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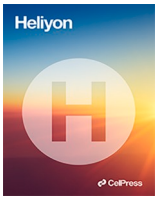

Review article

Ensuring compliance: A review of EU regulations and standards for incorporating legume and legume by-product proteins in food formulations

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ABSTRACT

Consumers are increasingly seeking nutritionally enhanced products, unique flavours and packaging, and ethically sourced ingredients. Significant technological advancements and investments in product innovation by manufacturers are driving the overall market growth for plant-based protein alternatives. In Europe, this growth is largely due to the rising adoption of veganism and the flexitarian trend. During vegetable processing, certain activities generate large amounts of by-products, many of which are discarded by manufacturers. These legumes and their by-products contain substantial amounts of protein. Manufacturers using legumes and their by-products-based proteins in food formulations must comply with European Union (EU) regulations and standards to obtain market approval. For this study, the regulatory framework and novel food dossier application process were sourced from the official EU website (Europa), while relevant standards were obtained from the International Organisation for Standardisation (ISO) and European Committee for Standardisation (CEN)-European Committee for Electrotechnical Standardisation (CENELEC) website. This review provides an overview of protein extraction from legumes and their by-products, followed by an analysis of the legal requirements for processing, production, and commercialisation of these extracted proteins in food formulations. It addresses standardisation and relevant standards in areas such as characterisation and safety. Furthermore, the novel food dossier application process and the EU requirements for legume proteins, if considered novel in the EU, are discussed. This review aims to serve as a guide for manufacturers already using, or considering the use of, legume proteins in food formulations within the EU, providing essential insights for gaining market acceptance and regulatory approval for these ingredients, whether existing or novel. Further research is needed to explore the incorporation of proteins extracted from legume by-products into food formulations.

1. Introduction

Consumers today seek nutritionally enhanced products, unique flavours and packaging, and ingredients produced in an ethical manner. They view their food preferences as a reflection of their perspectives on health, well-being, and the environment. Willett et al.

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(2019) [1] believe that increasing the caloric intake from diverse plant-based proteins will play a crucial role in sustaining the health of the population and the planet. Significant technological advancements and investments by manufacturers in product innovation are driving the growth of the plant-based protein market. In Europe, this market growth is primarily driven by key factors such as the rise of veganism and the increasing popularity of the flexitarian lifestyle [2]. A variety of plant-based proteins sourced from pulses like peas, lentils, beans, and chickpeas are gaining significant attention. Additionally, the edible parts of these leguminous vegetables are being effectively utilised for protein extraction [3].

Traditionally, products made from legumes have been consumed in a variety of forms in different cultures without undergoing much additional processing. Nonetheless, certain activities within the vegetable sector such as freezing, canning, dehydrating, and pickling processes generate notable amounts of by-products. These are mostly discarded by the manufacturers and the industries. Italia Scarl, an Italian company, estimates that 5 %–25 % of residues are generated during legume processing [4]. Plant-based alternative sources of proteins can be extracted from both legumes and their by-products by employing green extraction techniques. They can be used in the formulation of numerous foods to form food products with desired characteristics having enhanced functional or technological properties.

The protein content of some species of legumes is shown in Table 1. In Europe, peas are especially popular because of their high protein content, making them a common choice for a variety of meal preparations [5]. Protein content in peas ranges from 22.2 % to 32.5 % dry matter (DM) [6]. Considerable parts of the pea plants like vines, pods, stalks, and leaves are discarded. The by-products mainly include seeds, pods and defective peas identified during the production processing stages of size-based and density-based separation and while visual screening for pods removal [7]. Pea by-products contain about 5–7% protein, with dry by-products containing 20–25 % protein [8]. Beans have a protein content ranging from 14.5 to 39.7 % [9–12]. Owing to the drying conditions that influence the quality of the seed, beans are difficult to mill industrially. Subsequently, a large amount of bean crop residues is generated that are mainly composed of broken seeds, pod husks, stems and leaves [13]. Depending on the percentage of stems, pod husks, and leaves, the chemical composition of bean crop residues can change. The leaves have a much greater protein content (up to 20 %) than the stems and pod husks (8 and 4 %, respectively) [14]. Lupin have a protein content of about 34–44 % DM, which is greater than other legumes like lentils, peas, chickpeas, and faba beans but almost similar to soybeans [9]. The dehulling process of lupin processing leads to the generation of by-products like embryonic axes, broken cotyledons, and a mixture of seed coats. The protein content of lupin by-products is more or less similar to that of the peas by-products. Lupin seeds are recognised as a significant protein source containing between 33 % and 47 % DM [15]. The industrial processing scheme of fresh legumes and consequently the protein extraction from legumes and its by-products are shown in Fig. 1.

The techniques of aqueous alkaline extraction followed by isoelectric precipitation and salt extraction are commonly employed to isolate legume proteins [16]. Protein extraction can be performed using either dry or wet processing, usually preceded by pre-treatment methods. Dry fractionation typically involves milling pulses into flour followed by air classification, separating starch-rich coarse fractions from protein-rich fine fractions based on particle size and density [17]. Other dry protein extraction techniques include sieving and densification. Sieving works by separating pulse flour particles based on differences in their size. A series of screens with increasing mesh sizes helps separate protein from starch. Densification uses centrifugation to produce a lighter protein-rich fraction and a heavier starch-rich fraction [18]. Due to the lack of a solvent and a drying process, this method is very popular and is therefore viewed as a sustainable pathway because it uses less resources and requires less energy. The concentrates produced by dry process possess exceptional technological and functional qualities. However, the proteins it yields have relatively poor purities, which restricts their use in high-value applications [19].

In wet processing, legumes are solubilised using alkaline, acidic, or neutral solvents, followed by separation via enzymatic extraction, ultrafiltration, or isoelectric precipitation. The proteins are extracted from the starch and other ingredients. Following that, the starch slurry (insoluble substance) is separated from the dissolved protein (supernatant liquid) to form protein concentrates, which are further concentrated and purified. Starch-rich seeds like fava beans or peas separate adequately by the dry processes whereas the oil-rich seeds like soya bean and lupin demand wet processing [20]. Wet extraction produces flours with much higher protein purity (up to 91 %) than dry processing [21]. Thus, considering the amount of by-products generated and by employing the available technology to them, food ingredients can be made to formulate high-protein products.

Commercial operations produce protein-rich legume fractions using either dry or wet methods. Those with a protein content between 60 % and 80 % are called 'protein concentrates,' while those with a protein content of >80 % are termed 'protein isolates' [22]. Both wet and dry fractionation methods can be used to produce protein concentrates (60–80 % protein content), but only wet fractionation is commercially used to produce protein isolates (>80 % protein content) [23]. Irrespective of the procedure, the overall

Table 1
Protein content (%, w/w) of different species of legumes [9–12].

Legume	Protein content (%)
Red kidney bean (*Phaseolus vulgaris*)	20.9–28.7
Faba bean (*Vicia faba*)	26.4–39.7
Lima Bean (*Phaseolus lunatus*)	14.5–24.0
Mung bean (*Vigna radiata*)	25.8–27.5
Chickpea (*Cicer arietinum*)	24.0–33.0
Cowpea/Black eyed pea (*Vigna unguiculata*)	23.6–33.0
Lentil (*Lens culinaris*)	19.5–26.3
White lupin/field lupin (*Lupinus albus*)	25.9–32.6

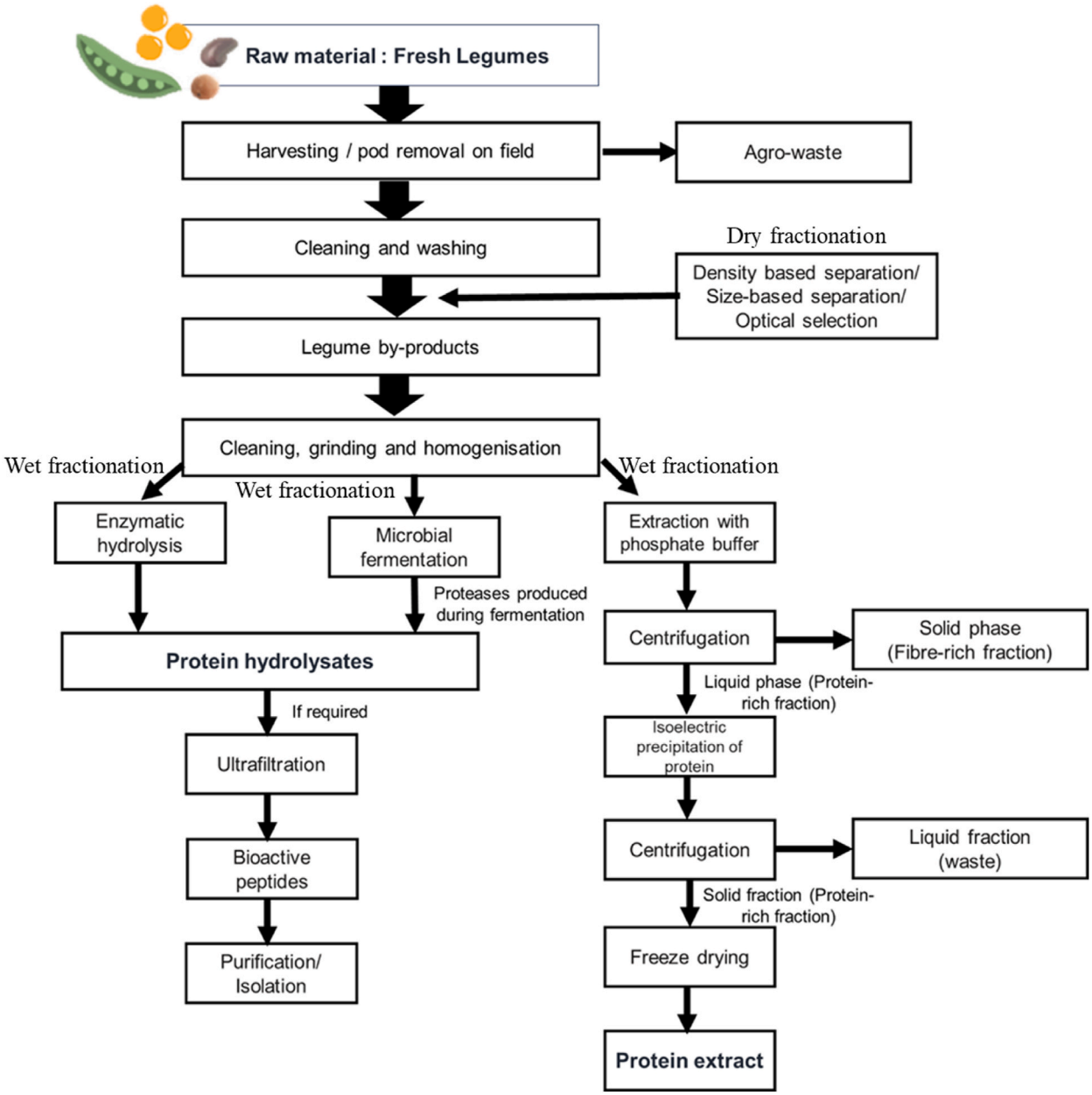

Fig. 1. The production process for obtaining protein hydrolysates and protein extracts from legume by-products.

strategy for producing high-protein ingredients is to preferentially remove sections of non-protein material from the raw material, primarily starch and fibre. Protein concentrates or isolates are often made using a wet process that produces side streams of soluble materials that contain soluble proteins, starch, and fibre. In food processing, choosing the right method and circumstances for protein extraction is crucial since these factors might affect the final protein product's technological, functional, and nutritive qualities [24]. Fig. 2 shows the regulatory compliance required at each stage of integrating the proteins from legumes and legume by-products into food matrices.

2. Methods

The objective of this study is to provide a detailed regulatory framework in the EU, which would serve as the starting information to help adhere to the relevant regulations, ensure compatibility and interoperability with what already exists in the market through directives, regulations and decisions, as well as to implement a uniform system for interaction with the EU market stakeholders. The regulatory framework was primarily developed by reviewing Europa [25], the official EU website, where EUR-Lex [26] provides

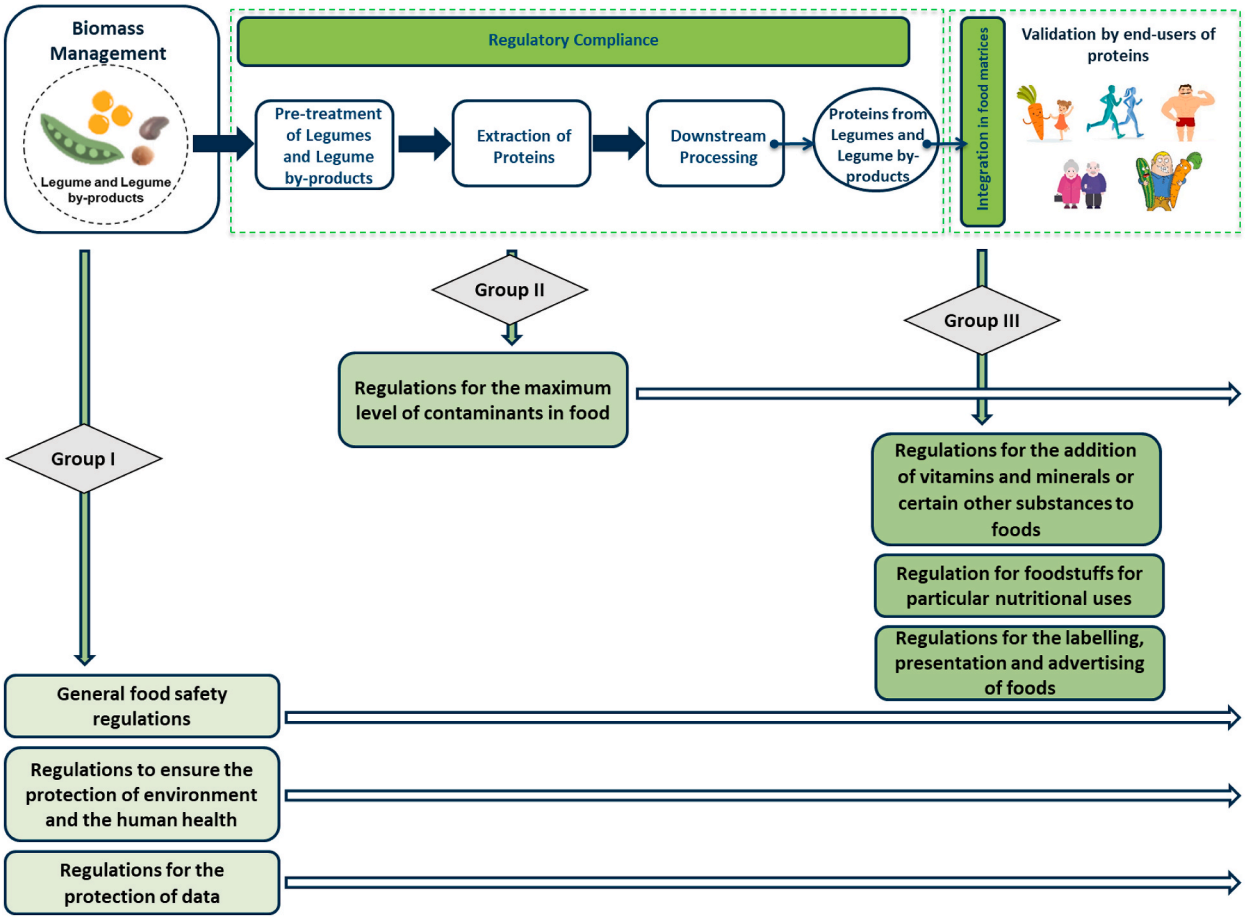

Fig. 2. Regulatory compliance necessary for the various stages of the integration of proteins from legumes and legume by-products in food formulations.

summaries of EU legislation. This website gave summaries of the main types of legislation passed by the EU including directives, regulations, and decisions. These summaries are grouped into 32 policy fields, each linked to the full version of the respective act. All the policy fields were checked to ensure that every stage of the process from raw material acquisition until the commercialisation of the product is considered. The full version of the act was then checked for details relevant to any stage from the processing, production, and commercialisation of the extracted proteins in food formulations. However, since the official website of the EU for summaries of EU legislation provided only the major legislation, it was necessary to carry out an in-depth search to compile all the regulation for each stage of the production process. Thus, the 'quick search' assistant on the official website of the EU was used [27]. When searching for relevant legislation, keywords like "pesticides", "food safety", "feed safety", "animal protection", and "additives" were used. For identifying relevant standards in relation to the key areas like characterisation, safety and toxicology, biorefinery, and product validation, information was gathered from the International Organisation for Standardisation (ISO) [28] and the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (CENELEC) i.e., CEN-CENELEC website [29] using the search function. The novel food dossier application process and EU requirements for the use of legume proteins in food formulations were obtained from the Europa website [30].

3. Regulatory framework

Since 2007, lupin has been classified as a food allergen under European legislation, necessitating appropriate labelling. Additionally, as per Regulation (EU) 2021/567 [31], labelling is required for the presence of the quinolizidine alkaloids like lupanine, 13-hydroxylupanine, and angustifoline, which are the primary causes of the bitter taste of lupin seeds [32]. Accurate labelling is therefore essential where lupin is commonly used as an ingredient or may be present in food products due to shared production or processing facilities. As highlighted in a report published by Circular Bio-based Europe Joint Undertaking (CBE JU), there is a need for consistent legislative and policy objectives to enhance industrial regulation and specific standardisation, facilitating a shift from fossil-based to bio-based production and consumption. A lack of a comprehensive regulatory framework may pose barriers to market access [33]. Thus, it is crucial to identify and comply with EU regulations during the pre-treatment, production, and processing stages

of protein extraction from legumes and legume by-products to ensure successful market acceptance of food formulations. Several different legislative acts are used to achieve the goals outlined in EU treaties, as shown in Table 2.

As illustrated in Fig. 2, the regulations related to the various stages of incorporating proteins from legumes and their by-products into food formulations can be categorised into three main groups: regulations relevant to all stages, regulations applicable after protein extraction from legumes and their by-products, and regulations applicable after the integration of legume-derived proteins into food formulations. Table 3 provides a detailed overview of the key aspects of each regulation within these groups.

3.1. Group I: regulations relevant to all stages

As shown in Fig. 2, the regulations under the 'General food safety regulations', 'Regulations to ensure the protection of the environment and human health', and 'Regulations for the protection of data' groups are relevant to all stages of integrating proteins from legumes and their by-products in food formulations. This includes the extraction process, the scaling up of the optimised extraction process, the validation of protein extracts for food applications, as well as the distribution and transportation phases Throughout these stages, factors such as environmental impact, economic viability, and market feasibility must be considered to ensure both consumer acceptance and market approval.

3.1.1. General food safety regulations

Regulations like Regulation (EC) No 178/2002, Regulation (EC) No 852/2004, and Directive 2009/32/EC under the 'General food safety regulations' group (as shown in Table 3) are general food laws ensuring a high level of protection for human health as well as the environment, allowing only food products that are safe and fit for consumption to reach the market. A critical aspect of this process is the use of solvents in extraction. For example, the European Commission requested assistance from the European Food Safety Authority (EFSA) to evaluate the safety of hexane, a solvent used in the production of food ingredients and food products [54]. This examination assessed the presence of contaminants in hexane, whether initially present or introduced during the recovery process, as these pollutants may accumulate during successive evaporation in extracted foods. The focus was on technical hexane, a mixture obtained from petroleum distillation and hydrogenation, mostly composed of n-hexane and associated hydrocarbons like 2-methyl--pentane, 3-methyl-pentane, and heptane. Directive 2009/32/EC does not provide specific guidelines for technical hexane, despite its prevalent use in preparing protein concentrates, particularly from soya [54]. Thus, it is of importance that the residue levels of solvents are below the maximum residue limit in proteins extracted from legumes and legume by-products to ensure the safeguarding of consumer health. Additionally, food business operators (FBO's) must implement traceability systems that can track the source of food and food-related substances (one step back) as well as where the food is distributed (one step forward). This allows for the identification and recall of products in case of any risk to human health.

3.1.2. Regulations to ensure the protection of the environment and human health

The regulations outlined in the 'Regulations to Ensure the Protection of the Environment and Human Health' category (as shown in Table 3) specify safety and inertness principles for all food contact materials (FCMs), which include objects that are likely to come into contact with food or transfer their constituents to it under normal or anticipated conditions. It is important to note that migration can also occur indirectly when food is contaminated by materials or surfaces not in direct contact, such as through interactions between external and internal packaging layers during storage or transport. These regulations aim to protect both the environment and human health by emphasizing efficient waste management, recovery, and recycling practices to conserve resources. FCMs designed to contact food, or likely to transfer substances into food, must adhere to regulations that safeguard human health, prevents undesirable changes in food composition, and avoid degradation of flavour or texture. These rules also establish guidelines for good manufacturing practices (GMP) in the production of food-contact materials. One example is printing inks, which are highly complex chemical formulations comprising solvents, photoinitiators, monomers, and pigments. This was published by EFSA as a report on 'Risk Assessment of Food Contact Materials'. Although generally associated with non-food contact surfaces of packaging, the migration of these compounds may nevertheless occur via diffusion or partitioning. There is no specific regulation for printing inks in food contact materials

Table 2
Different legislative acts used to achieve the goals outlined in the EU treaties and their characteristics [34].

Legislative act	Characteristics of the act
Regulation	- It is a legally enforceable legislative measure. - It must be implemented uniformly throughout the European Union.
Directive	- It is a legislative measure that establishes a specific objective. - All European Union member states are obligated to accomplish the stated objective. - The responsibility lies with each national country to formulate their own legislation about the means to achieve these objectives.
Decision	- It is legally binding for the recipients (such as an EU country or a sector) and can be directly enforced.
Recommendation	- It is non-binding. - It enables institutions to express their opinions and propose a course of action without placing a legal obligation on the recipients.
Opinion	- It is a tool used by institutions to express a message that does not have any legal responsibility for the recipients. - It does not have the power to impose a legal obligation or requirement. - The main EU institutions (Commission, Council, Parliament), the Committee of the Regions, and the European Economic and Social Committee have the authority to issue it. - During the process of lawmaking, committees provide opinions based on their specific regional, economic, and social perspectives.

Table 3
Regulations (and the key aspects of the regulation) relevant to the various stages of integrating proteins from legumes and their by-products into food formulations.

Regulation	Outline of the regulation	Key aspects of the regulation	References
Group I: Regulations relevant to all stages			
General food safety regulations			
Regulation (EC) No 178/2002 of the European Parliament and Council, 28 January 2002	This regulation establishes the general principles governing food and food safety at the community and national levels. It sets procedures for matters with direct or indirect impact on food safety.	- Establishes the European Food Safety Authority (EFSA) to offer scientific guidance and the Rapid Alert System for Food and Feed (RASFF) to manage crises across the food supply chain. - Provides a framework for safeguarding human health and protecting consumer interests. - Ensures the internal market's efficient functioning, including for traditional products. - Outlines responsibilities, principles, and organisational structures for decision-making on food safety.	[35]
Regulation (EC) No 852/2004 of the European Parliament and Council, 29 April 2004, on the hygiene of foodstuffs	This regulation sets general rules for food business operators regarding the cleanliness and safety of food products.	- Stresses that food safety is the responsibility of the food business operator. - Requires food safety at every stage of the food supply chain, starting from primary production. - Emphasises the importance of maintaining the cold chain, especially for perishable and frozen foods. - Implements Hazard Analysis and Critical Control Points (HACCP) principles.	[36]
Directive 2009/32/EC of the European Parliament and Council, 23 April 2009	This directive applies to extraction solvents used in the production of foodstuffs or food additives.	Excludes solvents used for extracting food additives, vitamins, and other nutritional additives, unless specifically mentioned.	[37]
Regulations to ensure the protection of environment and the human health			
Regulation (EC) No 1935/2004 of the European Parliament and Council, 27 October 2004	This regulation applies to materials, including active and intelligent food contact materials, that are intended to come into contact with food.	Ensures the efficient functioning of the internal market regarding materials that come into direct or indirect contact with food within the European Union.	[38]
Commission Regulation (EC) No 2023/2006	This regulation establishes guidelines for good manufacturing practice (GMP) for materials intended to contact food.	Covers materials used for food contact applications, including recycled materials.	[39]
Directive 2008/98/EC of the European Parliament and Council, 19 November 2008	This directive focuses on minimising the harmful effects of waste generation and management to protect the environment and human health.	- Aims to reduce the overall impact of resource consumption. - Ensures waste policies minimise negative effects on human health and the environment.	[40]
Regulations for the protection of data			
Regulation (EU) 2016/679 of the European Parliament and Council, 27 April 2016	This regulation establishes rules for the protection of personal data during processing.	- Regulates the free movement of personal data across the EU. - Protects individuals' fundamental rights, particularly personal data protection. - Applies to both automated and non-automated personal data processing.	[41]
Directive 2002/58/EC of the European Parliament and Council, 12 July 2002	This regulation standardises data privacy regulations across member states in the electronic communications sector.	- Facilitates the free movement of personal data and services. - Ensures the protection of subscribers' interests in electronic communications. - Sets uniform rules for privacy and data protection.	[42]
Group II: Regulations relevant to stages after extraction of proteins from legumes and their by-products			
Regulations for the maximum level of contaminants in food			
Commission Regulation (EU) 2023/915 of 25 April 2023	This regulation establishes the highest permissible levels of contaminants in food products to protect public health.	- Foods exceeding these levels cannot be sold or used as ingredients. - Foods that meet the limits must not be mixed with those that exceed them. - The limits apply to food as sold and to the edible parts unless stated otherwise.	[43]
Regulation (EC) No 396/2005 of the European Parliament and Council, 23 February	This regulation aligns with Regulation (EC) No 178/2002 and focuses on uniform pesticide residue levels.	- Establishes consistent standards for the maximum levels of pesticide residues in plant and animal-derived foods. - Applies to fresh, processed, or composite foods containing pesticide residues.	[44]

(*continued on next page*)

Table 3 (*continued*)

Regulation	Outline of the regulation	Key aspects of the regulation	References
Group I: Regulations relevant to all stages			
General food safety regulations			
Group III: Regulations relevant to stages after integration of legume and their by-products derived proteins into food formulations			
Regulation for the addition of vitamins and minerals or certain other substances to foods			
Regulation (EC) No 1925/2006 of the European Parliament and Council, 20 December 2006	This regulation establishes rules for the inclusion of vitamins, minerals, and other substances in food.	- Specifies permitted vitamins and minerals. - Conducts scientific risk assessments to determine maximum allowable amounts in food.	[45]
Regulation for foodstuffs for particular nutritional uses			
Regulation (EU) No 609/2013 of the European Parliament and Council, 12 June 2013	This regulation concerns food products formulated to meet specific nutritional needs.	- Sets levels of vitamins and minerals in products targeting specific consumers. - Establishes composition and labelling guidelines for dietary foods used for medical purposes. - Provides a list of permitted chemicals prioritising safety and suitability for consumption.	[46]
Regulations for the labelling, presentation and advertising of foods			
Regulation (EC) No 1924/2006	This regulation outlines rules for nutrition and health claims made on food products.	- Ensures the internal market functions effectively while providing high consumer protection. - Applies to nutrition and health claims on food labels, presentations, and advertisements.	[47]
Commission Regulation (EC) No 353/2008	This regulation provides specific rules for submitting health claim applications.	- Health claim applications must be based on strong and reliable scientific evidence. - All relevant data must be considered to validate the health claim before approval.	[48]
Regulation (EU) No 1169/2011 of the European Parliament and Council, 25 October 2011	This regulation establishes the framework for consumer protection in food information, particularly food labelling.	- Provides principles and responsibilities for food information. - Ensures consumers have access to relevant food information and processes.	[49]
Commission Implementing Regulation (EU) 2018/775	This regulation specifies how to indicate the country of origin or place of provenance for food.	- Does not apply to geographic terms that are part of common or generic names. - Excludes geographic indications protected by other regulations such as Regulation (EU) No 1151/2012, Regulation (EU) No 1308/2013, Regulation (EC) No 110/2008, or Regulation (EU) No 251/2014, or those that are protected under international agreements.	[50]
Commission Implementing Regulation (EU) 2017/2469	This regulation provides guidelines for the execution of Article 13 of Regulation (EU) 2015/2283 on novel foods.	- Requires all novel food applications to include adequate scientific information and evidence for safety evaluations. - Specifies comprehensive safety evaluation requirements, including toxicological test data.	[51]
Commission Regulation (EU) No 432/2012	This regulation establishes the list of approved health claims that can be made on food products.	Lists approved nutrients, substances, and food categories along with conditions for using health claims.	[52]
Commission Implementing Regulation (EU) No 828/2014	This regulation informs consumers about the absence or reduction of gluten content in food products.	- Provides guidelines for foods processed to reduce gluten levels. - Applies to gluten-free foods and those naturally free of gluten.	[53]

at the European level. They must adhere to the EU Regulation (EC) No 1935/2004 regarding FCMs and Regulation (EC) No 2023/2006 on GMP [55].

3.1.3. Regulations for the protection of data

Regulation (EU) 2016/679 and Directive 2002/58/EC protect individuals under the General Data Protection Regulation (GDPR) when their data is processed by both the private sector and most public sector entities. These regulations guarantee the confidentiality of communications, the security of personal data management, and the notification of any personal data breaches. Additionally, unsolicited communications that have not been authorised by the user are prohibited. For the integration of extracted proteins from legumes and their by-products, several stages and processes require stringent data protection. Personal data including employee data, employee roles and responsibilities, customer information, and supplier details need to be processed and stored correctly. This is especially important during the validation stage of protein extracts for food formulations. For instance, in a study examining the factors influencing the price and choice of legume snacks (LS) among Italian industries and consumers, key internal and external determinants were identified. The research used a discrete choice experiment, a survey method designed to estimate consumer preferences, behaviours, and their willingness to pay. Since, the data was collected via an online questionnaire, the researchers had to be careful that the study was in compliance with regulation (EU) 2016/679, ensuring that personal data was protected and not disclosed to third parties or used for personal interests [56]. Additionally, to demonstrate compliance and provide proof of scientific data for applications, it is necessary to implement data protection measures and a record of all processing activities.

3.2. Group II: regulations relevant to stages after extraction of proteins from legumes and their by-products

The regulations in this group (Commission Regulation (EU) 2023/915 and Regulation (EC) No 396/2005) (as shown in Table 3) are relevant from the extraction process through the scaling up of the optimised extraction process and until the validation of the extracts for food applications. To safeguard the health of EU citizens, including vulnerable groups such as children, the elderly, and pregnant women, regulations establish maximum limits for specific food contaminants. The maximum residue level (MRL) of pesticides is set for all food intended for human consumption to protect public health. Legumes are of particular concern due to their high incidence of pesticide residues. Pesticide use remains significant in many EU countries, with residues frequently found in legumes. Lentils were identified as having the highest glyphosate residue levels among all products analysed in a survey conducted by EFSA [57]. Therefore, stringent quality control and safety measures are essential to monitor and manage contaminant levels in legume-based protein foods, ensuring their safety for consumption across the EU and maintaining high food safety standards and market consistency.

3.3. Group III: regulations relevant to stages after integration of legume and their by-products derived proteins into food formulations

'Regulation for the addition of vitamins and minerals or certain other substances to foods', 'Regulation for foodstuffs for particular nutritional uses' and 'Regulations for the labelling, presentation and advertising of foods' are particularly relevant to the stages of incorporating the protein extracts and the validation of these extracts as additives in food formulations or to produce protein enriched food products, as shown in Fig. 2.

3.3.1. Regulation for the addition of vitamins and minerals or certain other substances to foods

Regulation (EC) No 1925/2006 specifies that only vitamins and minerals listed in this regulation can be added to foods. These vitamins and minerals, in bioavailable forms, may be added to: (a) Address known deficiencies in the population or specific groups, or low nutrient intake levels; (b) Improve nutritional status or correct dietary deficiencies due to changing habits; and (c) Advance scientific knowledge on the role of vitamins and minerals in health [45]. At present, no protein isolates from legumes or their by-products are approved as food additives in the EU [58].

3.3.2. Regulation for foodstuffs for particular nutritional uses

Regulation (EU) No 609/2013, which covers foodstuffs for particular nutritional uses, aims to protect consumers by regulating the composition and marketing of foods intended for infants, young children, special medical purposes, and total diet replacements for weight control. Specific regulations on food labelling apply to each of the specific products. For instance, common legume foods that often cause allergic reactions in children include peanuts, tree nuts and soya [59]. Currently, only certain plant proteins, including soya protein isolates, are approved for use in infant formula, with specific limits (1.35–1.96 g/100 g). Due to growing demand for plant-based infant formulas, researchers are exploring alternatives like pea, faba bean, lentil, and chickpea, which offer high protein content. These plant proteins should have an essential amino acid profile similar to breast milk. While soya is the main plant protein used in infant formulas, its potential to cause allergies, remains a topic of concern. Between 10 % and 14 % of infants who are allergic to cow's milk are also allergic to soya protein. Additionally, allergenic cross-reactivity can occur between soyabeans and other legumes, such as lentils, peas, lupins, peanuts, and chickpeas, due to shared epitopes found in the allergens of these legumes [60]. This highlights the importance of carefully addressing allergenicity in labelling, presentation, and advertising when developing legume-based infant formulas. Furthermore, pesticide regulations have also been extended to include foods for infants and young children with special medical needs. Thus, this regulation plays a key role in ensuring compliance with legal requirements, as well as securing consumer acceptance and market approval for these specific food formulations.

3.3.3. Regulations for the labelling, presentation and advertising of foods

The regulations under this group (as shown in Table 3) seek to protect consumers' right to information by defining the general guidelines, requirements, and responsibilities for the labelling of the food they consume. They aim to ensure that nutritional and health claims made on labels, presentations, and advertisements are clear and supported by accepted scientific data. For instance, a biotechnological approach using enzymatic treatment and lactic acid bacteria fermentation was tested to improve the nutritional value of semolina pasta enriched with chickpea, hemp, and milling by-products. With protein content at 13 % and fibre at 6 %, this fortified pasta was labelled as a "source of fibre" and a "source of protein" under regulation (EC) No. 1924/2006 on nutrition and health claims made on food [61]. Additionally, these regulations also provide guidelines to ensure that an authorised product does not pose a risk to human health or mislead consumers. Three leguminous crops-lupin, soyabean, and peanut-are among the 14 allergens specified in Annex II of regulation (EC) No 1169/2011 which require mandatory labelling when used as ingredients. IgE-binding (and hence potentially allergenic) proteins have been identified in the majority of legumes, including peas, beans, lentils, and chickpeas [62]. Cross-reactivity also poses a major risk with undisclosed allergens in products [59]. Consumption of a product lacking a primary allergen while containing an unreported cross-reactive allergen could endanger the health of an allergic individual. The presence of undeclared allergens in food labelling is an issue of public safety for certain groups. Despite the need to identify allergens, instances of food mislabelling are rising, often lacking enough information on the allergens present and hence presenting a risk to those with allergies. Consequently, these concerns have been included into the Rapid Alert System for Food and Feed (RASFF) [59]. Precautionary allergen labelling (PAL) was also introduced to manage and mitigate hidden allergen risks under European Regulation No 1169/2011 [49]. PAL is voluntary and must not mislead consumers. Additionally, it should be clear, unambiguous, and based on relevant scientific and quantitative data when applicable [63]. Therefore, the mandatory labelling of allergenic compounds is crucial for patients to avoid

foods that contain allergens in their formulations.

4. Standardisation and standards

Standardisation is defined as 'an activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at achieving the optimum degree of order in a given context' [34]. The aim of standardisation is to ensure that a product, process, or service is suitable for its intended use. The product, process, or service developed should be fit to serve a defined purpose under specific conditions. Standardisation may have one or more specified objectives depending on the aim [34]. The standardisation bodies are active at the national, regional, and international levels. Each country has a national standardisation organisation or body at the national level. The Spanish Association for Standardisation (UNE), the German Institute for Standardisation (DIN), the National Standards Authority of Ireland (NSAI), and the Portuguese Quality Institute (IPQ) are a few examples of national standardisation bodies. The International Organisation for Standardisation (ISO), which operates internationally, is a network of 171 national standards organisations that act as ISO's local representatives. ISO is responsible for coordinating the development of these standards and ensuring their accessibility [64].

Standards are documents developed by consensus within recognised organisations. They define rules, standards, or characteristics for actions or their outcomes, aiming to establish a high level of order within a specific environment. Standards may include a range of criteria or measures. Standards can be.

- International standards, adopted by an international standards organisation and made publicly accessible.
- Regional standards that are adopted by a regional standardising/standards organisation and made publicly accessible.
- National standards that are adopted by a national standards body and made publicly accessible.
- Provincial standards that are adopted and made publicly accessible at the level of a country's territorial division [34].

Although the use of standards is voluntary, they provide a simple and cost-effective means for businesses to comply with applicable national or regional legislation. Standardisation organisations, such as CEN, collaborate with public authorities to develop standards that support legislation and public policies [65]. The European Parliament and the EU Council adopted the European Union (EU) regulation 1025/2012 [66], which establishes the legal foundation for standardisation, and it came into effect on January 1, 2013.

Additionally, standards are a critical part of a functioning marketplace, and the application of existing standards ensures that results will adhere to existing practices and achieve better market application. Legume and legume by-product proteins as food ingredients must adhere to relevant standards in order to gain full compliance and pre-market approval in European markets. As a result, using standardised techniques throughout the production activities can ensure compliance with applicable laws.

4.1. Relevant standards

At the European and international levels, there has not been significant development of standards for legumes. However, there is a dedicated working group on pulses under ISO/TC 34/SC 4 - Cereals and pulses, which is of importance. The objective of this Technical Committee (TC) is to standardise terminology, sampling, testing and analytical procedures, product standards, and requirements for packaging, storage, and transportation in the field of cereals and pulses as well as their products [67]. The nutritional characterisation of raw materials, i.e., legumes, legume by-products, and the extracted proteins should be assessed. Protein quantification and amino acid composition are two crucial aspects of the extracted proteins' characterisation. Currently, there are no standardised techniques available for protein extraction or processing from legumes or legume by-products.

Given the lack of standardised techniques for protein extraction from legumes, ensuring the safety of these extracted proteins is particularly important. The primary objective of the European Commission's (EC) food safety regulations is to ensure a high level of protection for human health within the food industry [68]. Safety evaluations include microbiological testing, heavy metal detection, and pesticide detection of extracted proteins. Microbiological evaluation takes into account the main spoilage and pathogenic microorganisms. While heavy metals pose a significant risk due to bioaccumulation and biomagnification in living tissues, certain metals like copper (Cu), zinc (Zn), and manganese (Mn) are permitted as food additives under specific regulations, such as regulation (EC) No 1925/2006 [45]. As per the scientific opinion on dietary reference values published by EFSA, the adequate intake (AI) of Mn in adults in the EU is 3 mg/day [69], AI of Cu for adults in the EU is 1.3–1.6 mg/day [70] and the population reference intake (PRI) of Zn for adults in the EU is 7.5–16.3 mg/day [71].

Plant protection product regulatory frameworks have been formed at the global, regional, and national levels, with the European regulatory system being regarded as one of the strongest and most comprehensive pesticide laws [72]. The use of hazardous pesticides on grain legumes adversely impacts the environment by depleting soil fertility and harming soil microfauna. In addition, repeated use of chemical pesticides frequently results in the development of resistance in diseases, nematodes, and insect pests, and leads to carcinogenic, teratogenic, and mutagenic effects in animals and humans [73]. According to Directive 2009/128/EC [74], if the basic principles with the crop and sector-specific standards for integrated pest management or other techniques, like non-chemical alternatives to pesticides, are followed by all farmers, it would result in the better-targeted use of pesticides. Allergenicity should also be studied as part of the safety evaluation of extracted legume proteins.

The solubility, emulsification, foamability, and gelation of the extracted proteins are assessed in terms of their technological properties. There are no standardised methods available on the subject matter. To determine the viscoelastic properties of the gels made from the protein extracts, rheology experiments should be conducted. There are no standards available for rheological

Fig. 3. Standards for microbiological analysis of food and water relevant to pre-treatment, production and processing of the extracted legume proteins in food formulations.

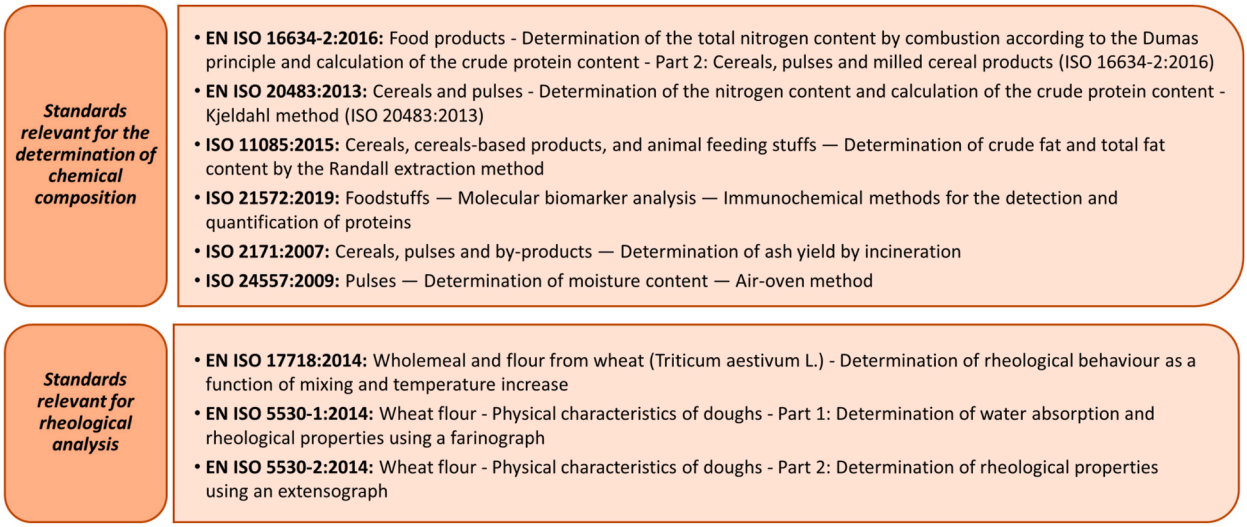

Fig. 4. Standards for determination of chemical composition and for rheological analysis relevant to pre-treatment, production and processing of the extracted legume proteins in food formulations.

assessment of proteins. However, there are numerous standards for rheological measurements of wheat flour/dough, which can be of significance to the extracts of the legume proteins. Finally, the major aspect that plays a crucial role in whether or not the production method can be scaled up sustainably depends on the life cycle sustainability assessment (LCSA) of the production, product category rule (PCR), eco-design of processes to optimise and analyse various scale-up strategies and scaling up of the optimised processes. The relevant standards for the entire process—from pre-treatment and production to the processing of legume proteins for use in food matrices—are listed in Figs. 3–5.

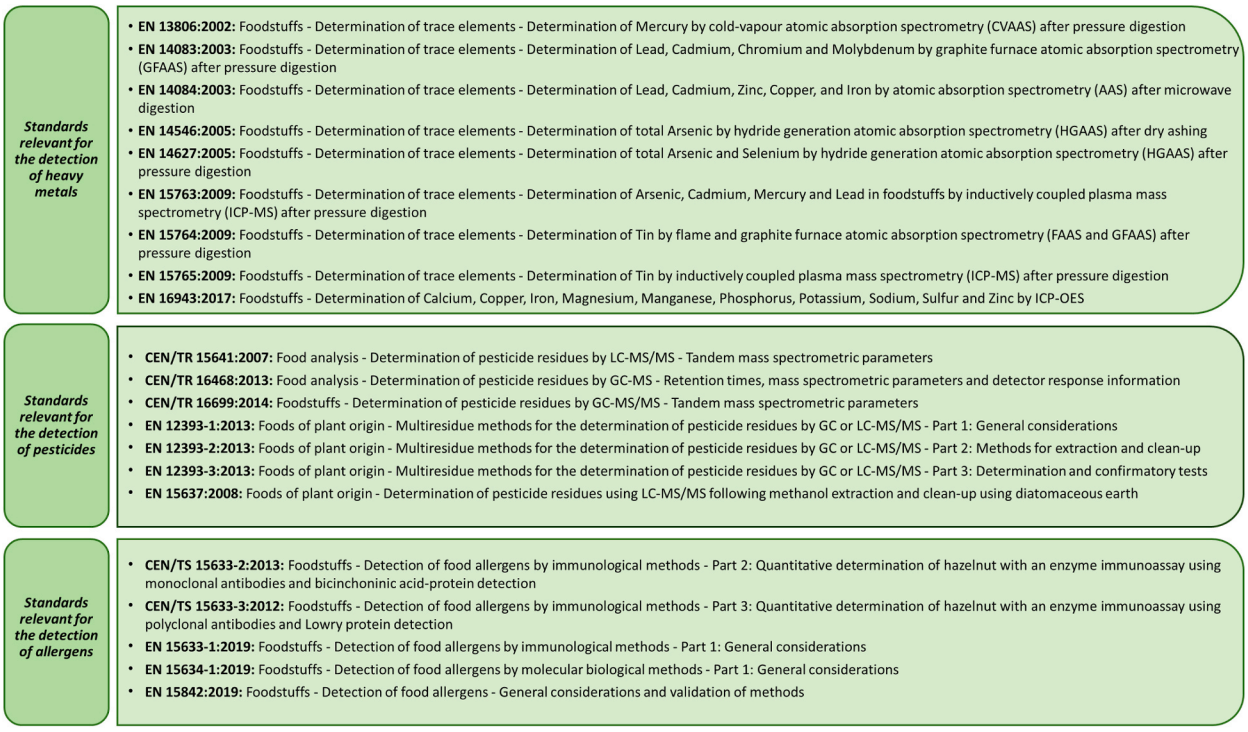

Fig. 5. Standards for detection of heavy metals, pesticides and allergens relevant to pre-treatment, production and processing of the extracted legume proteins in food formulations.

5. Legume protein as a novel ingredient

Novel food is defined as 'food that had not been consumed to a significant degree by humans in the EU before 15 May 1997'. Irrespective of when a country joined the EU, all current members are subject to the 15 May 1997 deadline. A person, producer, or importer who wants to sell a new protein must demonstrate 'significant human consumption within the EU' in order to show that it is not a novel product. Consumption outside of the EU does not count as evidence of significant consumption under regulation (EU) 2015/2283 [75]; only consumption within the EU qualifies. The term 'novel food' can refer to food that has recently been developed, food produced using new technologies and production processes, as well as food that is or has historically been consumed outside of the EU [75]. In the European Union (EU), novel food must comply with consumer safety standards. In order to avoid misleading customers, it is important to ensure that novel food is appropriately labelled. Additionally, if the novel food is intended to be a substitute for another food, it should not have any nutritional disadvantages for the consumer [30].

In the EU, each member state has its own regulatory and standard-setting body in addition to the EC and European Food Safety Authority (EFSA). Examples include the Federal Ministry of Food and Agriculture (BMEL) of Germany, the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) and Food Safety Authority of Ireland (FSAI) to regulate the food safety in their respective countries. Proteins with a long history of safe use, including legume proteins like soy protein and cereal proteins, particularly gluten protein, which are frequently used as regular ingredients for meat substitutes are known as traditional proteins. Other novel food ingredients include plant-based proteins, such as rapeseed protein [76], traditional foods consumed in other parts of the world, such as chia seeds [76] and baobab [76], and foods produced using novel processes, such as bread enriched with vitamin D2 through UV treatment [77], which have been approved as novel foods in the EU. However, many food ingredients lack a history of safe consumption and must undergo safety assessments before use including novel legume proteins. For novel food approval, the EU regulations provide guidelines to ensure a high level of protection for consumer interests and human health. For instance, novel food dossier applications have been submitted to the specific standard-setting body for the use of legume proteins extracted from yellow pea (*Pisum Sativum*) [78], lentils [79], mung bean (*Vigna radiata*) [80] and soy (*Glycine max*) [81] as food ingredients.

5.1. Regulations for novel food

Some relevant regulations for novel legume protein ingredient are shown in Table 4.

Table 4
Regulations and information in the regulations relevant for novel legume protein ingredient.

Regulation	Relevant information	References
Regulation (EU) 2015/2283 of the European parliament and of the council of 25 November 2015, on novel foods.	- The European Commission (EC), each member state, and the European Food Safety Authority (EFSA) jointly approve new food ingredients for the EU market as novel foods. EFSA has published guidelines for the authorisation of novel foods. - The EC may request EFSA to conduct a risk assessment to ensure the safety of a novel food. A novel food must be safe and nutritionally advantageous, but not necessarily beneficial. - Additional scientific information and the presentation of data needed to support novel food applications, as well as the preparation of initial assessment reports, are outlined in Recommendation 97/618/EC.	[75]
Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain.	- Aims to improve the reliability, objectivity, and independence of studies used by EFSA and to enhance transparency throughout the EU food chain risk assessment process. It also reviews EFSA's governance to ensure long-term sustainability. - Incorporates public consultations in the process of evaluating applications for the approval of regulated products. - Ensures that EFSA is notified of all commissioned studies in a particular area, ensuring that companies applying for authorisation submit all relevant information. - Allows citizens access to scientific studies and information submitted to EFSA by industry early in the risk assessment process. - Grants the EC the ability to request further research data from EFSA.	[82]
Commission Implementing Regulation (EU) 2017/2469, laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.	- Applications mentioned in Article 10(1) of Regulation (EU) 2015/2283 must include sufficient information and scientific evidence to enable the European Commission to verify their credibility and for EFSA to conduct thorough risk assessments. - The safety evaluation plan should include comprehensive descriptions, such as detailed raw data, the relevance of test materials used in toxicological tests, and procedures for the detection and characterisation of engineered nanomaterials.	[51]

5.2. *Novel food application dossier process*

Before starting the novel food application dossier, the information required for submission of the novel food application dossier and the recommended format is outlined in Fig. 6.

The general procedure for submitting a novel food dossier application for approval is outlined below.

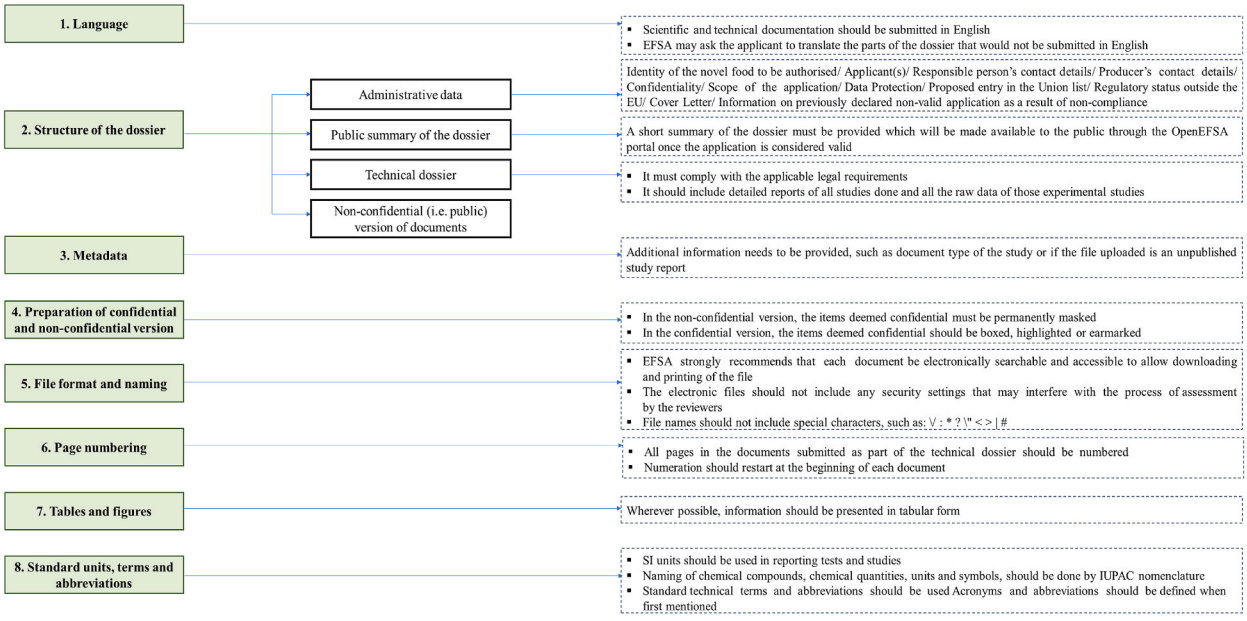

Fig. 6. Information required and the recommended format for the novel food application dossier.

- An applicant must submit their application to a Competent Authority (CA) for novel food in one EU member state in order to place a novel food product on the EU market. There is a CA for novel food in each EU member state, and it has the legal responsibility to execute regulation EU 2015/2283.
- An applicant must submit their application to a Competent Authority (CA) for novel food in one EU member state to place a novel food product on the EU market. Each EU member state has a CA for novel food, with legal responsibility for executing Regulation (EU) 2015/2283.
- The application to the CA of the first member state should be accompanied by a dossier containing all required details and copies of completed studies. The applicant must simultaneously send a copy of the dossier to the European Commission (EC).
- The EC forwards the request, the identity of the CA responsible for the preliminary safety evaluation, and a summary of the dossier to the CAs of other member states. The dossier is also sent to the European Food Safety Authority (EFSA) for further evaluation.
- The CA evaluates the dossier and issues a preliminary assessment report, determining whether a subsequent assessment is necessary.
- The national CA sends its preliminary assessment report to the EC. The EC forwards a copy of the report to the CAs of other member states for comments or justified objections.
- If the first member state concludes that no additional assessment is needed and no objections are raised, it notifies the applicant that the novel food product may be placed on the market.
- The applicant must inform the EC of any novel food that is 'substantially similar' to currently available food or ingredients in terms of composition, metabolism, nutritional value, intended use, and levels of undesirable substances.
- Most applicants typically submit a notice dossier to the CA of a member state to obtain the CA's opinion on the product's equivalence status. The notification dossier for the EC is then submitted along with the CA's opinion, and the EC forwards the notice to the CAs of each member state.
- If EFSA issues a positive opinion, the EC drafts a proposal for the authorisation of the novel food, which is then published in the Official Journal of the European Union.
- Although general procedures are comparable across the EU, national CAs vary. A fee must be paid to the CA in the member state where the application is submitted for the preliminary evaluation. The fee amount depends on whether the application is for authorisation or notification and is determined by the respective member state.

The novel food application dossier process from submission of the application dossier to adoption of EFSA's scientific opinion is summarised in Fig. 7.

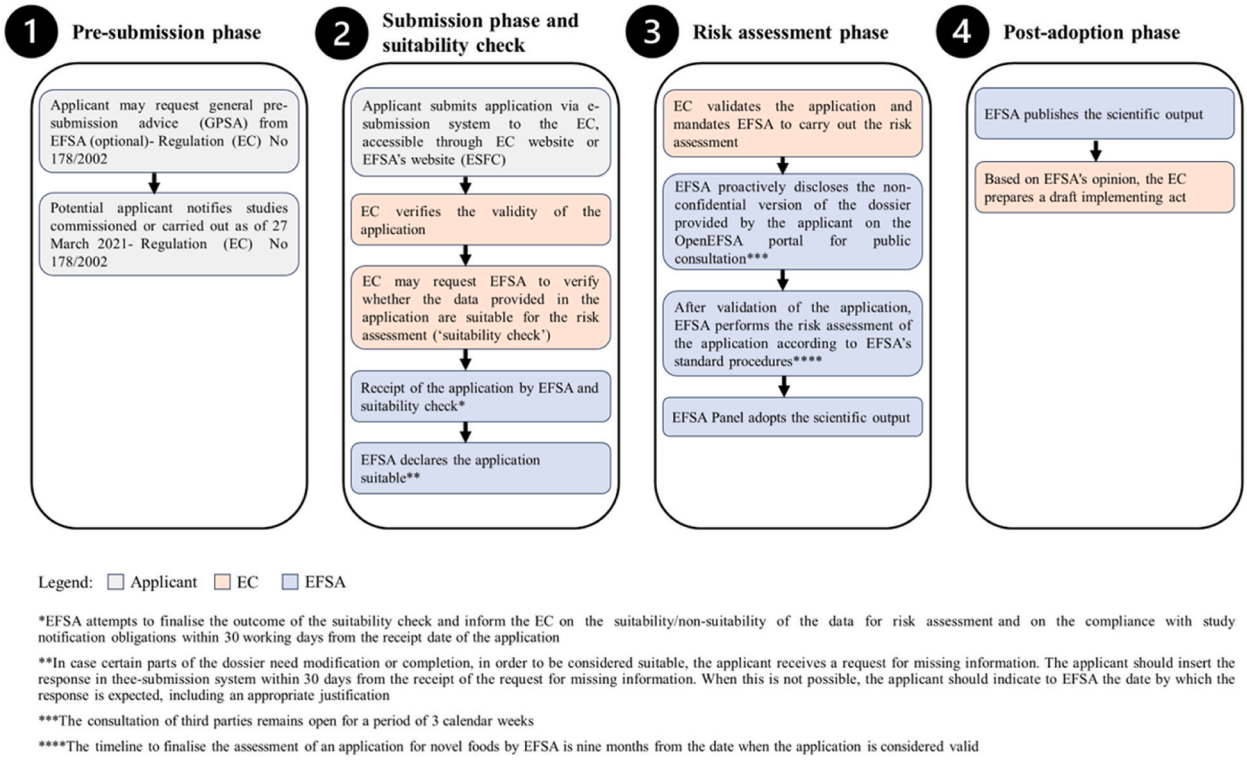

Fig. 7. Novel food application dossier process from submission of the application dossier to adoption of EFSA's scientific opinion.

6. Conclusions

With the growing focus on plant-based diets, the food and agricultural sectors would benefit from standardised methods for bio-refineries, which will facilitate the acceptance and utilisation of plant-based food formulations. Proteins can be extracted from both legumes and their by-products using green extraction techniques. These proteins can be incorporated into various foods to create products with enhanced functional and technological properties. To gain pre-market approval in the European market, protein extracts from legumes and their by-products must comply with relevant regulations and align with EU policies. Standardised methods throughout pre-treatment, production, and processing ensure adherence to these regulations.

This study provides a comprehensive overview of the key European regulations governing the use of legume and legume by-product proteins in food formulations, as well as the standards related to nutritional characterisation and safety. Additionally, when a particular legume or its by-products are considered novel ingredients in the EU, the requirements for preparing novel food application dossiers and the relevant regulations are outlined. Ensuring that these products meet regulatory standards will help deliver safe and compliant food products to the EU market.

This review aims to serve as a valuable resource for manufacturers already using or considering legume or legume by-product proteins in food formulations within the EU, providing essential guidance for achieving market acceptance and regulatory approval of these plant-based ingredients, whether traditional or novel. Further research is needed to explore the incorporation of proteins extracted from legume by-products into food formulations.

CRediT authorship contribution statement

Hitika Shah: Writing – review & editing, Writing – original draft, Visualization, Conceptualization. **Lubna Ahmed:** Supervision, Writing – review & editing. **Catherine Barry-Ryan:** Supervision, Resources, Project administration, Funding acquisition, Writing – review & editing.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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