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CURRENT STATUS AND THE NEED TO IMPROVE THE STANDARDIZATION OF ESSENTIAL OILS INTENDED FOR THE PRODUCTION OF FOOD SUPPLEMENTS

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review paper

Summary

The purpose of essential oil standardization is to ensure the quality, safety, and efficacy of their use in the production of food supplements, as well as in other pharmaceutical and cosmetic products. The current situation is characterized by fragmented standards, inconsistent quality control practices, and insufficient regulatory frameworks, which hinder their broader and safer application. Standardized essential oils or isolated active components most commonly peppermint, oregano, lemon, lavender, cinnamon, clove, basil, and others are frequently used in food supplement formulations. Due to potential toxicity at higher doses, they must be used with great caution. Numerous internal, national, and international standards are currently applied in defining the quality of essential oils. Standardization is most often based on pharmacopoeial monographs (e.g., Ph. Eur., USP), ISO standards (ISO/TC 54), the Codex Alimentarius, GRAS status (FDA, USA), and European regulations (EFSA). Regulation (EC) No 1334/2008 defines the use of flavorings, including essential oils, in food and food supplements, while Regulation (EC) No 1925/2006 regulates the addition of biologically active substances to food. Manufacturers of food supplements, in accordance with GMP and HACCP principles, must meet clearly defined requirements related to essential oils. Although certain standards and statuses, such as ISO and GRAS, exist, they still do not cover the full complexity and variability of essential oils as functional components. The aim of this paper is to define the current status and the need to improve the standardization of essential oils intended for the production of food supplements.

Keywords: essential oils, standardization, food supplements

Introduction

Essential oils (EOs) are complex mixtures of volatile bioactive compounds, such as monoterpenes, sesquiterpenes, phenols, and esters, which contribute to their pharmacological properties. Their chemical composition depends on the plant species, phenological stage, geographical origin, climate, cultivation method, and extraction technique (Bakkali et al., 2008; Turek and Stintzing, 2013). Their use in food supplements has been increasing due to their potential benefits for immunity, digestion, mood, and stress relief (da Silva Bomfim et al., 2020). However, the market faces major challenges, including fragmented standards, a lack of harmonization, and insufficient quality regulation (Petina, 2023). Variability in plant species, geographical origin, and extraction methods results in inconsistent quality and composition, which poses a challenge for ensuring safety, efficacy, and regulatory oversight (da Silva Bomfim et al., 2020; Petina, 2023).

Standardization aims to ensure consistent quality, safety, and efficacy of essential oils in food supplements. Essential oils generally contain primary, secondary, and trace components, leading to significant batch-to-batch variability. There are risks of toxicity associated with certain compounds, such as eugenol or menthol, when used in high doses. Additionally, adulteration (e.g., dilution with cheaper oils, addition of synthetic additives) remains common on the global market. Therefore, it is necessary to establish standardized protocols for sourcing, manufacturing, analysis, and application to protect public health (Chemat et al., 2020).

The aim of this paper is to provide a critical overview of key issues in the standardization of essential oils intended for food supplements, clarify the existing regulatory and technical framework, and highlight the need for improvement and harmonization of standards.

Chemical nature and bioactivity of essential oils for the production of food supplements

Essential oils show pronounced variability due to differences in botanical origin, geographical and climatic conditions, and extraction methods. Active components determine their therapeutic properties but also their potential for toxic reactions when consumed in high doses (Burt, 2004). For example,

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menthol—the main constituent of peppermint oil—has calming effects, but excessive intake may cause irritation.

The main chemical groups present in essential oils include monoterpenes (e.g., limonene, pinene), sesquiterpenes (e.g., β-caryophyllene), phenols (e.g., thymol, carvacrol), aldehydes, ketones, esters, and oxidized derivatives. Essential oils may contain:

- primary components (20–95%) – e.g., menthol in peppermint oil
- secondary components (1–20%) – contribute to synergistic effects
- trace components (<1%) – may exert strong biological activity despite low concentrations (da Silva Bomfim et al., 2020)

Due to their lipophilicity, bioactive molecules from essential oils readily cross cell membranes and exhibit diverse biological activity, including antimicrobial (bacteria, viruses, fungi), anti-inflammatory and antioxidant effects, immunomodulatory, sedative, and carminative actions, as well as stimulation of gastric secretions and bile flow, which supports digestion (Chemat et al., 2020).

Depending on the dose, composition, and route of administration, essential oils may function as beneficial dietary supplements or, in some cases, as potential toxicants. For example, high concentrations of eugenol may cause cytotoxicity, whereas limonene and linalool show good tolerability at low oral doses (European Commission, 2008).

In supplement formulation, essential oils are used because of their potential functional benefits (e.g., digestive and immune effects), aromatic properties that facilitate intake, and synergistic action with other active substances (e.g., vitamins, probiotics). Due to their complex and variable nature, ensuring a standardized chemical profile through methods such as GC-MS (gas chromatography–mass spectrometry) and chemometric analysis is essential for their safe and effective application in food supplements (Pavoni et al., 2020). Essential oils in food supplements represent one of the fastest growing areas of functional and natural nutrition. Their use has expanded from aromatherapy into clinical nutrition due to bioactive compounds with anti-inflammatory, antimicrobial, digestive, and sedative effects (EFSA, 2021; Kasper et al., 2010). They are used to support immunity, digestion, mental health, and circulation (EFSA, 2021). Advances in technology have enabled microencapsulation, adsorption, and complexation of essential oils with cyclodextrins to enhance stability and facilitate processing into conventional forms—tablets and capsules (Gharsallaoui et al., 2007; Szente and Szejtli, 2004). Demand for plant-based and natural supplements, particularly within clean-label, EU, U.S., halal, and kosher markets, is increasing (Halal Control, 2022; OU Kosher, 2023).

Essential oils are increasingly combined with vitamins, minerals, and probiotics to create synergistic formulations supporting immune, nervous, and digestive functions. They show potential for therapeutic supplementation in conditions such as IBS, stress, insomnia, and menopause (Kasper et al., 2010). Nevertheless, challenges include the need for standardization, clinical trials, and precise labelling of constituents (EFSA, 2021).

Dry extracts of essential oils in food supplements

Dry extracts of essential oils represent processed forms adapted for use in food supplements. Although technically not pure essential oils in their original state, they retain active components and provide simpler, more stable, and safer oral administration. Dry extracts rely on specific production technologies such as microencapsulation, adsorption, cyclodextrin complexation, and dry emulsions.

In microencapsulation, essential oil is enclosed within a protective coating via spray-drying and converted into powder. In adsorption, the oil is bound to carriers such as silica and transformed into powder. In cyclodextrin complexation, active molecules are incorporated into cyclic molecules that protect them. In dry emulsions, stable emulsions of essential oils are dried and used as granulate (Gharsallaoui et al., 2007; Szente and Szejtli, 2004). Advantages of dry forms include improved stability against light, oxygen, and heat, reduced intensity of aroma and taste, easier dosing and formulation into capsules or tablets, increased safety for oral intake, and suitability for industrial processing and transport. However, dry forms may contain only part of the components from the original oil, are not considered pure essential oils according to ISO 9235, and must be clearly labelled as essential oil extracts (e.g., microencapsulated lavender extract) (ISO, 2013). Examples in practice include lavender oil tablets (e.g., Silexan) for anxiety and stress, oregano capsules for antibacterial and immunostimulatory effects, and powdered preparations containing lemon oil in beverages for immune support (Kasper et al., 2010).

Dry extracts of essential oils constitute functionally valuable forms for food supplements. Their safety, stability, and convenient use make them an increasingly frequent choice for manufacturers. It is

essential that they are clearly declared, properly dosed, and compliant with technological and regulatory standards.

Current status of regulation and standards

Standardization of essential oils refers to a set of controlled procedures and measures ensuring that an essential oil has a known and consistent chemical composition, meets qualitative and quantitative specifications, and is safe, effective, and suitable for its intended use (food, cosmetics, pharmaceuticals). Standardization includes identification of the botanical source (Latin name, plant part, origin), definition of the chemical profile (GC–MS analysis), establishing limits for key components (e.g., ≥30% linalool in lavender), restricting undesirable compounds (e.g., thujone, safrole), control of physical parameters (density, refractive index), and documentation on cultivation, extraction, and storage (ISO, 2013; EFSA, 2021). Example: according to ISO 3515 (ISO, 2002), standardized lavender oil must contain 30–45% linalyl acetate, 25–38% linalool, and <0.5% camphor.

Standardization is essential because it ensures consistent functionality in every batch, eliminates toxic components, enables regulatory compliance with legal requirements, ensures clinical efficacy with known doses of active compounds, and provides a market advantage through higher value and consumer trust. Standardization of essential oils is crucial for the safety, quality, and regulatory compliance of products. It enables the use of essential oils in food, supplements, and pharmaceutical preparations in a scientifically substantiated manner.

Numerous challenges exist in the standardization and quality assurance of essential oils in food supplements. Variability in composition complicates consistent bioactivity (Petina, 2023), adulteration with cheaper substitutes is common (Smith et al., 2023), GC–MS analyses are not standardized across laboratories (Pavoni et al., 2020), formulations may be unstable if not properly developed (Saka and Chella, 2020), regulatory approaches are not globally harmonized (FDA, 2021; European Commission, 2008), and transparency regarding raw material origin is often lacking (Compliance Gate, 2025).

Standardization is carried out according to the following frameworks:

- ISO standards 9235 and 3515 – international standards;
- Ph. Eur., USP, BP – pharmacopoeial standards;
- Codex Alimentarius – food guidelines;
- EFSA and FDA – safety assessments (FAO/WHO, 2001; EFSA, 2021).

ISO standards

ISO standards provide technical guidelines but are voluntary and often not integrated into national legislation for food supplements. Their value lies in ensuring consistency between laboratories, but they do not define permissible limits or health claims.

The technical committee ISO/TC 54 is responsible for developing international standards related to the analysis, specification, and labelling of essential oils (ISO, 2025a). The committee operates within ISO headquartered in Spain and collaborates with organizations such as Codex Alimentarius, FAO, WHO, and industry associations such as IFEAT. To date, more than 160 international ISO standards have been published for specific essential oils, including rosemary oil, grapefruit oil, sandalwood oil, and standards for determining trace benzene in essential oils (ISO, 2025b; ISO, 2024a; ISO, 2024b).

ISO has developed technical specifications standardizing ingredient terminology (ISO, 2025c). The standards define methods such as GC–MS chromatographic fingerprinting (ISO 11024-1:1998), optical rotation, relative density, freezing point, and packaging labelling requirements. Implementation of these standards ensures laboratory consistency in quality assessment but does not prescribe therapeutic doses, allowable concentrations, or health claims, limiting their regulatory value in the context of food supplements (Ibáñez, 2016).

Despite their scientific value, ISO standards face practical limitations. They are voluntary and not legally binding, leading many manufacturers to apply them inconsistently (Ibáñez, 2016). National legislations rarely incorporate ISO standards, further limiting their regulatory influence. Specialized essential oils often deviate from ISO profiles to meet market demands for aroma or price. It is recommended that ISO standards be harmonized with regulatory frameworks of EFSA, Ph. Eur., GRAS, and formally integrated into EU legislation for food supplements containing essential oils, making their application mandatory in industrial production (ISO, 2025a; ISO, 2024b).

Pharmacopoeias

Pharmacopoeias are official compendia of standards defining the quality, purity, identity, and analytical methods for medicinal substances, including essential oils when used for medicinal, cosmetic, or nutritional purposes. The two most important sources are:

- European Pharmacopoeia (Ph. Eur.) – published by the European Directorate for the Quality of Medicines (EDQM), legally binding in the EU.

- United States Pharmacopeia (USP) – recognized standard in the USA, mandatory for products on the U.S. market.

Both pharmacopoeias include documents defining chemical composition, identification methods, purity, and contaminant limits for specific oils. They contain monographs for individual essential oils with clearly defined purity criteria (Ph. Eur., 2023; USP, 2023). Monographs are fundamental in ensuring quality and identity, harmonizing manufacturing and batch control, and providing the legal basis for inspections and market authorization.

European Union regulations

EU Regulations No. 1334/2008 and 1925/2006 form the key legal frameworks for essential oils in food and dietary supplements. Although they recognize essential oils as flavourings, they do not define their therapeutic or functional status when used in food supplements (European Commission, 2008; 2006).
Essential oils are classified as "flavourings of plant origin". They are permitted exclusively as flavourings, without health claims or therapeutic indications. Regulation (EC) No. 1925/2006 regulates the addition of vitamins, minerals, and other substances with nutritional or physiological effects. Essential oils are not explicitly listed, and their functional use requires a specific EFSA assessment. These regulations prohibit claims such as “supports immunity” or “has antibacterial effects” unless previously approved by EFSA, creating legal uncertainty for manufacturers wishing to position essential oils as functional ingredients (Petina, 2023).

FDA regulation of essential oils in dietary supplements

In the United States, GRAS status allows the use of small amounts of oils but does not cover therapeutic doses (FDA, 2021). The Food and Drug Administration (FDA) regulates essential oils through several mechanisms depending on their intended use. Two key aspects include GRAS status and labelling/claims requirements (FDA, 2024).
Many essential oil constituents have GRAS status for use in food products, meaning they are considered safe when used in low concentrations as flavourings (FDA, 2024). Examples include menthol, eugenol, limonene, and linalool listed in 21 CFR §182.20 (CFR, 2024). GRAS status does not cover therapeutic use. If essential oils in dietary supplements are marketed with health claims, such claims must be scientifically substantiated, and manufacturers must include the appropriate FDA disclaimer (FDA, 2023).
Manufacturers intending to use essential oils in dietary supplements must:

- use only GRAS-recognized components,
- comply with labelling regulations and avoid unauthorized claims,
- implement good manufacturing practices (cGMP),
- ensure scientific evidence of safety and efficacy.

Codex Alimentarius and essential oils in food supplements

Codex Alimentarius is an international collection of standards and guidelines for food safety and quality, developed by FAO and WHO. Its purpose is to protect consumer health and facilitate international food trade (FAO/WHO, 2023).
Codex does not directly regulate essential oils as ingredients in food supplements but classifies them as flavourings and technical additives. Due to its voluntary nature, application varies widely among countries, posing challenges for manufacturers and global trade.

GAP and organic production standards

Good Agricultural Practices (GAP) represent a set of minimum principles applied during plant cultivation to ensure safety, quality, and traceability of raw materials (FAO, 2023). In essential oil production, GAP is crucial for maintaining chemical profiles, reducing pesticide residues, and ensuring hygienic conditions.
Organic production involves cultivation without synthetic pesticides, GMOs, chemical fertilizers, or growth regulators (IFOAM, 2022). In the EU, Regulation (EU) 2018/848 defines conditions for certified organic production of plants intended for distillation and use in food products.
Organic oils often carry certifications such as EU Organic, USDA Organic, Ecocert, or Soil Association, which increase their market value and consumer trust.
GAP ensures basic hygiene and safety standards, while organic farming represents an advanced certification system. For supplements containing essential oils, organic production offers higher quality and market acceptance (Turek and Stintzing, 2013; IFOAM, 2022).

Halal, Kosher and similar standards

The status of dietary supplements containing essential oils varies among world religions depending on dietary rules, ethical norms, and production processes. Such supplements may be acceptable in most religions if they meet criteria of purity, origin, and ethical production.

Halal and kosher certification is essential for the Muslim and Jewish populations. Other religions emphasize natural origin, non-violence, and the absence of alcohol or harmful additives.

Most common formulations of essential oils in food supplements

Formulations of essential oils in food supplements include softgel capsules, emulsions, nanoemulsions, tablets, capsules, oral dispersible powders, and sublingual sprays. Nanoemulsions show improved bioavailability (Saka and Chella, 2020), whereas powder products are more stable but may exhibit lower efficacy (da Silva Bomfim et al., 2020).

Vegetable oils and essential oils most commonly used in food products and supplements in Bosnia and Herzegovina and neighbouring countries are presented in the table below. All oils comply with EU regulations and Codex Alimentarius guidelines (EFSA, 2021; FAO/WHO, 2001).

Table 1. Commonly used essential oils in food supplements

Name of oil	Latin name	Effect / use
Peppermint oil	*Mentha piperita* / *arvensis*	Digestive, against bloating and nausea
Lavender oil	*Lavandula angustifolia*	Calming, anti-stress, for sleep
Lemon oil	*Citrus limonum*	Antioxidant, stimulant, supports immunity
Ginger oil	*Zingiber officinale*	Digestive, anti-inflammatory, circulation
Immortelle (helichrysum) oil	*Helichrysum italicum*	Antioxidant, cell protection, aromatic use
Basil oil	*Ocimum basilicum*	Digestive, antimicrobial
Rosemary oil	*Rosmarinus officinalis*	Cognitive support, antioxidant
Lemongrass oil	*Cymbopogon citratus*	Digestion, anti-inflammatory
Wild oregano oil	*Origanum vulgare*	Antibacterial, immunostimulant
Clove oil	*Syzygium aromaticum*	Antiseptic, analgesic, oral care
Black seed oil	*Nigella sativa*	Immune support, antioxidant
Anise oil	*Pimpinella anisum*	Digestion, against bloating
Coriander oil	*Coriandrum sativum*	Digestive, antioxidant
Cinnamon oil	*Cinnamomum zeylanicum*	Anti-inflammatory, glucose support
Thyme oil	*Thymus vulgaris*	Respiratory health, antimicrobial

These oils are permitted in accordance with EU regulation (Reg. (EU) 1334/2008) and Codex Alimentarius. In supplements, they are used in the form of capsules, emulsions, drops, or tea blends with added essential oils. For their use in functional foods, it is important to adhere to recommended doses according to EFSA guidelines. For religious certifications (halal/kosher), excipients and manufacturing processes must also be taken into account (EFSA, 2021; FAO/WHO, 2001).

Essential oils represent an important segment of natural dietary supplements due to their functional and aromatic properties. Their safety and usability in the food industry depend on origin, extraction method, purity, and regulatory compliance.

Conclusion

The safety and applicability of essential oils in the food industry depend on origin, extraction method, purity, and regulatory compliance. They are promising ingredients in food supplements, but standardization of analytical, regulatory, and labelling practices is necessary to ensure their safety and efficacy. The standardization process includes: identification of the plant source, GC–MS analysis, establishing limits for active and toxic components, and compliance with purity and stability requirements. For the development, production, and use of essential oils in food supplements, standardization must be the starting and final point of every process. This is the only way to ensure a safe, effective, and legally acceptable product for the end user. Harmonization of ISO and GRAS standards, introduction of GC–MS as a mandatory test, digital verification of origin, and inter-institutional collaboration (EFSA, FDA, ISO) are recommended.

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