

Grant Proposal

SAFEMAPS: Integrated analytical solutions for improving the compliance and quality of products obtained from medicinal and aromatic plants to ensure the consumer's protection and the sustainable exploitation of biodiversity

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Abstract

Herbal food supplements produced from medicinal and aromatic plants (MAPs) are becoming increasingly popular to complement synthetic pharmaceuticals. This category of products is regulated under more lenient food product regulations rather than the stringent rules applicable to medicines. The effectiveness and safety of these products rely on various factors, including the varying phytochemical composition of the original plant material, potential adulteration, substitution and contamination from biological and chemical sources. The SAFEMAPS scientific research project aims to provide integrated analytical solutions that enhance the compliance and quality of food supplements derived from aromatic and medicinal plants. This project seeks to improve the safe use of these products by consumers, while promoting the sustainable exploitation of plant biodiversity. Within this project, an experimental model will be developed to assess the identity, authenticity, traceability and quality of herbal food supplements. This model

includes analytical solutions that integrate phytochemical and molecular genetic analyses. The proposed solutions will prioritise the needs of the food supplements industry, particularly regarding the quality and compliance of herbal products sold in Romania and across the European single market. These solutions will also tackle various aspects of the supply chain, including growers or collectors of medicinal and aromatic plants, processors, importers and final consumers.

Keywords

commercial herbal products, food supplements, food safety, food quality, label ingredients, declared composition, *Hippophae rhamnoides* (syn. *Elaeagnus rhamnoides*), *Lavandula angustifolia*, *Gentiana lutea*, *Dactylorhiza maculata*

State of the art: Regulatory framework, Quality issues and Risks associated with Commercial Herbal Food Supplements

European and Romanian national legislation on herbal food supplements

In the European Union (EU), herbal products are categorised into two groups: herbal medicines, which are regulated by medicinal product laws and herbal food supplements, which are considered food products. The main regulatory framework for herbal food supplements in the EU is Directive 2002/46/EC (EU 2002), which harmonises the regulations of Member States (MS) regarding food supplements. Additionally, Directive 2004/24/EC on traditional herbal medicinal products (EU 2004) provides a simplified procedure for registering certain herbal products as medicinal products. The European Medicines Agency (EMA), through its Committee on Herbal Medicinal Products (HMPC), creates monographs that outline the therapeutic uses and safety conditions for medicinal and aromatic plants (MAPs) and their derived products. The HMPC collaborates with the European Directorate for the Quality of Medicines and HealthCare (EDQM) to develop Ph. Eur. monographs, which include quality standards and analytical methods for controlling and identifying plant material and impurities (EDQM 2023). Romanian legislation aligns with European regulations through several national laws and orders: Law 56/2021 regarding food supplements; Law 491/2003 concerning medicinal and aromatic plants; Order 244/2005 related to the processing, manufacturing and marketing of medicinal and aromatic plants; Orders 1228/2005 and 63/2006, which establish technical standards for marketing food supplements; Order 1946/2014, which outlines the notification process for finished products based on medicinal plants; and Order 1069/2007, which includes standards pertaining to food supplements (Consiliul Concurenței 2022). Plant food supplements must be registered before entering the Romanian market. The Ministry of Health oversees supplements consisting solely of vitamins or minerals. Meanwhile, the National Institute of Research and Development for Food Bioresources (IBA) and the Regional Public Health Centres monitor supplements that contain substances beyond vitamins and minerals with physiological and/or

nutritional functions. Notifications for herbal tea and plant food supplements are directed to the IBA. To market food supplements within the EU, Regulation (EC) No. 764/2008 mandates that an MS must permit the sale of products legally sold in another MS, even if they are produced according to different technical standards (EU 2008). EU Directive 2002/46/EC establishes dosage limits and labelling requirements; however, each EU MS is responsible for its national enforcement and regulation (EU 2002).

Quality issues of herbal food supplements

Herbal food supplements consist of complex combinations of plant materials and phytochemical compounds. The natural variability in the phytochemical profile of raw plant materials - stemming from environmental factors, soil conditions, climate and other influences - directly impacts the quality of the final product. This variability can lead to significant differences in the bioactive content of the supplements (Ichim et al. 2024). Several external factors, beyond natural variations, can negatively affect the quality of herbal food supplements. These include adulteration, substitution and contamination (Ichim and Booker 2021, Ichim et al. 2020, Ichim 2019). Adulteration involves illegal practices, such as the deliberate addition, partial or total replacement or modification of product components. Economic reasons often drive this and may consist of using plant fillers, substituting lower-quality or cheaper plant materials or adding natural or synthetic substances to create a specific chemical profile or biological effect. Substitution is the accidental replacement of a component due to misidentifying plant species, often occurring amongst similar species within the same genus or hard-to-distinguish hybrids. Misinterpretations of vernacular names and scientific synonyms can further complicate raw material identification. Contamination arises from chemical (e.g. heavy metals, toxins) or biological (e.g. microorganisms, unintended plant or animal species) sources occurring naturally or through poor agricultural and processing practices, careless harvesting etc.

Risks associated with low or variable quality of herbal food supplements

The risks associated with the low or variable quality of medicinal and aromatic plant herbal food supplements (Ichim et al. 2024) stem from the deliberate or accidental use of undeclared ingredients and can arise at any point along the supply chain, from raw plant material to the final marketed product (Badea et al. 2017).

Incorrect processing, manufacturing and storage methods, as well as false or incomplete labelling, can reduce or eliminate beneficial effects and may cause severe adverse reactions (Raclariu-Manolica et al. 2020). Additionally, processors often rely on non-professional collectors to meet the high demand for MAPs. These collectors, lacking basic knowledge of sustainable harvesting, pose a serious threat to vulnerable medicinal plant species, some of which are on the verge of extinction (INCDDBA – IBA București 2018).

In Romania, herbal food supplements are marketed without being subject to a monitoring programme of adverse effects (nutriviigilance) (Morgovan et al. 2019) similar to the pharmacovigilance programme for conventional medicines (INCDBA – IBA București 2018). This is particularly concerning because food supplements can be purchased without a prescription (over-the-counter) and specialist recommendations. They are widely available in pharmacies, health food stores, supermarkets and online (Consiliul Concurenței 2022).

These issues, combined with misleading claims about the absolute safety of herbal food supplements (Posadzki et al. 2012), create serious health risks for consumers. Therefore, it is essential to develop and implement analytical methods that provide accurate information about the composition and quality of the final product (Raclariu-Manolică et al. 2023, de Boer et al. 2015).

Solutions, Objectives, Innovative Aspects and Contribution

Project proposed solutions

Within the SAFEMAPS project, a series of solutions will be developed to enhance consumer safety and promote the sustainable use of plant biodiversity. This will ultimately lead to significant improvements in the market for herbal food supplements.

These solutions include:

- Recommendations to improve transparency and regulatory compliance in the trade of herbal food supplements.
- A study on consumer perception of herbal food supplements will be conducted to assess their level of awareness and identify potential vulnerabilities in the regulatory and control framework.
- Laboratory-scale analytical procedures for evaluating the identity, authenticity and quality of herbal food supplements used in phytotherapy.
- Laboratory-scale analytical procedures for assessing the identity, authenticity and traceability of food supplements derived from plant species under special protection and conservation regulations.
- An experimental model for evaluating identity, authenticity, traceability and quality of herbal food supplements. This model will integrate analytical solutions to enhance consumer safety and promote the sustainable exploitation of biodiversity.

The proposed solutions are customised to meet the needs of the herbal food supplement industry, particularly in maintaining product quality and ensuring regulatory compliance. Leveraging the knowledge gained from this project, these solutions can be transferred from research to market applications as innovative tools, enhancing competitiveness - especially internationally.

Project objectives

The SAFEMAPS project aims to develop and verify, at the laboratory level, an experimental model for evaluating the identity, authenticity, traceability and quality of herbal food supplements. This model will consist of integrated analytical solutions designed to enhance consumer safety and promote the sustainable use of biodiversity. The new analytical solutions will complement existing tools and address the entire supply chain — from growers and collectors to end users — helping consumers make informed decisions and increasing their confidence in the safety of herbal food supplements. The project will also improve the identification and authentication processes for processed herbal products, which have often been challenging or impossible to verify using traditional analytical methods.

The general objective of this project is to evaluate medicinal and aromatic plants (MAPs) and their derived products to ensure their safe use for human health within the framework of a sustainable bioeconomy and the responsible exploitation of plant biodiversity.

The specific objectives of the project are as follows:

1. Enhancing transparency, compliance and oversight in the trade of herbal food supplements by identifying specific challenges and developing recommendations to address deficiencies.
2. Ensuring a high level of consumer protection by identifying obstacles related to the identity, authenticity and quality of food supplements through analytical and experimental studies, as well as by developing analytical testing procedures.
3. Promoting the sustainable use of biodiversity by evaluating the identity, authenticity and traceability of food supplements derived from plant species under special protection and conservation regulations through analytical and experimental studies.
4. Integrating experimental results to develop and validate comprehensive analytical solutions for assessing herbal food supplements' identity, authenticity and quality.

Innovative aspects of the project

In relation to the current state of the field at both the national and international levels, the novelty of the SAFEMAPS project lies in the fact that it will:

1. Conduct a comprehensive and integrative study to identify vulnerabilities throughout the entire supply chain of herbal food supplements. This study will lead to the development of customised analytical solutions and practical recommendations to improve the regulatory framework and enhance accountability amongst economic operators.
2. Perform a complex analysis of transparency and compliance in the national trade of herbal food supplements to identify critical issues that may compromise consumer safety.

3. Assess consumer perception of herbal food supplements to evaluate their level of awareness and identify potential vulnerabilities in the regulatory and control framework.
4. Conduct a comprehensive phytochemical and genetic analysis to evaluate herbal food supplements' identity, authenticity, traceability and quality. This analysis will cover various study models, including plant species used in phytotherapy and food and those under special protection and conservation regulations.
5. Develop integrated analytical solutions for evaluating herbal food supplements' identity, authenticity and quality. These solutions will be transferable to economic operators in the industry, improving product safety and compliance.

According to publicly available information, these studies and analyses will be conducted for the first time in Romania within an institution entirely independent of the regulatory and control system and with no financial ties to any actors in the food supplement market. This guarantees both the impartiality of the approach and the scientific rigour derived from the project team's demonstrated expertise and experience.

Scientific and technical contributions

The results of the SAFEMAPS project will significantly enhance research in this field, offering original, innovative and competitive contributions. The recommendation package for improving transparency and compliance in the trade of medicinal and aromatic plant (MAP)-based food supplements stands out due to its foundation in comprehensive analytical and experimental studies covering all links in the supply chain. This package will identify key issues and propose targeted solutions, ensuring its practical applicability in shaping regulations for the herbal food supplement industry.

Unlike the unidirectional approaches of some market actors (e.g. the Competition Council, which focuses solely on market competition), this recommendation package provides a holistic and exhaustive perspective. The study on consumer perception of herbal food supplements - designed to assess awareness levels and identify potential vulnerabilities - differs from previous studies in that it primarily focuses on human health risks. This study will be based on qualitative and quantitative data derived from the analytical and experimental research conducted within the project.

Additionally, incorporating real-world data from the national food market will be a crucial tool for conveying consumer expectations to market regulatory institutions and economic operators throughout the supply chain. Compared to existing analytical procedures, the new analytical methods developed in this project will be specifically tailored to the unique characteristics of each investigated plant species. These methods will be designed to optimise the balance between specificity, ease of implementation and cost-effectiveness, ensuring high applicability within the industry.

The experimental model developed through this project will be unparalleled in its complexity. Integrating analytical, experimental, phytochemical and genetic studies will provide a comprehensive and holistic approach through integrated analytical solutions.

This will enhance consumer safety and promote the sustainable exploitation of biodiversity.

Approach and Activity planning

Methodological approach

The study models will include the following plant species:

- *Hippophae rhamnoides* L. (syn. *Elaeagnus rhamnoides* (L.) A. Nelson) (sea buckthorn);
- *Lavandula angustifolia* Mill. (lavender);
- *Gentiana lutea* L. (great yellow gentian);
- Orchidaceae species, specifically *Dactylorhiza maculata* (L.) Soó (heath spotted orchid).

These species were chosen based on their: (i) significance to the bioeconomy, (ii) widespread use in phytotherapy amongst the population and (iii) challenges related to identifying plant material using standard analytical methods. Furthermore, the two plant groups under special protection and conservation status were selected for their essential role in biodiversity conservation (CITES 2025), even though they are used as ingredients in herbal food supplements.

The status of trade compliance herbal food supplements will be assessed by comprehensively analysing product labels and their presentation to consumers. The rapid growth in the supply and sale of food supplements is particularly evident online, representing a less transparent and more challenging marketing channel that increases consumers' risk of deceptive practices (WHO 2013). In this context, our project will concentrate on products available in physical stores (e.g. pharmacies, grocery stores, health food stores) and online platforms (e-commerce), including manufacturers, pharmacies and health food stores, to ensure their transparency and compliance with existing standards and regulations.

Reference materials for the models studied will include:

- Biological material (systematically authenticated) sourced from wild flora, certified cultivations and botanical garden collections, amongst others.
- Authenticated product samples and extracts, including fixed and volatile oils, obtained from manufacturers and/or speciality traders.
- Authentic phytochemical spectra and fingerprints derived from authenticated biological material and/or extracted from official monographs, virtual libraries and specialised literature.

- DNA sequences are used as references from authenticated biological material and public databases such as GenBank/NCBI and the Barcode of Life Data System (BOLD).

The biological reference materials (including herbarium vouchers) and authenticated product specimens will be stored in a dedicated space under optimal, controlled conditions (e.g. temperature, humidity, light), thereby establishing a permanent collection. Specific phytochemical and genetic analytical methods will be used to evaluate identity, authenticity and quality.

To assess quality and authenticity, phytochemical investigations will be conducted using the following analytical techniques: Thin-Layer Chromatography (TLC), High-Performance Liquid Chromatography with Ultraviolet Diode Array Detector (HPLC-UV-DAD), Gas Chromatography coupled with Mass Spectrometry (GC-MS) and UV-Vis Spectrophotometry, based on the classes of specific bioactive compounds (marker compounds) for each species. Given the phytochemical complexity of plant raw materials and derived products, the limitations of some analytical methods and the increasingly intricate strategies for adulteration, relying on a single analytical method may not yield enough data for quality and adulteration control (Ichim et al. 2024). Therefore, utilising multiple complementary phytochemical analysis methods can deliver a more comprehensive understanding of the data.

Genetic investigations will use the DNA barcoding method to identify raw materials and authenticate food supplements labelled as containing the target species. This technique supports global efforts to promote innovative genetic methods alongside traditional phytochemical approaches (Thakkar et al. 2020). The DNA barcoding method is widely utilised as a molecular identification tool, including for verifying the authenticity of food products to identify labelling deficiencies, adulteration or contamination (Raclariu et al. 2017, Raclariu-Manolică and de Boer 2022). Adopting innovative tools that can enhance plant food supplements' regulation and quality control processes is a top priority in this field and the DNA barcoding method stands out as one of the most endorsed analytical approaches in this context (Raclariu-Manolică et al. 2023).

Activity planning

The activities are organised into four annual stages:

- I. Evaluation of online and over-the-counter trade in herbal food supplements.
- II. Evaluation of identity, authenticity and quality of food supplements – a case study of *E. rhamnoides* (sea buckthorn).
- III. Evaluation of identity, authenticity and quality of food supplements – a case study of *L. angustifolia* (lavender) and *G. lutea* (great yellow gentian).
- IV. Evaluation of identity, authenticity and traceability of food supplements derived from orchid species.

V. Development of a demonstrative model for assessing the compliance and quality of herbal food supplements.

Cross-sectional activities:

I. The dissemination and communication of the project results will be conducted in phases according to the dissemination and exploitation plan.

II. Management activities include monitoring, resource management, preparation of work plans, experiment planning, preparing stage/annual and final reports and communication with the Contracting Authority.

Project impact

Scientific impact

The project will advance scientific research in the field of herbal food supplements by generating new knowledge regarding the current situation of the Romanian market. It will also introduce new procedures and analytical approaches for evaluating herbal supplements' identity, authenticity and quality. These outcomes will serve as a foundation for expanding research on the project's theme and can be applied in the teaching activities of post-secondary and higher education institutions in the field. Through communication and dissemination, the national and international scientific communities will know the integrated analytical solutions proposed within the SAFEMAPS project. These solutions address the quality of food supplements and the compliance of the trade profile, as well as the impact of these aspects on consumer safety. Additionally, SAFEMAPS will contribute to establishing new collaborations and consortia with researchers and research institutions interested in exploring and deepening this topic.

Socio-economic impact

The scientific achievements of this project will have an economic impact by benefitting economic agents in the food supplements industry who are interested in applying sound research practices and business strategies that align with specific regulations while promoting innovation within their companies. The integrated analytical solutions developed within the framework of the project will assist manufacturers of herbal food supplements in overcoming challenges related to product design, development strategies and research-related issues. Companies can produce higher-quality products by implementing phytochemical and molecular authentication processes, along with quality assessment during the product design and development cycle. This approach will enable them to create a new marketing strategy focused on product quality and safety, offering a competitive advantage in the market. The project's outcomes could also be economically capitalised by launching a spin-off or start-up that provides molecular authentication services to suppliers of raw materials (such as plant material, extracts, oils etc.) and businesses that produce or import food supplements. These services would

verify and document the quality control of their products. Authenticated products have added value and can command higher prices and easier access to broader markets. The feasibility of developing such a spin-off or start-up will be evaluated as part of the assessment of authentication methods. This opportunity will be discussed and agreed upon with the Business Technology Incubator (ITA BINNOTEH) of the National Institute of Research and Development for Biological Sciences (NIRDBS) if it is deemed viable.

Social impact

The expected results focus primarily on enhancing the quality of life by establishing a more transparent, higher-quality and safer food supplement market. Raising public awareness of this issue will empower consumers to make informed decisions regarding the products available on the market. Simultaneously, drawing from the analyses and experimental studies conducted within the project, recommendations will be formulated to improve the regulatory framework governing the food supplements market. Moreover, the project seeks to promote greater responsibility within the industry by increasing awareness amongst economic agents in the food supplements field about the risks of adulteration and contamination. Additionally, the project will build consumer confidence in the food supplements sold in the Romanian market. This will foster market growth and increase the sector's income and job opportunities.

Environmental impact

Through its activities, the project will raise awareness of the use of wild plants, focusing on species with special conservation status, such as vulnerable or endangered species. The results of the project, particularly in addressing traceability issues related to species with special conservation status, will contribute to achieving the goals of the Nagoya Protocol. The protocol calls for the "fair and equitable sharing of the benefits arising from the use of genetic resources, including through adequate access to these resources and the appropriate transfer of relevant technologies, while considering all rights over those resources and technologies, as well as ensuring proper financing. This, in turn, contributes to the conservation of biological diversity and the sustainable use of its components.

Dissemination and Exploitation of Results

The dissemination and exploitation activities proposed in SAFEMAPS aim to facilitate the communication of information and research results to all relevant stakeholders. These include the national and international scientific community, regulatory and policy-making authorities in the food supplements market, based on PMA, public institutions in the field of environmental protection, the herbal food supplements industry, NGOs in the field and the general public interested in this topic — primarily consumers (to protect their health). The dissemination plan includes a well-defined schedule of dissemination actions and the periods for their implementation.

The project results will be published in articles in Clarivate's Web of Science (WoS)-indexed journals. The Open Access (OA) publishing option will be selected whenever possible. Additionally, during the project's implementation, the results will be disseminated through oral and/or poster presentations at scientifically relevant international conferences. A bilingual website (RO/EN) dedicated to the SAFEMAPS project will be created and updated at least every six months to provide an easy access point for information about the project (scope, purpose, objectives, activities, results, resources and team members). To communicate the project's topic and results, a SAFEMAPS workshop will be organised, focused on communication and interaction with representatives of target groups.

The main results obtained within the project, which have potential applicability in the economic sector, include laboratory-scale analytical procedures for evaluating the identity, authenticity and quality of food supplements. These procedures can be applied to raw materials (such as plant material, extracts, oils etc.) and finished products. The methods and procedures developed within the project will diversify the research services NIRDDBS provides to professional economic agents and other public and private institutions.

Letters of support

Letters of support were received from the Competition Council (Consiliul Concurenței), Association for Romanian Consumer Protection (Asociația pentru Protecția Consumatorilor din România), and Ministry of Environment, Waters and Forests (Ministerul Mediului, Apelor și Padurilor).

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Grant title

Integrated analytical solutions for improving the compliance and quality of products obtained from medicinal and aromatic plants to ensure the consumer's protection and the sustainable exploitation of biodiversity (SAFEMAPS).

Hosting institution

"Stejarul" Research Centre for Biological Sciences (Piatra Neamt, Romania) of the National Institute of Research and Development for Biological Sciences.

Author contributions

All authors have contributed equally to the project proposal.

Conflicts of interest

The authors have declared that no competing interests exist.

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