborate with auditing firms to develop their own standards (e.g. Tesco with GlobalG.A.P., with the Nurture 11.4 add-on module)

Regardless of the fact that most VSS include modules for MAPs<sup>34</sup>, few of them are commonly required in Western Balkans, the most common being summarized in the **Annex**.

It is possible that multiple certificates are required, each relevant to a specific stage of the supply chain, or a combination of different types of certifications. For example, it is possible that BRCGS is required for food safety (BRCGS *Food Safety v9*) and, in addition, SMETA or Fairtrade certification for workers conditions (SMETA) or management of production contracts (Fairtrade). Moreover, certification for compliance with requirements and standards of different categories can also be demanded (e.g. organic certification, plus ISO 9001:2018, plus BRCGS Food Safety v9).

More broadly, buyers are increasingly demanding the adoption of voluntary standards. In many cases, specific requirements that are not associated with a formalised standard are requested.

## Standards related to cultural and religious values

The most common standards of this category are those products classified as "Halal" and "Kosher". In Albania, there is a full supply chain specialized in "Halal" products, but not MAPs exporters.

On the contrary, in the Albanian domestic market, it is quite rare to find "Kosher" certified products, while 10% of the enterprises considered in the study are certified as "Kosher".

The main features pertaining to Kosher and Halal certification are described in the **Annex**.

<sup>&</sup>lt;sup>33</sup> The database covers all countries worldwide, but has a specific focus on a limited number of agricultural commodities, excluding fruits and vegetables and MAPs. The database provides information on the following topics: i) a review of over 300 sustainability standards, ii) a tool for multi-criteria comparison of different standards, iii) a tool for self-assessment vs. a specific standard and, iv) monitoring trends of certification schemes (area, number of producers, variation in last year). Among different monitoring features, the database provides: iv.1) an overview of the most common standards adopted for different crop categories and countries, iv.2) trends and figures regarding the use of different standards (surface, number of certified enterprises, growth over time).

<sup>&</sup>lt;sup>34</sup> For example, RA – Rainforest Alliance has specific sub-modules for sage, oregano, thyme, lavender and Helichrysum. However, there is no known demand for RA MAPs certifications from Western Balkans producers.





## 5.1 BACKGROUND

The Quality Infrastructure System (QIS) is a combination of initiatives, institutions, organizations, activities and people contributing to a myriad of policy priorities, including agriculture development, trade competitiveness, efficient use of natural and human resources, food safety, health, the environment and climate change (UNIDO, 2016). It includes a national quality policy and institutions to implement it, a regulatory framework, quality service providers, enterprises, customers and consumers (with citizens considered as "consumers" of government services).

There are various levels of stakeholders involved in ensuring the functioning of the quality infrastructure in Albania, including: i) institutions responsible for the preparation of the regulatory framework and quality policy at central and local level government bodies, ii) quality infrastructure institutions, iii) bodies responsible for monitoring the quality infrastructure services, iv) specific stakeholder categories, including farmers, processors and importers of food products, v) consumers, vi) quality promotion stakeholders, including central state agencies, media, donors, academia and civil society (Table 5.1).

TABLE 5.1: THE COMPONENTS OF THE QUALITY INFRASTRUCTURE IN ALBANIA

Level	Component	Stakeholders
Regulatory framework and quality policy	Key government institutions	Parliament, Council of Ministers, MARD (including agencies, divisions, technical committees and commissions) and MFE.
Quality infrastructure institutions	Metrology, Calibration Accreditation	GDM, GDS, GDA
Quality infrastructure	Inspection	NFA, NAVMP, SIMS
services	Testing	FSVI, NFA laboratories, AUT laboratory, private laboratories.
	Certification and control	Certification bodies
Quality promotion	Educational institutions	AUT, UFN, vocational schools
	Quality awareness	AIDA and ANES
	Associations	Associations active in the MAPs sector (2) and associations related to F &V value chain (3)
	Donors	SDC projects, EU, GIZ, WB, FAO.
VC Actors	From input to foreign market	input providers, farmers, processors/exporters
Consumers	State and private initiative	Consumer Associations and National Committee for CP

Source: Author's own elaboration based on interviews

## 5.2 REGULATORS AND THE GOVERNMENT

# 5.2.1 Role and responsibilities of Government bodies and regulators

Governments and regulators are the backbone of the QIS, which serves as a critical tool for fulfilling their missions.

Governments utilise QIS for two main purposes: i) to fulfil their responsibilities for public health and safety, including food safety, and ii) as a policy implementation tool in many areas, including economic development,

competitiveness in global markets, environmental and climate-related policies and public health.

Regulators utilise QIS as a support tool to specify standards and conformity assessment processes that can be used to ensure that objectives of public interest values, such as public health and the environment, are met. Part of these standards are often translated into legally binding requirements and conformity assessment is often made mandatory.

Quality governance in Albania is organized at various levels. At the central level, the main institutions are the Parliament, the Council of Ministers, and the line ministries.

The Parliament: In the Albanian Parliament, several Parliamentary Commissions are dedicated to activities related to QI, with the most notable being: i) the Parliamentary Commission for Production Activities, ii) the Parliamentary Commission for Trade and Environment, which plays an important role in drafting and amending relevant legislation and proposals for reforms in trade, agriculture, environmental protection etc.

The Council of Ministers and the Line Ministries. The Council of Ministers approves various by-laws (e.g. legislation, regulations) and policies in all areas. The line ministries which are related to QI in the agrifood sector (including MAPs) are the Ministry of Agriculture and Rural Development (MARD); the Ministry of Finance and Economy (MFE) and the Ministry of Environment and Tourism (MET).

The Ministry of Finance and Economy (MFE) is the responsible institution at the top policy level for coordinating the following quality infrastructure institutions: i) General Directorate of Metrology (GDM); ii) General Directorate of Standardization (GDS); iii) General Directorate of Accreditation (GDA), iv) General Directorate of Industrial Property<sup>35</sup>, and v) Albanian Investments Development Agency (AIDA). Key QI institutions (namely GDA, GDS and GDM) are discussed in more detail in subchapter 5.3, while AIDA is discussed in detail in subchapter 5.7.1.

The Ministry of Agriculture and Rural Development (MARD): MARD's mission is to develop and implement policies on agriculture, rural development, food safety, consumer protection, fisheries and aquaculture and the sustainable use of water resources. It drafts by-laws (e.g. ministerial orders). There are various divisions within MARD that are responsible for strengthening the quality infrastructure. Structures within MARD that are involved in quality infrastructure policies include the General Directorate of Food Safety, Veterinary, Plant Protection and Fishery<sup>36</sup>, as well as the Directorate of Policies on Plant Health, Seeds, Seedlings and Fertilizers (DPPHSSF) (see subchapter 5.4.1. for a more detailed description of their role in controlling agricultural inputs and product quality).

<sup>35</sup>The General Directorate of Industrial Property is a government institution tasked with overseeing all the procedures related to industrial property rights. It is responsible for ensuring reliable examination and registration related to: patents, trademarks, industrial design and geographical indications.

<sup>36</sup>The General Directorate of Food Safety, Veterinary, Plant Protection and Fishery bears the responsibility for the following functions: i) develop the procedures related to the registration of PPPs, active ingredients, additives, etc; ii) steer and monitor the activity of plant protection services at the central and regional level, in the context of the implementation of the plant protection law; iii) draw up rules for special control measures to prevent the entry and spread of pests within the country; and, iv) guide the agencies that are responsible for the implementation of the respective legislation (NAVPP, NFA, FSVI).

The food safety, veterinary and phytosanitary policy is separately organized through various structures. The food safety and quality assurance functions are implemented through the National Food Authority (NFA), the National Authority of Veterinary and Plant Protection (NAVPP) and the Food Safety and Veterinary Institute (FSVI). In particular:

- » NFA is the Competent Authority to coordinate, plan and carry out the official control of food, feed, and live animals along the entire chain of their transport, storage, and trading, including import and export;
- » The National Authority of Veterinary and Plant Protection (NAVPP) and the Albanian National Extension Services (ANES) are responsible for the sustainable use of inputs/PPP in the Albanian territory;
- The Food Safety and Veterinary Institute (FSVI) is the National Reference Laboratory, responsible for conducting analyses related to food, veterinary and plant protection.

Both NFA and NAVPP have inspection responsibilities. Their functions are described more in detail in subchapter **5.4.3** below.

An inspection body subordinate to the MFE is the State Inspectorate of Market Surveillance (SIMS)<sup>37</sup>.

The Ministry of Environment and Tourism (MET) serves as the high-level policy-making body responsible for overseeing the sustainable use of natural resources.

For the issues relevant to this study, the implementation body of MET is the National Agency for Protected Areas (NAPA). This Agency is responsible for the preparation of the necessary documentation and procedures for issuing permits, licenses, and authorizations related to the use of natural resources in protected areas, including wild MAPs collection. The monitoring of natural resources and their use is a responsibility of the Regional Agencies for Protected Areas (RAPA).

Municipalities are responsible for market vigilance, including wholesale markets. Municipalities can require market operators to report data as part of their contract with the companies managing the markets. They are responsible for the administration of green markets. In addition, they should support the agricultural sector as an important economic activity<sup>38</sup>. Limited resources reduce the capacity of the Municipalities to actively participate in supporting agriculture. Last, but not least, Municipalities have the authority to administrate forests and pastures that

<sup>&</sup>lt;sup>37</sup> It was established by DCM no. 36, dated 20/01/2016 "On the establishment, organization and functioning of the State Market Surveillance Inspectorate".

<sup>&</sup>lt;sup>38</sup>Few municipalities organise fairs for the promotion of local products. Municipalities can also take part in the establishment and functioning of the Local Action Groups (LAGs). There are few examples of measures or programmes for the support of agriculture from municipalities. For instance, the Municipality of Divjakë is providing soil analyses through the Urban Lab.

fall outside the jurisdiction of the Regional Agencies for Protected Areas (i.e. those areas which are not protected). It is worth mentioning that the majority of forestry and pasture resources in Albania belong to the municipalities.

## Main policy gaps

In most countries, the National Quality Policy (NQP) is the basic government instrument for establishing and overseeing the QIS (UNIDO, 2018). Among other features, the NQP defines the roles and responsibilities of the Quality Infrastructure Institutions, the inspection and testing entities and other entities involved in the implementation of quality policies. According to UNIDO (2016), the NQP should harmonise the policy measures concerning standards, quality and technical regulations found in strategies related to industrial development, boosting export trade, environmental management, food safety and/or security, advancement in science and technology, and similar issues. The presence of a well-defined governing body is essential to spearhead the National Quality System.

In Albania, there has not previously been a comprehensive NQP in place. However, various elements of a NQP are already included in the draft "Intersectoral Strategy for Consumer Protection and Market Supervision (ISCPMS) 2023 – 2030"39.

The main areas covered by this strategy are:

- » Safety of food and non-food products; drugs for human use; cosmetics; quality infrastructure; market surveillance etc.;
- » Consumer protection beyond safety aspects, including: i) consumer protection in terms of commercial practices; ii) enforcement of consumer rights; iii) alternative and online dispute resolution; protection of consumer interests in the fields of environment, tourism, digitization etc.;
- » Consumers' awareness and information, as well as inter-institutional cooperation with other stakeholders such as consumer organizations, civil society, businesses etc.

The ISCPMS 2023-2030 is a strategic document tackling quality issues. Considering the current situation, there is a need to address at sector level the quality policy and address various weaknesses which go beyond the issue of safety, consumer protection and consumer awareness. Furthermore, there is no governing body defined to oversee the National Quality Infrastructure System and effectively implement the NQP.

## 5.2.2 Legal framework gaps

<sup>39</sup> The strategy was developed under the coordination of a steering Committee led by the Ministry of Finance and Economy (MFE) in the first quarter of 2023. The Steering Committee could potentially become a de-facto governing body for Albania's National Quality Infrastructure System.

Based on interviews with policy stakeholders and market operators several aspects of legislation have been identified that are not yet in alignment with the EU legal framework. The harmonization of these aspects should be addressed within the framework of a NQP, namely:

- The accreditation of conformity assessment bodies.
- 2. Good Laboratory Practice (GLP).
- 3. Marketing standards as part of a common market organization (CMO).
- 4. Albania's legislation on accreditation and market surveillance.
- 5. The norms that are still based on the 'old approach' (GT Engineering, 2023)<sup>40</sup> such as those for food pre-packaging<sup>41</sup>.
- 6. The relationship between (voluntary) standards and (mandatory) technical regulations<sup>42</sup>

In addition, there are also several recent regulations pertaining to specific QI components (e.g. Regulation (EU) 2018/2948 "On organic production and labelling of organic products") that the Albanian legislation should be aligned with.

Other regulations that will likely require review and assessment in the upcoming pre-accession rounds of legal framework alignment include those associated with the high added-value downstream products

- <sup>40</sup> The old approach represented the conventional method by which national authorities formulated technical legislation, delving into extensive details, typically driven by a lack of trust in the diligence of economic operators concerning matters related to public health and safety. In certain sectors (e.g. legal metrology), this even led public authorities to issue certificates of conformity themselves. "Historically, EU legislation for goods has progressed through four main phases:
- The traditional approach or 'old approach' with detailed texts containing all the necessary technical and administrative requirements.
- The 'new approach' developed in 1985, which restricted the content of legislation to 'essential requirements', leaving the technical details to European harmonised standards. This, in turn, led to the development of the European standardisation policy to support this legislation,
- The development of conformity assessment instruments became necessary for the implementation of various Union harmonisation acts, encompassing both the new approach and the old approach,
- 4. The 'New Legislative Framework' adopted in July 2008, which built on the New Approach and completed the overall legislative framework with all the necessary elements for an effective conformity assessment, accreditation and market surveillance, including the control of products from outside the Union."
- $^{41}$  Food pre-packaging refers to packaging that is done either at the production site (e.g. boxes used for collecting vegetables in the field) or before sale
- <sup>42</sup> It is important for the government to ensure that the country implements standards and technical regulations consistently with world trade rules. These rules are established by the World Trade Organization (WTO). Due to the mandatory nature of technical regulations, they have the potential to become technical barriers to trade (TBT) that prevent or hinder the flow of goods and services between countries. Although standards are generally voluntary, they become mandatory when referenced in regulations.

derived from processed MAPs, such as novel food<sup>43</sup> and other preparations derived from MAPs that claim to possess therapeutical effects, which, for purposes of EU legal alignment, should undergo a similar approval process as that of pharmaceutical drugs.

Poor capacities for evidence-based policy development and limited stakeholder involvement in the process of legal harmonization were the main reasons for the alignment gaps.

The role of the National Standards Body in bridging the gap in meeting the legal requirements set forth in the EU's "New Legislative Framework"

The "New Legislative Framework" adopted by the EU in July 2008 introduced a more flexible approach

both to the adaptation and modification of standards in EU member states and to the process of legal harmonization in pre-accession countries, such as Albania. The "New Legislative Approach" reduces the reliance on primary legislation (i.e., laws), which now serves as a framework legal tool, and shifts the responsibility for designing and adapting specific provisions (i.e., standards) to more flexible tools such as national standard bodies. These groups of standards developed within the framework legislation retain legal binding force and become legal requirements.

# 5.2.3 Synopsis of institutional challenges and suggested improvement actions

The table below provides a summary of the main gaps and the proposed intervention.

**TABLE 5.2:** THE MAIN GAPS AND POSSIBLE INTERVENTIONS FOR IMPROVING QUALITY INFRASTRUCTURE FOR THE POLICY-MAKING FRAMEWORK

## **PROFILE**

The Parliament and parliamentary commissions (e.g. the Commission for Production Activities, Trade and Environment).

The Council of Ministers

MARD Agencies (NFA, NAVPP, FSVI)

MFE: (GDA, GDM and GDS)

Municipalities: Market infrastructure, forest and pasture planning.

## **CHALLENGES**

The Parliament and parliamentary commissions (e.g. the Commission framework on:

- » Accreditation of conformity assessment bodies;
- » Good Laboratory Practice (GLP);
- » Market standards as part of Common Market Organization (CMO);
- » Legislation on accreditation and market surveillance;
- » The 'old approach' product legislation, especially on prepackaging and bottle measurement;
- » Weak capacities for evidence-based policies and stakeholder inclusion;

## **RECOMMENDATIONS**

- » Develop a comprehensive NQP framework based on best practices and define the roles and responsibilities of each stakeholder in the QI system through the preparation of a national regulatory framework on quality;
- » Establish a coordinating body in order to implement NQP for supporting the quality infrastructure and harmonising technical regulation activities;
- » Increase budgetary support to strengthen capacities in QI institutions (e.g. standards, metrology and accreditation) and other components of the QI system (quality promotion, inspection, testing, certification, calibration & verification); distribute resources according to the revised assignment of roles and responsibilities;
- » Support the expansion of the legal alignment in the field of QI with a focus on adopting and implementing legislation in the area of 'new and global approach' product legislation in Albania.

Source: Own elaboration

<sup>&</sup>lt;sup>43</sup> In the EU legal framework, novel food is regulated under Regulation (EU) 2015/2283

## 5.3 QUALITY INFRASTRUCTURE INSTITUTIONS

Within a QIS, the main quality institutions are those responsible for accreditation, metrology and standards. As highlighted above, these institutions operate under the authority of the MFE. The following subchapters describe these institutions in more detail.

## **General Directorate of Accreditation (GDA)**

According to the ISO Council Committee on Conformity Assessment (CASCO), accreditation is the process through which an authoritative body formally recognizes that a specific body or individual is competent to perform specific tasks (UNIDO, 2016).

The national accreditation body in Albania is the General Directorate of Accreditation (GDA), which has the authority to provide formal recognition to organisations providing certification, testing, inspection and calibration services<sup>44</sup> in accordance with the SSH EN 45011 standard. GDA is a member

<sup>44</sup> The GDA is subordinate to the Ministry of Finance and Economy and operates under Law No.116/2014, dated 11/09/2014 "On the accreditation of conformity assessment bodies in the Republic of Albania", DCM No. 667, dated 29/07/2015, "On the organization and functioning of the General Directorate of Accreditation" and the requirements of standard S SH ISO / IEC 17011 "General requirements for accreditation bodies performing the accreditation of conformity assessment bodies".

with full rights of the European Accreditation Body (EA) General Assembly<sup>45</sup> and a signatory of the European Cooperation for Accreditation Multi-Lateral Agreement (EA MLA) in the fields of Inspection and Management Systems Certification. Based on agreements with the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC), GDA certifies management systems based on ISO 17021-1. GDA operates a management system that aligns with the requirements of SSH ISO/IEC 17011.

So far GDA has acquired the capacity to accredit TIC for process standards, but not yet for product standards (e.g. Global G.A.P. standards). There is a need to enhance the accreditation capacities for product standards in the MAPs sector and to increase the engagement of sector stakeholders in the GDA technical groups.

**Table 5.3** shows the main gaps and recommendations for improving accreditation.

<sup>&</sup>lt;sup>45</sup> Membership is contingent on establishing an agreement with the EA to become a signatory of the mutual recognition agreements in the field of testing laboratories. This would enable the recognition of testing conducted by GDA-accredited laboratories at the European level



**TABLE 5.3:** THE MAIN GAPS, CHALLENGES, NEEDS AND POSSIBLE INTERVENTIONS FOR IMPROVING ACCREDITATION FOR THE MAPS SECTOR

## **PROFILE**

GDA is the single national accreditation body that assesses, in accordance with international standards, organizations that provide certification, testing, inspection and calibration services. GDA also provides accreditation to certification bodies and laboratories in the agrifood sector (e.g. soil analysis, food safety etc.).

## TASKS AND RESPONSIBILITIES

Pursuant to Law No. 116/14, dated 11/09/2014 and DCM No. 667, dated 29/07/2015, the GDA tasks are to:

- Cooperate with GDS, GDM, relevant ministries and interested associations on accreditation issues.
- 2. Undertake activities in the field of interlaboratory comparisons and proficiency tests.
- 3. Receive data from accreditation bodies of other countries for accredited organizations that perform activities in Albania.
- 4. Impose fines on non-accredited subjects.
- 5. Handle appeals for accreditation submitted with the General Directorate of Accreditation.

GDA has 4 technical working groups (TWG) which consist of the TWG for Testing and Calibration Laboratories, TWG for Medical Labs, TWG for Certifying Bodies and TWG for Inspection Bodies.

## **CHALLENGES**

- » No accrediting TIC bodies in place for agriculture product standards (e.g. GlobalG.A.P);
- » Low level of trust/reputation, especially among foreign operators;
- A limited number of technical assessors operate with relevance for VCs (testing, calibration, certification and inspection);
- » Poor engagement of MAPs representatives in the technical working groups (TWG).

## RECOMMENDATIONS

- » Increase awareness of GDA on the targeted VC and support capacity-building in VC-specific areas;
- » Provide support to GDA to develop:
  - i. ISO/IEC 17065-based accreditation for product certification schemes (e.g. GlobalGAP);
  - ii. ISO 22003-1-based accreditation of Food Safety Management System Certification Bodies under the FS 22000 Scheme;
  - iii. ISO/IEC 17025-based accreditation of testing laboratories for VC-specific activities (focus on humidity, pesticide and bacteria testing);
- Support the adoption of rules, processes and competence criteria for the accreditation by EA MLA and facilitate the participation of GDA lead assessors and technical assessors as observers in assessments performed by an EA MLA accreditation body for accreditation schemes in the MAPs sector;
- Train a pool of technical assessors with relevant experience to service the MAPs sector (testing, calibration, certification and inspection), and mentoring to the point of being declared competent;
- » Enhance monitoring of GDA lead assessors and technical assessors in order to bolster trust among market operators.

Source: Own elaboration

## General Directorate of Standardization (GDS)

Standards are "documented agreements that translate desired characteristics into dimensions, tolerances, weights, processes, systems, best practices and other specifics, so that products and services that conform to their requirements provide confidence to buyers and

users" (UNIDO, 2016). Within a QIS, standardization is usually the responsibility of a National Standards Body (NSB) that may represent the country's interests within organizations such as ISO (the International Organization for Standardization).

In Albania, the national body responsible for

standardization is the General Directorate of Standardization (GDS)<sup>46</sup>, which is under the authority of the MFE. GDS is a full member of the European Telecommunication Standards Institute (ETSI), an affiliate member of the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), and an associate member of the International Electrotechnical Commission (IEC).

As of 2017, GDS had incorporated all harmonized European standards into the Albanian standards. Foreign national standards, including those from the United States, are not utilized in Albania unless they have been adopted by international organizations to which Albania adheres. The GDS archive, up until May 2021, includes 40,400 standards and standardisation documents, with roughly 95% of them being either European or international standards. National standards are adopted in conformity with European standards (CEN, CENELEC and ETSI standards).

<sup>46</sup>The work rules and procedures for national standardization activities have been drawn up by the General Directorate of Standardization (DPS) pursuant to Law No. 9870, dated 04/02/2008 "On Standardization", as amended.

GDS is responsible for developing, adopting, approving, implementing, and publishing Albanian standards in all fields. GDS has adopted several standards regarding chemical determinations, analyses, and test methods for plants, working in collaboration with the relevant Technical Committee. The institution is in the process of revising the old Albanian standards to abolish and replace them with equivalent European and international standards.

According to interviews, the technical committees of GDS do not currently involve stakeholders or experts from the MAPs sector. In addition, there is limited awareness among market operators on the scale and importance of GDS services. The rules governing GDS are not yet aligned with the EU regulatory framework. Law No. 9870, dated 04/02/2008, "On Standardisation", is the main legal act governing the process. In addition, the capacity to enforce the already adopted EU regulations is diminishing the GDS authority in regulating the standards in the Albanian markets.

Table 5.4 shows the main gaps and recommendations for improving standardisation for the MAPs sector.



## **PROFILE**

GDS is the National Body of Standardization in Albania. GDS is certified according to ISO 9001 and ISO 9001:2015, accredited by GDA under the IAF Multilateral Recognition Arrangement (MLA).

Based on Law 9870 "On Standardization" and other bylaws, GDS is the WTO/TBT National Notification Authority and Enquiry Point for technical standards.

## Tasks and responsibilities

- Align and coordinate all activities for a modern standardization system at the national level.
- 2. Facilitate the transfer and accessibility of the latest European and International standards to the local economy and interested parties, while actively pursuing their adoption as Albanian Standards (SSH).
- Raise public awareness of the importance of adopting European and International standards and European conformity assessment procedures for trade and the consumer.
- 4. Provide transparency, inclusion and the attainment of consensus among all interested parties throughout the entire process of drafting and adopting standards.

## **CHALLENGES**

- » Limited involvement in technical bodies and technical committees of stakeholders or experts regarding MAPs;
- » Limited awareness among stakeholders about GDS role/services and limited information on proposed technical regulations;
- » Rules governing GDS need further legislation alignment with the EU framework;
- » Limited enforcement capacity for legislation that has already been adopted (EU Regulation 1025/2012 "On European Standardization" / Decision of the Council of Ministers 382/2018 "On the approval of the Regulation on Standardization Activities", as amended);

## **RECOMMENDATIONS**

- » Provide capacity building to increase expertise and speed up the legislation alignment;
- » Strengthen active participation of stakeholders from the MAPs sector in the Technical Committees dedicated to this sector, in order to increase their contribution to the drafting, approval and adoption of standards pertaining to this sector;
- Provide support for capacity building on Good Standardisation Practices to: i) GDS staff and ii) Technical Committees, with a focus on the MAPs sector;
- » Assist GDS in establishing a network of contacts among market operators who benefit from the notification procedure, in order to ensure the establishment of a rapid alert system or its equivalent;
- » Support GDS in developing guidelines, manuals, infographics, etc. to raise awareness about standards among relevant regulators and value chain operators;
- » Identify the need for Albanian standards related to MAPs that could be used to improve the quality and potentially serve as a foundation for regional or international standards in the future;
- » Translate the most relevant CEN, ISO and other standards relevant to the targeted sectors into Albanian language (using digitalization processes, e.g. machine-readable standards) and promotion through platforms and dissemination materials;
- » Involve interested parties from the targeted value chains in the drafting, approval and adoption of Albanian standards and their voluntary implementation as stipulated in the Law on Standardization No. 9870;
- » Provide training to the GDS staff with a focus on aligning legislation and implementing legislation that has already been adopted (EU Regulation 1025/2012 "On European Standardization" / Decision of Council of Ministers 382/2018 "On the approval of the Regulation of Standardization Activities", as amended);

Source: Own elaboration

## General Directorate of Metrology (GDM)

Ensuring rigorous measurement contributes to promoting fair production and trade. Legal metrology regulates measurement and addresses fair trading, food safety, health and environmental standards (UNIDO, 2021).

In Albania, the primary national conformity assessment body is the General Directorate of Metrology (GDM)<sup>47</sup>.

<sup>&</sup>lt;sup>47</sup> The General Directorate of Metrology is a public legal entity specialized in metrology, based in Tirana and organized into 4 service sectors, subordinate to the Minister of Finance and Economy. It exercises its activity based on Law No. 126, dated 15.10.2020 "On metrology", and on the by-laws issued in implementation thereof.

GDM develops the national metrology system in line with European standards and harmonizes technical procedures for conformity of measurements in order to avoid technical barriers to trade. GDM activities include three basic and overlapping activities: i. Scientific metrology, ii. Industrial, applied or technical metrology and iii. Legal metrology.

In Albania, Law No. 10489 "On the trading and monitoring of non-alimentary products" stipulates that private authorized entities can act as conformity assessment bodies for purposes of certification, inspection, and testing. The Law also defines procedures for conformity assessment and aims to align Albanian legislation with EU regulations, including EU Regulation 765/2008.

Pursuant to Law No. 10489, certificates, tests and inspection reports issued by conformity assessment bodies in countries outside the European Union are recognized and accepted in Albania if these bodies

are accredited by an accreditation body which is a signatory to multilateral agreements with the European Organization for Accreditation, the International Organization for the Accreditation of Laboratories or the International Accreditation Forum (IAF).

Based on the interviews, GDM has a limited scope of services relevant to the MAPs, particularly related to legal metrology activities. The legal base is not yet aligned with the EU regulatory framework. Another important issue is that the GDM itself lacks accreditation according to ISO/IEC 17025 for laboratory competencies related to services required by the MAPs market operators. It also has to uphold compliance with the requirements of ISO/IEC 17025 concerning laboratory competencies, particularly in electrical, temperature, humidity, length and chemistry laboratories. **Table 5.5** below highlights the main gaps and recommendations for improving metrology for the MAPs.

TABLE 5.5: THE MAIN GAPS AND RECOMMENDATIONS FOR IMPROVING METROLOGY FOR THE MAPS SECTOR

#### **PROFILE**

GDM is the primary national conformity assessment body. The national metrology system includes national standards laboratories, calibration laboratories, testing laboratories, and certification entities authorized to perform legal metrology activities.

GDM has four regional offices.

#### Tasks and responsibilities

- Maintain and use national standards for units of measurement;
- 2. Protect consumers through the control of measuring instruments in the field of official and commercial transactions, health protection, environment and technical safety, as well as perform quantitative assessment of pre-packaged goods;
- 3. Provide calibration services to manufacturers and users of measuring instruments.

#### **CHALLENGES**

- » The limited scope of calibration services (mainly thermometers, volume and density) does not fully meet the requirements of operators (e.g. even simple humidity calibration in MAPs);
- The law "On metrology" is not aligned with Directive 2009/34/ EC and other directives on pre-packaged goods;
- » No accreditation according to ISO/IEC 17025 concerning laboratory competencies, particularly in electrical, temperature, humidity, length and chemistry laboratories;

### **RECOMMENDATIONS**

- » Fully align the Albanian Law No. 126/2020 "On metrology" with the EU legislation. According to the notes in Law No. 126/2020, the law is only partially aligned with Directive 2009/34/EC;
- » Update the GDM strategic plan (scope of calibration related to MAPs).
- » Support GDM (e.g. test methods) to become ISO/IEC 17025 accreditation-ready, with a focus on chemical and humidity laboratories, which are important for the MAPs value chain;
- » Conduct simulated EA MLA Peer Assessment with a focus on MAPs;
- » Determine the legal metrology and pre-packaging requirements for MAPs;
- » Provide reference materials for the measurement of product humidity, pesticide residues, bacteria and metal (lead) contamination;
- » Support cooperation with other National Metrology Institutions to support initiatives for MAPs.

Source: Own elaboration

# 5.4.1 Agricultural inputs registration and control

The main agricultural inputs are: i) propagation material (PM), ii) Plant Protection Products (PPP) and iii) fertilizers.

The system of registration, inspection and testing of agricultural inputs and their use is quite complex and involves several units within the MARD and Agencies which depend on MARD. Registration and certification of agricultural inputs

**Propagation material**: The **State Entity for Seeds and Seedlings (SESS)** is the body responsible for authorizing the production and import of certified propagation materials (PM). (Law no. 10416, dated 07/04/2011). According to the law, only certified PMs can be traded. Albania recognizes the internationally accepted PM certifications (e.g. certified saplings or seeds); as for domestic production, only SESS authorised nurseries can produce and sell certified propagation materials.

- » Plant Protection Products (PPPs): The responsible body for PPP registration is the PPP Registration Commission. The Commission is a collegial technical body, consisting of representatives from MARD, NFA and FSVI. All PPPs that are traded or used in Albania should be registered and included in the Register of Plant Protection Products (RPPS)<sup>48</sup>. Only PPPs that are registered in one of the EU Member States can be included in RPPS.
- » Fertiliser Products: The responsible body for fertilisers is the Fertiliser Products Registration Commission (FPRC) in MARD; FPRC is a collegial, technical, permanent and decision-making body.

# Agricultural inputs inspection and testing

Inspections of agricultural inputs, including border post inspections. The *National Food Authority-NFA* is responsible for this task. NFA controls the import, trade and storage of agricultural inputs, whether they are imported or domestically produced, through documentary inspections. However, NFA also has the authority to collect samples and restrict potentially suspicious inputs, requesting testing from national reference laboratories which, depending on the input, are ISUV (PPP, fertilizers) or the AUT phytosanitary laboratory of Durrës (phytosanitary hazards related to propagation materials).

# 5.4.2 Inspection bodies for food products, food producers, agricultural inputs and input dealers

Inspection bodies and reference laboratories play an essential role in cross-border trade. They act on behalf

of governments and business partners (importers and exporters) by inspecting imported goods and materials. The overall aim is to reduce risks to the buyer, owner, user or consumer of the item being inspected (UNIDO, 2016). Below, we provide an overview of the main inspection bodies relevant to the MAPs sector.

National Authority of Veterinary and Plant Protection – NAVPP<sup>49</sup>

NAVPP is in charge of on-farm inspections & controls, including the on-farm use of agricultural inputs. The mission of NAVPP is to guarantee in-farm human, animal, plant and environmental health. NAVPP is also in charge of overall phytosanitary and animal health monitoring. For this purpose, NAVPP implements short-term, medium-term and long-term action plans. The agency is also responsible for the on-farm use of PPPs that present a high risk to human health and the environment, as well as for the issuance of the relevant certifications<sup>50</sup>. However, controls on PPP imports, trade and storage outside farms fall under the responsibility of NFA, which is also responsible for the control of PPP residuals and other contaminants in food products from farm-gate-on.

NAVP and ANES are responsible for the implementation of DCM No. 317, dated 15/05/2019, "On the approval of the regulation on the durability of use of plant protection products, as well as the qualification criteria for users", which ensures the sustainable use of PPPs in the Albanian territory<sup>51</sup>. The object of NAVPP inspections is summarized in **box 2** below.

<sup>&</sup>lt;sup>48</sup>Law No. 105/2016, "On Plant Protection"

 $<sup>^{49}</sup>$ See Law No 71/2020 "On some changes and amendments to Law No. 10465/2011" and DCM No 683/2020 "On the establishment, organization and functioning of the National Authority of Veterinary and Plant Protection".

<sup>5°</sup>Based on the International Plant Protection Convention (IPPC) Model NAVPP issues the "Internal phytosanitary certificate", the "Phytosanitary certificate for export" or the "Phytosanitary certificate for re-export". During 2022, NAVPP was part of the pilot project for the electronic application and completion of phytosanitary certificates for export and re-export in SEED+ through the TRACES NT system.

<sup>5</sup>º This decision has been partially approximated with Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishment a framework for Community action to achieve the sustainable use of pesticides, CELEX number: 32009L0128. Official Journal of the European Union, series 309, dated 24/11/2009, pages 71-86.

The object of NAVPP inspections is as follows:

- » Contaminants: controls are carried out based on annual planning. The sample is collected randomly. It does not require supporting documents. No certificate is issued;
- » PPP residues: controls are carried out based on annual planning. The sample is collected randomly before entering or in collection centres. It does not require supporting documents. No certificate is issued;
- » Phytosanitary: Controls are based on information, inspections, sampling and testing performed and/or official information on the status of pests in the country of production, zone, or place of origin, and/or the plant passport. For products to be exported, the phytosanitary certificate is issued by the Sanitary Certification and PPP monitoring sector at the regional directories of NAVPP;
- » Labelling: Inspections are conducted at various stages of the trading chain, particularly when their function involves providing information to consumers. It does not require supporting documents.

Source: Own elaboration

An assessment of NAVP gaps, challenges and needs is presented later in this report.

### National Food Authority - NFA<sup>52</sup>

NFA is responsible for the inspection of food processing establishments and all food products from farm gate to market. NFA is structured with its General Directorate in Tirana and 12 Regional Directorates in each region, as well as 13 Border Inspection Posts - BIPs, which are responsible for the control of imported products

<sup>52</sup> The Authority was established by Law No. 9863, dated 28/01/2008 "On food", as amended. The organization and functioning of the institution are outlined in DCM No. 1081, dated 21/10/2009, as amended. The institution commenced its operation on 20/05/2010.

of animal and non-animal origin, live animals, plants and plant products and agricultural inputs.

The NFA Regional Directorates of the National Food Authority carry out the technical-technological, hygienic and phytosanitary controls for compliance of food products and PPPs. The BIPs primarily perform documentary checks of imported food products, agricultural inputs, live plants and animals.

The NFA inspection system is risk-based and it is structured based on annual and multi-annual plans. A more detailed description of the system is provided in box3 below, which also indicates the point of interaction between NFA and other agencies and bodies dealing with the inspection of food products, agricultural inputs, live animals and plants.



#### **BOX 2: NFA INSPECTION PLANNING AND IMPLEMENTATION**

Every year, NFA conducts a risk assessment-based inspection and testing plan for food and animal feed products; based on the assessed level of risk. The risk assessment is product-wise (operators are categorized in relation to product categories) and not FBO-wise (i.e. based on the profile risk of each FBO, regardless of the sector where it operates).

The actual inspections are based on the annual plan, but retain flexibility, considering changes in the level of risk, denunciations, citizen complaints, media alerts, alerts from the RASFF system and specific orders. A scoring system is used considering these risk factors.

The matrix of non-complying cases is submitted with the Regional Agricultural Extension Agency (RAEA), which will cooperate in ensuring the product's withdrawal from the market, tracing back the non-compliant product or input.

Inspections performed in raw agricultural products collection centres and food processing units are related to the fulfilment of legal requirements in terms of hygiene, storage, packaging and transport conditions, traceability and application of legal provisions on labelling.

The enforcement activity of NFA includes FBO inspection and control of imports in BIPs.

BIPs primarily conduct documentary inspections and visual checks and take samples only in cases of suspected non-compliance.

When suspected or confirmed instances of non-compliance are identified (following inspections conducted in FBOs, BIPs, input dealers and markets), various courses of action are employed, depending on the specifics of the case:

- » If suspected or actual non-compliance is detected at BIPs, samples are sent to FSVI or a phytosanitary laboratory for testing;
- » If suspected or actual non-compliance is identified at FBO level, samples are sent to FSVI. The responses are then communicated to the Regional Directorate of MARD. In case of non-compliant farms, measures are implemented by NFA or are jointly undertaken by NFA and NAVPP;
- » When assessing market risks, NAVPP conducts inspections in cooperation with AREB;
- » If risks are observed at the farm level and are specifically related to phytosanitary concerns, the Directorate of Plant Protection within the Regional Directorate of NAVPP is the authority responsible for leading the procedure;
- » If a non-compliance alert is sent by EU RASFF, inspections are conducted by the competent NFA Regional Directorate, in some cases in cooperation with SIMS.

Source: Own elaboration of MARD, 2022a

### State Inspectorate of Market Surveillance (SIMS)

The coverage at the national level is limited due to the absence of a comprehensive legal framework (particularly for testing procedures) and poor human and logistic capacities, particularly in monitoring prepackaged products and measurement instruments (SIMS, 2020).

# 5.4.3 Assessment of key QI institutions for agricultural inputs and food inspection

The two largest QI institutions for agricultural inputs and food certification, registration, inspection and testing are NFA and NAVPP. An assessment of the gaps, challenges and needs of these two QIS bodies is provided in **table 5.6** and **table 5.7** below.

# **TABLE 5.6:** MAIN GAPS, CHALLENGES AND NEEDS AND POSSIBLE INTERVENTIONS FOR IMPROVING INSPECTION

#### **PROFILE**

NFA is the agency responsible for the implementation of legal provisions related to food safety, with inspection and control powers over stakeholders within the food chain, spanning from agricultural input suppliers to those involved in food trade, but excluding farms and nurseries;

NFA inspects a network of laboratories at the regional level with limited testing capacities

#### **RESPONSIBILITIES:**

- » Coordinates the food safety risk assessment process;
- » Coordinates and carries out controls related to food safety and licensing compliance in terms of food and agricultural inputs production, through a planning process based on risk assessment;
- » Permanently or temporarily suspends the activity of stakeholders within the food chain when non-compliance with legal requirements is found.

#### CHALLENGES

- » Responsibilities for inspection along the food chain are fragmented between NFA, NAVPP, RAEA, SIMS;
- » Limited resources and capacities to inspect agricultural input traders and food processors and limited categories of plants subject to control.
- » Limited capacities at BIP;
- » Inspections of agricultural inputs and input are mainly based on documentation, with limited testing;
- » Ineffective traceability system in place for agricultural inputs.

#### **RECOMMENDATIONS**

- » Introduce online inventory control to improve the food safety management system and the traceability of agricultural inputs and food products;
- » Capacity building for BIP staff, NFA laboratory staff and inspectors to enhance their capacity;
- » Transition from product-specific to FBO-oriented risk assessment methodologies used in the annual inspection planning process.

Source: Own elaboration

The main challenges of the NAVPP, as well as the required interventions, are listed in the following table.

#### **PROFILE**

The mission of NAVPP is to implement policies and strategies for the protection of human, animal, plant and environmental health at the farm level.

The Agency has also the overall responsibility for the implementation of phytosanitary control at the national level.

NAVPP facilities include a central office in Tirana and the Regional Directorates of Veterinary and Plant Protection (RDVVP) located in Tirana, Shkodër, Elbasan and Vlora.

#### **CHALLENGES**

- » No clear MRL specifications by products type in the Albanian legislation;
- » Insufficient knowledge and updates on the MRL and contaminant limits set by EU provisions for products intended for the EU market;
- » Lack of laboratory-based control at the farm level for the horticulture sector (including MAPs) (controls are rare and only visual);
- » Inadequate pharmacovigilance practices that result in limited oversight of the utilization of Plant Protection Products (PPPs);
- » Improper institutional division of competencies input retailers are controlled by NFA, despite its close connection to farmers; control through NAVPP could be more effective;
- » Lack of protocols for the use of PPPs based on the type of plant.

### **RECOMMENDATIONS**

- » Clearly define and disseminate MRL (maximum residue levels) by type of product etc.;
- » Further align legislation with the EU acquis on contaminants;
- » Define tasks, responsibilities/competencies concerning the control of input retailers;
- » Update monitoring plans at the farm and input retailers level;
- » Disseminate the protocols for the control of contaminants, pesticide residues, plant health in each segment of the VC chain in order to increase trust and awareness;
- » Invest in Phytosanitary Information Systems (PIS) for plant health and plant protection.

Source: Own elaboration

# 5.5 CONFORMITY ASSESSMENT AND TESTING

Conformity assessment is related to the processes and procedures that are used to demonstrate that a product or a service, management system, organization or personnel meets the specified requirements. These requirements are usually stated in international standards developed by organizations such as ISO (International Organization for Standardization) (UNIDO, 2016).

Agreements between nations or regions on the mutual

acceptability of requirements, assessment methods, inspection or test results, etc., can all help to reduce or remove technical barriers to trade. Testing is the most common form of conformity assessment. Testing also provides the basis for other types of conformity assessment, such as inspection and product certification.

The estimated value of the overall market size for food testing in Albania is EUR 3 mln. The main clients are

exporters, whose specific demands depend on the buyers' requirements, the scale of processing and the specifics of the destination markets.

In Albania, the testing infrastructure includes the National Reference Laboratory (FSVI), the NFA laboratories and private laboratories, whether accredited or not accredited. In addition, research institutes laboratories provide services mainly in the framework of their research missions and scope. The main stakeholders in the testing system are described in the chapter below.

# 5.5.1 Public laboratories

# The Food Safety and Veterinary Institute (FSVI)

The FSVI is the National Reference Laboratory for Public Health and for Food Safety; it has a wide range of testing and conformity assessment responsibilities relevant to food products. FSVI also monitors the epizootic situation in the country. The main FSVI regular testing activity is the provision of laboratory analyses in the application of the National Residue Monitoring Plan (PPPs, heavy metal and mycotoxins contaminants). FSVI is aligned and compliant with all EU requirements for fresh MAPs products, for more than 600 matrix-Reference Materials (RMs). The plan is expanding on an annual basis, in parallel with the increase of FSVI capacities<sup>53</sup>. The range of accredited and non-accredited testing services is also expanding.

FSVI human resources are relatively numerous and qualified. The main challenge is to guarantee a laboratory reference system to support the MAPs sector. There is also a need to expand the range of accredited MAPs analyses. For this purpose, there is a need for further effort in terms of capacity building (in terms of human resources and equipment, such as the LC/MS/MS) and larger budget assignments to cover the costs of increasing the number and range of testing activities.

# NFA regional laboratories

The regional food laboratories: NFA manages 7 regional laboratories subordinated to the Risk Assessment Directorate at the General Directorate. While all laboratories provide analyses<sup>54</sup> for food safety, only 3 of them are structured to cover plant protection (Durres,

<sup>53</sup> In 2022, the laboratory has conducted over 130,000 analyses for various indicators. The staff consists of 99 people, out of whom 74 are women and 28 have scientific degrees. The main equipment has a value exceeding EUR 6 million.

Korce and Shkoder). The NFA regional laboratory in Durrës specializes in providing plant protection analyses. It has been supported by SAFIAL project<sup>55</sup>. While this laboratory provides physiochemical, microbiological and phytosanitary analyses, it is not yet accredited. However, the laboratory may transfer the samples for further analyses to other laboratories, namely ISUV (for quality indicators on PPP), the AUT plant protection laboratory (planting and plant propagation material), the State Entity for Seeds and Seedlings (quality indicators on seeds) and quality indicators on fertilisers (ATTC Fushë-Krujë).

The NFA laboratory activity is performed based on the implementation of risk-based monitoring and emergency plans, taking into account the current capacities. The laboratory activity is part of the official inspection and, as a result, their activity is carried out based on the implementation of: i) the risk-based plan ii) monitoring and emergency plans for purposes of official controls, as well as iii) selfinspection by Food Business Operators (animal health and protection plants). The documentation used by the Laboratory Sectors is mainly based on Order No. 24, dated 30/01/2013 "On the unification of the procedures, methods and documentation related to the operation of laboratories". The main challenge of NFA laboratories is related the technical capacities of their staff and the coordination among laboratories, with a focus on regions with a larger production of MAPs. According to the NFA reports, the Laboratory Information Management Systems (LIMS) is not operational.

# Laboratory for Scientific Research on Plant Protection (AUT)

The Laboratory for Scientific Research on Plant Protection is a public laboratory established in 2015 at the Agricultural University of Tirana (AUT). The laboratory is accredited for performing tests in accordance with ISO/IEC 17025:2017.

At present, the laboratory has 8 staff and some relatively modern equipment and premises. The laboratory can provide a limited number of analyses, 6 of which are accredited by the GDA.

There is a need to invest in the renovation of laboratory premises and equipment (e.g. an immunofluorescent microscope) and to increase human resources (two persons can be trained for the monitoring and sampling of quarantine pests and interlaboratory tests) as well as financial resources for covering accreditation costs (on new virological and bacterial testing methods).

<sup>&</sup>lt;sup>54</sup> The types of analyses performed in each laboratory are as follows: i. The Chemical-Physical Laboratory conducts analyses related to the quality indicators of both animal and non-animal food products, labelling indicators, as well as some analytical indicators related to food safety. ii The Microbiological Laboratory conducts analyses related to safety criteria for food products and those pertaining to hygiene processes. lii. The Laboratory of Animal Health and Welfare performs analyses for the diagnosis of various diseases and parasites in animals, and iv. The Laboratory of Plant Protection conducts analyses for the diagnosis of pests and parasites in plants and plant products.

<sup>55</sup> SAFIAL aims to improve food quality in compliance with hygiene and health standards by strengthening the capacities of competent bodies (the Institute of Food Safety and Veterinary Medicine, the Albanian Food Agency AKU and the National Veterinary and Plant Protection Authority) to perform controls and inspections on plant material and to operate in the veterinary sector. The Italian Ministry of Foreign Affairs and the International Cooperation/Italian Agency for Development Cooperation.

# Laboratory of Agro-Environment and Ecology (LAME)

This is another laboratory under the umbrella of AUT. It was established in 2010 and accredited by the GDA to perform laboratory analyses in accordance with SSH ISO/IEC 17025: 2017. The laboratory staff consists of 9 members, the vast majority of whom are women under the age of 40 and with a PhD. The laboratory performs 22 tests accredited on the following matrix-Reference Materials: determination of the content of various elements in soil. In LAME, during 2022 there were carried 4000 analyses of soil, water and plant matrices.

The main needs include: support with accreditation costs (extending accreditation for already implemented analyses, accrediting tests that are still unaccredited, and covering procurement costs), purchase of equipment (laboratory equipment for organic waste, reagents related to these tests) and capacity building (qualifying external personnel, training for organic waste test procedures, and fostering collaboration).

# ATTC FusheKruje Laboratory

The laboratory was established in 2006 at the premises of ATTC. The staff consists of 7 members, who are mainly women under 40 years old. The laboratory is certified with ISO 9001:2015. The laboratory performs about 2000 analyses per year for about 10,000 indicators (namely physical, chemical - macro and microelements, heavy metals in soil and water), chemical content (fertilizers), plant content (animal feed) and biological material content. One major innovation is making available to farmers the results of soil analysis online. Almost 70% of the agriculture area has been analyzed. Farmers can access the results of soil analyses online. Farmers can be assisted to make use of the information related to soil analysis.

The priorities for improvement are related to the development and functioning of the microbiological laboratory, which needs support in terms of: i) human resources capacity building, ii) assistance in the process of accreditation of new tests for soil, plant and water monitoring and sampling and, iii) purchase of new equipment.

# 5.5.2. Private laboratories

Some accredited laboratories are managed by private entities. The list of private laboratories which carry out soil or food analysis that are accredited by GDA is published by GDA (GDA, 2023). Four of these laboratories provide specific analyses for the horticulture sector<sup>56</sup>. Some of the largest laboratories are the following:

- » ECCAT sh.p.k;
- » Tenuis LABORATORIES (Noval); this laboratory is

<sup>56</sup>Interview with GDA staff.

reported to be the largest private laboratory in terms of capacities and services;

- » Alpha Studio sh.p.k;
- » BIO-V sh.p.k;
- » VITROS LAB shpk;

# **BOX 3:** NOVAL (TENUIS) LABORATORY

Noval (Tenuis LABORATORIES) was established in 2018. It holds ISO: 17025 accreditation. The staff consists of 13 professionals (3 males, 10 females). Three members have a PhD and 9 have a MsC diploma in related sciences. Most staff members are young (12 of 13 are less than 40 years old). The equipment is worth 1 Mln Euro. The laboratory performs 50,000 analyses annually and is able to cover more than 2,000 parameters and 600 pesticide elements (with relevant matrix-Reference Materials). At present, approximately 30% of the operators using the Albanian laboratories are oriented toward the use of these laboratory services. While the range of elements that are analysed is expanding, still it does not cover all the needs of the export market.

Source: Semi-structured interviews

# Laboratory infrastructure gaps

There are various challenges hampering the further development of the laboratories.

- High average fixed costs (unit costs): The majority of costs are fixed (in the range of 80% of the total). Considering the present demand, unit costs are high. A rising demand for laboratory services could lead to reduced unit costs which can be reflected in lower prices. In fact, recent interventions to enforce specific aspects of the regulatory framework (e.g. water analyses, label analyses) have already reduced average unit costs for those analyses;
- » Lack of trust by the market operators: Based on the survey conducted in the framework of this study with market operators, approximately 25% of the interviewees expressed scepticism about the results obtained from laboratory analyses for residuals (PPP) and contamination (e.g. heavy metals).
- » Trust in accreditation: According to interviews with laboratory operators, trust is undermined due to the questionable accreditation received by some smaller laboratories.
- Partial information: There is no publicly available information on the yearly assessment of the laboratories or a documented yearly plan for the monitoring of the laboratories' offers and capacities. An inventory of the laboratories' capacities is not available to the public.

**TABLE 5.8:** MAIN CHALLENGES AND NEEDS FOR THE LABORATORY NETWORK IN ALBANIA, WITH A FOCUS ON THE MAPS SECTOR

#### **PROFILE**

FSVI: is the National Reference Laboratory. FSVI is developing testing capacities and consolidating its role as a National Reference Laboratory.

NFA: There are 7 laboratories at the regional NFA Directories (3 of which are focused on plant protection).

AUT laboratories.

Private laboratories.

#### **CHALLENGES**

- » High laboratory services average fixed costs per unit;
- » Poor capacities to provide services for the MAPs sector;
- » Poor trust of VC operators in the service quality of Albanian laboratories;
- » Few accredited laboratories and limited testing services;
- » Poor logistical capacities in the NFA laboratories
- » Lack of Laboratory Information Management Systems (LIMS);
- » Lack of accessible information on the capacities of private laboratories;
- » Scarce coverage elements (over 600 matrix-Reference Materials for MAPs) and high costs for additional accreditations;

#### RECOMMENDATIONS

- » Support FSVI to increase its capacities and consolidate its position as a reference laboratory and to serve the needs of the MAPs stakeholders;
- » Support the strengthening of laboratories for the accreditation of new tests (as requested by certification bodies, inspection bodies or traders), etc.;
- » Provide incentives for the strengthening of a reputable laboratory (in the phytosanitary field) which is monitored and supported by FSVI. A feasibility study is required to determine the costs and select the targeted laboratories;
- » Raise awareness of laboratory managers on exporters' needs and the requirements of foreign markets;
- » Increase information on laboratories using laboratory databases established in other countries as a reference<sup>57</sup>;
- » Increase trust in the laboratory's services using certified intermediaries to carry out the sampling procedure;
- » Implement pilot projects with MAPs associations and laboratories for large scale testing campaigns;
- » Promote the LabNet database to users and engage more laboratories to contribute information on their capacities, the type of analyses they provide and their geographic location;
- » Support NFA in the establishment of LIMS.

Source: Own elaboration

<sup>&</sup>lt;sup>57</sup>See the example of LabNet via the link: https://hub.unido.org/labnet

#### 5.6 CERTIFICATION BODIES

Certification (by a certification body) assures operators that a product, service, process, personnel, organization or management system conforms to specific requirements. Product certification consists of the initial testing of a product (based on initial testing, surveillance and type of testing, e.g. testing-based or sampling-based) combined with an assessment of its supplier's quality management system (UNIDO, 2018).

Organizations that conduct audits for company certification, assist in the certification process, perform inspections for certification issuance or renewal, and hold licenses or accreditation to issue certifications are collectively referred to as "TIC (Testing, Inspection, Certification) bodies".

The certification body is accredited by GDA if it holds certification in accordance with ISO/IEC17065, European Standard EN 45022, or is fully compliant with these standards. The certification body shall submit the results of the inspections carried out regularly and whenever requested. The detailed criteria for the approval and competence of certification bodies shall be established by decision of the Council of Ministers.

In Albania, there are several certification bodies accredited by GDA. 7 of these operate in the area of food safety, such as ISO 22000-1-2018. Below is the list of accredited certification bodies.

#### **BOX 4:**LIST OF CERTIFICATION BODIES

- » "Austrian Institute of Excellence" sh.p.k
- » ALCERT sh.p.k
- » AQScert
- » AXE REGISTER Sh.p.k
- » Career Cert Insitute CCI sh.p.k
- » CERTIS Shpk
- » ECIT sh.p.k
- » EQSC shpk
- » H.V.A.T sh.p.k
- » HTM sh.pk
- » LEGAL CERT sh.p.k
- » NOA CONTROL sh.p.k
- » Swiss Approval Albania sh.p.k
- » TCPE sh.p.k
- » UNICERT sh.p.k
- » Unitec-Studio sh.p.k
- » WR ERN BERATUNG Shpk CERT-ERN

Source:GDA, 2023

Key MAPs exporting operators are certified according to the European Organic Standard and the US Organic Standard (representing the main markets for Albanian MAPs). Organic certification is carried out by several certification bodies: Ecocert SA, ICEA, BCS, Oko-Garantie GmbH, BioInspecta AG, CERES GmbH, Control Union Certifications B.V., IMO CH, IMC srl.

Historically, the only local certification body based in Albania has been Bio-inspecta (former Alb-inspect), which is accredited by Swiss Accreditation Services. In the light of recent legal changes, organic certification bodies could also be accredited by Albanian institutions (e.g. GDA)<sup>58</sup>. As highlighted earlier, at present there are no Albanian TICs accredited for GlobalG.A.P. certification; this service is provided by foreign accredited bodies.

**TABLE 5.9:** MAIN CHALLENGES AND NEEDS FOR CERTIFICATION IN ALBANIA

### **PROFILE**

TIC bodies provide audit, control and certification services aimed at facilitating the adoption of standards.

#### **CHALLENGES**

- » Lack of national accredited TIC for most standards; in particular, no accredited TIC for GlobalG.A.P. standards certification;
- » Scarce human resources for the TICs staff;
- » Small market resulting in high fixed certification costs.

# **RECOMMENDATIONS**

- » Increase awareness of the need for certification;
- » Support GDA to expand its accreditation capacities.

Source: Own elaboration

<sup>58</sup>Interview with GDA staff.

# 5.7.1. Institutional actors for quality promotion

The main organisations involved in the development and dissemination of culture for quality in Albania are: i)\_the Albanian National Extension Service (ANES), ii) the Agriculture Technology Transfer Centres (ATTCs) and, iii) the Albanian Investments Development Agency (AIDA); other important stakeholders include business associations, media, international development projects, academia and consumers. The activites and fuctions of ANES, ATTCs and AIDA are outlined below.

# Main stakeholders the development of culture for quality

- » ANES. Public extension service provides free of charge information, advice and training to farmers and agri-businesses. Farmers are the main target of ANES activities. The work of ANES is based on a yearly program where topics of relevance are chosen based on surveys and expert choices, in cooperation with MARD experts and ATTCs.
- **ATTCs:** These semi-autonomous units subordinate to MARD are responsible for performing applied research activities and transferring know-how to farmers communities, prioritizing innovations and quality. There are five ATTCs, each specialised in one or more topics, but also expected to provide a wider range of services to farmers and other value chain operators in the region where they are located. ATTC Shkodër is specialised in MAPs, also producing MAPs seedlings. It is developing new MAPs varieties. However, they need to improve their capacities to assess the oil content of existing and new varieties that they are developing, as well as to carry out analyses for MAPs operators to reduce their costs. Supporting ATTC Shkodër to upgrade its laboratory capacities should be considered. Another relevant ATTC is Fushë-Krujë, which is in charge of soil analysis and the application of IPM practices (in addition to other aspects related to other sectors);
- » The aim of AIDA is to enhance the competitiveness of the private sector, to strengthen the export potential of the country to promote/support foreign direct investment in Albania, and to promote the country's tourism potential. As part of its mission, AIDA promotes exports of goods and services and provides assistance to SMEs for this purpose (AIDA, 2023). Its mission includes promoting a culture for quality, developing knowhow on legal requirements for export and raising awareness on different aspects of Quality for Value Chains.

# Other institutional stakeholders in the development of culture for quality

Donors and development agencies: Efforts are being made to foster synergy through the One UN approach and the Agenda 2030 framework. In addition to the activities performed by UNIDO, SDC, UNDP, GIZ and FAO are implementing development projects and interventions which are related to the issue of sustainable agriculture.

**Academia/research:** Agriculture-related research is dominated by state-owned institutions, primarily universities and public research institutes. In addition to ATTCs, universities play a key role in applied research. Three universities are particularly involved in QI issues in the field of agriculture and food production, namely: i) the Agricultural University of Tirana (AUT), ii) the University of Tirana (Faculty of Natural Sciences) and, iii) F. S. N. University of Korça (Faculty of Agriculture).

# 5.7.2. Non-institutional stakeholders for quality promotion

The role and contribution of non-institutional stakeholders in the promotion of culture for quality can be summarized as follows:

**Media:** the media plays a crucial role in shaping the behaviour of policy-makers, farmers, consumers etc. Media information regarding non-compliance with food safety and quality standards affects consumer awareness and concerns about food safety. Alerts are documented in brief news reports or special documentaries. Media coverage also exerts pressure for more assertive action from inspection and conformity assessment bodies, as well as for overall QIS improvement.

**Business Associations:** There are several specific umbrella associations operating in the agricultural sector.

International Chamber of Commerce of Albania - ICCA: ICCA is a member of ICC World Chambers Federation, thus being the authority in charge for the issuance of the certificate of origin (ICC, 2023)<sup>59</sup>. ICCA has a clear and specific role in the QIS;

<sup>&</sup>lt;sup>59</sup>The Certificate of Origin is a document certifying the non-preferential origin of the goods. The Certificate of Origin is issued by ICCA based on a written request from the person concerned. Ref: https://certificates.iccwbo.org/

This certificate is different from the Certificate of Origin Form A, which is a document certifying the Albanian preferential origin of goods exported to countries which have granted trade preference to Albania on the basis of the General System of Preferences (GSP). The certificate of origin Form A is issued by the Customs authorities where the customs export declaration is submitted, following a written request from the exporter (see also <a href="https://dogana.gov.al/english/dokument/659/certifikata-e-origines">https://dogana.gov.al/english/dokument/659/certifikata-e-origines</a>)

» Albanian Agribusiness Council (KASH): this is the largest agribusiness sector association. It encompassed all sectors of agribusiness and is a member of other entities such as the Economic Consultative Council;

**Sector associations.** Smaller associations in specific value chains are established. There are two MAPs sector associations, namely: i) the Essences Producers and Cultivators Association (EPCA)<sup>60</sup> and, ii) the Association of Medicinal and Aromatic Plants of Albania (AMAP)<sup>61</sup>.

Other professional associations/NGOs: there are other smaller associations focused on specific product categories or business functions, the most relevant being: i) the Institute for Organic Agriculture and, ii), the Albanian Association for Marketing.

**BOX 5:** LEVEL OF ENGAGEMENT OF BUSINESS ASSOCIATIONS IN RAISING AWARENESS ON QUALITY

According to 54% of interviewees in the MAPs sector, it was reported that the existing associations are not raising awareness on quality issues or promoting quality in the value chain. However,79% of the MAPs interviewees reported that their business has participated in quality awareness activities, organised by specialised service providers or consultants in the framework of the capacity building initiatives implemented through international development agencies.

Source: UNIDO/GQSP 2023 Survey

**Consumers' Associations:** Consumers' associations are weak and not very well organized. The *Albanian Consumers Association* and the *Commission for the Protection of Consumers* are the main entities.

### Main challenges for institutional stakeholders

- » The components of the Agricultural Knowledge and Innovation System (AKIS) are fragmented and scarcely coordinated. This is due to institutional and operational gaps: ANES and ATTCs objectives, focus and funding are provided by MARD, while AIDA is subordinate to MFE, academia and research centres activities are subordinate to the Ministry of Education and Sciences (MES). Both programmes are scarcely related to the objectives set by the Strategy for Agriculture, Rural Development and Fishery (SARDF) 2021-2027;
- » As a result, the work and programmes of ANES, ATTC and AIDA are not synergic with the activities of academia and research.
- » ANES coverage is scarce, while the technical content of the advisory services is often not

- up-to-date and is focused on production issues rather than on quality standards;
- » Research activities and the technology transfer role of academia and vocational schools<sup>62</sup> is limited and not integrated with the ATTCs yearly activities.

There is a clear need for capacity building for staff, premises and logistic upgrading (Zhllima, 2023) for institutions providing advisory services and technology transfers at Albanian farms; however, these improvements would have a limited impact without an increased synergy between AKIS components.

A possible approach to increase synergy already adopted at the regional level is the application of a demand-driven approach similar to EIP Agri Operational Groups (EC, 2023j). In this respect, SWG is deploying some efforts to establish Operational Groups in Albania to address both safety and quality challenges influencing the competitiveness in agrifood sectors, including the MAPs sector.

An experience in increasing the synergy of AKIS components synergy is also provided by the Agricultural and Rural Development Fund ARPDF. Since 2022, it has been supporting MARD in providing extension services to farmers and bolstering the capacity of ANES to provide such services; this action is implemented through the Agricultural University of Tirana. Improving QI is a substantial part of this initiative.

#### Main challenges for non-institutional stakeholders

Improving Culture for quality is the key to improving the QIS in Albania;

- » In the food business community, the main focus should shift from formal compliance (documents, certifications) to actual compliance, i.e. awareness and knowledge of the different aspects of food safety and quality and acknowledgement of the importance of compliance with requirements as a pre-requisite for staying in the business and not as a rule to be formally complied with;
- In addition to a greater focus on compliance, non-institutional stakeholders should also perform bolder advocacy and lobbying actions towards institutions with a focus on: i) filling some important legal gaps, such as alignment with EU marketing standards (Common Market Organization, "secondary CMO legislation" and "Breakfast Directives") and improvement of the traceability system and ii) improving the effectiveness of the inspection system;
- Among the general public, awareness of the risks of food safety hazards and the importance of consuming qualitative food is already high, but what it means in practice is much less clear, with

<sup>60</sup>https://www.map-epca.com/

<sup>61</sup>https://amap.org.al/?page\_id=236&lang=en

<sup>&</sup>lt;sup>62</sup>There are 34 public vocational schools in Albania, out of which nine schools provide agricultural qualifications and one vocational school in Albania provides forestry qualification (in the city of Shkodër).

little trust in QIS and in general for institutionalised and formalised systems (including the quality system) and high trust on personal relations with primary food producers or neighbourhood retailers.

The role of non-institutional actors in improving this situation is even more important than the role played by institutional actors.

At present, the contribution of sector product associations and consumer associations to this goal is limited, as associations are generally weak. The advocacy and lobbying influence of lead individual

entrepreneurs is generally stronger than that of sector associations.

The media should be also more systematically engaged in increasing consumers' awareness of culture for quality.

A synopsis of the gaps, challenges and recommendations aimed at enhancing the role of institutional stakeholders (AKIS) and non-institutional stakeholders (sector associations, interest groups, media) in promoting a culture for quality is provided in **table 5.10** (for institutional stakeholders) and **table 5.11** (for non-institutional stakeholders) below.

**TABLE 5.10:** THE MAIN CHALLENGES AND NEEDS OF INSTITUTIONAL STAKEHOLDERS FOR THE PROMOTION OF CULTURE FOR QUALITY IN ALBANIA

#### **PROFILE**

**ANES** - advice and training to farmers and agri-businesses, including use of agricultural inputs.

**ATTCs** – Technologies and knowledge transfer to primary producers.

**AIDA:** Support to SME development and export.

Academic institutions (AUT, UT and F.N.Korce): education and research.

# **CHALLENGES**

- » There is no "one stop shop" to provide information on export procedures, legal requirements and most common standards for export;
- » AIDA export guide is limited to market practices;
- » AKIS system is fragmented and not structured as a coherent system;
- » Overload of ANES with different tasks, as compared to resources;
- » Limited interrelation between ANES and Academia;
- » Very limited ATTC outreach to value chain operators;
- » Poor engagement of the Universities in conducting applied research for QIS components;

### **RECOMMENDATIONS**

- » Support the establishment of an effective and efficient AKIS which can better disseminate information and raise awareness on QI;
- » Increase awareness on standards and protocols;
- » Increase capacities and cooperation of academia, ATTC and ANES;
- » Establish operational groups to address quality problems building on the EU example;
- » Strengthen academic capacities for applied research (e.g. PAs control and climate change aspects), promote quality and provide testing services;
- » Promote a culture for quality among consumers through media.

Source: Own elaboration

#### **PROFILE**

Associations of value chain operators

- » Two umbrella-like associations: i) International Chamber of Commerce Albania and ii) Albanian Agribusiness Council (KASH);
- » Two MAPs sector associations;
- » Associations focused on exports
- » Professional associations/NGOs: Institute for Organic Agriculture, the Albanian Association for Marketing.
- » Consumer associations and interest groups;
- » Albanian Consumers Association;
- » Commission for the Protection of Consumers.
- » Media;
- » Some specialized programs in public broadcast media;
- » Few specialized magazines for food professionals, mainly distributed in social media<sup>63</sup>.

#### **CHALLENGES**

- » Scarce cooperation and poor financial support for the business associations;
- » Poor representation and low impact in terms of regulatory framework;
- » Poor advocacy towards quality assurance;
- » Poor lobbying and advocacy influence;
- » Insufficient focus on key issues.

#### RECOMMENDATIONS

- » Institutional QIS subjects should engage media in a long-term effort to build up a culture for quality in the public, introducing specific communication slots media programs;
- » UNIDO and other relevant international development cooperation initiatives should communicate with sector associations on the necessity to focus lobbying and advocacy activities on fixing key legal gaps (such as marketing standards and traceability) and shortcomings in inspection function;
- » Introduce and implement a dissemination programme to communicate the structure and functioning of the QIS to non-institutional stakeholders;
- » Increase advocacy for a more transparent and independent market surveillance system;

Source: Own elaboration

# 5.8 CULTURE FOR QUALITY AMONG CONSUMERS AND VALUE CHAIN STAKEHOLDERS

# **5.8.1.** Consumer awareness related to food safety and quality standards

Consumers in the EU and other developed countries (e.g. US and Switzerland) are characterized by high and growing awareness about food safety and quality. Recent studies suggest that over a third of Europeans have a very high or high level of awareness of food safety topics. On the other hand, consumers in the EU tend to trust institutions which are in charge of food safety control. According to a recent study, more than 8 out of 10 respondents trust doctors (89%), university/publicly funded scientists (82%) and consumer

organisations (82%) for information on food risks. Likewise, trust in national and EU institutions is also high, at about two-thirds (EFSA, 2023).

In Europe, there is a growing awareness and demand for different voluntary standards. A growing number of European consumers (37%) report recognizing the Fair Trade logo. Whereas, in the case of organic food, the growing demand is not only linked to food quality (consumers use organic production as a quality cue) but also environmental protection. A smaller but still significant share report recognizing the EU's PDO logo (Goudis and Skuras, 2021).

<sup>63</sup> See: https://ubgreen.al/, https://agroweb.org/shendet, https://www.artigatimit.com/ and https://shijeonline.wordpress.com

The increasing awareness and demand for higher standards related to food products, coupled with the growing requirements from EU institutions and supermarket chains (in the case of the EU, which is also the main targeted market for the selected value chains), implies that the presence in such markets is and will continue to be increasingly challenging.

Although the focus of the study is the export market, local consumer behaviour and expectations are also key factors influencing the orientation of the local industry towards standards. Therefore, it is important to have insight into local consumers too.

Consumer behaviour in Albania reflects the concerns about serious issues with the national food safety control systems. The issues related to food safety and their perception by consumers have been identified by several studies.

As food safety is a credence attribute, the use of cues to deduce safety (and other aspects of quality) is linked to trust in the source of the information. In developed countries with consolidated institutions (such as the case of EU countries and institutions, highlighted above), consumers tend to trust public institutions and/or supermarket chains to guarantee food safety. In the case of countries with a poor institutional framework, such as Albania, the level of trust in public institutions to guarantee food safety may be lower and consumers might place more trust in retailers than in public institutions for guaranteeing food safety (Zhllima et al. 2015; Imami et al. 2011). In addition to developing trust in retailers, when possible, consumers prefer to buy food directly from producers as a strategy to ensure safety and quality, which is common in the case of some agrifood products (Imami et al. 2013). Consumer trust has traditionally been closely linked to the length of the supply chain: the shorter the distance between consumer and producer, the higher the trust (Imami and Skreli, 2013). In broader terms, consumers would even prefer in principle direct purchase from farmers than purchase from a trusted supplier/trader.

Purchasing directly from producers not only provides a perceived assurance of quality but also of the product's origin. Origin and brand reputation are important attributes for Albanian consumers to guarantee food safety. Information about expiry date, domestic origin/ local origin, and knowing the producer or the brand name are the most frequently used food safety and quality cues for Albanian consumers. Previous study findings indicate that university educated female consumers with higher income are, on average, more concerned with food safety measures. Women and consumers with higher levels of education tend to check food safety and quality-related information more frequently than men or individuals with lower levels of education. Also, younger consumer groups and higher income groups use food safety and quality related information more often (Haas et al. 2019).

# Awareness of value chain stakeholders about food safety

Most Albanian farmers across agri-food sectors lack information or awareness related to food safety standards and other relevant standards (e.g. animal and plant health, environmental standards etc). Lack of awareness about standards results in standards non-compliance, posing a threat to consumer health and also resulting in lower market access (especially in the case of exports) and constraints in access to funds whose access is conditioned by meeting certain standards in a documented way (e.g., IPARD) (FAO, 2020).

Lack of proper warehousing and drying technology is the main reason why MAPs products are contaminated or lose some of their properties (e.g., colour). This requires an upgrade in storage capacities and awareness at the farm level.

Concerning the use of agriculture inputs, small farmers do not have sufficient information about inputs and have difficulty finding information, as the public extension services do not have the resources to reach out to all farmers.

One problem which is becoming a growing concern for MAPs is the presence of PAs. Limited labour force and time constraints reduce the possibility to control the presence of plants, which increases the level of contamination from PAs. The controls on market entry, particularly in major destination markets like the EU, are on the rise. For instance, maximum accepted levels of glyphosates were reduced from 0.03 to 0.00. Therefore, coping with the risks of contamination from other plants is becoming a very costly process. Due to the high level of alkaloids, an increasing number of cases of banned deliveries is emerging. One interviewed exporter stated that, during 2022, approximately 50 export deliveries were blocked. In terms of returned deliveries, costs are quite high. For instance, two trailers hold more than 34 tons of MAPs, which is equal to 7 months worth of income/profit according to one interviewee. According to exporters, there is a limited possibility to control PAs during post-harvest, especially when the product undergoes the sorting and cutting process. Sterilisation capacities and investments are limited due to high costs (sterilisation lines cost up to EUR 100 thousand).

# Albanian exporters practices related to standards

As highlighted above, the lack of proper warehousing and drying technology is the main reason why MAPs products are contaminated or lose some of their properties (e.g., colour). These upstream value chain stakeholders are aware of the deficiencies and are more than willing to address them, but lack the financial resources. In contrast, large consolidators and exporters are better equipped to implement the required quality standards. Thus, there is an urgent

need to invest upstream in the value chain in terms of food safety and quality standards.

This situation also helps to explain why some consolidators/processors/exporters are also investing to take direct control of the production of the MAPs they use, starting large-scale cultivations of MAPs they need most.

According to the survey conducted in the context of this study, most exporters in both sectors apply GAP (Good Agriculture Practices) standards. The vast majority of the surveyed MAPs exporters (91%) reported that their business observes national or international standards for quality management systems. Obviously, this pattern is pronounced for MAPs because it is deeply

export oriented and also due to the fact that MAPs are mainly intended for markets which are demanding in terms of standards (e.g. USA, Germany etc).

More than ¼ (namely 28%) of the interviewees reported that their companies have implemented Organic (BiO) USDA Organic or BioSUISSE Organic certification (which is still relatively uncommon in the MAPs sector) and 20% of surveyed exporters stated that they have HACCP certification. Other certifications such as Rainforest Alliance, FairTrade, Sedex Members Ethical Trade Audit and British Retail Consortium Global Standards (BRCGS), FSSC 22000 and Sedex Members Ethical Trade Audit (SMETA) were implemented only by a few (one or two in some cases) interviewed companies.

TABLE 5.12: MAIN CERTIFICATIONS IMPLEMENTED BY COMPANIES BY TYPE

Certification type	Share of interviewed exporters that have implemented them
Organic (BiO) USDA Organic or BioSUISSE Organic	28%
HACCP	20%
ISO 9001:2015	14%
Kosher	10%
BRC	8%
FSSC 22000	6%
Rainforest Alliance	2%
FairTrade	2%
Sedex Members Ethical Trade Audit (SMETA)	2%
British Retail Consortium Global Standards (BRCGS)	2%
Other	6%

Source: UNIDO/GQSP 2023 Survey

# 5.8.3. Leadership / governance, engagement of people and relationship management

Overall relations between MAPs exporters and international buyers are relatively solid. However, even when contracts are in place, it is uncommon for these contracts to specify precise quantities and prices in advance. Exporters are also unable to arrange long term contracts with buyers. Even in instances where arrangements have been made to purchase crops of significant interest for more than one season, the price of the crop has been subject to reduction. The position of the exporters in the international market chain is still weak.

Collectors of spontaneously grown MAPs and cultivators sell the product to local level collectors or directly to processors/exporters. Local collectors regulate cultivated supplies and maintain consistent supply relationships with buyers (processors/exporters) without exclusively committing their relation to one single person. Large processors/exporters manage

their export channels by gathering procurement offers through contracts. They also establish direct connections with local collectors and cultivate close relationships with farmers. Exporters covey market signals (product type, characteristics and prices) to harvesters and cultivators and provide support for cultivation (seeds and seedlings), technological services and advisory services on quality standards.

Traceability is very difficult. For example, each MAPs exporter typically has over 1500 farmer suppliers, even though many of these farmers, especially in the case of wild MAPs, provide relatively small quantities of produce. Furthermore, there are many exchanges between collection points and exporters. That also raises concerns about quality assurance. To mitigate risks, exporters often aggregate the products by dividing them into small lots and categorize the output based on the microregion of origin (typically comprising groups of villages that correspond to 15-20 farmers). Quality assurance is also difficult due to market behaviours of other stakeholders. There is

significant competition at the horizontal level, which reduces the efforts for maintaining quality standards. The absence of contract farming reduces the possibility of the exporters to keep suppliers under pressure. Punishment effects are not effective, since the supplier would choose another consolidator or exporter to sell the produce. If laboratory analyses reveal that the product quality is poor, products that have been packaged in bulk may need to be unpacked, sorted, and cleaned. This results in additional labour costs, loss of quantity and energy costs.

Main buyers, namely Martin Bauer, Kräuter Mix GmbH and others are defining the quality standards and prices. There is limited bargaining power when it comes to setting prices and securing advance contracts.

Information on quality standards is accessible mainly through the buyers and the certification bodies. There are cases where exporters are not able to defend themselves due to limited know-how and information on market requirements.

Most exporters (especially in the case of MAPs) have liquidity problems – this weakens their position/power to negotiate with buyers on one hand, and impose standards to farmers on the other hand (since they often buy from farmers who accept late payments, an attribute for exporters that is equally important compared to compliance with quality standards). Thereby, prices are often not linked to quality.

The vast majority of interviewed operators in the MAPs sector reported that their business has a quality management system and that they have someone who is responsible for quality management.

# 5.8.4. Process approach, evidence-based decision-making and improvement

At the heart of the evidence-based improvement process lies laboratory analysis. Practically, all exporters have their products analysed in laboratories based on buyer requests.

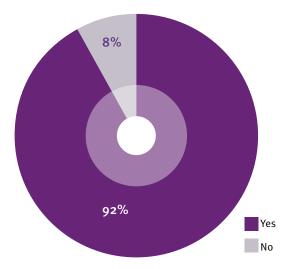
Export-oriented operators conduct lab analyses only when mandatory, otherwise they neglect it. Albanian laboratories are not yet prepared for providing a large array of analyses. For instance, 1000 elements are required for chemical analyses, while our laboratories possess less than 500 (with regard to laboratories services, see subchapter 5.5).

Having certain in-house laboratory capacities might make it easier or more efficient for exporters to control standards. Few processors have mini labs. Almost 1/3 of MAPs exporters reported that they have a quality control laboratory.

As highlighted earlier, some exporters provide agronomic technical assistance and supervision to ensure compliance with the standards. Furthermore, some exporters apply differentiated prices based on quality.

FIGURE 5.1: INVOLVEMENT OF STAFF IN QUALITY MANAGEMENT AMONG THE MAPS EXPORTERS

Does your business have a quality management system in place?



Source: UNIDO/GQSP 2023 Survey

If so, is there someone who is responsible for quality management?

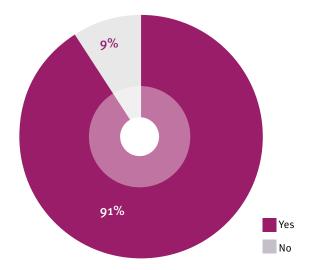


TABLE 5.13: SUMMARY OF CHALLENGES AND RECOMMENDATIONS FOR EACH VALUE CHAIN NODE/SEGMENT

VC NODE	CHALLENGES	RECOMMENDATIONS
Inputs suppliers	» Lack of system of control;	<ul> <li>» Need for an information system;</li> <li>» Need for a technology transfer system (e.g. electronic system similar to drugs system);</li> </ul>
Farmers  Exporters, processors	<ul> <li>» Scarce compliance;</li> <li>» Poor information and awareness about standards;</li> <li>» Low quality of inputs;</li> <li>» Partial implementation of GlobalGAP;</li> <li>» Lack of traceability, poor control, poor implementation of GAP, scarce use of certification, scarce use of contract farming, scarce availability of mini labs;</li> </ul>	<ul> <li>Increase the capacity of the inspection and testing system;</li> <li>Reduce the overlaps between inspection bodies and establish an online system of control for inputs;</li> <li>Provide capacity building and investments at collector and consolidator levels;</li> <li>Introduce digitalisation for traceability;</li> <li>Increase the ICT sustainability map and TRACE;</li> <li>Strengthen CIT capacities;</li> </ul>
		» Support projects for AKIS by establishing relevant Operational Groups;
Supermarket chains	» Weak contract farming and scarce use of quality signs;	<ul><li>» Support contract farming pilot projects;</li><li>» Introduce quality signs for supermarket chains;</li></ul>
Consumers	<ul><li>» Limited awareness about food safety;</li><li>» Lack of awareness about different certifications.</li></ul>	» Design consumer education campaigns related to food safety and quality, including information about key certifications.

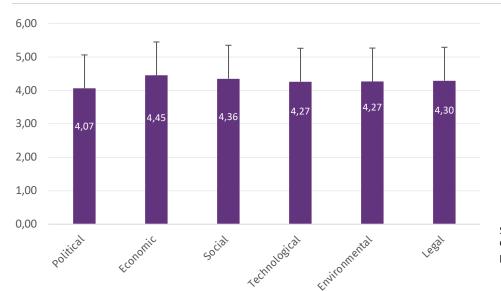
# 5.9 A SYNTHESIS OF QIS EVALUATION IN ALBANIA

In addition to the analyses of the secondary sources, documents and studies, in order to perform an overall analysis of the QIS in the MAPs sector, various participatory methods were used, namely PESTEL, SWOT and stakeholder mapping, as explained in the Methodology chapter. The results are provided in this subchapter.

The PESTEL analysis of the business environment for MAPs

The outcomes of the participatory PESTEL analysis show that economic, social and legal aspects of the business environment in the MAPs sector are slightly more prone to contribute to the improvement of the QI, while political, technological and environmental components are likely to provide a slightly lower contribution. However, all components are scored by stakeholder representatives near or above the median score "4".

FIGURE 5.2: RESULTS OF THE PESTEL ANALYSES ACCORDING TO THE MAIN COMPONENTS

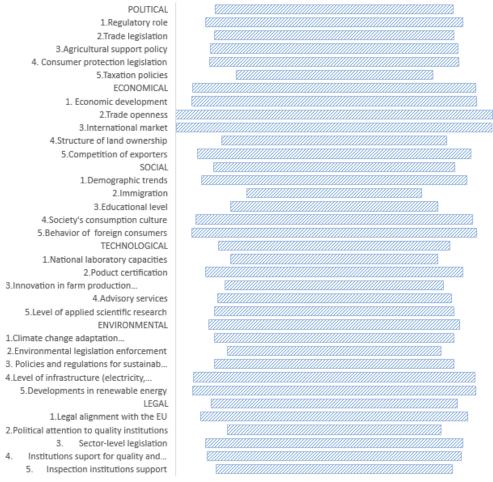


Source: Own processing based on discussions among workshop participants

The component with the highest score is the economic one and the one with the lowest score is the political one, meaning that support policies, trade policies and consumer protection policies and the overall government regulatory role are considered to have a low contribution to quality.

A more specific assessment of the contribution of specific factors to QIS development should be based on the analysis of the sub-components that are included in each component. **Figure 5.3** shows all the sub-components of the PESTEL analysis factors and their relevant scores.

FIGURE 5.3: RESULTS OF THE PESTEL ANALYSES SCORING ACCORDING TO SUBCOMPONENTS



Source: Own processing based on discussions among workshop participants

Based on the assessment of each sub-component, the most interesting and important factors driving change in QI performance and development were identified and commented. The assessment provided by stakeholders on the main single factors that are presently impacting QIS development is summarized in **Table 5.14** below.

TABLE 5.14: MAIN FACTORS PRESENTLY AFFECTING QI DEVELOPMENT, TRENDS AND IMPACT

Driving factor	Trend	Present impact on QIS
International trade (economic)	Increasing	Positive
Consumer awareness of quality and safety issues (social)	Improving	Positive
Migration (social)	Persistent negative net balance	Limited negative impact
Education (social)	Increasing	Limited positive impact
QI technical capacity (technical)	Improving	Not yet having impact
Innovation at farm level (technical)	Limited, only in larger farms	Limited positive impact
Sector associations	Weak, not improving	Very limited impact, potential to become positive
Climate change adaptation (environmental)	Weak capacity, not improving	Resistance factor to QI improvement
Policies and regulation for sustainability (environmental)	Limited, scarcely promoted	Limited impact on QI
Law enforcement (political)	Weak	Negative impact
Political focus on QIS (political)	Low (lowest score)	Negative impact

Source: Own processing based on discussions among workshop participants

The negative impact of low political focus on QI is particularly worthy to be described in detail, as political will serves as the key factor for shaping the QIS development policy and considering that this factor got the lowest score in PESTEL analysis. According to stakeholders' assessment and perception, the scarce political focus on QIS development prevents QIS institutions to achieve their full potential, thus creating a gap between legal responsibilities and provisions and actual function. Support to inspection institutions and therefore their contribution to QIS improvement is not considered satisfactory.

#### **SWOT Analysis**

A participatory SWOT analysis was conducted, in accordance with the methodology outlined in chapter 2. The integration of PESTEL and SWOT analysis exercises provides a clear image of the main factors that sector stakeholders deem important for sector development and their impact on QIS development: not all important factors affecting sector development necessarily have an important QIS implication or impact too, and all the factors which are influencing QIS development are among the main factors of concern for the stakeholders' assessment of sector development issues.

The ranking of weaknesses and threats, as determined through stakeholder assessments, is summarized in **table 5.15** below.

TABLE 5.15: SYNOPSIS OF MAIN WEAKNESS FACTORS AND THREATS TO MAPS SECTOR DEVELOPMENT

W	eakness factors ranking	Threats ranking	
1	Poor monitoring of wild MAPs harvesting practices affecting genetic erosion	1	Depopulation of rural areas, especially mountainous areas
2	Lack of knowledge on the control of alkaloids (PAs)	2	Limited capacity in market intelligence
3	Limitations of laboratory capacities for performing analyses according to the standard	2	Limited inspection, testing, certification and market monitoring capacities
4	Limited inspection, testing, certification and market monitoring capacities	3	Low demand for quality standards from farmers due to weak position, poor value chain coordination and high competition for raw MAPs
5	Low number of qualified technicians		

# THE HOLISTIC VIEW TO QIS GAPS

The accelerated and widespread expansion of agricultural trade and the emerging requirements from consumers resulted in a need for restructuring of the QI system in Albania.

QIS in Albania is fragmented, with various institutions having ill-defined or overlapping roles; cooperation is scarce and not embraced as a regular practice. **Figure 5.4** below reveals the type of relations between QI components. The high occurrence of indirect relationships is evidence of a non-functional QIS. The most vulnerable aspects of the QIS are the relations between farmers and the core QIS components, namely the regulatory and policymaking institutions, QI institutions and the conformity assessment bodies. In addition, the position of opinion formers is peripheral and consumers are entirely disconnected from the broader the QIS.

Considering the dispersed relations, the ability of the QI system to function is limited, as the performance of each component of the QI system depends on the performance of the other components. For instance, the poor performance and scarce focus of QI institutions on MAPs might compromise the usefulness of laboratories. In downstream segments, the poor performance of the laboratories can undermine the quality of the certification, thus reducing the trust of foreign buyers. In addition, uncoordinated action of VC actors and focus on formal (documental) rather than actual compliance reduces the impact of any

investments carried in a single component of the QI.

However, considering that private investments through certification cannot control the lower segments of the value chains, efforts should be concentrated on implementing and maintaining a single QI national system. Limited attention from supermarkets regarding compliance with quality standards results in a lack of pressure on business operators and diminishes consumer expectations. This is related to the overall culture for quality, which needs to be promoted by the relevant stakeholders, namely business and consumer associations, academia, media, etc.

In summary, the development and proper operation of a QI demands considerable financial and human resources, which requires a larger presence of the VC operators as well as a stronger engagement of the consumers.

Interviews with experts and market operators have revealed that laboratory results can only be trusted if local laboratories establish a stronger relationship with VC operators and associations and enhance their services with reputable and accurate results. In the absence of feedback from domestic consumers, testing laboratories, auditors and certifiers have to be monitored and strengthened in order to improve their reputation and be recognized and accepted by clients in foreign markets.

Meeting safety and quality standards and demonstrating compliance cannot be achieved without

Support organizations **Opinion formers** (Industry, SME & (Media, donors, **Quality Associations**) academia, and NGOs) + vocational training organizations Government Processors, Consumers (Policy-makers, (National or regulators and foreign) exporters market surveillance agencies) **QI Institutions** (Standards. Accreditation and CABs Metrology) (Testing / Calibration labs, Inspection & Certification bodies)

FIGURE 5.4: THE RELATIONAL DIAGRAM OF THE QIS IN ALBANIA

Source: Own elaboration based on the UNIDO (2022) diagram

investments and increased costs for both the public and private sectors. Conformity, testing and inspection institutions remain the weakest part of the system. In a country where trust toward institutions is low and law enforcement is weak, there is a need for private operators to dedicate their energy and financial resources to ensuring better compliance along the entire supply chain.

Increased cooperation among exporters and an enhanced role of business associations are indispensable to increase their quality compliance and pursue conformity assessment procedures. The present individualistic approach is generating higher costs and lower quality in the whole system, as each VC operator aims to establish a vertically integrated business and a system of QI services of their own, procuring abroad the QI services that they cannot develop, as trust in local QI service providers is low. This approach can easily render exporters uncompetitive and vulnerable toward foreign buyers.

Awareness should be raised among decision-makers in the public and private sectors to prioritize a holistic approach to QIS development, provide budgetary support and competent human resources with the objective to identify and exploit existing and potential synergies in a coherent application of the EU "farm to fork" holistic approach, and establish an effective feedback system for identified hazards. To develop a more coherent and cohesive QIS, the following priority areas should be targeted: i) attaining legal alignment, ii) establishing a more functional traceability system, also to improve the hazard feedback system, iii) increasing administrative capacities, iv) applying the proper monitoring and support mechanisms for QI improvement; in particular, the efficiency and effectiveness of inspection bodies should be increased v) expanding the feedback system for identified hazards, not only for regulatory enforcement but also for providing advisory services aimed at improvement.

Another major issue is the transparent engagement of private sector organisations in the development of QI functions overseen by public Institutions. This will require a larger involvement of private sector representatives in the advisory boards and technical committees and increased efforts for openness and dialogue at the QI institutions, with a focus on GDA, GDS and GDM.

Participation should include active consultations and collaborative decision-making in drafting legal acts, compiling regulatory documents and coordinating awareness-raising activities.

Last, but not least, UNIDO and other development cooperation partners should enhance their coordination efforts, guided by a detailed roadmap involving stakeholders from the targeted VCs.





#### 6.1 MAIN STRATEGIC DOCUMENTS AND POLICY FRAMEWORK

After being granted the status of EU candidate country in June 2014, Albania made some progress in aligning its agricultural policy with the EU agricultural acquis. In 2007, the country adopted the Law on Agriculture and Rural Development, which constitutes the main legal framework governing the planning of agricultural policy.

After 2020, the policy framework was updated in terms of strategic documents. The National Strategy for Development and Integration 2021-2027 and the Programme of the Albanian Government (2021-2025) are the reference documents that define the overall goals and general objectives for the agricultural and rural development policies. A Strategy for Agriculture, Rural Development and Fishery (SARDF) 2021-2027<sup>64</sup> and an Action Plan are already available, as reflected in the National Plan for European Integration (PKIE) 2021-2023, within cluster 5 and in relation to Chapter 11, 12, 13 and the relevant horizontal legislation of Chapter 27

(Environment and Climate Change). In the Policy pillar of this Strategy, the general objective is as follows: "Promoting sustainable production and quality of food through the development of a competitive and innovative agri-food sector". The SARDF2021-2027 is also in line with Sustainable Development Goals (SDGs) 2, 5, 12, 13, 15, 15 and 17) (RCC, 2020) and embraces the main concepts and requirements emerging from various EU Farm to Fork Strategy for a sustainable agrifood sector. Implementation of medium-term priorities is detailed in annual action plans, which also provide the legal basis for setting up national support schemes (Zhllima, 2021).

A very important policy framework is also the adoption of the Instrument for Pre-Accession Assistance for Rural Development Programme (IPARD III) for the period 2021-2027 (EC, 2022). The policy intervention areas of the IPARD III programme are aligned with the main objectives of the SARDF 2021-2027.

# 6.2 FISCAL AND TRADE POLICIES

# 6.2.1 Fiscal policies

Fiscal policies related to agricultural inputs were subject to revision. The VAT registration threshold in Albania is an annual turnover of over ALL 10 million. Any person providing taxable supplies and whose annual turnover does not exceed ALL 10 million is not required to register, although voluntary registration is possible. Considering this value, a portion of Albanian farmers and traders are not subject to taxes declaration. Differently from the past years since 2022, there is no VAT compensation procedure for agricultural producers. Exporters are exempted from VAT. The 2022 revisions to Law "On value added tax" provided for the i. treatment with a reduced VAT rate of 10% of the supply of agricultural inputs, such as chemical fertilizers, pesticides, seeds and seedlings, except for hormones classified under code 2937 of the Combined Nomenclature of goods and ii. exemption from VAT for the import of machinery and equipment in order to execute investment contracts with a value equal to or greater than 500 million ALL, compared to the current 50 million ALL.

<sup>64</sup>The main specific objectives of SARDF 2021-2027 are to: i. Continue to improve the quality of life in rural areas and diversification of spaces and opportunities for economic activities. ii. Reduce inequalities in terms of living conditions between rural and urban areas iii. Increase exports through investments in the processing sector, facilitating capital enhancing investments and increasing access to new markets. V. Development of rural tourism by providing support mechanisms for women, youth and returned migrants. vi. Increase support for agriculture, livestock and rural development through direct support and IPARD III financing.

Starting from 2021<sup>65</sup>, beneficiaries of the support scheme for agricultural fuel receive fuel free of charge as an equivalent of fiscal exemption. The fuel price is exempted from the excise tax, tax on roads, carbon tax and VAT – counting for 44% of the fuel price. This price is converted into an equivalent quantity of fuel free of charge: the fuel required for conducting operations with agricultural machinery multiplied by the ratio of tax exemption to the average fuel price of the previous year. In 2022, this measure was expanded to provide a higher amount of compensation for covering the additional costs arising from the rise in fuel prices due to the Russia-Ukraine war (CM, 2022). The support continued in 2022.

# 6.2.2 Trade policies

The trade of semi-processed MAPs is not constrained by tariffs, quotas, or other non-trade barriers (AGT-DSA, 2021). In contrast, non-tariff barriers bear a higher relevance. Additional modest costs are incurred for obtaining the Phytosanitary certificate (2000 ALL) and the certificate of origin (2000 ALL) and for undergoing the customs scanning procedure (23 EUR or 2500 ALL). In total, for any delivery, the costs of the procedures is about 6500 ALL. An export promotion policy is

<sup>65</sup> Government of Albania Decision 1142/2020 "On defining the main criteria, the benefit quantity and the method of use of the fund allocated to the fuel support scheme for agriculture for the year 2021"

required. Market operators emphasized the necessity for partial financial assistance to cover expenses related to collective marketing strategies (such as branding), market promotions (such as participating in fairs), or concealed support for exports (including compensation for laboratory and freight costs).

# **6.3 BUDGETARY SUPPORT POLICIES**

During the period 2020-2021 the overall budgetary support for agriculture in Albania witnessed a significant increase over the past two years. In 2021, support allocated to agriculture reached 2.6 % of GVA, with EUR 68.3 million. The support amounts to EUR 54 per Ha or EUR 22 per inhabitant, which is still less than half of the average of the Western Balkan Countries. Despite growing trends, in terms of payments per hectare of agricultural land, Albania scores low, compared to the European Union and also to other countries in the Western Balkans (Zhllima, 2021).

In all documents, strategies and development programmes, MAPs are considered a strategic subsector for the whole Albanian agri-food sector; as such, it has been supported by several international development projects, mostly financed by bilateral funding implemented by ODAs and reference agencies (USAID<sup>66</sup>, SNV, GIZ/DANIDA). MAPs have also been considered as a key sector in development initiatives related to credit and financing within the agri-food sector (EBRD, Italian Cooperation).

Some support for small investments was also provided through bilateral development projects.

# Agriculture and Rural Development Program Fund

In the period 2019-2021, approximately 77 % of Albania's financing was derived from domestic sources. Therefore, the drafting and implementation

of the Agriculture and Rural Development Program Fund (ARDPF) remains a cornerstone of the overall budgetary support. One of the most consistent objectives of the ARDPF has been to expand areas planted with medicinal and aromatic plants (MAP) and ensure certification of agricultural products and organic farms. To support these goals, two national assistance measures have been in place since 2012: 1) Coverage of plantation costs: 50% of the total costs per hectare. 2) 50% coverage of production expenses for the transition to an organic production regime and 50% of the certification costs for export-oriented productions.

The table below outlines the eligibility criteria for support by year.

In 2022, a change was made in the support measure for MAPs. Payment shifted from being based on the number of seedlings purchased to being calculated according to the newly planted area in hectares. In 2023, this measure ceased to exist. A scheme that has experienced growth during 2020-2021 and has remained stable in recent years is the support measure for organic and certified organic farms (38%). Support for organic farms during the transition period is as follows: ALL 100,000 for the first year, ALL 150,000 for the second year, ALL 150,000 for the third year and ALL 200,000 for a certified farm. In addition, since 2018, support for GlobalGAP certification for vegetables, fruits, grapes, olives, citrus and other certifiable agricultural crops has been provided at the rate of 50% of the total value of the tax invoice, for areas of no less than 3 Ha.

TABLE 6.1: CRITERIA OF SUPPORT MEASURES FOR THE SECTOR OF MAPS BY YEAR

	Specific requirement	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Cultivation/ improvement of cultivation	Min. planted area (ha)	in blocks and	0.2	0.2	0.2	0.2	Variable *	-	Variable **	Variable **	1	NA
technology of MAPs Max. planted		chosen areas	10	10	5	20	-	Not spe- cified	Not spe- cified	Not spe- cified	NA	
area (ha) Organic	Min.	Not	Not	_	Not	Not	Not	_	0.5	0.5	0.5	0.5
production certification for cultivated plants	planted area (ha)	Speci- fied	Speci- fied		Speci- fied	Spe- cified	Speci- fied		0.5	0.5	0.5	0.5

<sup>\*</sup> o.5 for individual farmers; 1 for a group of farmers and 5 for ACS/ SHBB. \*\*o.2 for individual farmers, 1 for a group of farmers in a block, 5 for ACS/SHBB. Source: The relevant DCM on support measures.

<sup>&</sup>lt;sup>66</sup>USAID supported the MAPs sector through three subsequent projects over a ten-year timeframe: SBCA, EDEM and AAC.

In 2021, ARDPF provided diesel at an equivalent value to cover the total fuel tax exemption required for mechanical works on land, based on area-specific principles. In 2022, this measure was expanded to provide a higher amount of compensation for covering the additional costs arising from the rise in fuel prices due to the Russia-Ukraine war (CM, 2022). For a summarised view of the new measures introduced in 2023 in relation to the targeted sectors, see the box below

**BOX 6:** MAIN MEASURES OF RELEVANCE FOR MAPS FOR THE YEAR 2023

**Measure on organic farms**: Support for organic farms during the transition period is as follows: ALL 100,000 (one hundred thousand) for the first year, ALL 150,000 (one hundred and fifty thousand) for the second year, ALL 150,000 (one hundred and fifty thousand) for the third year and ALL 200,000 (two hundred thousand) for a certified farm;

Measure on GlobalGAP: Support for Global GAP implementation and certification for vegetables, fruits, grapes, olives, citrus and other certifiable agricultural crops amounts to 50 (fifty) % of the total value of the invoice tax, provided that: i. it does not exceed ALL 175,000 (one hundred and seventy-five thousand) for an area of no less than 1 (one) ha:

ii. it does not exceed ALL 500,000 (five hundred thousand) for an area of no less than 3 (three) ha in protected premises and no less than 10 (ten) ha in the open field.

**Measure on fuel**: support through the provision of oil for the performance of mechanized works in agriculture, at a value of up to ALL 1,328,000,000

Source: ARDA (2022)

### IPARD-like and IPARD II support

During the IPARD-like programming period from 2007 to 2013, the MAPs sector itself was not included among the supported sectors. Nevertheless, certain consolidators/processors/exporters were deemed eligible under Measure 1 and Measure 3<sup>67</sup> as part of investments related to processing. At the same time, primary production was only eligible for support by national schemes, which was significant only in the years 2013 and 2014. Considering all facilities, the number of investments which received capital investment support scored about EUR 4 mln in the period 2013-2020.<sup>68</sup>

In IPARD II, the MAPs sector has been considered as eligible under Measure 7 (as part of support to organic farming) and in particular: A) Sub-Measure 7.1 - Provision and production of medicinal and aromatic plants, fungi, honey, snails, and materials for the production of essential oils; and B) Sub-Measure 7.3 - Processing and marketing of wild or cultivated medicinal and aromatic plants, fungi, olive oil, honey, fish and fish products, production and marketing of essential oils.

Expenditure categories eligible for Measure 7.1 - Production of medicinal and aromatic herbs, mushrooms, honey, ornamental plants, snails, by categories were: i.production facilities, greenhouses (glazed and/or plastic tunnels with a minimum of 5 years warranty), including ventilation facilities and equipment, air conditioning and heating, alarm systems with electric generators, water tanks, and irrigation systems.ii. specialized equipment for horticultural production and nursery farms, including tractors up to 70 hp. iii.post-harvest facilities and equipment for collection/ventilation, drying, and storage.

The sector received a limited share of the support provided by IPARD and National schemes. In IPARD II, there have been five successful applications for MAPs, for a total investment value of EUR 1.1 mln<sup>69</sup>. Considering the importance of MAPs, MAPs processing was included in IPARD III programming and will be implemented during the upcoming years. Support of up to 50% of the total value of completed investment tax invoices was provided for the purchase of lines/machinery and equipment for the processing, packaging, standardization and labelling of several processed products, including MAPs. IPARD III is expected to become operational in 2023.

<sup>&</sup>lt;sup>67</sup> Classified as "Measure 2" in ARDA documents

<sup>&</sup>lt;sup>68</sup> In the programming period 2012-20 and in the last year of the previous programming period. The MAPs sector has been considered as eligible in IPARD II under Measure 7 (as part of support to organic farming) and in particular: A) Sub-Measure 7.1 - Provision and production of medicinal and aromatic plants, fungi, honey, snails, and materials for the production of essential oils; and B) Sub-Measure 7.3 - Processing and marketing of wild or cultivated medicinal and aromatic plants, fungi, olive oil, honey, fish and fish products, production and marketing of essential oils.

<sup>&</sup>lt;sup>69</sup>The amount refers to the first two calls only; a third call was closed in March 2020. However, all the available resources for Measure 7 have been allocated within the second call.

#### 6.4 OTHER DONOR SUPPORT INITIATIVES

Many programs funded or implemented by international development agencies, such as USAID, SIDA, FAO, and GIZ have supported this sector during the last ten years. Many large processors have benefited from grants provided by different programs implemented by USAID, GIZ, SDC, SIDA, and SNV. One of the programs that specifically targeted the MAPs sector was Promali, a program funded by Danida and implemented by SNV. In addition, CNVP: Connecting Natural Values and People has been implementing several projects related to MAPs cultivation and harvesting.

The recent extensive program implemented by GIZ, "Support to Agriculture and Rural Economic Development (SARED)" was initially followed by SRD (Sustainable Rural Development), which has now been concluded, and then by SRD2, which has just started. Through these programs, support has been provided to the selected value chains: (i) medicinal and aromatic plants, (ii) fruits and nuts, (iii) small ruminants, and (iv) rural tourism with the objective to achieve an economic transformation of rural areas in Albania which is valuable for the local population, including returnees. SRD2 puts a strong emphasis on innovation and particularly biological control/ fight of pests, to achieve a more sustainable and environmentally friendly agriculture. SDC has joined by providing support for SRD2.

In addition, FAO provided USD 340 thousand in the framework of the project: Development of the agricultural, agri processing and rural sector towards EU membership; Strengthening of MARD in the EU approximation process and the development of SDG targets and indicators. One of the objectives of the project is to complete the "Framework conditions for producers and businesses for strengthening their competitiveness in the domestic and export markets" by developing implementing procedures for the product quality legislation and preparing by-laws to support the implementation of a new law on organic production;

The Food Safety Project "Support to food safety, veterinary and phytosanitary standards" is a 5-million-euro programme funded by the European Union and implemented during 2019-2022 by the Food Safety Authority of Ireland in partnership with the Finnish Food Authority, the Irish Department of Agriculture, Food and the Marine and Creative Business Solutions in Albania.

During 2022, work was underway along with "SAFIAL" Project (which aims to strengthen the institutions of the Albanian Ministry of Agriculture for food safety management), financed by the Italian government and implemented by the International Centre for Advanced Mediterranean Agronomic Studies (CIHEAM) in Bari, Italy for investments in the laboratory services in Durrës, an enhancement of laboratory capacities and

an expansion of the range of analyses performed in the microbiological and physio-chemical laboratory, as well as in the plant protection laboratory.

SDC Risi Albania has a component on agriculture and another on tourism. The project has supported the application of global-GAP certification, at group levels (RisiAlbania, 2023). The RisiAlbania Project is supported by the Swiss Agency for Development and Cooperation (SDC), in partnership with the Ministry of Finance and Economy, and implemented by a consortium consisting of HELVETAS Swiss Intercooperation and Partners Albania. The overall goal of the project is to contribute to an increase in employment opportunities for young women and men (aged 15-29) in Albania. This goal will be achieved through: (i) enhanced growth and job creation by the private sector in three selected subsectors: agribusiness, tourism, and ICT (labour demand), (ii) improved access to job opportunities and labour market information and services (intermediation), and (iii) improved skills of young people by improving the offer of private training providers in the three selected sectors (labour supply).

Other initiatives are also being developed. The World Bank is expected to launch a new project "The Climate Resilient and Competitive Agriculture Project (\$70 million)" which will focus on improving innovation in agriculture, enhancing smart irrigation, and improving access to local and EU markets (World Bank, 2023). In addition, USAID is planning to start a project on capacity building for agriculture, which may include the MAPs sector. The project is expected to focus on improving market competitiveness for a 5-year period. CNVP is also implementing two cross-border projects jointly with other partners for the period 2023-2025, namely "Sustainable use of natural resources for transboundary socio-economic development of protected areas in North Macedonia and Albania (Korab-Koritnik, Shar and Albanian Alps" and the project titled "Sustainable Future For Shar/ Korab-Koritnik".





The establishment of the Quality Infrastructure (standardization, metrology, accreditation, testing-certification, conformity assessment) constitutes the foundation of reforms in the internal market (UNIDO,

2016), and remains one of the most positive and practical steps that a developing or emerging economy such as Albania can take on the path forward to increase the competitiveness of the primary and secondary

sectors, preserve the well-being of smallholders, processors and market operators in the MAPs sector, and protect the health of the consumers. Therefore, there is a need for compliance with increasingly strict legal requirements at the state institutional level for both dried and distilled products, especially in the EU market. At the same time, there is also an increased demand by the private sector for voluntary standards and certifications, including marketing standards. Compliance with increasingly demanding legal and additional requirements is not only necessary to maintain and improve market access, but also serves as a means to attain higher added value and/or higher prices.

Overall, there is limited awareness and application of food safety and quality standards, and a poor quality culture and awareness – thus, there is a need to raise awareness about such standards. This can be achieved in multiple ways, but the most efficient and sustainable approach is to cooperate closely with value chain leaders and with MARD extension services.

There is a need for a series of interventions in order to support QI improvement. In the pas,t the focus of the budgetary support has been on the expansion of the cultivated area and the increase of processing capacities, while recently the focus has shifted to ensuring the quality standards related to organic production. Considering the weaknesses identified in the QIS, the support should be provided in three main areas: i) establishing a more enabling environment and increasing the institutional capacities of the components of QI, ii) increasing the involvement of MAPs value chain operators and their association in QI development and management and, iii) strengthening the development of culture for quality for MAPs value chain operators, in parallel with increased knowhow for all aspects related to quality and quality infrastructure.

# 7.1 MAIN FINDINGS, KEY GAPS AND RELEVANT RECOMMENDED ACTION

This section groups the analysis of gaps and recommendations into two parts:

- i. Gaps, issues and recommendations for improvement related to the improvement of quality standards in the MAPs value chain by each VC stakeholder category (table 7.1), and;
- ii. Gaps, issues and recommendations for improvement related to the QIS (table 7.2).

The assessment of gaps, issues and recommendations for improvement related to the VC actors is addressed in a separate table, as the analysis of the MAPs sector allowed the identification of several issues and relevant opportunities for improvement, not all related to QIS, even if most of the highly relevant ones are actually QI issues;

Also, not all gaps have the same impact on the value chain performance and therefore not all opportunities for improvement have the same priority. A detailed description of the recommendations related only to the priority opportunities is provided in section 7.2 below,

**TABLE 7.1:** ACTORS, GAPS AND NEEDS FOR THE IMPROVEMENT OF QUALITY STANDARDS IN THE MAPS VALUE CHAIN

Stakeholders	Issues and gaps related to quality standards	Recommendations for improving quality standards
Collectors	Wild MAPs resources are not sustainably used, due to socio-economic and market mechanisms and trends and regulatory issues.  Almost no access to effective post-collection	Introduce a more effective traceability system.  Modify the system of collection quotas and connect it to
(wild MAPs)	No market segmentation of wild/cultivated MAPs, disproportionally affecting wild MAPs collection.  Major issues related to microbiological contamination and foreign matters level.	traceability.  Provide assistance and training on MAPs GACP.  Strengthen downstream inspection activities to enforce GACP application.

Stakeholders	Issues and gaps related to quality standards	Recommendations for improving quality standards
	GAP are not applied and are scarcely known.  Inadequate support from extension services.	Introduce a more effective traceability system. Support the introduction of MAPs
Small farmers/ primary producers	Production / cropping decisions are not based on laboratory (e.g. soil) analysis.	GACP.
(cultivated MAPs)	Increasingly strict legal and additional requirements in international markets due to increased risks and frequency of non-compliance	Improve access to extension services and use of laboratories.  Facilitate equitable farming
	with residuals and contamination.	contracts between small farmers and processors and/or
	MAPs processors/exporters increasingly prefer vertical integration to contract farming.	support the introduction of VSS certification schemes.
	Difficulties related to managing contact contamination risks related to new EU regulation on PAs.	
Consolidators in production areas	Unregulated competition and ineffective system of quotas	Develop and enforce a workable traceability system for wild MAPs
	Very poor post-collection and post-harvest services, especially for drying: major problems with microbiological contaminations and compliance	linked to collection quotas, to improve food safety and increase environmental sustainability.
	with required marketing standards, including an undue mix of different MAPs, persistent foreign matters issues	Provide technical assistance and increase inspections for GMP applications.
	Weak position in VC coordination  Weak or no practices of contracting	Develop and introduce at the national level dried MAPs standards based on international commercial practices or similar standards adopted in other exporting countries.
		Support the development of post-collection services.
		Promote the use of (improve access to) IPARD III facility.
Integrated VC operators (primary	Investment focuses on vertical integration rather than on increasing the size and development of new products/services.	Develop and enforce a workable traceability system for wild and cultivated MAPs.
production, processing, export)	Scarce knowledge and increasing costs to manage contact contamination risks related to new EU regulation on PAs.	Provide technical assistance and increase inspections for GMP application.
	Scarce in-country QI services, low trust in QI services especially for laboratory testing and certification.	Develop and introduce at the national level dried MAPs standards based on international
	Incomplete traceability for wild MAPs.	commercial practices or similar standards adopted in other
	Scarce cooperation for VC leadership / coordination.	exporting countries. Support more equitable
	Sector associative bodies are weak in terms of finance and representation.	production farming contracts, also including the provision of public extension services.
	Quality system and relevant certifications on MAP essential oils and other added value products are beyond the current possibilities of the industry and	Support the development of post- harvest services, also promoting
	QIS.	the use of the IPARD III facility. Strengthen TIC services.
		Support projects for AKIS using the Operational Grou

**TABLE 7.2:** ACTORS, GAPS AND NEEDS IN RELATION TO SERVICES PROVIDED TO ENSURE QUALITY FOR THE MAPS SECTOR

QI component	Stakeholders	Issues and gaps	Recommendations
Culture for quality	All institutional and private QI stakeholders	<ul> <li>» Focus on formal compliance at the moment of inspection/ testing rather than on substantial compliance consistent over time.</li> <li>» Low trust of Albanian consumers and foreign importers on Albanian QI, low trust between institutional actors and VC operators, and within VC actors.</li> <li>» Strong attitude of institutional and private actors to limit coordinated action and communicate/ exchange information.</li> </ul>	<ul> <li>Reinforce and coordinate inspection functions.</li> <li>Improve planning and implementation mode of inspections.</li> <li>Support the establishment of a wider range of QI services owned by accredited international subjects.</li> <li>Strengthen GDA and increase its effectiveness.</li> <li>Formalise aNQP and involve in the steering committee VC actors and consumer protection organisations.</li> </ul>
Regulatory framework and quality policy	Key government Parliament, Council of Ministers, MARD (Agencies, Divisions, Technical committees and commissions) and MFE institutions	<ul> <li>Albanian legislation partly aligned with EU legal framework.</li> <li>Lack in capacities related to accreditation of conformity assessment bodies.</li> <li>Gaps regarding Good Laboratory Practice (GLP).</li> <li>Albania's legislation on accreditation and market surveillance.</li> <li>Products regulatory framework still largely based on EU 'old approach', especially pre-packaging, bottle measurement.</li> <li>Weak capacities for evidence-based policies and stakeholder inclusion.</li> </ul>	<ul> <li>Establish a coordinating body and prepare a NQP for supporting the quality infrastructure and harmonising technical regulation activities.</li> <li>Define the roles and responsibilities of each actor in the QI system through the preparation of a national regulatory framework on quality.</li> <li>Provide budgetary support in order to strengthen capacities in QI institutions (e.g. standards, metrology and accreditation) and other components of the QI system (quality promotion, inspection, testing, certification, calibration &amp; verification).</li> <li>Support the expansion of the legal alignment in the field of QI with focus on implementing legislation, utilizing the EU 'new legislative framework' approach.</li> </ul>

QI component	Stakeholders	Issues and gaps	Recommendations
Quality infrastructure institutions	Accreditation	<ul> <li>» Lack of capacities to accreditGlobalG.A.P. Certification Bodies.</li> <li>» Low level of trust in/reputation of foreign operators.</li> <li>» Limited number and quality of technical assessors for QI services provision (testing, calibration, certification and inspection).</li> <li>» Weak engagement of sector representatives in the technical working groups (TWG).</li> </ul>	<ul> <li>Advocate for increased GDA focus on the MAPs VC and support for the increasing capacities in VC-specific areas.</li> <li>GDA capacity building for ISO/IEC 17065 accreditation of Albanian TIC bodies, focused on: i. GACP and GMP audit, inspection and certification (e.g. enabling TIC to be GlobalGAP authorised CB); ii. Food Safety Management Systems based on ISO 22000 family such as FS 22000 standard; iii. ISO/IEC 17025-based accreditation of testing laboratories for VC-specific activities (focus on humidity, pesticide and bacteria testing).</li> <li>Support adoption of rules, processes and competence criteria for the accreditation by European Accreditation Multilateral Agreement (EA and IAF MLAs) and facilitate the participation of GDA lead assessors and technical assessors as observers in assessments performed by an EA MLA accreditation body for accreditation schemes in the MAPs sector.</li> <li>Train a pool of technical assessors with relevant experience to cater to the needs of the MAPs sector (testing, calibration, certification and inspection), and provide them with mentorship until they have acquired the necessary competence.</li> <li>Increase monitoring of GDA lead assessors and technical assessors in order to increase trust from market operators.</li> </ul>
	Metrology	<ul> <li>» Limited scope of calibration services (mainly thermometers, volume and density) not fully meeting operators needs (humidity in MAPs).</li> <li>» Legal base "On Metrology" not aligned with Directive 2009/34/EC and other directives on prepackaged products.</li> <li>» Non-recognition of ISO/IEC 17025 accreditation for competence of calibration laboratories, especially in electrical, temperature, humidity, length, and chemistry laboratories.</li> </ul>	<ul> <li>Align the Albanian Law No. 126/2020         "On Metrology" with EU legislation.         According to the notes in Law No.         126/2020, the law is only partially aligned with Directive 2009/34/EC of the European Parliament and of the Council, dated April 23, 2009, regarding the common provisions for measuring instruments and metrological control methods, as well as other directives on prepackaged products.</li> <li>Update the strategic plan of the GDM (scope of calibration for the VCs).</li> <li>Support GDM (e.g. test methods) to become accreditation-ready with a focus on chemical and humidity laboratories, which are of particular relevance for the MAPs chains.</li> </ul>

QI component	Stakeholders	Issues and gaps	Recommendations
Quality infrastructure institutions	Metrology	<ul> <li>Lack of capacities to accreditGlobalG.A.P. Certification Bodies.</li> <li>Low level of trust in/reputation of foreign operators.</li> <li>Limited number and quality of technical assessors for QI services provision (testing, calibration, certification and inspection).</li> <li>Weak engagement of sector representatives in the technical working groups (TWG).</li> <li>Limited involvement of MAPs stakeholders or experts in relevant technical bodies and technical committees.</li> <li>Limited awareness among stakeholders about GDS role/services and limited information on proposed technical regulations.</li> <li>Need for further legislation alignment with EU framework.</li> <li>Limited enforcement capacity for legislation that has already been adopted (EU Regulation 1025/2012 "On European Standardization" / Decision of the Council of Ministers 382/2018 "On the approval of the Regulation on Standardization Activities", as amended)</li> </ul>	<ul> <li>Conduct simulated EA MLA Peer Assessment with a focus on MAPs.</li> <li>Determine the legal metrology and pre-packaging requirements for MAPs.</li> <li>Provide reference materials for the measurement of product humidity, pesticide residues, bacteria and heavy metal (lead) contamination.</li> <li>Support cooperation with other National Metrology Institutions to support initiatives for MAPs.</li> <li>Capacity building for GDS in order to increase expertise and speed up the legislation alignment.</li> <li>Provide support for capacity building for GDS staff and Technical Committees Chairs &amp; Secretaries on Good Standardisation Practices with a focus on the MAPs sector.</li> <li>Assist GDS in establishing a network of contacts among market operators who benefit from the notification procedure, in order to ensure the establishment of a rapid alert system or its equivalent;</li> <li>Support GDS in developing guidelines, manuals, infographics, etc. to raise awareness about standards among relevant regulators.</li> <li>Identify the need for VC-specific Albanian Standards that could be used to improve the quality of local products and potentially serve as a foundation for regional or international standards in the future.</li> <li>Translate the most relevant CEN, ISO and other standards relevant to MAPs sector into Albanian language (using digitalization processes e.g. machinereadable standards) and promote the use of such documentation through platforms and dissemination materials</li> <li>Involve interested parties from the targeted value chains in the drafting, approval and adoption of Albanian standards and their voluntary implementation as stipulated in the Law on Standardization No. 9870;</li> </ul>

QI component	Stakeholders	Issues and gaps	Recommendations
Quality infrastructure institutions	Standards		<ul> <li>Advocate for increased GDA focus         <ul> <li>Provide training to the GDS and</li> <li>MIE staff with a focus on aligning legislation and implementing legislation that has already been adopted (EU Regulation 1025/2012 "On European Standardization" / Decision of Council of Ministers 382/2018 "On the approval of the Regulation of Standardization Activities", as amended)</li> </ul> </li> <li>Strengthen active participation of stakeholders from the MAPs sector in the Technical Committees dedicated to this sector, in order to increase their contribution to the drafting, approval and adoption of standards pertaining to the relevant sectors.</li> </ul>
	Inspection NFA	<ul> <li>» Limited capacities for control at farm level and limited coverage of type of plants checked and sent for control at authorized laboratories system.</li> <li>» Limited capacities for custom inspection related to standards control.</li> <li>» Risk-based control plan focused on product risk, not VC operator risk.</li> <li>» Control of input suppliers mainly based on documentation (not laboratory analysis).</li> </ul>	<ul> <li>Apply pilot project for the online inventory control allowing real time food safety management system.</li> <li>Provide capacity building for Border Inspection Posts inspection staff, NFA laboratory staff and inspectors to enhance their capacity to control standards.</li> <li>Provide capacity building for an effective implementation of annual inspection plans based on astute risk assessment methodology.</li> </ul>
	Inspection NAVPP	<ul> <li>No clear definition of MRL (maximum residue level) by type of contaminant.</li> <li>Lack of laboratory-based control at farm level (controls are rare and only visual).</li> <li>Lack of Pharmacovigilance which implies limited oversight of the utilization of Plant Protection Products (PPPs).</li> <li>Improper institutional division of competencies – input retailers are controlled by NFA, despite its close connection to farmers; control through NAVPP could be more effective.</li> <li>Lack of protocols for the use of PPPs based on the type of plant.</li> </ul>	<ul> <li>Clearly define and disseminate MRL (maximum residue level) by type of product in order to comply with the "Guidelines for residue data under Regulation 1107/2009 and Regulation EC 396/2005". Further align legislation with the EU acquis on contamination.</li> <li>Introduce a Plant Protection Products Application Management System (PPPAMS)</li> <li>Establish a Phytosanitary Information Systems (PIS) for plant health and plant protection.</li> <li>Define tasks, responsibilities/competences concerning the control of input retailers.</li> <li>Update monitoring plans at the farm and input retailers level.</li> <li>Disseminate the protocols for the control of contaminants, pesticide residues, plant health in each segment of the VC chain in order to increase trust and awareness;</li> <li>Invest in Phytosanitary Information Systems (PIS) for plant health and plant protection.</li> </ul>

QI component	Stakeholders	Issues and gaps	Recommendations
Quality infrastructure institutions	Market surveillance	» No coordination between NFA and SIMS	» Support the institutional strengthening of NFA and SIMS
		» Limited coverage in SIMS tasks and functions, especially on prepackaged products and measurement instruments.	» Support the NFA and SIMS in increasing surveillance based on risk assessment plans.
	Testing Laboratory network (FSVI, NFA	» High average fixed costs per unit of laboratory services	» -Increase trust in laboratory services introducing controlled sampling made by certified subjects.
	laboratories, AUT laboratory,	» Poor capacities to provide services for the MAPs market operators.	» Implement pilot projects with MAPs associations and laboratories for large scale analyses.
	12 Private laboratories)	<ul><li>» Lack of trust in Albanian laboratories.</li><li>» Missing accreditation for</li></ul>	» Increase information on laboratories using databased of foreign laboratories (see: https://hub.unido. org/labort)
		<ul> <li>" Initial aboratories"</li> <li>" There is no accessible information on the capacities of the laboratories, such as the range of analyses provided, HR qualification, equipment and accreditation.</li> <li>" Lack of Laboratory Information Management Systems (LIMS);</li> <li>" Limited capacities for fulfilling the present requirements for testing on chemical contaminants (over 500 for MAPs) and high costs for each additional accreditation</li> </ul>	org/labnet).  » Support NFA in the establishment of LIMS.
	Certification and control Foreign certification bodies	block.  » Lack of Albanian locally accredited TICs (for some certifications) – no national subjects are accredited to become CBs for GlobalGAP and FS22000. Using only subjects accredited abroad raises the cost of services.  » Scarce human capacities for the provision of audit, inspection and certification services	<ul> <li>Increase awareness on the need of certification.</li> <li>Support GDA to expand its accreditation capacities.</li> </ul>

QI component	Stakeholders	Issues and gaps	Recommendations	
Quality promotion	Quality education and awareness- raising institutions ANES, ATTCs, AUT, UFN, vocational schools	<ul> <li>There is no unique window of information in terms of exporting procedures and required market standards for Albanian exporters and export-oriented VC operators.</li> <li>AIDA export guide is limited to market practices.</li> <li>AKIS system is not formalized and suffers high segmentation Overload of ANES with different tasks.</li> <li>Limited interrelation between ANES and the academia.</li> <li>ATTC activity, although promoting GAP, is not focused on the establishment of QIS.</li> <li>Poor engagement of universities in conducting applied research for QIS components;</li> </ul>	<ul> <li>Increase awareness on standards and protocols required for exporting a certain product by type of the destination market.</li> <li>Support the establishment of an effective and efficient AKIS which can better disseminate information and raise awareness on QIS</li> <li>Increase capacities and cooperation between academia, ATTC and ANES.</li> <li>Establish operational groups to address quality problems building on the EU EIP AGRI example.</li> <li>Strengthen capacities for applied research (e.g. PAs control), promote quality and provide testing services.</li> <li>Promote culture for quality: among businesses through business associations and ii. Other stakeholders; ii) among consumers through media.</li> </ul>	
	Sector associations	<ul> <li>Scarce cooperation and poor financial support for the business associations.</li> <li>Weak representation in policy making and regulatory bodies, with limited impact in terms of regulatory framework.</li> <li>Poor capacity to effectively promote and advocate for strengthening accountability to ensure culture for quality towards members and external stakeholders</li> <li>Need for full alignment of EU marketing standards (Common Market Organization, "secondary CMO legislation" and "Breakfast Directives").</li> <li>Weak or almost non-existent traceability systems or record-keeping tools calibrated to enable the identification of specific products at any specified stage of the food chain (from production to distribution), including the provenance of the food (one step back) and its destination (one step forward).</li> </ul>	<ul> <li>Advocate for the definition of the market standards (Regulation (EU) no. 1308/2013 and repeal of Council Regulations (EEC) no. 922/72, (EEC) No. 234/79, (EC) no. 1037/2001 and (EC) no. 1234/2007.</li> <li>Introduce digitalisation and other practices in order to increase traceability capacities.</li> <li>Support the collaboration of Associations with the Quality Infrastructure Institutions and Inspecting bodies</li> <li>Apply pilot projects for close cooperation between Associations and Laboratories.</li> <li>Promote culture for quality for consumers.</li> <li>Implementation of projects on consumer rights protection;</li> <li>Implementation of independent market surveillance activities</li> </ul>	

#### 7.2 RECOMMENDATIONS

Based on the assessment of gaps and needs for sector development and QIS improvement, as synoptically presented in tables 7.1 and 7.2, the actions with higher priority have been identified and described.

All the actions described in this chapter are considered as having high priority in relation to QIS and MAPs sector development. Each recommended action is also classified into one of three categories:

- Establishing a better enabling environment (i.e. related to policies, legal and regulatory framework) and increasing the institutional capacities of the QI components.
- 2. Increasing the involvement of MAPs value chain operators and their associations in QI development and management.
- 3. Strengthening culture for quality among MAPs value chain operators, in parallel with increased know-how on all aspects related to quality and quality infrastructure (i.e. implementing a pilot action or action programme limited in scope,

time and resources, in collaboration with several individual VC stakeholders or QIS stakeholders). This will result in increased compliance with mandatory and voluntary standards.

In addition to the above, there is a major issue related to the effectiveness of inspection activities and coordination between agencies involved in inspection activities at different stages of the value chain, i.e. NAVPP (primary production level), NFA (input, post-production, some aspects of distribution) and SIMS (market surveillance). The legal framework governing the functions and activities of these agencies is continuously evolving and each of these agencies is subject to a specific international support package, which already creates problems related to action coordination and potential overlapping. As a consequence of the above, no priority actions for UNIDO support are recommended with reference to these three agencies, even if the issues of inspection targeting and effectiveness, improved coordination of agencies and better delimitation of agencies' responsibilities are important factors for QI improvement.

#### 7.2.1 Selected recommended action to establish a better enabling environment

#### **ACTION: SUPPORT THE FORMALIZATION OF A NATIONAL QUALITY POLICY**

**Justification**: The National Quality Policy (NQP) serves as the fundamental governmental instrument for establishing and supervising the QIS. Some NQP components are included in the drafted "Intersectoral Strategy for Consumer Protection and Market Supervision (ISCPMS) 2023 – 2030", which is a strategic document tackling quality issues, but fails to cover all the elements included in a NQP.

Howevert, there is no national QIS governing body tasked with developing and facilitating the implementation of the NQP. Without a technical coordination body for implementation, the actions to improve the national QIS and to adapt the existing regulatory and legal framework would remain uncoordinated and more difficult to design and implement.

**Recommendation**: i) Support the establishment of a QIS governing body, with the task to design, update and facilitate implementation of the NQP, acting also a technical support unit to update legal and regulatory framework; for this purpose, technical assistance and training should be provided, also using twinning tools with similar bodies in EU member states. The steering committee of the ISCPMS 2023 2030 could eventually be transformed into a de-facto Governing Body. ii) Provide technical assistance for the development of the components of the NQP, with a focus on MAPs.

**Expected Outcomes**: i) A comprehensive NQP is fine-tuned to serve to the MAPs sector; ii) a coordination committee, with the function of a governing body for NQP updating and implementation, is established and operational.

**Actors/stakeholders**: The Council of Ministers; Ministry of Finance and Economy, Ministry for Europe and Foreign Affairs (legal acts and alignment), all QIS institutional actors.

## 7.2.2 Selected recommended action to increase institutional capacities of the components of QI

## ACTION 1: GDA AND TIC CAPACITY BUILDING, FOCUSED ON LABORATORY TESTING SERVICE PROVIDERS AND CERTIFICATION BODIES

**Justification:** Two important QI identified gaps are: i) the limited range and quality of testing services available in Albania and, ii) the limited number of certification bodies operating in Albania and the fact that those recognized abroad are mostly branches of operators accredited in other countries. There are no locally accredited Albanian certification/TIC bodies for some types of certifications (e.g. GlobalGAP).

GDA has not yet developed the capacity to accredit internationally recognized certification bodies / TIC for selected certifications and should improve its capacity to audit, accredit and control public and private laboratories, helping them to provide an increasing range of certified testing services.

This is relevant for both public and private laboratories, including FSVI, laboratories and the few private ones. International trade of dried MAPs and essential oils requires a large number of different tests70, often specific for each MAP. Laboratories should be accredited as infrastructure and certified with ISO/IEC 17025. Private laboratories need to expand the number of accredited tests.

TIC bodies should be able to provide auditing, inspection and certification services. In order to have their certifications recognized abroad, they should be accredited and certified themselves with ISO/IEC 17065.

The lack of locally accredited operators increases the cost/prices of services and reduces monitoring.

**Recommendation:** GDA capacity building focusing on Albanian TIC bodies and testing entities; capacity building should primarily include technical assistance and training; twinning initiatives with EU member states' equivalent bodies could be also promoted.

**Expected Outcome:** GDA acquires the capacity to: i) accredit Albanian TIC bodies and support them in ISO/IEC 17065 certification process; ii) increase the number of accredited and certified testing facilities, as well as the number of accredited FSVI testing services.

Actors/stakeholders: GDA, FSVI, Private laboratories, Albanian TIC bodies.

#### ACTION 2: GDS CAPACITY BUILDING FOR IMPROVING SERVICES PROVIDED TO THE MAPS SECTOR

**Justification:** GDS has adopted several standards for plants regarding chemical determinations, analyses, and test methods, working in collaboration with the relevant Technical Committee. However, there is limited awareness from MAPs operators on the scale and importance of GDS services. The GDS Technical committee does not include stakeholders/experts from the MAPs sector. GDS competences and capacities are yet to be developed. GDS capacity to enforce the already adopted EU regulations is limited (EU Regulation 1025/2012 "On European Standardization" / Decision of Council of Ministers 382/2018 "On the approval of the Regulation of Standardization Activities", as amended), which is diminishing its authority in regulating the standards in the Albanian markets.

**Recommendation:** Support GDS in increasing the engagement of stakeholders from the MAPs sector in the Technical committee in order to allow MAPs operators to take ownership in the process of drafting, approval and adoption of Albanian standards; Provide support for capacity building in terms of observing the Good Standardisation Practices for the MAPs sector; Train the GDS staff focusing on legislation alignment and on implementation of legislation already adopted (EU Regulation 1025/2012 "On European Standardization" / Decision of Council of Ministers 382/2018 "On the approval of the Regulation of Standardization Activities", as amended).

Provide support for GDS in order to increase the presence of and trust in MAPs stakeholders by preparing translated versions of relevant CEN, ISO and other standards relevant to the sector (based on digitalization processes e.g. machine-readable standards) as well as preparing guidelines, manuals, infographics for MAPs market operators.

**Expected Outcome:** GDS acquires the capacity to: i) translate and inform MAPs operators on the current standards used in the production and processing of MAPs products; ii) increase the number of stakeholders involved in the technical committees, iii) consolidate its role in ensuring standards used in the MAPs sectors.

**Actors/stakeholders:** GDS, MAPs associations and market operators.

 $<sup>^{70}</sup>$  A figure exceeding 500 different tests was reported in the field survey

#### ACTION 3: PROVIDE GDM CAPACITY BUILDING FOR IMPROVING SERVICES PROVIDED TO MAPS SECTOR

**Justification:** GDM has been undergoing a series of reforms and improving its legal base and institutional capacities. Yet, GDM has a limited scope of services relevant to MAPs sector, and its legal base is only partially aligned with EU regulations. For instance, the law "On Metrology" is yet not aligned with Directive 2009/34/EC and other directives on prepackaged MAPs. GDM is yet not accredited according to ISO/IEC 17043 "General requirements for the competence of proficiency testing providers". It also has to uphold compliance with the requirements of ISO/IEC 17025 concerning laboratory competencies, particularly in electrical, temperature, humidity, length and chemistry laboratories.

**Recommendation:** There is a need to support GDM in updating the strategic plan (scope of calibration for the VCs). The GDM capacities to inform the market operators on metrology legislation has to increase, especially on legal requirements related to MAPs sector in key markets, with a focus on the measurement of humidity, pesticide residues, bacteria and metal (lead) contamination.

In terms of legal updates, there is a need to assist GDM in preparing the legal metrology and pre-packaging requirements for the MAPs sector needs. In addition, GDM should be supported in fully aligning the Albanian Law No. 126/2020 "On Metrology" with EU legislation Directive 2009/34/EC;

In terms of capacity-building, there is a need to improve GDM accreditation. The GDM needs should be supported in developing testing methods in order to become ISO/IEC 17025 accreditation-ready, focusing on laboratories measures that hold significance for the MAPs value chain. In addition, the institution needs support in order to update its accreditation for ISO/IEC 17043 "General requirements for the competence of proficiency testing providers". In order to better cater to the needs of MAPs market operators, GDM should be assisted in terms of internationalization and cooperation with other National Metrology Institutions. The cooperation should lie on mutual initiatives for MAPs services, such as preparing and conducting simulated EA MLA Peer Assessment.

**Expected Outcome:** Ensuring a rigorous and more effective GDM contributes to better production, higher safety, health and environmental standards and fairer trades. GDM acquires the capacity to: i) increase awareness on legal requirements for the MAP market operators and further develop the legal metrology on pre-packaging requirements; ii) expand the types of services related to MAPs measurement needs, iii) consolidate its role in ensuring measures related to MAPs sector needs, including here ISO/IEC 17025 and ISO/IEC 17043.

Actors/stakeholders: GDM, MAPs associations and market operators.

#### ACTION 4: SUPPORT INCREASE AND IMPROVEMENT OF PUBLIC AND PRIVATE LABORATORY TESTING SERVICES

**Justification:** Testing capacities in Albania fall short of the needs, due to the inadequate number and accessibility of certified laboratories, a limited range of accredited tests/analyses, high service costs and a poor reputation. The issue is also related to the need for certified intermediaries in charge of taking the samples to be analysed, as there are several reports on issues related to the non-conformity of sampling.

Limits in certified testing capacity and accessibility include both testing services provided by public laboratories as part of the QI functions (FSVI, ATTC Shkoder and Fushe-Kruje) and testing services provided by private and public laboratories on a commercial basis (i.e. upon request of private subjects), i.e. within the framework of services to QI.

Few of the larger value chain actors have in-house (mini)laboratories, and those who do have face deficiencies in equipment and human resources capacities.

GDA capacity building (see above) contributes to create the conditions to increase and improve testing services for MAPs; however, a parallel action is required to expand public and private testing services (more certified services, more laboratories, increased control on certified laboratories).

AUT and ATTC reference labs (e.g. for MAPs in ATTC Shkoder and soil in ATTC Fushe-Kruje) have deficiencies in terms of the type of analysis and tests they carry out that can be upgraded with support.

The accessible financial sources required for this expansion of services should be thoroughly assessed, as there is a complex mix of private, public and international funds that can be used.

#### ACTION 4: SUPPORT INCREASE AND IMPROVEMENT OF PUBLIC AND PRIVATE LABORATORY TESTING SERVICES

**Recommendation:** Encourage, stimulate and support the expansion of public and private testing services (more certified services, more laboratories, increased control on certified laboratories); support the installation of mini-laboratories in the largest MAPs processing enterprises and support those with existing laboratories to enhance the laboratory equipment and human resources capacities.

AUT and ATTC reference labs (e.g. for MAPs in ATTC Shkoder and soil in ATTC Fushe-Kruje) can be supported to enhance their capacities and improve their services to farmers in cooperation with ANES/extension services.

The expansion of testing facilities should be based on a specific action plan, which will identify the needs, the investment absorption capacity in terms of demand and the availability of human, technical and financial resources. A specific analysis of the financial facilities that can be used to expand the testing resources for public laboratories (e.g. national budget, EU/IPA, international development banks loans, bilateral international cooperation) and private ones (e.g. IPARD III for MAPs processors and soft credit lines supported by bilateral cooperation and international development banks)

**Expected Outcome:** The range of certified testing services provided by public and private laboratories is extended to cover the majority of sector needs and the needs of public inspection agencies; the largest MAPs processors/exporters establish mini laboratories for quick test and daily needs.

**Actors/stakeholders:** GDA, FSVI, NFA, ATTC laboratories, private independent laboratories, main MAPs processors/exporters

## 7.2.3 Selected recommended action to enable the involvement of MAPs value chain operators and their associations in QI development and management

ACTION: PROMOTE AND SUPPORT GACP APPLICATION; DEVELOP AND INTRODUCE NEW PROTOCOLS TO COPE WITH EMERGING CHALLENGES IN MAPS PRODUCTION AND COLLECTION, PROMOTE THE ADOPTION OF INDIGENOUS AND NEW VARIETIES IN LINE WITH MARKET DEMAND

**Justification:** Various issues are affecting: i) wild MAPs collection and post-collection practices and, ii) cultivated MAPs.

For wild MAPs collection, which still represent the backbone of dried MAPs business, there are major problems related to inappropriate collection practices, improper post-harvest services and increasing problems with unsustainable exploitation of the wild MAPs resource, which is due to a combination of economic, social and regulatory factors. The introduction and control of the application of FAO Good Collection Practices or, even better, the introduction of those private standards embedding indicators related to environmental and social sustainability (e.g. rainforest or Fairtrade) would contribute to the improvement of one of the aspects related to QI in wild MAPs collection and processing sub-sector and to the establishment of a high-value value chain segment, different from the one based on cultivated MAPs.

As for cultivated MAPs, there are issues with the quality and use of agricultural inputs (residues, soil pollution, contamination). A widespread application of FAO GACP would help in this respect or, even better, the introduction of voluntary standards such as GlobalG.A.P. IFA v6 (for cultivation practices) or FSSC 22000 (focused on food safety in the entire supply chain, useful for vertically integrated companies).

Finally, there are a number of emerging issues related to i) changes in legal requirements, such as the risks of contact contamination between MAPs and other herbs having high content of pyrrolizidine alkaloids (PA)71 and, ii) climate change adaptation, such as the need to introduce a wider range of cultivated MAPs to replace collection of endangered wild MAPs with cultivation, the need to selectively contrast the uncontrolled diffusion of alien varieties (e.g. different varieties of salvia or oregano), the need to improve the quality of propagation material.

Special efforts are also needed to enhance capacities to adapt to climate change impact on MAPs. In this regard, it is essential to highlight the potential for adopting indigenous or new varieties, aligned with the market demand.

The above issues imply the need to develop new protocols for production and cultivation and to amend existing GAPs.

<sup>&</sup>lt;sup>71</sup> Commission Regulation (EU) 2020/2040 amending Regulation (EC) No 1881/2006 as regards maximum levels of pyrrolizidine alkaloids in certain food-stuffs

**Recommendation:** i) Make available and disseminate simple and graphically clear versions of MAPs GACP, possibly presenting them in agile formats (only relevant MAPs for growers, only collection practices to wild MAPs collectors); ii) Organise extension service and field training campaigns in cooperation with ATTC Shkoder and specialized universities (AUT and FN University of Korce); these campaigns should include a ToT component (capacity building and regular updating) and dissemination/extension campaigns. iii) Provide training for farmers, increase awareness among farmers, other value chain stakeholders and expert communities regarding the alarming influence of climate change on medicinal and aromatic plants in Albania. iv) Establish and make operational Operational Groups like EIP Agri in order to deal with specific challenges and provide climate change adaptation support, v) support cooperation between ATTCs, universities and private operators to introduce/adopt varieties that are well-suited to climate conditions and market requirements.

There is a need to conduct studies on the implications of climate change, encompassing current vulnerabilities, weaknesses and risks. This includes assessing the VC actors' awareness and current capacities regarding sustainability considerations and climate impact (with focus on quality and standards).

**Expected Outcomes:** i) Increased awareness and adoption of Good Collection Practices for wild MAPs; ii) Increased awareness and adoption of Good Agricultural Practices by growers; iii) availability of knowledge tools and know-how for an increased range of cultivated MAPs; amendment of GACP to account for evolution in legal requirements and to cope with environmental challenges

**Actors/stakeholders:** ANES, ATTC Shkoder, Fushe-Kruje and Lushnje, university and research institutes providing knowhow and training; MAPs small growers, vertically integrated MAPs sector enterprises (cultivating, processing and exporting MAPs) and private advisors attached to input dealers as beneficiaries, but also involved in creating suitable training modules

## 7.2.4 Selected recommended action to strengthen the development of culture for quality for MAPs value chain operators

#### **ACTION 1: IMPROVING THE CULTURE FOR QUALITY ENVIRONMENT**

**Justification**: Lack of trust among categories of stakeholders and between members of the same stakeholder category is the ultimate root of most problems in MAPs sector development, as well in QIS shortcomings. Insufficient culture for quality leads most institutional and non-institutional stakeholders to focus on formal compliance (documentary compliance, compliance at the moment of control) rather than on substantial compliance over time. Moreover, many stakeholders sincerely believe that the culture for quality of the other stakeholders (institutional and non-institutional) is minimal, with the ultimate result that there is no trust in the professionalism and independence of institutional and non-institutional QI service providers; more in general, good personal relations are often considered a better way to achieve good results than any application of standards or certification or other documentary confirmation of compliance or quality.

Another consequence is scarce cooperation between institutions, weak role of sector associations and limited cooperation between institutions and economic actors, with an overall low level of mutual trust.

Knowing this, many importers also do not trust the documentation provided by Albanian exporters and are often repeating tests and analyses or require such tests to be carried out in their country. This position is sometimes instrumental, as Albanian exporters have no real control on the testing process (e.g. the way in which samples are taken); the final result is that there is a relatively high number of non-compliance and/or poor quality claims, resulting in prices lower than average being paid to exporters.

**Recommendation**: Create a more positive working environment, building trust among stakeholders through a shared culture for quality achieved through communication, awareness and training. Awareness and technical training (ranging from field demonstrations to workshops to side events in conventions and fairs) should be primarily addressed to the upstream part of the supply chain operators, while the downstream, larger operators should develop increased consciousness on the fact that there is no alternative to increase collective actions and specialization for the growth of the sector and to develop a more in-depth knowledge about specific aspects to QI that require collective actions and qualified service providers.

**Expected Outcomes:** A more cooperative working environment would achieve the following objectives:

- 1. Shift focus from formal to substantial and consistent compliance by establishing a code of conduct on quality with the support of MAPs associations.
- 2. Streamline and facilitate relations between stakeholders, especially between testing, inspecting and certification stakeholders (institutional and non-institutional) and supply chain stakeholders.
- 3. Facilitate collective actions (e.g. the establishment of independent service providers), and value chain coordination (e.g. upturning decline of contract farming between processors and small growers).
- 4. Increase the role of ending segments of the value chain in promoting the vectors of quality and reliability of supply. Awareness-raising activities for consumers and business operators should be supported in cooperation with managing bodies of market outlets and supermarkets.
- 5. Better cooperation among QI institutional actors, e.g. between NAVPP and NFA on agricultural input controls or between GDA, FSVI, NFA and private testing facilities.
- 6. Improving and streamlining the legal framework is necessary to improve QIS, but a sincere attitude to cooperation can provide a major contribution to QIs increase.

**Actors/stakeholders**: Culture for quality is an holistic concept. It is therefore important to involve all stakeholders in this process and utilise different tools for different stakeholders groups, such as farmers and local consolidators/wholesalers; regular workshops/operational meetings should be organized to help institutional and non-institutional QIS stakeholders to trust in their potential to act as part of a single tool for quality.

#### **ACTION2: STRENGTHENING QIS IN WILD MAPS UPSTREAM SUPPLY CHAIN**

**Justification:** Wild MAPs component is still the backbone of the MAPs sector in Albania, but its role is rapidly declining because of raise in cultivation, essential oil production (based on cultivated MAPs), structural and unsolved food safety and quality issues and scarce environmental sustainability.

Key issues are the absence of traceability system in the upstream segment of the supply chain, partially related to dysfunctional sytem of wild MAPs collection quotas, lack of proper drying and sorting facilities in collection areas and, lack of clearly defined and enforced minimal quality standards to allow wild MAPs access to maket (i.e. the possibility for collectors to sell sub-standard and unsafe products)..

Another consequence is scarce cooperation between institutions, weak role of sector associations and limited cooperation between institutions and economic actors, with an overall low level of mutual trust.

#### Recommendation:

- » Establish a functional traceability system for wild MAPs, through the application of FAO GACP and incentives for specific certification schemes (eg. Rainforest), having specifi modules for wild MAPs.
- » Support the establishment of a NFA-controlled network of drying facilities in main collection areas.

#### **Expected Outcomes:**

Quality improvement in the Wild MAP component of the MAP value chain in terms of:

- 1. Improved food safety and marketing quality
- 2. Increased environmental sustainability

Actors/stakeholders: NARD, MET, NFA, Municipalities, value chain operators, Rural Parliament.

### ACTION 3: ADAPT AND IMPROVE THE SYSTEM OF INCENTIVES AND CONTROLS TO IMPROVE QUALITY ALONG THE VALUE CHAIN

**Justification**: Culture for quality, adoption of measures for quality improvement and effectiveness of inspection activities would be considerable improved through the revision of the system of incentives and disincentives.

Criteria to access to IPARD III Measures, components of some Measures and National Support Schemes should include elements related to QI. In particular:

- » The scoring criteria to access to IPARD III Measures 1 and 3 are Criteria are not related to the adoption of quality certification schemes.
- » The adoption of a full-fledged traceability system is not included in preferential criteria for access to IPARD III or National Support Schemes.
- » IPARD III facility is structurally oriented towards larger operators; however, a key quality function in MAPs sector, especially in wild MAP collection, is played by small consolidators at the local level, whose performance is poor in terms of food safety and who have no interest in implementing wild MAPs traceability
- The system of wild MAPs collection quotas, in absence of a functioning traceability system is dysfunctional, creating unaddressed risks for food safety and environmental sustainability

#### **Recommendation:**

- » Embed eligibility and scoring criteria to access to IPARD III Measures and National Support Schemes incentives to promote Culture for quality, QI reliability and QIS.
- » Introduce preferential mechanisms to support the establishment of improved MAPs driers addressed to wild MAPs post-harvest treatments near the collection area.
- » Introduce a National Support Scheme for municipal MAPs driers in main production areas, also as a tool to ensure traceability

**Expected Outcome**: Traceability along the VC is increased; the use of QIS and the adoption of certification schemes is substantially increased.

**Actors/stakeholders**: MARD, Municipalities, TIC, main MAPs value chain stakeholders and MAPs processor/exporter associations.



#### 7.3 DEVELOPING A PARTNERSHIP STRATEGY FOR QI IMPROVEMENT

Based on stakeholder analysis, a partnership strategy should be developed to promote compliance with quality standards.

**Figure 7.1** below was produced to display the main partners in terms of influence and closeness to the project. That is based on two dimensions: the vertical axis represents power/influence whereas the horizontal axis represents closeness.

According to the diagram, IDA & ODA, MARD and MoTE are the leading stakeholders. TIC institutions together with QIS institutions are the main institutions to be supported in the first phase. As part of the value chain, the MAPs consolidators and exporters are the most interested and influential stakeholders in bringing forward the QI improvement process. Their influence can be coordinated through the VC associations.

FIGURE 7: 1:STAKEHOLDER ATTITUDE AND INFLUENCE IN ORIENTATION TOWARD QI



Source: Own elaboration

The table below shows the partnership actions required for each of the stakeholders according to their influence and distance.

**TABLE 7.1:** PARTNERS AND PARTNERSHIP ACTIONS OF THE STAKEHOLDERS WITH REGARD TO THEIR EFFORTS FOR AN IMPROVED QIS IN ALBANIA

INSTITUTION	PARTNERSHIP ACTION TO IMPROVE QIS IN ALBANIA
MARD, MoFE	Support MARD in inception design, monitoring and evaluation of quality policy framework and alignment
NFA	Support for increasing awareness and monitoring.

Laboratories	Partnership with IFSV and support one national accredited laboratory (NFA Durres, ATTC Shkoder, AUT laboratory) for increasing human capacities and become accredited for tests required by MAPs operators.	
NAVPP	Support for designing terms of work and increasing inspection capacities at input suppliers and farm level.	
Development Assistance Agencies	Create stable partnerships and increase pool funding for capacity building.	
GDA	Support for legal alignment and increase of capacities for orienting services toward MAPs.	
GDM	Partnership for capacity building and awareness and in orienting services toward the targeted MAPs.	
GDS	Support for legal alignment, translation of standards and increase of capacities for orienting services for MAPs.	
Certification	Inform and consult and establish partnerships with certification bodies. Partnership with input providers (agrochemicals providers), marketing and traceability providers.	
Business associations	Partnership for the implementation of activities for the capacity building and awareness raising-Pilot project for cooperation with laboratories.  Additional cooperation for increasing quality awareness and strengthening culture for quality.	
Operators	Consult and inform and involve them in operational groups.	
Academia	Specific applied research, especially on pest control and PAs.	
ANES	Establish EIP AGRI operational group for overcoming certain issues related to quality and increasing innovation toward quality assurance.	
Media	Inform media and organise awareness-raising campaigns for raising consumers awareness.	
Supermarkets	Cooperate in the implementation of projects for the improvement of traceability.	
Wholesale markets	Cooperate in the implementation of projects for the improvement of traceability.	

Source: Own elaboration

The interventions should aim to improve the culture for quality environment among all nodes of the value chain and consumers. The approach should follow a stepwise process by giving priority to actions according to the time required for the implementation. Actions should aim to enhance capacities to improve QIs but also indirectly influence the achievement of crosscutting goals, namely gender-balanced inclusion. Gender-wise, the main type of support for each groups of actors is different. For women harvesters, there is a need for training on post-harvest and coaching in order to enhance the demonstration techniques in the use of simple dryers and in the use of hygienic harvesting

methods. In the long term, there is a need for strategic orientation of the industry, which can create adaptive conditions in the upstream level. Public extension services and specialized public agencies such as ATTC of Shkoder have the required know-how and experience to include women into training and coaching sessions. Capacity building interventions should consider the constraints hampering women efforts on participating to capacity building events such as training and field demonstration. More insight is needed about gender empowerment in conjunction to QI, based on which, recommendations specifically tailored to gender and QI can be provided.



AAFS, (2019). Medicinal and Aromatic Plants Sector Study. Albania Agribusiness Support Facility (AASF). Institute of Economics Studies and Knowledge Transfer Tirana, 2019. Available online at: https://aasf.com.al/wp-content/uploads/2019/08/Map-EN.pdf

AGT-DSA, (2021). Medicinal and Aromatic Plants sector study. Technical report prepared for GIZ. In: https://bujqesia.gov.al/wp-content/uploads/2021/12/04-MAP-Sector-Study\_FINAL.pdf

AIDA, (2023). Export guide. In: https://aida.gov.al/en/sme/expand-your-market/export-guide

ARDA, (2022). National Support Schemes for year 2022, available at: https://azhbr.gov.al/wp-content/uploads/2022/06/Udh%C3%ABzues-Skema-Komb%C3%ABtare-2022.pdf

Argyropoulos, D (2019). EIP-AGRI Focus Group Plant-based medicinal and cosmetic products. In: https://ec.europa.eu/eip/agriculture/sites/default/files/fg35\_starting\_paper\_2019\_en.pdf

CBI, (2022a). What is the demand for spices and herbs on the European Market? In: https://www.cbi.eu/market-information/spices-herbs/what-demand

CBI, (2022b). What requirements must fresh fruit or vegetables comply with to be allowed on the European market? In: https://www.cbi.eu/market-information/fresh-fruit-vegetables/buyer-requirements#:~:text=Food%20 placed%20on%20the%20EU,outside%20of%20the%20packaging)%3B

CBI, (2023). What requirements must processed fruit and vegetables comply with to be allowed on the European market? In: https://www.cbi.eu/market-information/processed-fruit-vegetables-edible-nuts/buyer-requirements

CFR, (2023). Code of Federal Regulations, Title 21, Volume 3, Part 182: "Substances generally recognized as safe". In: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-182#182.20

ECHA, (2020). Guidance on the compilation of safety data sheets. In: https://echa.europa.eu/documents/10162/2324906/sds en.pdf/01c29e23-2cbe-49co-aca7-72f22e101e20

EFSA, (2023). Cost a concern for EU consumers, with food safety close behind. In: https://www.efsa.europa.eu/en/news/cost-concern-eu-consumers-food-safety-close-behind, last accessed on 3rd February 2023

EMA (2022). Good agricultural and collection practice for starting materials of herbal origin - Scientific guideline. In: <a href="https://www.ema.europa.eu/en/good-agricultural-collection-practice-starting-materials-herbal-origin">https://www.ema.europa.eu/en/good-agricultural-collection-practice-starting-materials-herbal-origin</a>

Council of Ministers, (2022). In: <a href="https://wp-content/uploads/2022/04/Vendim-i-Këshillit-të-Ministrave-për-ndryshime-dhe-shtesa-në-Skemën-Kombëtare-2022.pdf">https://wp-content/uploads/2022/04/Vendim-i-Këshillit-të-Ministrave-për-ndryshime-dhe-shtesa-në-Skemën-Kombëtare-2022.pdf</a>

European Commission, (2004). Regulation (EC) no 852/2004 of the European parliament and of the council of 29 April 2004 on the hygiene of foodstuffs. In: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004R0852

European Commission, (2005). Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC Text with EEA relevance. In: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32005R0396

European Commission, (2006). Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. In https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006R1881

European Commission, (2009). Regulation (EC) No 1007/2009 of the European Parliament and of the council of 16 September 2009 on trade in seal products. In: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1007

European Commission, (2011a). Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. In: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=0J:L:2011:304:0018:0063:en:PDF#:~:text=This%20 Regulation%20provides%20the%20basis,functioning%20of%20the%20internal%20market.

European Commission, (2011b). Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors. In: https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:32011R0543

European Commission, (2013). Regulation (EU) no 1308/2013 of the European Parliament and of the council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007. In: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:347:0671:0854:EN:PDF

European Commission, (2016). Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC. In: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R2031

European Commission (2019). Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019. In: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3Ao2019R2072-20220714&qid=1675872280823

European Commission, (2021). TRACES NT Documentation. In: https://webgate.ec.europa.eu/IMSOC/tracesnt-help/Content/Home.htm?lang=en

European Commission, (2022). Instrument for Pre-Accession Assistance Rural Development (IPARD III) Programme 2021-2027, see description at https://agriculture.ec.europa.eu/international/international-cooperation/enlargement/pre-accession-assistance/overview en, last visited July 2022.

European Commission, (2023a). Food Safety. In: https://food.ec.europa.eu/index\_en#:~:text=The%20 central%20goal%20of%20the,largest%20manufacturing%20and%20employment%20sector.

European Commission, (2023b). Food law general requirements. In: https://food.ec.europa.eu/horizontal-topics/general-food-law/food-law-general-requirements\_en#traceability

European Commission, (2023c). Labelling and packaging. In: https://trade.ec.europa.eu/access-to-markets/en/content/labelling-and-packaging

European Commission, (2023d). Food Contact Materials. In: https://food.ec.europa.eu/safety/chemical-safety/food-contact-materials\_en

European Commission, (2023e). Trade in plants & plant products from non-EU countries. In: https://food.ec.europa.eu/plants/plant-health-and-biosecurity/trade-plants-plant-products-non-eu-countries\_en

European Commission, (2023f). How does TRACES work. In: https://food.ec.europa.eu/animals/traces/how-does-traces-work\_en

European Commission, (2023g). Rapid Alert System for Food and Feed (RASFF). In: https://food.ec.europa.eu/safety/rasff\_en#Learn \

European Commission, (2023h). EU Pesticides Database. In: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/products

European Commission, (2023i). Food Labelling Information System. In: https://ec.europa.eu/food/safety/labelling\_nutrition/labelling\_legislation\_en/food\_labelling\_information\_system/start/select-category

European Commission, (2023j). Operational Groups. In: https://ec.europa.eu/eip/agriculture/en/about/operational-groups

EUROSTAT (2022). International trade data retrieved from EUROSTAT database. Access database online at: https://ec.europa.eu/eurostat/web/main/data/database

FAO, (2006). Guidelines for value chain analysis, available at: https://www.fao.org/3/bq787e/bq787e.pdf

FAO (2014). Medicinal and Aromatic Plants Mini-sector Study. (For the preparation of ISARD)

FAO (2018). Market and value chain analysis of selected sectors for the diversification of rural economy and women's economic empowerment, available at http://www.fao.org/3/18909EN/i8909en.pdf

FAO (2020). Smallholders and family farms in Albania. Country study report 2019. Budapest

FAO, (2022). Labelling and certification schemes for Indigenous Peoples' foods Generating income while protecting and promoting Indigenous Peoples' values. In: <a href="https://www.fao.org/3/cc0155en/cc0155en.pdf">https://www.fao.org/3/cc0155en/cc0155en.pdf</a>

FDA (2005). CPG Sec. 555.425 Foods, Adulteration Involving hard or Sharp Foreign Objects. https://www.fda.gov/media/71953/download

GDA (2023). Organization accredited from GDA. In: <a href="http://GDA.gov.al/organe-te-akredituara/">http://GDA.gov.al/organe-te-akredituara/</a>

Gecaj, M., Shahu, E., Imami, D., Skreli, E., & Jambor, A. (2 o 1 9). Analysing the impact of subsidies on the Albanian agriculture sector. Bulgarian Journal of Agricultural Science, 2 5 (5), 883-890.

GIZ (2021). Gender Analysis for the Fruits, Vegetables, Small Ruminants, Medicinal and Aromatic Plants and agritourism Value Chains in Albania, a report prepared for SRD.

Goudis, A., &Skuras, D. (2021). Consumers' awareness of the EU's protected designations of origin logo. British Food Journal, 123(13), 1-18.

GT Engineering, (2023). The old and the new approach of EU Legislation. In: https://www.gt-engineering.it/en/insights/machinery-directive/the-old-and-the-new-approach-of-eu-legislation/ based on request.

Haas, R., Imami, D., Miftari, I., Ymerie, P., & Grunert, K. (2019). How do Kosovar and Albanian consumers perceive food quality and safety in the dairy sector?. Studies in Agricultural Economics, 121(3), 119-126.

ICC (2023). Certificates of origin. Verification website. In: https://certificates.iccwbo.org/

IDRA/ISETN (2018). Survey on the Fruits, Vegetables, Small Ruminants, Medicinal and Aromatic Plants value chains- An impact assessment report for SARED.

Imami, D. and Skreli, E. (2013). Consumer preferences for regional/local products in Albania. Technical report prepared for FAO GCP/ALB/014/EC IPA 2009.

Imami, D., Chan-Halbrendt, C., Zhang, Q., & Zhllima, E. (2011). Conjoint analysis of consumer preferences for lamb meat in central and southwest urban Albania. International Food and Agribusiness Management Review, 14(1030-2016-82798), 111-126.

Imami, D., Zhllima, E., Canavari, M., & Merkaj, E. (2013). Segmenting Albanian consumers according to olive oil quality perception and purchasing habits. Agricultural Economics Review, 14(389-2016-23484), 97-112.

IMF, (2022). Albania selected issues. In: <a href="https://www.elibrary.imf.org/view/journals/002/2022/363/article-A001-en.xml">https://www.elibrary.imf.org/view/journals/002/2022/363/article-A001-en.xml</a>

INSTAT (2022). The 2021 statistical yearbook. http://instat.gov.al/al/temat/bujq%C3%ABsia-dhe-peshkimi/bujq%C3%ABsia/#tab2

International Trade Centre (2015). Traceability in food and agricultural products. In: https://intracen.org/media/file/12127

MARD, (2022a). Strategy for Agriculture, Rural Development and Fishery, available for public consultation at: https://konsultimipublik.gov.al/Konsultime/Detaje/450, last visited June 2022.

MARD, (2022b), Report for the 13th Subcommittee Meeting Agriculture and Fisheries European Union – Albania.

Marmol, T., Feys, B. & Probert, C. (2015). PESTLE analysis. 50 minutes, gestion & marketing., v. 28, 9-10, ebook EAN: 978-280-6268-37-2.

Müller, D., & Hofmann, M. (2022). Impacts of climate change on agriculture and recommendations for adaptation measures in the Western Balkans.

Regional Cooperation Council (RCC), (2020). Sofia Declaration on the Green Agenda for the Western Balkans, available at: https://www.rcc.int/docs/546/sofia-declaration-on-the-green-agenda-for-the-western-balkans-rn, last visited July 2022.

Risi Albania, (2023). In: https://www.risialbania.al/job-demand/?lang=en

Skreli, E., & Imami, D. (2019). Medicinal and aromatic plants sector study. Institute of Econmics Studies and Knowledge Transfer and Albanian Agribuisness Support Facility (AASF)-ERBD., Tirana, Albania. Retrived from http://aasf.com.al/wp-content/uploads/2019/08/Map-EN.pdf.

SIMS (2020). Annual report for the year 2020, available at: https://ishmt.gov.al/wp-content/uploads/2021/03/Analiza-Vjetore-e-Punes-\_ISHMT\_2020.pdf

Standards Map, (2022). Standards Map free toolkit. In: https://www.standardsmap.org/en/home

Sustainability Map, (2023). In: https://www.sustainabilitymap.org/home

Sutton, W. R., Srivastava, J. P., & Neumann, J. E. (2013). Looking beyond the horizon: How climate change impacts and adaptation responses will reshape agriculture in eastern Europe and central Asia. World Bank Publications.

The Food Safety Project, (2023). Food Safety in Albania. https://www.thefoodsafetyproject.eu/

UNDP, (2022). The Fourth National Communication of Albania on Climate Change. In: <a href="https://www.undp.org/sites/g/files/2022-11/The%20Fourth%20National%20Communication%20of%20Albania%20on%20Climate%20Change.pdf">https://www.undp.org/sites/g/files/2022-11/The%20Fourth%20National%20Communication%20of%20Albania%20on%20Climate%20Change.pdf</a>

UNIDO (2016). Quality infrastructure building trust for trade. In: https://www.unido.org/sites/default/files/2016-05/UNIDO\_Quality\_system\_o.pdf

UNIDO (2023). Quality infrastructure for sustainable development (QI4SD) index. In: https://www.unido.org/sites/default/files/files/2021-06/Factsheets\_KNOWELEDGE\_HUB\_links.pdf

UNIDO, (2011). Pro-poor Value Chain Development: 25 guiding questions for designing and implementing agroindustry projects, available at: https://www.unido.org/sites/default/files/2011-12/Pro-poor\_value\_chain\_development\_2011\_0.pdf

UNIDO, (2018). Quality policy-A practical tool. Available at: https://www.unido.org/sites/default/files/files/2018-06/QP\_PRACTICAL\_GUIDE\_08062018\_online.pdf, last visited May 2023.

UNIDO, (2021). Smart quality infrastructure-Shaping a sustainable future, available at: https://hub.unido.org/sites/default/files/publications/ONLINE\_EN\_SMART\_QI\_PUBLICATION\_o.pdf, last visited May 2023.

UNIDO, (2022). Boosting competitiveness with quality and standards-UNIDO tools and methodlogies, available at: https://www.unido.org/sites/default/files/files/2021-06/Factsheets\_KNOWELEDGE\_HUB\_links.pdf

UNSTAT, (2022). International trade data retrieved from UNCOM Trade Database. Access database online at: https://comtrade.un.org/data/

USDA, (2022). USDA database. Available online at https://apps.fas.usda.gov/gats/ExpressQuery1.aspx

WHO, (2007). WHO guidelines on good manufacturing practices (GMP) for herbal medicines. In: https://apps.who.int/iris/bitstream/handle/10665/43672/9789241547161\_eng.pdf

World Bank, (2023). World Bank's New Country Partnership Framework Supports Greener and More Resilient and Inclusive Growth in Albania. In: https://www.worldbank.org/en/news/press-release/2023/03/16/worldbank-new-country-partnership-framework-supports-greener-and-more-resilient-and-inclusive-growth-in-albania

Zhllima, E., (2021) et Martinovska Stojcheska, A. M., Kotevska, A., Stamenkovska, I. J., Dimitrievski, D., Zhllima, E., Vaško, Ž., ... & Ciaian, P. (2021). Recent agricultural policy developments in the context of the EU approximation process in the pre-accession countries (No. JRC124502). Joint Research Centre (Seville site).

Zhllima, E., Imami, D., &Canavari, M. (2015). Consumer perceptions of food safety risk: Evidence from a segmentation study in Albania. Journal of Integrative Agriculture, 14(6), 1142-1152;

Zhllima, E., Imami, D., Nam, J., Shoshi, P., & Gjika, I. (2022). Awareness of Climate Change Impact and Adaptation in Agriculture—The Case of Albania. European Countryside, 14(4), 604-622.





# ANNEX. MAIN STANDARDS ADOPTED IN MAPS IN WESTERN BALKANS AND RELEVANT CONTENTSPRIVATE STANDARDS MOST COMMONLY ADOPTED IN MAPS SUPPLY CHAINS IN ALBANIA

## A1. MAIN STANDARDS ADOPTED IN MAPS IN WESTERN BALKANS AND RELEVANT CONTENTS

## A1.1 Demand for standards introduction and TIC services MAPs sectors in Albania

As part of the sector analyses, a field survey has been carried out primarily among processing companies, traders and, service providers.

In primary production, certified organic production is relatively common (28% of the sample); the main certified subjects are MAPs processors/exporters which are increasingly vertically integrated, producing the organic MAPs they need.

In the *quality management* area 10% of the sample is certified ISO 9000, mostly in the MAPs sector.

In the *food safety* area, 28% of value chain operators are HACCP certified. HACCP is not a standard, but a management technique, based on principles and control points, which is *mandatory for compliance* under most legal frameworks (including the Albanian one), but whose *certification for compliance is not mandatory*. HACCP compliance is a component of ISO 22000 standard and FSSC 22000 private standard, so those companies which adopt these two certifications are also HACCP compliant.

In the surveyed sample there are no value chain operators certified ISO 22000 (food safety), but 6% of the total is certified FSSC 22000, a private standard based on ISO 22000.

The most common standard adopted for value chain management, including food safety is the private standard BRCGS (10% of the sample).

There is also a relatively high number of MAPs exporters certified Kosher (10%), probably an effect of exporters' interest in the valuable USA kosher market niche.

All other standards are adopted only by a few operators; in particular, the adoption of private VSS standards is very low, while no operators of the sample have an ISO certification related to sustainable production methods (use of energy, social sustainability, environmental management, sustainable use of natural resources, fair trade etc.).

This annex is divided intothree parts:

- 1. Analysis of ISO standards most commonly adopted in MAPs value chains.
- 2. Analysis of private standards adopted by MAPs value chains operators in Albania.
- 3. Review of main private standards adopted by MAPs value chains operators in Western Balkan countries, by standard focus (value chain stage, mixed, voluntary sustainability standards VSS, standards based on cultural values)

For the purpose of this document, the nomenclature and classification used in the International Classification of Standards, Level 1 (fields) has been considered but is not strictly applied, as the purpose of this document is to analyse separately ISO standards from private ones (regardless of content) and VSS standards from standards related to food quality and safety and these last from enterprise management standards.

## A.1.2 Most adopted ISO standards in MAPs processing sectors in Albania and Western Balkans

#### ISO 9000 standards family

The ISO 9000 family is a set of five standards for quality management systems in all sectors. The five standards cover all aspects of the system, from conceptual definition and vocabulary (ISO 9000), to the guidelines to be used by TICs to audit the management systems (ISO 19011)

Out of the five standards, the most relevant for certified implementation by value chain operators is *ISO 9001:15* "Quality system – Requirements", which is a reference point, recognized worldwide, for the certification of the quality management system of businesses of all sectors and of all sizes.

ISO 9001 specifies the requirements against which your quality management system can be certified by an external body. The standard recognizes that the term "products and services" applies to services, processed material, hardware and software intended for your customer.

There are seven clauses in the standard specifying activities that need to be considered when you implement the quality system, namely: i) Context of the organization, ii) Leadership, iii) Planning, iv) Support, v) Operation, vi) Performance evaluation, vii) Improvement.

The standard is referred to the management of the company as a whole (i.e. not to a single product/ service or products/services portfolio) and is processwise, i.e. refer to one or more linked activities that require resources and must be managed to achieve a predetermined output, which may directly constitute the input to the next process.

As part of the standard implementation and certification, a manual, or other documented information, must be prepared to demonstrate how the company meets the ISO 9001 requirements.

Closely connected to ISO 9001-15 there is another standard of the ISO 9000 family, i.e. the standard ISO 9004 "Managing for the sustained success of an organization", which extends the ISO 9001-15 applications to all partners of the certified enterprise.

#### ISO 22000 standards family

The ISO 2200 family is a set of seven standards or groups of standards for food safety management:

- ISO 22000:2018 "Food safety management system Requirements";
- 2. ISO 22001 "Guidelines on the application of ISO 9001:2000 for the food and drink industry"<sup>72</sup>;

- ISO/TS 22002:2009 "Prerequisite programmes on food safety", divided in 6 parts:Part 1: Food manufacturing; Part 2: Catering; Part 3: Farming; Part 4: Food packaging manufacturing; Part 5: Transport and storage; Part 6: Feed and animal food production;
- 4. ISO 22003:2007 "Requirements for bodies providing audit and certification of food safety management systems";
- 5. ISO TS 22004:2005 "Guidance on the application of ISO 22000";
- 6. ISO 22005 "Traceability in the feed and food chain" General principles and basic requirements for system design and implementation;
- 7. ISO 22006 Quality management systems Guidance on the application of ISO 9002:2000 for crop production.

The most relevant standards for the enterprises covered by this study are ISO 22000:2018 and some parts of ISO 22002:2009.

The ISO 22000:2018 standard is based on four elements which are expected to ensure food safety along the food chain, namely: i) interactive communication; ii) system management; iii) food safety hazard control using prerequisite programs and HACCP and, iv) continual improvement and food safety management system updates.

ISO 22000:2018 standard (like previous versions of the same standard) embeds HACCP management system, adding several other features; The HACCP principles and 12 steps are mirrored inside ISO 22000 clauses; correspondence tables are also published.

ISO 22000:2018 is **not** GFSI recognized. However, ISO 22000:2018, ISO TS 22002-1 (food manufacturing) and ISO TS 22002-4 (food packaging) are embedded, together with additional features in the standard in *FSSC 22000*, a private food safety standard, which is GFSI recognized.

No one of the sampled enterprises is certified ISO 22000:2018; however, there are several enterprises certified HACCP (i.e. satisfying part of the requirements for ISO 22000:2018) and a few ones certified *FSSC* 22000.

#### A.2 PRIVATE STANDARDS MOST ADOPTED IN MAPS SUPPLY CHAINS IN ALBANIA

#### A.2.1 Food safety and quality standards and standards related to supply chain segments

#### GLOBALG.A.P. STANDARDS

GlobalG.A.P. is the most popular family of private standards dealing with *primary food production*; however, its additional modules cover also other supply chain segments.

These standards and the relevant certifications have the purpose to ensure the counterparts of the certified company about the application of internationally recognized good practices. The GlobalG.A.P. standards consist of General Rules and Control Points and Compliance Criteria (CPCC.).

GlobalG.A.P. standards include several specifications for value chain segments and/or specific markets and add-on modules.

The primary GlobalG.A.P. certification is IFA – Integrated farm assurance, devoted to mixed farming activities, but there are more specific standards referred (IFA v6) to specific value chain segments. Table 4.x below details standards, add-on modules and other GlobalG.A.P. tools.

The articulated structure of standards offers also the possibility of a gradual introduction of increasingly complex standards. **FigureA 4.1** below offer an example of such approach: in a production system characterized by small production, predominantly localized markets, but high demand for quality it is possible to start introducing LocalG.A.P PFA (Primary Farm Assurance), which is essentially a capacity building tool for gradual introduction or more complex standards.

For those companies which are dealing with only part of the supply chain, it is also possible to introduce good practices referring only to a segment of the supply chain, e.g. the Product Handling Assurance (handling), the Produce Safety Assurance (primary production) or Harmonized Produce Safety Standard (primary production specifically developed for USA market).

For market, market niches or buyers with specific requirements it is also possible to introduce add-on modules, e.g. the BioDiversity add-on to IFA, which guarantees that, in addition to standard IFA provisions, specific good practices for the preservation of biodiversity are also applied. Some add-on modules were developed in cooperation and according to specific buyers' requirements, such as Nurture Module (Tesco, a UK retailer), AH-DLL GROW (for Albert Heijn in the Netherlands or Delhaize in Belgium), Coop Italia Pesticide Transparency.

The IFA standard includes:

- » All Farm Base Module targeting multi-activity farms. This is the foundation of all Scope and Sub-Scope Modules;
- » Scope Modules for specialized farms; there are three scope modules for plants, livestock and aquaculture;
- » Sub-Scope Modules for specific products or segments of the supply chain. These CPCC cover all the requirements for a particular product or different aspect of the food production and supply chain.

**Table A.1** shows the different GlobalG.A.P standards and the good practices to which they are referred. Those standards which are particularly suitable for the fresh plants sector and for the EU market are highlighted in the following table.

FIGURE A: 1GLOBALG.A.P. FAMILY OF PRODUCTS



Customised Solutions: Any customised Standard, Local g.a.p, Add-on, etc

Source: GlobalG.A.P. websitehttps://www.globalgap.org/uk\_en/what-we-do/globalg.a.p.-certification/localg.a.p./

TABLE A.2: SYNOPSIS OF GLOBALG.A.P. STANDARDS AND MAIN TOOLS

STANDARDS	DESCRIPTION		
GlobalG.A.P. Integrated Farm Assurance - IFA	All Farm Base Module for mixed farming activities. defines all the requirements that all producers must first comply with to gain certification.		
Sub-categories: IFA v5.2-v6	Scope Module for flowers, ornamental, hops, aquaculture. Present: IFA v5.2. IFA v6 in force from Q3/2024. If specific for flowers and ornamental plants the standard is known as IFA FO5.2		
	Scope Module for flowers, ornamental primary producers.		
IFA Plants	Scope Module for aquaculture primary producers.		
IFA Aquaculture	Scope Module for livestock primary producers.		
IFA Livestock			
Produce Safety Assurance	Sub-Scope Modulefocused only on food safety elements, thus resulting in a much more limited scope as compared to IFA $^{73}$ .		
Crops for processing	<i>Sub-Scope Module</i> for crops to be frozen, juiced, used to make pre-cooked meals, and used for animal feed, among other types of processing. These crops will be held to the same standard as IFA crops, with the exception of two differences: the risk-based approach to food safety and the auditing rules.		
Chain of Custody	Sub-Scope Module to ensure traceability and segregation of Global G.A.P. products, to prevent dilution or mixing with non-certified products <sup>74</sup> . It is obligatory for companies that label products with a GLOBALG.A.P. identification number.		
Produce Handling Assurance (PHA)	Sub-Scope Module for post-harvest activities, including handling and storage. Mostly used for supply chains.		
Harmonized Produce Safety	Sub-Scope Module for fresh plants is benchmarked to the Global Food Safety Initiative (GFSI) and is comprised of the Combined Harmonized Standard from the International Fresh Produce Association. It has been primarily developed for USA market subjects selling in the USA market.		
Compound Feed Manufacturing	Sub-Scope Module for for quality assurance in the production, supply, and purchase of raw materials destined as feed ingredients for compound feed for those animal productions covered by relevant IFA standards (IFA, IFA v6, IFA livestock, IFA aquaculture).		
Livestock transport	Sub-Scope Module for livestock transport.		
GGFSA v2.1	This module combines Global G.A.P. IFA standard and the FSA (Farm		
GlobalG.A.P./SAI platform solution	Sustainability Assessment) tool developed by Sustainable Agriculture Initiative (SAI) Platform. The producers adopting this solution comply both with Global G.A.P. IFA standard and with the highest environmental standards included in the FSA.		

#### **IFA FRUITS & VEGETABLES STANDARD**

Figure 1. IFA Fruits & Vegetables Standard (Control Points 221)

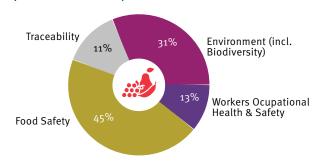
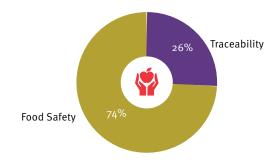


Figure 2. Produce Safety Assurance Standard (Control Points 141)



<sup>73</sup> Produce Safety Assurance has 141 control points (CPSS) vs. 241 CPSS foreseen by IFA
74 The chain of custody standard: "i) Identifies products originating from GLOBALG.A.P. certified production processes and safeguards this reflection of custody standards. "I) Identifies products originating from GLOBALG.A.P. Certified production processes and safeguards this status throughout the entire process, from farm to retailer; ii) Lays out strict requirements for the handling of products originating from certified production processes, including the proper segregation of products that originate from GLOBALG.A.P. certified production processes from those which do not; iii) Obligatory for companies that label products with a GLOBALG.A.P. identification number (e.g., GGN, CoC Number) or participate in the GGN label initiative; iv) Enhances supply chain transparency and product integrity, providing added value and customer reassurance" Source: Global G.A.P. website in: <a href="https://www.globalgap.org/uk">https://www.globalgap.org/uk</a> en/for-producers/globalg.a.p./coc/

Additional modules	Description		
Biodiversity	Includes rules, principles, and criteria for biodiversity management practices, including also IPM practices, protection and restoration measures, biodiversity and soil & nutrients management plans.		
FSMA PSR	Specifically for USA fresh plants market, to comply with the Food Safety Modernization Act Product Safety Rules (FSMA-PSR). In addition to the main IFA module.		
Nurture Module v11.4	Specific to Tesco, adds 20 control points and compliance criteria related to the handling of "unfinished" Tesco products, i.e., products that are not ready for retail sale at the time of dispatch.		
GRASP	Assess social practices on the farm, addressing specific aspects of workers' health, safety and welfare.		
Responsible operations	For animal feed sustainable production (livestock and aquaculture). Applies to feed mills; add on to Compound Food Manufacturing standard. Includes practices such as energy and water reduction, waste and effluents prevention, social engagement promotion, additional product declarations on feed efficiency, environmental impact and GMO.		
SPRING- Sustainable Programme for Irrigation and Groundwater Resources	For improved water resources management. Initially developed for Swiss retailer Coop in 2016, was later generalised.		
RT4 biosecurity	Specifically developed to improve the prevention of banana FOC 4 pathogen.		
SMI-Sustainable Meat Initiative	Specifically developed for Dutch pig breeders finishing pigs for the domestic market; includes additional provisions for animal health, animal welfare and environment protection.		
Animal Welfare	For enhanced animal welfare.		
NON-GM/"OhneGenTechnik"	This add-on to the Compound Feed Standard is aligned to the German OhneGenTechnik voluntary standard75 and allows to get the VLOG logo; this add-on module is applicable to Compound Feed, Livestock, Aquaculture and Chain of Custody (animal products) Standards and is applicable only in EU countries, countries adopting equivalent rules to Reg. 1829/2003 and reg. 1830/2003 or where cultivation and import of GMOs products is not allowed.		
SIZA Environmental	This add-on to GlobalG.A.P. IFA v6 (specific for fresh plants) is specifically developed for South African Producers and allows them to comply also with SIZA environmental standard76 and get the relevant certification.		
Impact-Driven Approach to Sustainability	Specific for flowers and ornamental plant growers. Add on to IFA FO v <sub>5.2</sub> , it is in line with Floriculture Sustainability Initiative requirements regarding digital registration for environmental metrics.		
AH-DLL GROW	This add-on module to IFA v6 is specific for fresh plants and is required for those producers that supply fresh produce to Albert Heijn in the Netherlands or Delhaize in Belgium. Developed with these two supermarket chains; introduces additional control points for hygiene, pesticide residues and foreign bodies for increased requirements as compared with EU legal provisions. Based on Albert Heijn Residue Protocol version 2 (AHP v2). Introduced in 2020.		
Coop Italia Pesticide Transparency	This add-on module to IFA is specific for fresh plants and is required to those producers that supply Coop Italia-branded fresh plants. Initially introduced in 1993 aims at evaluating and monitoring the potential use of a shortlist of agrochemicals.		

75

The German government developed a NON-GM label in line with EU legislation and licensed it to the German association VLOG e.v., the Industry Association Food without Genetic Engineering. Those companies applying the standard have the right to use this logo



The German government developed a NON-GM label in line with EU legislation and licensed it to the German association VLOG e.v., the Industry Association Food without Genetic Engineering. Those companies applying the standard have the right to use this logo



<sup>&</sup>lt;sup>76</sup> SIZA is a South African standard for sustainable management of environmental resources in fresh plants production

Other tools	Description
GGFSA v2.1 GlobalG.A.P./SAI platform solution	This module combines Global G.A.P. IFA standard and the FSA (Farm Sustainability Assessment) tool developed by Sustainable Agriculture Initiative (SAI) Platform. The producers adopting this solution comply
	both with Global G.A.P. IFA standard and with the highest environmental standards included in the FSA.
LocalG.A.P. PFA	Specifically developed for small producers selling primarily in local markets as a capacity-building tool, or to be applied as a local standard for agricultural supply chains especially in emerging markets. It does not provide a certification, but represents the first step towards IFA certification.

FSSC 22000 standard

FSSC 22000 is a *food safety* certification scheme developed by the Foundation for Food Safety Systems Certification (FSSC). The standards cover manufacture of animal products, perishable plant products, products with a long shelf life, and other food ingredients such as additives, vitamins and organic crops and materials for food packaging.

The FSSC 22000 standard was developed by the Foundation for Food Safety Systems Certification (FSSC) based on the need for an independent, ISO-based food safety scheme. The standard is recognized by the Global Food Safety Initiative (GFSI)

FSSC 22000 contains a certification program for food safety systems that incorporates the standards ISO 22000, ISO 22003, and technical specifications for sector prerequisite programs (PRPs), like ISO 22002-1 and PAS 223.

FSSC 22000 applies to organizations of any size which produce food within the following categories:

- » Perishable products of animal origin (meat from cattle, swine, sheep, poultry, eggs, dairy and products from the sea and fishing), excluding slaughterhouses and previous stages;
- » Perishable plant products (fruits and fresh and canned vegetables, canned vegetable products);
- » Products with long life exposed to room temperature (canned, cookies, snacks, oil, mineral water, beverages, pasta, flour, sugar, salt);
- » Biochemical products for food production (vitamins, additives and biocultures), excluding reactions catalysts and other technical and technological aids.

## BRCGS - Brand Reputation Compliance Global Standards

BRC Global Standard for Food Safety is a safety and quality certification scheme. It was developed by BRC, the *British Retail Consortium* (BRC) and covers the whole food manufacturing process, not only retailing; in 2016 BRCGS was purchased by LCG group; following this acquisition the "BRC" acronym was changed to "Brand Reputation Compliance", to provide a more global outreach to the standard, removing the words

"Retail" and "British", considered too limitative.

The standard provides a framework for food manufacturers to assist them in the production of safe food and to manage product quality to meet customers' requirements.

The standards include: i) a main standard, focused on food safety and quality in the whole manufacturing process (i.e. excluding primary production), and, ii) standards referred to specific value chain segments (e.g. handling), actors or inputs (e.g. packaging) and, iii) assessment tools. The specific standards and the assessment tools are summarized in the table below.

The BRCGS standards do not include primary production; however, most standards are suitable for essential oils manufacturing and marketing and for products based on essential oils

Among the assessment tools is worth of mention the "Food Safety Culture Excellence", one of the few audit tools focused on culture for quality.

**TABLE A: 3BRCGS STANDARDS AND MAIN FEATURES** 

STANDARDS	MAIN FEATURES			
STANDARDS FOR CATEGORIES OF PRODUCTS				
Consumer products – 2 standards	Includes also non-food products, articulated in two categories:			
	» General merchandise.			
	» Personal care and household (including cosmetics).			
Plant-based Certification	» Includes operational criteria to ensure that plant-based products are free of material of animal origin;			
	» Can be used as add-on module to any other GFSI recognized standard;			
Gluten-Free Certification Program	» Risk-based, including risks of cross-contamination			
STANDARDS FOR VALUE CHAIN SPE	CIFIC ASPECTS			
Ethical trade and responsible sourcing global standard	» Developed for food and non-food manufacturing, secondary processing and packing sites, including also services to these sites and enterprises			
	» First and so far only scheme of its kind to be recognised by SSCI $^{77}$			
Food safety v9	» Applicable to the food and food ingredient manufacturing, processing and packing industry, not to primary production;			
	» First standard to be benchmarked by GFSI <sup>78</sup> ;			
Storage and Distribution v4	» Ensures quality and safety of products during storage and distribution-including logistics- throughout the supply chain;			
	» Designed for logistics operations dealing with Food, Packaging, and Consumer Products;			
	» Includes add-on modules for: i) wholesale, ii) e-commerce, iii) cross-docking, iv) contracted packaging services, v) contracted waste management, vi) contracted inspection services;			
Packaging Materials V6	» For companies supplying packaging to food producers;			
	» First of this category recognized by GFSI;			
	» Includes also re-packaging activities;			
	» Specifies product safety, quality and operational criteria that must be in place within a packaging manufacturing organisation for legal compliance and consumer protection;			
Retail	» To reduce losses through regulatory fines, product wastage, operational shrink, and customer litigation in retailing;			
	» Involves audits of management systems and assessment of practices and inspection, as compared to inspection-only methods;			
Start!	» Specifically designed for SMEs in food and consumer goods sectors;			
	» Recognises and encourages the development of food safety systems in small sites where food safety management systems are immature;			

It has been announced that, from 2024, the Floriculture Sustainability Initiative (FSI), the Sustainability Initiative Fruits and Vegetables (SIFAV) and the Sustainable Juice Covenant (SJC) will only accept audits from third-party social sustainability standards that have been benchmarked and recognised by the Consumer Goods Forum (CGF) Sustainable Supply Chain Initiative (SSCI).

78 Global Food Safety Initiative

STANDARDS FOR VC ACTORS	
Agents or brokers	For food traders: provides a framework to manage product safety, authenticity, quality and legality for businesses that buy, sell or facilitate the trade of food products, but do not manufacture, process or store the products in their own facilities or on their own sites
ASSESSMENT TOOLS	
Food Safety Culture Excellence	<ul><li>» Based on 20 indicators;</li><li>» Merges indicators of 4 different categories into a single value.</li></ul>

Standards are modified in accordance with the evolution of legal framework and trends. In particular, a new and more comprehensive standard for traceability has been proposed to comply with the "Requirements for Additional Traceability Records for Certain Foods", which is one of the last remaining elements of the FDA's Food Safety Modernization Act (FSMA) to be fully implemented. This enhanced traceability standard would apply to 18 food types, including: i) tomatoes, ii) peppers, iii) melons and, iv) herbs<sup>79</sup>.

10% of the enterprises surveyed in this study were certified  $BRCGS^{8\circ}$ 

**IFS** 

IFS is a family of private standards covering six areas: i) Food products; ii) Logiswtics; iii) Packaging (PACSecure) products; iv) Wholesale Cash & Carry; v) Brokering activities; vi) Human Personal Care (HPC) products. For some areas (Food, Logistics, PACSecure, HPC) there is a twin version of the standard: the basic one and the "Global Markets" one (e.g. "Food" and "Food GM").

IFS "Food" and "Food GM" standards are focused on food quality and safety. The specific characteristic of "Food GM" vs. the basic "Food" standard is its flexibility, as it is possible to scale up compliance with requirements from "Food" to "Food GM" based on a customized approach, i.e. it is possible to set the pace for full compliance with "Food GM" standards, ideally in agreement with customers' needs.

IFS standards are focused on production processes or segments of the supply chain, i.e. are product/service-oriented, not enterprise oriented, as, for example, most ISO standards.

In the surveyed sample in Albania there are no companies certified IFS, but in WB countries there are some, also in areas such as logistics, packaging and cosmetics (HPC), which can be of interest for MAPs processors/exporters

A.2.3 VSS categories and overall EU buyers demand for VSS

VSS categories, private organisations owning them and main TIC

79 It is not clear from the standard if the category of "herbs" includes also spices or other MAPs.

The Voluntary Sustainability Standards – VSS are standards linked to the Sustainable Development Goals; these VSS are commonly divided into nine sub categories, namely: i) Due diligence, ii) Credibility, iii) Traceability, iv) Food Safety, v) Quality, vi) Sustainable business, vii) Human and Labour rights viii) Environment and climate change and, ix) Gender. Each VSS can be included in one or more categories, depending on its scope.

Some ISO standards such as ISO 45001 (Occupational health &Safety), ISO 14001 (Environmental management system) and, ISO 50001 (Energy management) are also linked to SDG, but cannot be classified as VVS according to UNCTAD definition.

There is a large number of VSS. The ITC *Standards Map database* (Standard Map, 2022) considers over 300 VSS<sup>81</sup>, many of which are part of VSS families, such as GlobalG.A.P., which is made of core standards, production-oriented specific modules (which generate a separate standard) and add-on modules. Some large buyers, such as supermarket chains, collaborate with auditing firms to develop their own standards (e.g. Tesco with GlobalG.A.P., with the Nurture 11.4 add-on module)

Regardless of the fact that most VSS include modules for fruit and vegetables and MAP82, few of them are commonly required in Western Balkans, the most common being summarized in table A4below.

It is possible that multiple certificates are required, each relevant to a specific stage of the supply chain. For example, it is possible that GlobalG.A.P is required for general agriculture practices (GlobalG.A.P. IFA v6) and, in addition, IFS for food safety, even if the

<sup>80</sup> Including answers "certified BRC" and" certified BRCGS".

<sup>&</sup>lt;sup>81</sup>The database covers all countries worldwide, but has a specific focus on a limited number of agricultural commodities, excluding fruits and vegetables and MAPs. The database provides information on the following topics: i) a review of over 300 sustainability standards, ii) a tool for multi-criteria comparison of different standards, iii) a tool for self-assessment vs. a specific standard and, iv) monitoring trends of certification schemes (area, number of producers, variation in last year). Among different monitoring features, the database provides: iv.1) an overview of the most common standards adopted for different crop categories and countries, iv.2) trends and figures regarding the use of different standards (surface, number of certified enterprises, growth over time).

<sup>82</sup> For example, RA – Rainforest Alliance has specific sub-modules for sage, oregano, thyme, lavender and Helichrysum. However, there is no known demand for RA MAPs certifications from Western Balkans producers.

same level of certification could be obtained with a GlobalG.A.P. add-on module, such as Produce Safety Assurance and/or Product Handling Assurance - PHA

More broadly, buyers are increasingly demanding the adoption of voluntary standards. In many cases, specific requirements that are not associated with a formalised standard are requested.

Certifications such as GlobalG.A.P. and Smeta emerged as very important factors to be considered as serious and reliable counterparts on the European market.

TABLE A: 4 MAIN VSS ADOPTED FOR FRESH FRUITS AND VEGETABLES AND FRESH AND PROCESSED MAP

ISSUER AND STANDARD/ SCHEME	MAIN FEATURES	MAIN MARKETS WHERE IS REQUIRED	
Issuer: Global G.A.P. Standards: IFA v6	» Sustainable Agriculture practices;	All EEA markets, especially Northern Europe and supermarkets	
Issuer: Sedex Standard: Smeta	» Social audit on workers' conditions;	UK, Germany and other EEA countries; several supermarket chains adopt SMETA	
Other Standards required for	MAPs import in EEA markets, but not commo	nly required from WB producers	
Issuer: Global G.A.P.	» Nurture Module v11.4 – Tesco;	» Nurture Module: UK;	
<b>Standards</b> : buyers-specific modules	» AH-DLL GROW (AlberthHeijn and Delhaize);	» AH-DLL: Netherlands, Belgium;	
	» Coop Italia pesticide transparency;	» CIPT: Italy;	
Issuer: Global G.A.P.	» Biodiversity,		
<b>Standards:</b> Environmental and social responsibility add	<pre>» SPRING (water use);</pre>		
on modules	» GRASP (workers welfare, health, safety);		
Issuer: Global G.A.P.	» Made up of a Global Standard and a separate ETRS Risk Assessment.;	» Most EEA countries;	
<b>Standard</b> : ETRS - Ethical Trade and Responsible Sourcing	·		
<b>Issuer</b> : Amfori	» Social audit system;		
Audit system: BSCI	» Focused on supply chain;		
	» Does not lead to certification;		
	» Can be used as preparatory system for SA8000 certification;		
Issuer: SAI	» Social responsibility certification;		
Audit system: SA8000			
Issuer: Ecocert Standards: Fair for Life	» Fair trade – linked to supply chain;	Buyers, mainly in EEA, (France, Switzerland, Belgium, Netherlands, Germany main countries)	
Issuer: Ecocert Standards: Fair for Life	» Corporate responsibility – social, environmental;	France and other EEA countries	
- and and it districts	» Several companies dealing with essential oils (Serbia, Bulgaria);		

<b>Issuer</b> : Rainforest Alliance <b>Standard</b> : Sustainable Agriculture Standards V1.3: i) farm; ii) supply chain	<ul> <li>Main indicators (88%): environmental, human and labour rights, due diligence, credibility; also gender indicators;</li> <li>Includes wild and cultivated MAPs and herbal teas;</li> <li>1 certified company in Albania;</li> <li>In Europe applicable to Albania, Bulgaria, Croatia, Germany, Poland, Spain;</li> </ul>
Issuer: LCG Group Standard: BRCGS	<ul> <li>» Food safety and quality in processed products (non-primary products);</li> <li>» Several specific standards for supply chain segments or components (e.g. packaging);</li> </ul>
Issuer: GFSI Standards: IFS Food 7	» Food safety and quality in processed products (non-primary products);
Issuer: Fairtrade Standards: Family of 7 standards	<ul> <li>Family of standards relevant to different aspects of sustainability in terms of labour, environment, fair trading conditions;</li> <li>Specific standards for small growers;</li> <li>Applicable to producers in some emerging countries, not including any European country;</li> </ul>
Standards widely adopted in	EEA and USA, but not applicable to Albania
Issuer: Rainforest Alliance	» Focused on sustainable value chains;
Standard: UTZ	» With the introduction of RA Sustainable Agriculture Standards v1.3 is gradually phased out;

#### SUMMARY DESCRIPTION OF MOST RELEVANT VSS

#### **ECOCERT FAIR FOR LIFE AND FOR LIFE**

Fair for Life and For Life standards and certifications schemes are complementary

Fair for Life (FFL) and For Life (FL) are considered by the issuer as two complementary standards sharing a common ground:

- » Respect human rights and fair working conditions;
- » Respect ecosystems and promotion of biodiversity, sustainable agricultural practices;
- » Positive local impact.

The two standards focus on different aspects:

- » FFL is a product certification programme for fair trade and responsible supply chains;
- » FL is a certification programme addressed to companies willing to demonstrate their corporate social responsibility. FL product certification is also an option.

#### Fair for Life

"Fair for Life is a certification programme for *fair trade* in agriculture, manufacturing and trade. It was created in 2006 by the Swiss Bio-Foundation in cooperation with the IMO Group and then taken over by the Ecocert Group in 2014 to meet a specific demand from organic farming stakeholders"<sup>83</sup>.

Fair for Life is based on the concept of "responsible supply chains", giving value to exemplary supply chains, where stakeholders have chosen to act responsibly by implementing good economic, social and environmental practices, including practices such as long-term contracts with fixed prices and volumes, which facilitates the establishment of fair partnerships along the supply chain.

So far, there are over 700 Fair for Life certified companies, whose supply chains involve over 235,000 suppliers and workers. There are no certified Fair for Life companies in Western Balkans, except one in Greece dealing with non-food products.

Depending on the percentage of certified Fairtrade

components a product can be labeled as "Fair Trade" (over 80% of fair trade components) or "Made with Fair Trade Ingredients")

Among the certified Fair for Life companies there are also EU cosmetic producers, which buy essential oils for their activity. More in general, certified Fair for Life enterprises could be interesting as buyers, as they should seek long-term and stable contracts and fair prices.

#### **For Life**

For Life standard and certification is a standard for corporate social and environmental responsibility, i.e. it is focused on a single company rather than on its value chain, including suppliers.

The For Life certified enterprises are less numerous than those ones certified Fair for Life; A Serbian company dealing with essential oil export is the only For Life certified company in Western Balkans

#### GFSI International Featured Standard -IFS Food 7

The Global Food Safety Initiative (GFSI) IFS Food 7 standard is a benchmarked standard for food manufacturers, wholesalers, distributors, agents and brokers. It is mostly used when products are processed or when there is a risk of contamination during packaging in primary packaging. Emphasis is placed on food safety and the quality of processes and products. IFS Food 7 is more commonly used in German and France, but is recognised all over Europe.

It does not cover primary production.

#### **SMETA – Sedex Members Ethical Trade Audit**

Sedex - Supplier Ethical Data Exchange, is an online system to keep data on ethical and responsible practices and allows suppliers and customers to share this information.

SMETA is an audit, designed by Sedex, to help protect workers from unsafe conditions, overwork, discrimination, low pay and forced labour. It is focused on standards of labour, health and safety, environmental performance, and ethics within the audited company or at a supplier site.

SMETA focuses on the whole value chain, i.e. not only on internal corporate performance in terms of responsible practices, but is extended to its suppliers; in the case of Albanian exporters of fruit and vegetables and MAP, they should be SMETA audited in order to supply SMETA certified or BSCI complying buyers.

SMETA is conceptually similar to BSCI (see below); however, it includes some additional parameters, such as maximum working hours.

According to Sedex, SMETA is the world's most widely

used labour audit. Supermarket chains such as Tesco, Lidl and Coop Swiss are among SMETA certified supermarket chains.

More in general, SMETA is designed for a wider European market, as compared with BSCI, which is more focused on EU-countries. However, there is mutual recognition between SMETA certified and BSCI audited companies, meaning that a BSCI audited supplier is considered a suitable partner for a SMETA certified buyers and vice-versa.

One of the enterprises surveyed in this study was certified SMETA

#### SA8000 certification and BSCI social audit system

The Business Social Compliance Initiative – BSCI is a social audit methodology focused on working conditions along the supply chain. Producers that meet all BSCI requirements are can go further and achieve the SA8000 social management certification.

The BSCI audit system is developed by Amfori, while the SA8000 certification was developed by Social Accountability International (SAI).

BSCI is focused, as SMETA, on standards of labour, health and safety, environmental performance, and ethics. Compliance is to be ensured along the value chain, i.e. within the audited company or at a supplier site. This means that suppliers of BSCI audited buyers should also be BSCI compliant or SMETA certified.

BSCI is conceptually similar to SMETA (see above), but is primarily designed for EU subjects, while SMETA was designed for a wider European range of customers.

There is mutual recognition between BSCI audited and SMETA certified companies, meaning that a SMETA certified supplier is considered a suitable partner for a BSCI audited buyers and vice-versa.

#### **Rainforest Alliance**

Developed by Rainforest Alliance, a non-profit organisation, the *Sustainable Agriculture Standards V1.3* is a benchmarked standard, including indicators of different categories.

The main categories, representing 86% of total weight include: i) due diligence, ii) credibility, iii) labour and human rights and, iv) environmental. Other indicators include gender, traceability, sustainable business.

The *Sustainable Agriculture Standards* is articulated on two standards: i) for farmers and NTFP collectors and, ii) for responsible supply chains.

The UTZ certification programme for sustainable agriculture was included in Rainforest Alliance in 2018. With the introduction of the 2020 RA version of the *Sustainable Agriculture Standards* (version 1.3) the UTZ certification programme is gradually phased out.

The RA Sustainable Agriculture Standards is one of the few standards with specific provisions for MAPs (cultivated and processed for herbal teas) and NTFP (wild non-timber forestry products, including MAP). RA can therefore certify sustainable value chains for wild MAPs collection (a NTFP category).

In Albania, there is a single RA certified operator, dealing with MAPs supply chain.

#### **Fairtrade**

Fairtarde is the mark corresponding to a set of standards owned by Fairtrade International, an NGO involving national representatives, e.g. UK Fairtrade Foundation.

Fairtrade International is structured into two organisations: i) Fairtrade International EV, an NGO that develops and adapts the standards over time; ii) FLO-CERT Gmbh is the TIC associated to Fairtrade standards; however, while FLO-CERT is in charge of certification, licensing and regulating the use of the mark is the task of each national representative.

There are seven groups of standards, each with related product-specific standards: i) Standards for small-scale producers; ii) Standards for hired labour organizations (companies); iii) standards for contract production; iv) trader standards (for traders dealing with Fairtrade products); v) Climate standards (for carbon credits); vi) textile standard (covering the whole supply chain and; vii) gold standards (small-scale mining activities).

The standards are primarily focused on the establishment of equitable relations between value chain actors (e.g. fair prices paid to primary producers or fair payment for work), working conditions (e.g. freedom of association, not using child labour) and environmental indicators.

Not all the standards are applicable to all countries: in most standards, it is specifically indicated to which products and countries they are referred.

In Albania, 2% of the surveyed companies are certified Fairtrade.

3.3 Standards related to cultural and religious valuesThe most common standards of this category are those products classified as "Halal" and "Kosher". In Albania, there is a full supply chain specialized in "Halal" products, but not MAPs exporters.

On the contrary, in the Albanian domestic market, it is quite rare to find "Kosher" certified products, while 10% of the enterprises considered in the study are certified as "Kosher".

The main features referred to Kosher and Hala certification for fruit and vegetables and fresh and processed MAPs are described herein below.

#### **Halal standards**

Halal standards refer to those products whose consumption is considered compatible with Muslim religion<sup>84</sup>. There is not a single Halal standard; different countries may apply different standards; different certifying agencies also apply different standards.

Halal principles are applied to all products, including food products, essential oils and products having essential oils as components, such as cosmetics.

Three standards in Halal Food certification were agreed upon and went into effect at a conference held by the member nations of the Islamic Countries Standardization Institute due to research conducted under the framework of the Organization of Islamic Cooperation.

Halal food standards contain Islamic laws that must be observed in various phases of the manufacturing process, including sourcing, preparation, processing, categorization, packing, labelling, regulating, loading, unloading, transportation, distribution, and storage.

Regardless of the production process, some food products are considered "Haram" or not suitable for "Halal" diet.

MAPs are "halal" except those ones that produce drunkenness; however, the standards foresee the risk of contact contamination: any "halal" product which is mixed or comes in contact with not allowed products (e.g. cherries under spirit or herbal spirits) can no longer be classified as "halal".

#### **Kosher standards**

"kosher" is a Jewish word that roughly translates "fit or suitable.". Under Kosher standards, all food falls into three categories: i) meat, ii) milk, iii) all other food ("pareve")

Fresh horticulture products and grains are, in their natural unprocessed state, kosher and pareve. They do not need kashrut certification and can be used with either dairy or meat. However, once a vegetable is combined with a dairy or meat product, it becomes dairy or meat respectively.

A major issue, especially in organic productions is the possible presence of insects on the product. The prohibition against consuming insects, even very tiny ones — as long as they are visible to the naked eye — is mentioned five times in the Torah and is very strict. As a consequence, all products certified Kosher should be carefully tested for the absence of any visible insect.

Kosher certifications can be challenging to achieve for growers. In general, the focus is on cleanliness and washing systems. There are several steps to the process, and each one can be difficult to pass if the produce shows any signs of contamination.

<sup>84&</sup>quot;Halal" means "allowed"

First, the certification agency will examine a sample of the crops. If this sample is determined to be clean, the next step consists of a site inspection. In this inspection, certifiers will examine the entire cycle of operations, including the condition of growing plants and how they are handled after harvest.

Once certification is achieved, each crop must continue to be inspected before and after washing. The afterwash inspection is the most difficult to pass as any evidence of insect matter, no matter how minimal, will render the entire crop unsuitable for Kosher certification. In some cases, Rabbis must be present for the washing process to ensure that everything is done to the highest standards and purity is achieved.

Other issues are relevant to the processing activities, such as equipment which has processed nonkosher products must be completely cleaned before processing a lot to be certified as Kosher.

Kosher market niches are quite important in some markets, as is the case for dried MAPs to be exported to theUSA. In fact, 10% of the exporters interviewed for this study are certified Kosher.





#### **ABBREVIATIONS**

**AASF** Albania Agribusiness Support Facility

ACS Agricultural Collaboration Association

ADAD Organization of Agriculture Development in Mountainous Regions

**AGT** AGROTEC S.p.A.

AIDA Albanian Investments Development Agency

**AKIS** Agriculture Knowledge and Innovation System

**AKVMB** National Veterinary and Plant Protection Authority

**ALL** Albanian lek

**AMAP** Association of Medicinal and Aromatic Plants of Albania

**ANES** Agricultural National Extension Services

**APHIS** Animal and Plant Health Inspection Service

ARDA Agency for Rural Development and Agriculture

ARDPF Agriculture and Rural Development Program Fund

AREB Regional Agricultural Extension Agency

**ASTA** American Spice Trade Association

**A&T** Awareness and Training

ATTC Agriculture Technology Control Center

**AUT** Agriculture University of Tirana

**BIP** Border Inspection Points

**BRC** Brand Reputation Compliance

**BRCGS** Brand Reputation Compliance Global Standards

**BSCI** Business Social Compliance Initiative

**CAS** Chemical Abstract Services

**CASCO** Council Committee on Conformity Assessment

**CBP** Commission of Biologic Production

**CCI** Career Cert Institute

**CEFTA** Central European Free Trade Agreement

**CENELEC** European Committee for Electrotechnical Standardization

**CFR** Code of Federal Regulations

CIHEAM International Centre for Advanced Mediterranean Agronomic Studies

**CLP** Classification, Labelling and Packaging

**CMO** Common Market Organization

**COA** Certificate of analysis sheet

**COI** Electronic certificate of inspection

**COMTRADE** United Nations Commodity Trade Statistics Database

**CNVP** Connecting Natural Values and People

**CPCC** General Rules and Control Points and Compliance Criteria

**DANIDA** Danish International Development Agency

**DCM** Decision of Council of Ministers

**DPPHSSF** Directorate of the Policies in the Plant Health, Seed, Seedling and Fertilizer

**DSA** Development Solutions Associates

**EA** European Accreditation Body

**EBRD** European Bank for Reconstruction and Development

**EC** European Commission

**ECHA** European Chemical Agency

**EEA** European Economic Area

**EEC** European Economic Community

**EFSA** European Inventory of Existing Chemical Substances

**EINECS** European Inventory of Existing Chemical Substances

**EIP-Agri** Agricultural European Innovation Partnership

**EPA** United States Environmental Agency

**EPCA** Essences Producers and Cultivators Association

**ETO** Ethylene Oxide

**ETRS** Ethical Trade and Responsible Sourcing

**ETSI** European Telecommunication Standards Institute

**EU** European Union

**EUROSTAT** Statistical office of the European Union

**FAO** Food and Agriculture Organization

**FAOSTAT** Food and Agriculture Organization Corporate Statistical Database

**FBO** Food Business Operators

**FDA** Food and Drug Administration

**FFL** Fair for Life

**FL** For Life

**FPRC** Fertilizer Products Registration Commission

**FSMA** Food Safety Modernization Act

**FSSC** Food Safety System Certification

**FSVI** Food Safety and Veterinary Institute

**F&V** Fruit and vegetable

**GACP** Good agricultural and collection practice

**GAP** Good Agriculture Practices

**GDA** General Directorate of Accreditation

**GDM** General Directorate of Metrology

**GDS** General Directorate of Standardization

**GFSI** Global Food Safety Initiative

**GGN** Number for organic certification

Globally Harmonized System of Classification and Labelling of Chemicals

GIZ Deutsche Gesellschaft für Internationale Zusammenarbeit

**GLP** Good Laboratory Practice

**GMO** Genetically Modified Organisms

**GMP** Good Manufacturing Practices

**GQSP** Global Quality and Standards Program

**GVA** Gross Value Added

**HS Code** Harmonized System Code

**HACCP** Hazard Analysis and Critical Control Point

IAF International Accreditation Forum

ICC International Chamber of Commerce

IDRA Institute for Development, Research and Alternatives

IEC International Electrotechnical Commission

**IFA** Integrated farm assurance

**IFS** International Featured Standards

**IFSV** Institute of Food Safety and Veterinary

**ILAC** International Laboratory Accreditation Cooperation

IMF International Monetary Fund

**INSTAT** Institute of Statistics of Albania

**IPA** Instrument for Pre-Accession Assistance

IPARD Instrument for Pre-Accession Assistance for Rural Development

**IPM** Integrated Pest Management

**IPPC** International Plant Protection Convention

ISARD Inter-Sectoral Agricultural and Rural Development

**ISCPMS** Intersectoral Strategy for Consumer Protection and Market Supervision

ISETN InstitutSupérieur des Etudes Technologiques de Nabeul

**ISO** International Organization for Standardization

**FSVI ISUV** Institute of Food and Veterinary Safety

ITC International Trade Center

KASH Albanian Agribusiness Council

**LAG** Local Action Group

**LAME** Laboratory of Agro-Environment and Ecology

**LPIS** Land-parcel information systems

MAP Medicinal and Aromatic Plants

MARD Ministry of Agriculture and Rural Development

**MET** Ministry of Environment and Tourism

MFE Ministry of Finance and Economy

MLA Multi-Lateral Agreement

MLR Maximum Level of Residuals

MRA Multilateral recognition agreements

NAPA National Agency of Protected Area

**NAVPP** National Authority for Veterinary and Plant Protection

NCS Natural Complex Substances

**NDC** Nationally Determined Contributions

**NFA** National Food Authority

**NQP** National Quality Policy

**NSB** National Standards Body

NTFP Wild non-timber forestry products

**PDO** Protected denomination of origin

**PESTEL** Political, Economic, Social, Technological, Environmental and Legal Analysis

**PGI** Protected Geographical Indication

**PHA** Product Handling Assurance

**PIS** Phytosanitary Information Systems

**PKIE** National Plan for European Integration

PMRA Pest Management Regulatory Agency

**PPM** Product Prioritization matrix

**PPP** Plant Protection Products

**PPPAMS** Plant Protection Products Application Management System

**PPPRC** Plant Protection Products Registration Commission

**QI** Quality Infrastructure

**QI4VC** Quality Along the Value Chain

**QIS** Quality Infrastructure System

**QMS** Quality Management System

**QR Code** Quick response code

**QSC** Quality Schemes Committee

**QUID** Quantity of certain ingredients

**RA** Rainforest Alliance

**RAEA** Regional Agricultural Extension Agency

**RAPA** Regional Agency of Protected Area

**RASFF** Rapid Alert System for Food and Feeds

**REACH** Registration, Evaluation, Authorization and restriction of chemicals

**RFID** Radio Frequency Identification System

**RPPS** Register of Plant Protection Products

**SAFIAL** Institutional strengthening of the Albanian Ministry of Agriculture and Rural Development for

the food safety management

**SAI** Social Accountability International

**SARDF** Strategy for Agriculture, Rural Development and Fisheries 2021 -2027

**SARED** Agriculture and Rural Economic Development

**SDC** Studies and Development Center

**SDG** Sustainable Development Goals

**SDS** Safety Data Sheets

**SECO** State Secretariat for Economic Affairs

**SESS** State Entity of Seeds and Seedlings

**SID** Substance registration dossier

SIDA Swedish International Development Cooperation Agency

**SIMS** State Inspectoriate for Market Surveillance

**SMETA** SEDEX Members Ethical Trade Audit

**SIMS** State Inspectorate of Market Surveillance

**SNV** StichtingNederlandseVrijwilligers ("Foundation of Netherlands Volunteers")

**SPHPR** Sector of the Plant Health and Protection and Residues

**SRD** Sustainable Rural Development

**SSCI** Sustainable Supply Chain Initiative

**SSH** Albanian Standard

**SWG** Regional Rural Development Standing Working Group

**SWOT** Strengths, Weaknesses, Opportunities and Threats Analysis

**TBT** Technical barriers to trade

**TDS** Technical Data Sheet

**TIC** Testing, Inspection, Certification

**TRACES** Trade Control and Expert System

**TSG** Traditional Specialities Guaranteed

**TWG** Technical working groups

**UFI** Unique formula identifier

**UFN** University Fan NoliKorce

**UN** United Nations

**UNCOMTRADE** The United Nations Comtrade

**UNDP** United Nations Development Program

**UNECE** United Nations Economic Commission for Europe

**UNICERT** United Certification

**UNIDO** United Nations Industrial Development Organization

**UNSTAT** United Nations Statistics Division

**USA** United States of America

**USD** United States Dollar

**USDA** United States Department of Agriculture

**VAT** Value added tax

VC Value chain

**VVS** Voluntary Sustainability Standards

**WB** World Bank

WHO World Health Organization
WTO World Trade Organization





United Nations Industrial Development Organization (UNIDO)

Department of Digitalization, Technology and Innovation (DTI)

Global Quality and Standards Programme (GQSP)

gqsp@unido.org

HUB.UNIDO.ORG