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REVIEW ARTICLE

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Regulation of food supplements in Algeria: Current situation, issues, and perspectives

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ABSTRACT

Background: The Algerian food supplements market has witnessed substantial growth, especially during the COVID-19 pandemic. To safeguard consumer health, a robust regulatory framework for these products is imperative. **Aims:** This article thoroughly examines the existing regulatory framework for food supplements in Algeria, identifying shortcomings and potential areas for improvement. **Methods:** Regulatory texts published in the Algerian Official Journal were collected and analyzed. These texts were then compared with regulations from the USA, Australia, Canada, the European Union, and the Democratic Republic of Congo. Key regulatory aspects, including approval processes, manufacturing standards, adverse event reporting, labeling requirements, and evidentiary standards for claims, were scrutinized. **Results**: In Algeria, food supplements are classified as food products, mandating adherence to Good Hygiene Practices and Hazard Analysis and Critical Control Points (HACCP) guidelines. While labeling must avoid misleading claims, prior authorization for production and marketing is not required. Instead, compliance is ensured through batch analyses and market inspections conducted by the Ministry of Trade. A rapid alert system is in place to monitor supplements posing health risks. **Conclusion:** A comparison of the Algerian regulatory framework for food supplements with international standards reveals the need for significant improvement to enhance consumer protection. A revised version of this framework, initiated by an interministerial committee but yet to be published in the official journal, is expected to address and rectify these deficiencies.

Keywords: Food supplements, dietary supplements, natural health products, complementary medicine, regulation.

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1 Introduction

The global food supplements market has experienced substantial growth in recent years, reaching an estimated value of 177.5 billion USD in 2023. Projections indicate continued expansion with a compound annual growth rate (CAGR of 9.1% from 2024 to 2030 (GrandViewResearch, 2024 . In the line with this global trend, a survey conducted by Immar Research and Consultancy revealed that 28% of Algerians consume food supplements (Immar Research & Consultancy, 2018 . Moreover, the Algerian Minister of Pharmaceutical Industry reported in 2022 that Algeria imports food supplements valued at approximately 500 million euros annually (Redaction AE.,2022 .

Despite the limited available literature on food supplements in Algeria (Bayazid et al., 2021; Chebaiki et al., 2020; Diaf & Khaled, 2018; Kennas et al., 2024; Tazi et al., 2024 , their prevalence among Algerian consumers is significant. Thus, it is imperative to implement stringent regulations to oversee these products and ensure the protection of consumers (Augustsson et al., 2021; Avigan et al., 2016 . The regulatory landscape surrounding food supplements is intricate and varies significantly from one country to another. While some countries classify them as foodstuffs, others categorize them as

therapeutic products or even prescription drugs. Given the lack of a comprehensive analysis of food supplements regulation in Algeria, the aim of this study was to clarify the national regulatory landscape for these products, identify its shortcomings and propose recommendations for improvement aligned with international regulatory standards.

2 Material and Methods

The present study is divided into two main sections. The first section entails a descriptive exploration of the regulatory landscape concerning food supplements within Algeria. This was accomplished through an extensive investigation of regulatory texts published in the Algerian Official Journal (General Secretariat of Government, Presidency of Republic, People's Democratic Republic of Algeria, 2024 . The second section comprises a comparative analysis of global regulations governing food supplements. Recognizing the shared challenges encountered by Algeria and neighboring countries such as Tunisia and Morocco in establishing regulatory frameworks for these products, the current study examines regulations from countries with well-established frameworks, including the United States (USA, Australia, Canada, and the European Union (EU. The Democratic Republic of Congo (DRC was also included in the comparison, as a francophone African country. It is noteworthy that countries such as China, India and Japan, which possess regulatory frameworks encompassing traditional medicine, were excluded from this comparison due to their unique focus.

This comparative analysis considers several common elements that are essential to characterizing these products. These elements encompass the process for obtaining approval for food supplements sales, provisions related to manufacturing, mechanisms for reporting adverse events, regulations governing labeling practices, and, where applicable, the required type and quality of supporting evidence for claims (Dwyer et al., 2018 .

3 Results

3.1 Algerian regulation of food supplements

Drawing upon regulatory documents extracted from the Algerian Official Journal, the following stipulations pertaining to food supplements that are manufactured and/or marketed within Algeria are delineated.

3.1.1 Definition

While not explicitly defined in a dedicated text, the definition of food supplements in Algerian regulations can be found in an executive decree addressing food additives and their utilization in foodstuffs, specifically Executive Decree 12-214 (Official Journal of People's Democratic Republic of Algeria, 2012). The definition is introduced in the decree's introductory segment as a contextual clarification, alongside other definitional elements to enhance understanding and implementation. Worth noting, this definition exclusively pertains to food supplements comprising vitamins and minerals (Table 1). No subsequent references to food supplements are found elsewhere within the Algerian regulatory landscape.

Annex II of the aforementioned Executive Decree 12-214 categorizes foodstuffs. Within this classification, "food supplements" are designated as sub-category No. 13.6, falling under the broader mantle of category No. 13 designated as "Foods intended for specific nutritional purposes" (Algerian Ministry of Trade. Annex II of Executive Decree N°12-214, 2012).

Decree 12-214 was promulgated in accordance with Law No. 09 – 03 concerning consumer protection and fraud prevention (later modified and supplemented). This Law defines foodstuffs as "any substance, whether processed, semi-processed, or raw, intended for consumption by humans or animals. This encompasses beverages, chewing gum, and all substances employed in food manufacturing, preparation, and treatment, excluding materials exclusively used as drugs, cosmetics, or tobacco" (Official Journal of People's Democratic Republic of Algeria, 2009).

As such, food supplements find their place within the category of foodstuffs, a classification that serves to differentiate them from pharmaceutical drugs. It is important to highlight that in the subsequent sections, the regulations pertinent to foodstuffs will serve as the basis for delineating the regulatory prerequisites governing food supplements in Algeria.

3.1.2 Manufacturing and distribution conditions

As with any commercial activity, manufacturers, importers, and distributors of food supplements are required to register with the National Trade Registry Center. This registration is essential to obtain the necessary authorization for conducting their business operations (Official Journal of People's Democratic Republic of Algeria, 2018). Beyond this registration requirement, food supplement manufacturers are not obligated to seek prior authorization from a competent authority for the operation of their production facilities.

Throughout the process of bringing food supplements to the market, manufacturers, importers, and distributors must adhere to Good Hygiene Practices (GHP), a mandate applicable to all types of food. These GHP standards must be explicitly outlined and detailed in the company's internal

Table 1. Comparison of terminologies and definitions used for food supplements

Country	Official terminology	Official definition
Algeria	Food supplements	The only categories of food supplements that are defined in Algerian regulation are "vitamin and mineral food supplements". They are defined as "concentrated sources of these essential nutrients, whether individually or in combination, available in the forms of capsules, tablets, powder, or solution. They are not designed to be ingested like typical food products but rather in limited quantities. Their primary objective is to rectify deficiencies of vitamins and/or minerals in the regular diet" (Official Journal of People's Democratic Republic of Algeria, 2012).
United States	Dietary supplements	The "dietary supplement" is defined as a product other than tobacco, intended to supplement the diet; that contains a vitamin, mineral, herb or botanical, dietary substance, or a concentrate, metabolite, constituent, extract, or combination of the above ingredients; that is intended for ingestion, is not represented as food or as a sole item of a meal or diet, and is labeled as a dietary supplement; These rules cover products in the form of pills, capsules, tablets, and liquids (U.S. Food and Drug Administration (FDA), 1994).
Canada	Natural Health Products (NHPs)	NHPs are classified as a subgroup of drugs and are subject to regulation by Health Canada. NHP means a substance (vitamin, mineral, amino acid, essential fatty acid, probiotics, plant or plant material, alga, bacterium, fungus, non-human animal material) or a combination of these substances, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in: - diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans. - restoring or correcting organic functions in humans; or - modifying organic functions in humans (Government of Canada. Natural Health Products Regulations (SOR/2003-196), 2003; Powers et al., 2019).
European Union (EU)	Food supplements	In EU, food supplements means "foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients (vitamins, minerals) or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities (European Commission. Directive 2002/46/EC of the European Parliament and of the Council, 2002).
Australia	Complementary medicine	Complementary medicine means a therapeutic good consisting wholly or principally of one or more designated active ingredients (vitamin, mineral, plant or herbal material, amino acid, essential oil, enzymes, algae, fungi, microorganism, homoeopathic preparation, non-human animal material, lipids, essential fatty acid, substances produced by or obtained from bees, etc.), each of which has a clearly established identity and a traditional use (Australian Government. Federal Register of Legislation Therapeutic Goods Regulations, 1990).
Democratic Republic of Congo (DRC)	Food supplements	Refers to any health supplement or nutritional product intended to supplement the diet, and must include all of the following: - contains one or more of the following: vitamins; minerals; amino acids; essential oils; natural substances of plant or animal origin; enzymes; substances having a physiological nutritional function. - is intended for oral administration in the form of a tablet, capsule, powder, granules or liquid. - is not intended for use as a conventional food or as a single element of a meal or diet. - is labeled as such. must not carry a therapeutic claim or indication (Democratic Republic of Congo. Ministerial Order No. 1250/CAB/SP/MIN/006/CPH/OBF/2015, 2015).

protocols, accompanied by concrete, practical examples (Official Journal of People's Democratic Republic of Algeria, 2017).

The adoption of the Hazard Analysis and Critical Control Points (HACCP) system is a further mandatory requirement for foodstuffs, including food supplements. Its primary purpose is to evaluate potential hazards and discern critical control points that could compromise the safety and integrity of products, and to manage and mitigate these hazards (Official Journal of People's Democratic Republic of Algeria, 2021).

Companies involved in the import, manufacture, and/or distribution of food supplements bear the responsibility of ensuring that individuals entrusted with executing GHP and implementing HACCP principles possess adequate training. Each establishment must establish a competent HACCP team

to develop and implement guidelines based on hygiene measures outlined in relevant regulations and the applicable Codex Alimentarius usage codes, that is, the "food code" joint program of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) (Codex Alimentarius FAO/WHO, 2005). The validation of these guidelines in Algeria is overseen by the president of the National Codex Alimentarius Committee (NCAC), following a thorough review and amendments by NCAC members (Official Journal of People's Democratic Republic of Algeria, 2021). The inception of this National Committee dates back to January 30, 2005, operating under the auspices of the ministry of trade (Official Journal of People's Democratic Republic of Algeria, 2005).

Regarding the retail distribution of food supplements, no specific regulatory requirements are established. In practice, these products are retailed through various channels, including pharmacies, supermarkets, and fitness centers.

3.1.3 Marketing Authorization for Food Supplements

At the national level, there is no regulatory mandate requiring prior authorization from a supervising authority for marketing food supplements, nor is there a prescribed dossier to be furnished for this purpose. However, for imported food supplements, a dossier must be presented as part of the customs clearance procedures and will be presented later, in the border control section.

3.1.4 Labeling

Similar to all foodstuffs, the labeling of food supplements must include specific information for product identification (product name, batch identification, and expiration date), composition (list of all ingredients, energetic value, nutrient quantities), storage conditions, recommended usage and instructions. The label must also identify the marketing company and the manufacturing site. This information should be presented in Arabic, with the option of including translations in one or more other languages comprehensible to the consumer. This labeling information must be prominently displayed, legible, and resistant to erasure (Official Journal of People's Democratic Republic of Algeria, 2013). Consequently, there are no additional labeling requirements for food supplements beyond those applicable to general food products.

3.1.5 Claims

In accordance with Algerian regulations, the term "allegation" or claim is meticulously defined as "any representation or advertisement that declares, suggests, or insinuates that a product possesses specific attributes associated with its origin, potential nutritional benefits, inherent characteristics, processing, composition, or any other discernible quality". Aligned with the broader context of food products intended for consumption in Algeria, food supplements are mandated to refrain from being depicted or presented in a manner that is inaccurate, deceptive, or misleading. Such depictions should not create a false impression about their inherent nature. Promoting excessive consumption or implying that a balanced diet is insufficient to provide the essential nutrients is prohibited. Furthermore, claims referencing the preventive or remedial qualities against human diseases are strictly prohibited unless the average consumer can readily comprehend the presented beneficial effects (Official Journal of People's Democratic Republic of Algeria, 2013).

Since 2017, Algerian regulations have introduced the terminologies of "nutritional claim" and "health claim". As outlined in the inter-ministerial decree pertaining to nutritional labeling, a nutritional claim is precisely delineated as "any representation or promotional communication that explicitly states, suggests, or insinuates the possession of specific nutritional attributes by a food product". Nutritional claims must be grounded in well-accepted and substantiated scientific evidence. The entity proposing a nutritional claim is obligated to provide valid justification for its usage. In contrast, health claims require prior approval from the authorized health services under the purview of the Ministry of Health (Official Journal of People's Democratic Republic of Algeria, 2018).

3.1.6 Control

Market control

Algerian regulations mandate that companies engaged in the manufacture, importation, and/or distribution of food products, encompassing food supplements, conduct meticulous quality analyses and thorough conformity assessments of the products they manufacture and/or offer for sale, prior to their market introduction. These companies are required to possess an analysis report for each batch that enters the market (Official Journal of People's Democratic Republic of Algeria, 2009).

Table 2. Differences in regulatory requirements for food supplements

Criteria	**Algeria (**GS of Government, Presidency of Republic, People's DR of Algeria**;** OJ of People's Democratic Republic of Algeria, 2017; OJ of People's Democratic Republic of Algeria, 2021a; 2021b; 2005; 2013; 2018; 1990; 1989; 1995; 2005; 2012)	**United States (**U.S. Food and Drug Administration (FDA), 1994; U.S. Food and Drug Administration (FDA))	**Canada (**Government of Canada. Natural Health Products Regulations (SOR/2003-196)**;** Government of Canada. Canada Vigilance Program**)**	**Australia (**Australian Government. Federal Register of Legislation. Therapeutic Goods Regulations, 1990**;** Binns et al., 2018**)**	**European Union (**EC. Directive 2002/46/EC of the EP and of the Council, 2002**;** Konik et al., 2011**;** EC. Regulation (EC) No. 852/2004, 2004**;** EC. Regulation (EC) N°1924/2006, 2006**;** E C. Directive 92/59/EEC of the European Council, 1992**)**	**Democratic Republic of Congo (**DR of Congo. Ministerial Order No.1250/CAB/SP/MIN/006/CPH/OBF/2015, 2015**;** DR of Congo. Ministerial Order No. 1250/CAB/MIN/SP/011/CPH/OBF/2015, 2015**)**
Regulation authority	Ministry of trade and export promotion	Food and Drug Administration (FDA)	Health Canada	Therapeutic Goods Administration (TGA)	European Commission and competent authority of each Member State	Ministry of Public Health
Regulatory Text Dedicated to food supplements	No	Yes The Dietary Supplement Health and Education Act (DSHEA) of 1994.	Yes Regulations on Natural Health Products (SOR/2003-196)	Yes Therapeutic Goods Regulations 1990.	Yes Directive 2002/46/EC regarding food supplements.	Yes Ministerial Order No. 1250/CAB/SP/MIN/006/CPH/OBF/2015
Prior Authorization Before Marketing	No	No	Yes	Yes	No Except if it contains a novel Food.	Yes
Quality Control under Manufacturer's responsibility	Yes	Yes	Yes	Yes	Yes	Yes
Manufacturing Conditions	Good Hygiene Practices (GHP) + Hazard Analysis and Critical Control Points (HACCP).	Current Good Manufacturing Practices cGMP for Food and Dietary Supplements	Good Manufacturing Practices (GMP)	GMP	GHP + HACCP	GMP
Labelling (Specific warnings)	No specific warning	Warning: "This product is not intended to diagnose, treat, cure, or prevent any disease".	Registration number of the product.	Classification of the complementary medicine (Listed/ Registered) to be mentioned.	Warning "Cannot be used as a substitute for a varied diet".	Warning about the potential undesirable effects that may arise from excessive consumption
Permitted Claims	Yes. Scientifically justified Nutritional claims are authorized if included in the "positive list" (pre-approved claims). Health claims necessitate prior approval from authorized health services.	Yes. Nutritional claims authorized based on scientific evidence. Health claims must be subject to a prior authorization request.	Yes. Claims to be substantiated by scientific evidence, and authorization to request from Health Canada.	Yes. Listed products can make only pre-approved low risk health claims. For Listed products with slightly riskier health claims ("Assessed Listed" products) and for Registered products, it may be applied to use a "TGA assessed" claim.	Yes. Nutritional claims are authorized if they are included in a positive list defined by the EU. Health claims must undergo an evaluation.	No. Must not contain any claims or therapeutic indications
Nutrivigilance program	Yes Rapid Alert System -Ministry of trade.	Yes Safety Reporting Portal -FDA.	Yes Canada Vigilance Program.	Yes Adverse Event Management System - TGA.	Yes Rapid Alert System: A network that involves the member states, the EU Commission, and the European Food Safety Authority	Yes Reporting to Ministry of Public Health

This requirement does not preclude the vigilance of anti-fraud agents, acting under the jurisdiction of the ministry of trade, in executing conformity checks across all stages of bringing the product to the market. These checks might involve an examination of documents and/or interactions with pertinent stakeholders, facilitated by direct observations through visual inspections or employing measurement instruments. When necessary, samples may be collected for analysis, testing, or experimentation (Official Journal of People's Democratic Republic of Algeria, 1990).

Samples collected in adherence with relevant regulations undergo a series of assessments, including physicochemical, bacteriological, and biological purity analyses, as well as any other essential tests, to ensure compliance with regulatory standards. These evaluations are conducted by the Algerian center for quality and packaging control (Official Journal of People's Democratic Republic of Algeria, 1989). This public institution operates under the auspices of the Ministry of Trade and maintains a nationwide network of fraud control laboratories.

Border control

Imported food supplements undergo control at various points of entry, land, sea, and air border posts. These checks are carried out by border inspectors, prior customs clearance. The inspection process is based on a dossier submitted by the importer, encompassing both administrative documentation and any records validating the product's conformity to authorized standards and/or legal stipulations, including an analysis report.

Visual examinations are routinely conducted, and sampling procedures may be applied. In the absence of national regulatory standards or specifications, imported food supplements are evaluated against Codex Alimentarius guidelines. If a product does not comply with these standards, the regulatory provisions of the country of origin should be invoked. The outcome of the border inspection determines whether the product is authorized for entry or rejected. This decision is communicated to the importer (Official Journal of People's Democratic Republic of Algeria, 1995; 2005).

3.1.7 Nutrivigilance

In line with the oversight afforded to any product introduced to the Algerian market, food supplements that pose potential risks to consumer health and safety undergo monitoring through a rapid alert system. This operational network comprises representatives from various ministries and is overseen by a representative from the Ministry of Trade. The rapid alert system shall promptly withdraw from circulation any product deemed to pose health or safety hazards to consumers and ensure that consumers are duly informed about the associated risks (Official Journal of People's Democratic Republic of Algeria, 2012).

3.2 Comparison with international regulation

A global consensus regarding the precise definition and classification of food supplements remains elusive. Moreover, the terminology employed for these products varies across nations, likely reflecting their divergent treatment within distinct jurisdictional regulatory frameworks. Table 1 presents the terminology used in each country, and a comparison of the definitions of these products with the Algerian definition is provided. Table 2 compares key elements of food supplement regulation between Algeria and the selected international countries.

4 Discussion

Various terms are employed globally to describe the products under study. In Algeria, the term "food supplements" aligns with the nomenclature used in DRC and EU. Notably, Algeria, DRC and EU are members of the Codex Alimentarius Commission (CAC), which also employs the term "food supplements" to denote these products (Codex Alimentarius FAO/WHO, 2005). In the USA, the term "dietary supplements" remains largely congruent. Consequently, for all these countries, food supplements fall under the purview of food-related regulations, as noted by Thakkar et al. This regulatory framework, in most instances, restricts the ability to make therapeutic claims (Thakkar et al., 2020). However, in Canada, products commonly recognized as dietary supplements worldwide generally fit into one of the following regulatory categories: "foods", "supplemented foods", or "Natural Health Products" (NHPs). The categorization of a product primarily hinges on factors such as its format, composition, representation (including health claims), and its historical usage. For instance, products in pharmaceutical-type formats like tablets and capsules are consistently classified as NHPs, whereas formats such as bars and yogurts are consistently categorized as foods (Government of Canada. Natural Health Products Regulations, 2003; Powers et al., 2019).

In Australia, while a limited subset of these items falls under food regulations, the majority are specifically referred to as "complementary medicines" (Australian Government. Federal Register of Legislation. Therapeutic Goods Regulations, 1990). These products can be categorized as either "listed" or "registered" category, depending upon their constituents and the claims (Binns et al., 2018; Brownie, 2005). As highlighted by Dwyer et al. (2018), the classification of these products as drugs in Canada and Australia allows for a broader scope of therapeutic claims. This

distinction subsequently impacts the regulatory prerequisites of these nations, including the necessity for pre-market registration of dietary supplements and the requirement to furnish substantiated evidence of efficacy in specific instances.

Regarding food supplements categories, Algerian definition of food supplements is limited to vitamins and minerals. Other categories commonly recognized in other countries, such as amino acids, fatty acids, probiotics, enzymes, plant-based products or preparations, and substances with nutritional or physiological effects, are not included in the Algerian definition. This may be attributed to the frequent references to the Codex Alimentarius in Algerian regulatory texts, as the Codex Alimentarius definition of food supplements does not encompass these categories due to a lack of harmonization among CAC members (Official Journal of People's Democratic Republic of Algeria, 2005a;2005b). To align with international standards, the Algerian definition of food supplements should be revised to include all necessary categories, particularly given the growing market for herbal products in Algeria (Ernst, 2002).

While the EU definition also does not include herbal products, the EU's approach differs from Algeria's (European Commission. Directive 2002/46/EC of the European Parliament and of the Council, 2002). As observed by Binns et al. (2018), certain botanicals are recognized as traditional herbal medicinal plants in the EU, falling under the purview of medicinal products rather than food supplements. As with all EU Directives, implementation is delegated to individual member states, providing them with the flexibility to adapt provisions to their respective national legal frameworks. An example of this is evident in France, where an official decree is established to enumerate the authorized plants used in dietary supplements and specify their conditions of use (Official Journal of the French Republic, 2014). Other plants products, those identified as "Herbal medicinal products" falls under another EU Directive, Directive 2004/24/EC, which classifies them as medicines, leading to undergo a simplified marketing authorization procedure before they can be introduced to the market (Konik et al., 2011, European Commission. Directive 2004/24/EC of the European parliament and of the council, 2004). Hence, as advised by Eberhardie (2007), stakeholders involved in revising the Algerian food supplements regulatory framework should prioritize discussions and consensus-building to address the overlapping areas between food supplements and herbal remedies.

Regarding manufacturing conditions, the Algerian regulatory framework aligns with European Union's (EU) approach for food supplements, as both adhere to food-related regulations. The EU compliance with to GHP and the implementation of HACCP procedures to ensure the suitability of food products for consumption (European Commission. Regulation (EC) No. 852/2004 of the European Parliament and of the Council, 2004). For all other compared countries, Good Manufacturing Practices (GMP) applies.

In the USA, the Dietary Supplement Health and Education Act (DSHEA) established a dedicated set of GMP standards specifically tailored for dietary supplements, including HACCP requirements. Recognizing that pharmaceutical and food GMPs may not always be suitable for supplements, especially botanical supplements, the DSHEA facilitated the development of GMP standards designed to ensure the quality and safety of dietary supplements (U.S. Food and Drug Administration (FDA), 1994; Wollschlaeger, 2003).

In Canada, Australia, and DRC, the production of dietary supplements is governed by Good Manufacturing Practices GMPs that are identical to those mandated for pharmaceutical product manufacturing. Consequently, these regulations are more stringent compared to those applied in Algeria (Government of Canada. Natural Health Products Regulations, 2003; Australian Government. Federal Register of Legislation, 1990; Democratic Republic of Congo. Ministerial Order No. 1250/CAB/SP/MIN/006/CPH/OBF/2015, 2015).

Regarding marketing food supplements in Algeria, there is no obligation in the existing regulatory framework for businesses to seek prior authorization from a designated competent authority before introducing these products into the market. In contrast, the marketing of food supplements in countries such as Canada, Australia, and DRC, is contingent upon obtaining Market Authorization. This authorization serves multiple purposes, including identifying stakeholders involved in the process of delivering food supplements to consumers, ensuring traceability, evaluating safety data, and contributing to the protection of public health. In specific instances, it even enables the assessment of the efficacy of food supplements, as is the case in Canada and Australia.

In the USA and EU no prior authorization requirement is imposed for dietary supplements. In the USA, as dietary supplements fall under the purview of the food category, the post-market regulatory approach is predominant, as emphasized by Bailey (2020). Here, the responsibility for the products placed on the market rests solely with the operator (U.S. Food and Drug Administration (FDA), 1994). In the EU regulatory framework for food supplements is more complex. While the EU primarily focuses on vitamins and minerals within food supplements, maintaining a positive list of these nutrients, food supplements that comply with this list can be marketed without prior authorization. Companies

seeking to market a substance not yet included in the positive list, must initiate an application process directed at the European Commission (Binns et al., 2018). This prerequisite for authorization is particularly relevant when the food supplement contains a new component, as it would be classified as a "novel food" (Thakkar et al., 2020). However, as noted by Eberhardie (2007), the introduction of a positive list in Directive 2002/46/EC raised concerns among manufacturers regarding the potential exclusion of existing products that had been safely used for years. If Algeria revises its food supplement regulatory framework, careful consideration should be taken to whether a positive list is appropriate, as it could inadvertently exclude a wide range of food supplements already available in the local market.

It is important to note that individual EU member states may introduce additional requirements within their respective legislations. For example, in France, prior notification is necessary to the competent authority is necessary, regardless of whether a product is covered by the positive list (Official Journal of the French Republic (Official Journal of the French Republic. Decree No. 2006-352, 2006).

Regarding all regulations, there are no specific restrictions stipulating authorized venues for the marketing of food supplements at the national or international levels. These products can be sold through various outlets, including pharmacies, supermarkets, and other retail locations.

In Algeria, the labeling of food supplements is subject to stringent regulations aimed at ensuring consumer safety and preventing misleading claims. While several countries outline specific mandatory information to be included on supplement labels (as summarized in Table 2), Algeria's approach predominantly emphasizes what should not appear on the label. These prohibitions serve to maintain the integrity of food supplement information.

Regarding nutritional and health claims, most countries permit nutritional claims when substantiated by widely accepted evidence, and require prior authorization for health claims. This approach is identical to Algeria's. However, in the DRC, both claims and therapeutic indications are prohibited. In the EU, health claims are only allowed if they are specifically listed in the annex of the regulation governing nutrition and health claims for food products.

When it comes to analytical controls for food supplements, each country adopts its unique approach. In the USA and EU, systematic controls are not routinely conducted; rather, the FDA and relevant authorities initiate sampling and analytical control in response to suspicions or reports of quality defects (U.S. Food and Drug Administration (FDA), 1994; European Commission. Directive 2002/46/EC of the European Parliament and of the Council, 2002).

In Algeria, the regulatory framework for food supplements aligns closely with the EU's approach. In the DRC, administrative oversight of imported food supplements occurs at customs warehouses, involving customs officials, the responsible agent, and a pharmacist or their representative. The pharmacist overseeing the inspection collects samples for analysis in accordance with applicable procedures and standards (Democratic Republic of Congo. Ministerial Order No. 1250/CAB/SP/MIN/006/CPH/OBF/2015, 2015). This approach, while more stringent and costly, may be difficult to apply to all batches of food supplements.

Food supplements can offer potential health benefits, but also carry the risk of causing adverse effects that must be promptly reported to competent authorities. These authorities wield the authority to take action, including removing product from the market or suspending commercialization. The authority responsible for managing undesirable effects and food supplements recalls varies from country to country, occasionally falling under the jurisdiction of the Ministry of Health and in other cases, under the jurisdiction of the ministry of trade. The rapid alert system applied in Algeria is similar to the European system as food supplements are treated as foodstuffs. In the USA, the Food and Drug Administration oversees this process, while in the DRC, Canada, and Australia, healthcare professionals play a more active role in the adverse event reporting process. The latter approach may be better suited for Algeria to safeguard consumer health and enable a swift response, as consumers and healthcare professionals are not well-informed about the procedure for reporting adverse events related to food supplements, unlike the pharmacovigilance process. Additionally, involving healthcare professionals may lead to better management of interactions between food supplements and drugs.

Perspectives

Following a public health incident in Algeria in December 2016 involving a locally manufactured food supplement claiming therapeutic effects for diabetes, an inter-ministerial commission was established. This task force, led by representatives from the Ministry of Health and in collaboration with the Ministry of Trade, examined the existing regulatory framework for food supplements, identified its shortcomings and formulated a dedicated text proposal for their regulation. The primary aim of this initiative was to enhance the regulatory oversight of these products (Business France, 2018 . The project engaged various stakeholders, including academic experts and professional associations. Notably, the National Union of Pharmacy Manufacturers advocated for the establishment of food supplements GMP specifically for food supplements, while the National Algerian Union of Community Pharmacists

proposed the exclusive sale of food supplements in pharmacies to mitigate potential interactions between drug and food supplements, and improve traceability. Nevertheless, the adoption of the dedicated text proposal remains pending.

A significant development was the establishment of a dedicated ministry for the pharmaceutical industry in Algeria in 2020, which subsequently became involved in the aforementioned project. In 2022, the Minister of Industry and Pharmaceutical Production announced the imminent adoption of a new decree specifically for food supplements, aimed at implementing stricter oversight of these products. This decree will require both inspection and authorization for food supplement production, aligning their regulation more closely with that of pharmaceutical drugs (Redaction AE., 2022 .

5 Conclusion

This study has revealed significant deficiencies in the regulatory framework governing food supplements in Algeria. The current regulatory texts are fragmented and lack precision. Notably, the absence of a comprehensive definition encompassing all categories of food supplements, the omission of a prerequisite market authorization requirement for food supplements, and the lack of an independent authority tasked with inspecting manufacturing establishments collectively contribute to challenges in regulating activities associated with food supplements.

Evidence suggests that within a lax regulatory framework, some products have evaded scrutiny, jeopardizing the well-being of certain individuals (Gottlieb & McClellan, 2022). Notably, an investigation conducted in February 2022 by the Algerian Ministry of Trade resulted in the prohibition of several food supplements, containing undisclosed drugs typically used to address sexual impotence (Algeria Press Service, 2022).

The collaboration among diverse stakeholders, including experts, policymakers, representatives from regulatory bodies, product companies, and research institutions, should play a pivotal role in facilitating the regulation of food supplements in Algeria (Ng et al., 2022).

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