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Food supplement safety and market entry in Germany, Bulgaria, North Macedonia and China

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Abstract

Objective: To compare market entry controls for food supplements in Germany, Bulgaria, and North Macedonia with the health food framework of mainland China, and assess their relationship to scientific safety evaluation. Methods: A functional comparative legal review of legislation, judgments, and regulatory guidance was combined with a targeted medical literature review. Sources were checked through September 24, 2026. Vitamin B6, green tea extracts, and red yeast rice illustrate dose-related toxicity and regulatory responses. Results: Germany uses notification, Bulgaria requires prior registration, and North Macedonia uses a compliance opinion followed by registration. China distinguishes registration involving assessment of safety, health function, and quality controllability from catalog-based filing supported by technical documentation. Chinese health foods and European food supplements are not identical legal categories. The examples demonstrate the importance of total exposure, preparation-specific toxicity, and continued reassessment after market entry. An administrative status or regulatory dose ceiling cannot establish universal safety or therapeutic efficacy. Conclusion: Good practice combines transparent classification, proportionate evidence requirements, prominent warnings, controlled product changes, and post-market surveillance. Chinese functional assessment adds a distinct comparator but does not establish superiority in health outcomes. The review supports cooperation between legal, toxicological, nutritional, and clinical expertise, while identifying limits arising from documentary access and the absence of comparative outcome data.

Keywords: Food supplement; Food safety; Toxicology; Registration; China

1 Introduction

Food supplements are concentrated sources of nutrients or other substances with a nutritional or physiological effect, intended to supplement the normal diet and marketed in dose form. A capsule or tablet is a means of presentation and dosing, not sufficient evidence of medicinal status. This review concerns orally consumed food supplements, excluding technological food additives, medicinal products, and foods for special medical purposes. [1, 2, 3]

Their public health significance arises from ready availability, concentrated exposure, and the possibility that consumers may rely on benefits not established for the intended use. The German Nutrition Society distinguishes supplementation for particular needs from nonspecific consumption when dietary intake is adequate. Regulatory communication should preserve this distinction. [4]

The term registration is frequently used as a generic description of different administrative mechanisms. This obscures whether an authority merely receives information, examines compliance before marketing, or issues a decision on which market entry depends. Germany, Bulgaria, and North Macedonia offer contrasting procedural models. Mainland China adds a dual registration and filing system for health foods (baojian shipin). This category overlaps with, but is not identical to, European food supplements; the comparison is functional rather than an assertion of equivalent legal definitions. [5, 6, 7, 8]

The objective is to compare these models and identify practices that can improve health protection without imposing unjustified administrative burdens. The central question is how each market entry mechanism relates to substantive safety requirements and the continuing responsibility of the food business operator.

2 Materials and methods

A doctrinal and functional comparative legal review was conducted using legislation, judicial decisions, and official administrative guidance. Targeted searches in Bulgarian, German, Macedonian, English, and Chinese covered the Bulgarian State Gazette, EUR-Lex, CURIA, Gesetze im Internet, the Chinese Ministry of Commerce legal database, and relevant regulatory websites, including the State Administration for Market Regulation (SAMR). Medical publications were identified through PubMed and publisher platforms. The search cutoff was September, 2026.

Sources were selected for direct relevance to product classification, market entry, composition, labeling, claims, and subsequent changes. Medical sources were selected to illustrate surveillance, efficacy assessment, and three contrasting hazards: nutrient neurotoxicity, extract-associated hepatotoxicity, and statin-like constituents in fermented products. These are explanatory examples, not matched products tested in all four jurisdictions. The analysis extracted the competent authority, procedural requirements,

timing, documentation, fees, consequences of product modifications, and relationship with European Union (EU) law for each country.

This is a targeted narrative review rather than a systematic review. Binding rules, administrative explanations, scientific recommendations, and proposals for improvement are distinguished throughout. Where only an abstract or an indexed passage was accessible, interpretation was confined to the result that could be verified. Individual administrative files, representative refusal series, operator compliance costs, and comparative health outcomes were not examined. The research used public documents and published aggregate findings; it involved no recruitment of human participants, identifiable patient data, or animal experiments.

3 RESULTS AND DISCUSSION

3.1 The European Union framework

Directive 2002/46/EC harmonizes core elements of food supplement regulation, including the definition, permitted vitamins and minerals, and presentation requirements. Article 10 allows national notification through submission of a label specimen for monitoring purposes. It does not establish a single EU authorization for every finished product. The European Commission also identifies incomplete harmonization of maximum amounts and substances other than vitamins and minerals. [1, 9]

Regulation (EC) No 178/2002 supplies the general safety framework: unsafe food must not be marketed, operators are responsible for compliance, and traceability and action in response to risk are required. Notification or registration does not transfer these responsibilities to the administration. [10]

Three assessments must be distinguished: the permissibility of the ingredient and its quantity, the national procedure for the finished product, and the legality of statements about its effects. Novel foods fall under Regulation (EU) 2015/2283 and must meet the conditions of authorized use. National notification cannot remedy the absence of a required novel food authorization. [11]

Nutrition and health claims are in regulation of Regulation (EC) No 1924/2006. A permitted claim concerning reduction of a disease risk factor is not equivalent to a promise to prevent or treat the disease itself. Product information is also subject to Regulation (EU) No 1169/2011, including its requirements for distance selling. [12, 13]

3.2 Germany

3.2.1 Legal basis and competent authorities

The specific national instrument is the Nahrungsergänzungsmittelverordnung (NemV). Under section 5, the manufacturer or importer must notify the Federal Office of Consumer Protection and Food Safety (BVL) no later than the first placement on the

German market and provide a label specimen. Where notification has already taken place in another Member State that requires it, the relevant authority must be identified. BVL forwards the information to the competent authorities of the federal states. [2]

The mechanism is therefore notification. BVL guidance expressly distinguishes acknowledgment of receipt from certification that a product is legally compliant. The procedure provides neither prior approval of efficacy nor an individual guarantee of safety. Supervision is undertaken by the federal states, while the operator remains responsible for compliance. [14]

3.2.2 Documentation and timing

The federal service description on Bayern Portal requires a German-language label and, where applicable, authorization for a representative. Labels for packaging or flavor variants are supplied as relevant. Electronic submission is available without an administrative fee. There is no waiting period for product approval within this notification mechanism. The guidance also requires communication of changes, such as modifications to the formulation, recommended intake, or business address. [5]

Administrative simplicity does not reduce substantive obligations. It places greater importance on the operator's compliance dossier and subsequent official surveillance. A receipt or reference number demonstrates notification; it should not be presented as government endorsement of product quality. This interpretation follows from the expressly limited function of the procedure. [14]

3.2.3 Scientific guidance

The German Federal Institute for Risk Assessment (BfR) publishes recommended maximum amounts of vitamins and minerals. These are scientific guidance rather than independently binding statutory limits. Their practical value lies in relating the supplemental dose to total intake and the susceptibility of particular groups. Distinguishing advice from law avoids both unsupported administrative restrictions and the mistaken assumption that any dose is acceptable whenever a fixed legal maximum is absent. [15, 16]

3.3 Bulgaria

3.3.1 Legal basis and prior registration

The principal instruments are the Food Act, particularly Articles 79–81, and the 2021 Ordinance on Food Supplements, amended in 2025 and 2026. The Executive Director of the Bulgarian Food Safety Agency (BFSA) is the competent authority. Article 79(11) requires entry in the register before market placement. Submission of an application does not replace registration. [17, 18, 19, 20]

The application identifies the operator and relevant establishments, product, qualitative and quantitative composition, intended use, and proposed marketing date. Supporting documents include the label intended for Bulgaria, the original label for a foreign-manufactured product, and a declaration of compliance. BFSA may request scientific information and opinions from competent institutions, including on medicinal classification and risk. [17]

3.3.2 Time limits and administrative practice

Article 79 provides for a proposed marketing date at least 14 days after application, an initial examination within 10 days, and at least 10 working days to correct deficiencies. The period relating to the proposed marketing date is suspended when deficiencies require correction. Article 79(9) establishes a separate seven-day period for registration or refusal linked to specified procedural events. These provisions do not create unconditional permission to sell after a fixed number of days. [17]

The official description of administrative service 3125 states a 17-day service period and no fee. A successful outcome is reflected in the public register rather than a separate certificate. Deficiencies require correction or may lead to refusal. Operators should therefore plan market entry around the actual registration status rather than treat an advertised processing period as automatic consent. [6]

3.3.3 Composition, labeling, and changes

The Ordinance regulates permitted vitamin and mineral forms, maximum daily amounts for persons over 18 years of age, and prohibited ingredients. Labels must contain specific warnings and the registration number and date. Separate provisions address sales channels and distance selling. Product registration and registration of the business activity or establishment are consequently distinct compliance matters. [18]

The 2025 amendment updated provisions and lists, including references to the Union list of novel foods. In July 2026, monosodium L-5-methyltetrahydrofolate and magnesium L-threonate were added as permitted forms, with references to the conditions in that list. Inclusion of a chemical form is not permission for unrestricted use. [19, 20]

Article 80 distinguishes updating particular registered circumstances from changing product identity. A change in the name or qualitative or quantitative composition is a ground for deleting the previous entry. The practical implication is that a revised product should be assessed for a new registration before sale rather than automatically use its predecessor's number. [17]

3.4 North Macedonia

3.4.1 Legal basis and administrative model

The overarching instrument is the Food Safety Law, listed in the official legal catalog of the Food and Veterinary Agency (FVA). Specific sources are the 2012 rulebook on supplement safety and the 2015 procedural rulebook, issued under Article 54(5) of the Law. The scope of verification of the consolidated Law is addressed in section 3.10. [3, 21, 22]

An operator applies for an individual opinion, termed mislenje, concerning a domestically manufactured or imported product. Under Article 4 of the procedural rulebook, FVA examines composition, quantities, labeling, and presentation materials. An approved product is then entered in an electronic register. Functionally, this is prior compliance assessment resulting in registration, although the formal document is called an opinion. [22]

3.4.2 Core dossier and additional evidence

FVA guidance identifies the original packaging or its proposed design, Macedonian-language labeling, the manufacturer's composition specification, and proof of payment of procedural costs. Domestic production also requires documentation concerning the establishment or operator. Depending on the issues requiring assessment, additional evidence may include pharmacological and toxicological opinions from designated academic bodies, laboratory results, evidence of marketing status abroad, or safety studies. These are conditional additions rather than necessarily a universal dossier for every supplement. [7]

The guidance also connects the application with separate requirements concerning health claims and foods produced using innovative technologies. Evidence that a product is marketed in the EU may therefore support assessment but does not replace the national procedure. [7]

3.4.3 Substantive rules and product changes

The 2012 rulebook addresses categories including amino acids, enzymes, prebiotics and probiotics, fatty acids, plants, fungi, and algae. It contains provisions on permitted and prohibited substances, minimum and maximum quantities, dosing, and warnings. Article 7 prohibits attributing disease prevention, treatment, or cure properties. Express alignment with Directive 2002/46/EC demonstrates a similar regulatory approach, not necessarily identical permitted formulations. [3]

Article 7 of the procedural rulebook specifies 2,000 Macedonian denars per product for issuing an opinion. This is the stated procedural cost, not the total expense of analysis, translation, or expert services. Under Article 8, a change in composition and/or labeling

constitutes a new product requiring a new opinion. A general exemption for minor label changes should not be inferred where the provision does not state one. [22]

3.5 China (People's Republic of China)

3.5.1 Scope and legal basis

The Food Safety Law, as amended in 2025, treats health foods as specially regulated foods. Articles 74–79 connect market access with safety, substantiated health functions, ingredient catalogs, labeling, and advertising controls. This review addresses mainland China's ordinary health food market; it excludes medicinal products, Hong Kong and Macao regimes, and special cross-border retail import arrangements. A product sold as a supplement abroad must first be classified under Chinese law. [8]

The 2016 Measures for Health Food Registration and Filing, revised in 2020, operationalize the distinction. SAMR handles registration and filing for eligible first-imported nutrient supplements; provincial market regulation authorities handle domestic filing. Registration assesses safety, health function, and quality controllability, whereas filing records a dossier demonstrating compliance with established requirements. [23]

3.5.2 Registration and filing routes

Registration applies to health foods using ingredients outside the relevant catalog and generally to first-imported health foods. The latter rule has an exception for eligible vitamin, mineral, and other nutrient supplements. Domestic catalog-compliant products may use filing; catalog inclusion alone does not waive formulation, dose, or technical requirements. This asymmetry means a foreign botanical product cannot assume the domestic filing route is available. [8, 23]

Registration documentation includes research and development, formulation, manufacturing, safety and health-function evaluation, analytical specifications, stability information, labeling, and samples. For first-import registration, the overseas manufacturer acts through a Chinese representative or agent and supplies the prescribed foreign-marketing evidence or alternative safety report. [23]

Filing also requires technical evidence and testing; it is not equivalent to Germany's label notification. Official filing guidance links the dossier to ingredient catalogs, evaluation requirements, and mandatory standards. [24]

Registration certificates are valid for five years. Relevant changes require the prescribed amendment procedure; filing changes must also be reported. Review periods exclude specified verification activities and may restart after supplementary materials, so a nominal review deadline is not a guaranteed launch date. [23]

3.5.3 Health functions and consumer information

The 2023 non-nutrient health-function catalog contains 24 functions, accompanied by evaluation arrangements and a five-year transition for relevant existing products. Standardized functional wording facilitates scrutiny, but does not establish therapeutic efficacy or authorize disease-treatment claims. [25]

Article 78 requires labels to identify appropriate and inappropriate consumer groups and to state that the product cannot replace medicine; Article 79 requires prior approval of health food advertising. SAMR's warning-label guide, effective in 2020, specifies a warning area covering at least 20% of the principal display panel of the smallest sales package. This provides a concrete communication practice for reducing confusion between health foods and medicines. [8, 26]

3.6 Comparison of the four frameworks

Table 1 distinguishes the regulatory outcome and evidentiary role of each procedure. China's health-function assessment adds a substantive dimension that would be obscured by describing all four systems merely as registration. None of these food procedures constitutes medicinal authorization.

Table 1. Market entry mechanisms and the meaning of regulatory status

Jurisdiction	Entry mechanism	Evidence and administrative outcome	Continuing obligations
Germany	BVL notification by first marketing	Label submission; acknowledgment does not certify compliance	Operator safety responsibility; communicate changes
Bulgaria	Prior BFSA registration	Dossier examination; specialist opinions possible; public register entry	Maintain compliant formulation, labeling, and registration status
North Macedonia	FVA compliance opinion and registration	Composition, label, and presentation assessment; additional evidence where required	New opinion for composition and/or label changes
Mainland China	SAMR registration or eligible national/provincial filing	Registration assesses safety, health function, and quality; filing requires a compliant technical dossier	Registration renewal; amendment or filing updates; approved labeling and claims

Sources: [2, 6, 7, 14, 17, 22, 23, 24]. BVL, Federal Office of Consumer Protection and Food Safety; BFSA, Bulgarian Food Safety Agency; FVA, Food and Veterinary Agency; SAMR, State Administration for Market Regulation.

Shared features include continuing operator responsibility, control of composition and presentation, and limits on medicinal claims. Differences concern prior intervention, evidence intensity, institutional allocation, and handling of modifications. Registers help verify status but can be misunderstood as endorsements of clinical benefit. These observations concern regulatory design; no comparative reduction in harm is demonstrated.

3.7 Issues affecting market placement

3.7.1 Mutual recognition and legal approximation

Regulation (EU) 2019/515 protects goods lawfully marketed in another Member State where nonharmonized national technical rules apply. It does not automatically abolish every prior national procedure or validate noncompliance with harmonized requirements. The existence of a prior authorization procedure and a substantive refusal based on a national technical rule are separate legal questions. [27]

The Bulgarian Ordinance refers to mutual recognition and the Food Act. A German notification should therefore not be presented as a universal European registration certificate. For North Macedonia, EU rules do not apply directly as they do in a Member State. Approximation of national law and evidence of EU sales do not by themselves create automatic recognition or internal market access. [7, 18]

3.7.2 The boundary between food and medicine

Case C-319/05, Commission v Germany, concerning garlic capsules, illustrates the importance of proportionality in medicinal classification. It does not establish that every botanical preparation is food. Rather, classification cannot be justified solely by dose form or a general physiological effect without considering the specific product characteristics. [28]

Operators should examine composition, dose, intended use, and presentation together. A product name or promotional material can create a classification problem even if the chemical formulation is unchanged. A documented assessment of the product category is a proposed organizational practice, not an additional document universally required by all four jurisdictions.

3.7.3 Botanical health claims

In Case C-386/23, Novel Nutriology, the Court of Justice considered botanical claims concerning psychological and behavioral functions. Its judgment of April 30, 2025, confirms the prohibition of unauthorized claims unless the relevant use falls within Article

28(6). Pending evaluation is therefore not, by itself, authorization: the particular claim and relevant transitional regime must be examined. [12, 29]

Compliance review should cover labels, product webpages, advertising images, and commissioned social media content. A lawful formulation can still be promoted through unlawful promises. For online sales, mandatory precontractual food information is also part of compliance. [13]

3.7.4 Ingredient permission and safe exposure

The Bulgarian 2026 amendment illustrates layered assessment. A substance may appear among permitted chemical forms while its use remains subject to novel food conditions. Operators must check specifications, quantity, target population, and labeling rather than simply locate an ingredient name in an annex. [11, 20]

Nutrient reference values, scientific tolerable upper intake levels, and statutory product maxima serve different purposes. Catalog eligibility in China similarly requires checking the specific formulation and conditions; it cannot establish permissibility in an EU Member State. [24]

3.8 Scientific safety and clinical evidence

3.8.1 Three illustrative safety problems

Vitamin B6 demonstrates that an essential nutrient can become toxic at excessive exposure. In 2023, the European Food Safety Authority (EFSA) established an adult tolerable upper intake level of 12 mg/day based on peripheral neuropathy. This is a total-intake reference, not an automatically binding maximum for each supplement. A dossier should therefore consider concurrent products and background dietary intake rather than evaluate each label in isolation. [30]

Green tea illustrates preparation-specific risk. EFSA's 2018 assessment associated supplemental intakes of at least 800 mg/day of epigallocatechin-3-gallate (EGCG) with increased serum transaminases in intervention studies and could not identify a safe supplemental dose. Evidence concerning traditional infusions cannot simply be transferred to concentrated extracts. [31]

Regulation (EU) 2022/2340 introduced a daily portion below 800 mg EGCG for the covered extracts and warnings concerning empty-stomach consumption, simultaneous green tea products, pregnancy, lactation, and persons under 18. The numerical restriction must not be described as a scientifically established safe threshold. [32]

Red yeast rice illustrates the interface between biological activity and toxicity. EFSA's 2025 reassessment retained concerns about severe muscular and hepatic effects reported at monacolin K intakes as low as 3 mg/day. The submitted evidence did not establish safety below 3 mg/day or identify an intake without safety concerns. This

scientific conclusion supports continuing reassessment; it is not itself a legislative prohibition or a complete statement of current marketability. [33]

Together, these examples justify examining chemical identity, extract or fermentation characteristics, daily exposure, target users, and interactions. They do not establish that identical products have been authorized or refused in the four jurisdictions.

3.8.2 Surveillance and demonstrated benefit

Geller et al. analyzed US surveillance data from 63 emergency departments for 2004–2013 and estimated approximately 23,000 emergency visits annually associated with supplement-related adverse events. This estimate cannot be quantitatively extrapolated to the four jurisdictions reviewed. It nevertheless illustrates why post-market surveillance matters for products marketed as foods. [34]

Navarro et al., using the US Drug-Induced Liver Injury Network, documented liver injury associated with herbal and dietary supplements. The clinically selected cohort does not estimate risk among all consumers, but demonstrates that natural origin does not establish absence of toxicity. Ingredient identity and quality, multiple constituents, and actual exposure are relevant to product assessment. [35]

The VITAL trial illustrates the distinction between marketability and demonstrated clinical benefit. In its primary analysis, vitamin D3 at 2,000 IU/day did not significantly reduce invasive cancer or major cardiovascular events compared with placebo in the study population. This does not negate treatment of deficiency; it does not support a general promotional promise to prevent these diseases. [36]

Safety must therefore be evaluated for the particular dose and use, while benefit must be evaluated for the particular claim and population. Neither a scientific paper about an ingredient nor an administrative entry substitutes for these assessments. The review by Bendadani et al. similarly highlights regulatory gaps and the need for consistent consumer protection measures. [37]

3.9 Regulatory implications and good practices

The comparison supports six practices grounded in the reviewed rules or official guidance. Their proposed transfer between jurisdictions requires evaluation; a more extensive dossier alone does not demonstrate better health outcomes.

First, clearly explain regulatory status. BVL's distinction between receipt and approval and China's prominent warning against substituting health foods for medicines address complementary sources of misunderstanding. Registers should explain what was assessed and what an entry does not establish. [14, 26]

Second, combine accessible electronic procedures with verifiable current product information. German electronic notification, Bulgarian and North Macedonian registers,

and Chinese disclosure provisions provide foundations. Linking superseded product versions is a proposed improvement, subject to confidentiality protection. [5, 6, 7, 23]

Third, make evidence requests proportionate and explicit. Bulgarian and North Macedonian specialist consultation and Chinese technical filing illustrate different means of addressing uncertainty. Published criteria should connect requested tests to ingredient identity, dose, vulnerable groups, and intended claims. [7, 17, 24]

Fourth, maintain controlled versions of composition, specifications, dose, labels, and promotional claims. Before changing a product, identify whether notification, amendment, renewal, or a new procedure is required. The divergent national rules make this a substantive compliance task. [5, 17, 22, 23]

Fifth, periodically reassess exposure and warnings against current toxicological evidence. BfR guidance and EFSA assessments illustrate why scientific values must be distinguished from binding maxima and why newly identified hazards warrant review even after administrative acceptance. [15, 16, 30, 31, 33]

Sixth, connect batch traceability and withdrawal procedures with clinical safety reports and independent claims review. EU food law supplies traceability and corrective-action obligations; standardized supplement adverse-event reports are a proposed development. Assessment of regulatory performance should examine serious noncompliance, response times, and recall completion, rather than registration counts alone. [10, 12, 29, 34, 35]

3.10 Limitations

The review compares legal structures and published guidance, not observed infringement rates, processing times, or clinical harm. Published time limits are not measured average durations; statutory fees exclude other compliance costs. Medical examples are illustrative and do not constitute a comprehensive assessment of all supplements.

The official North Macedonian catalog links to a 2025 consolidated Food Safety Law, but its full text was not accessible for substantive verification through the public interface used. Detailed procedural findings rely on the 2012 and 2015 rulebooks and published FVA guidance. Exhaustive coverage of subsequent amendments to the general Law cannot therefore be claimed. [3, 7, 21, 22]

Chinese legal terms are rendered descriptively in English; the Chinese texts remain authoritative. Catalogs and implementing requirements evolve, and consultation drafts are not treated as enacted rules. The three toxicological examples are not product-specific determinations of Chinese market eligibility. Law and guidance change over time. No comparable outcome dataset was examined that would permit a causal link between the procedural model and health outcomes across the four jurisdictions.

Recommendations should consequently be understood as legally grounded proposals requiring subsequent implementation and evaluation.

4 Conclusion

Germany, Bulgaria, and North Macedonia use notification, prior registration, and a compliance opinion resulting in registration, respectively. Mainland China adds registration with safety and health-function assessment and a distinct catalog-based filing route. These food frameworks do not authorize disease treatment. EU rules provide common requirements for Germany and Bulgaria; neither North Macedonian approximation nor Chinese registration confers automatic EU market access.

The most defensible practices combine transparent regulatory status, proportionate assessment, current scientific evidence, control of product changes, and effective post-market monitoring. Their value lies in maintaining compliance throughout the product lifecycle. Comparative evaluation of actual safety outcomes remains necessary before any national procedural model can be considered superior.

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