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AFIRS
ASIA FOOD INNOVATION-READY REGULATORY SYSTEMS INITIATIVE

PILOT ASSESSMENT UNDER THE ASIA INNOVATION-READY FOOD REGULATORY SYSTEMS INITIATIVE

Goji Berry and Goji-Derived Ingredients

Regulatory Status, Safety Assessment and Health-Function Evidence

Purpose of this pilot

To use Goji berry and Goji-derived ingredients **as a regulatory case study,** drawing on their long history of traditional use and heritage, the accumulated scientific knowledge base, and regulatory experience in China, together with approaches taken across Asian and international jurisdictions. The pilot examines how this experience can be used to **identify and generalize the scientific and regulatory requirements needed to establish the acceptability of traditional ingredients** as they are transformed through modern extraction, concentration and purification. Its purpose is to derive **practical guidance for determining novelty**, establishing **safety, and appraising and substantiating health-function claims, thereby providing a foundation for the regulatory management of innovation involving traditional and traditionally derived food ingredients.**

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Contents

Executive Summary

This report forms part of the work programme established following the Regional Think Tank on Innovation-Ready Food Regulatory Systems in Asia, held in Hong Kong, China, on 20-21 April 2026. The Think Tank identified Goji berry-derived ingredients, together with gamma-aminobutyric acid (GABA), as pilot cases through which participating experts could test practical approaches to novelty determination, safety assessment and health-claim substantiation. The broader objective is to extract principles that can support future consensus guidance and collaborative scientific assessment across Asian jurisdictions.

Goji berry, principally Lycium barbarum L., is a particularly useful pilot because it spans a regulatory continuum. The whole dried berry has a long history of food use and is commonly consumed in conventional preparations. At the other end of the continuum are concentrated and purified preparations such as Lycium barbarum polysaccharides (LBPs) and Lycium barbarum glycopeptides (LbGP), whose composition, exposure and intended use may differ materially from traditional dietary consumption. The pilot therefore illustrates why the regulatory history of a source food and the regulatory status of a derived ingredient are related but not necessarily identical.

The pilot draws together regulatory experience, ingredient-specific safety information, international studies and health-function evidence to examine how the evidentiary expectations change as Goji moves from a traditionally consumed whole food to extracts, enriched fractions and purified glycopeptide preparations. The analysis therefore focuses on the relationship between **traditional familiarity and modern ingredient characterization**, including when additional compositional, toxicological or human evidence becomes necessary because processing, concentration, intended use or exposure has changed materially.

Taken together, the evidence supports three separate regulatory questions that should remain distinct throughout the assessment: first, **whether the ingredient is novel** in the form and under the conditions in which it is proposed to be used; **second, whether that ingredient is safe** at **the anticipated exposure**; and third, whether **any proposed health function claim** is substantiated by evidence that is relevant to the specific ingredient, dose, population and claimed effect. This three-part structure is the central organizing principle of the report.

1. Introduction and Purpose of the Pilot

The Regional Think Tank on Innovation-Ready Food Regulatory Systems in Asia convened regulators, scientists, academic experts and industry representatives in Hong Kong in April 2026 to identify practical ways to improve regulatory preparedness for functional ingredients and non-nutrient health claims. The meeting established a work programme around three mutually reinforcing areas: development of consensus regulatory guidance, collaborative scientific assessment of selected pilot ingredients, and, once sufficient outputs are available, a shared information platform. Goji berry-derived ingredients were prioritized because they combine strong links to traditional Asian food and medicine systems with modern extraction, purification and functional-food applications.

The present report uses Goji berry as a regulatory case study to examine how **Asian and international jurisdictions have treated the safety assessment of a relatively well-known ingredient rooted in traditional use and traditional heritage**. The objective is to identify the regulatory logic applied as that familiar food is transformed into extracts, enriched fractions and purified functional ingredients, and then to determine which elements of that experience can be generalized into guidance for other traditional ingredients. Particular attention is therefore given to **novelty determination**, the **level of safety evidence appropriate to the degree of transformation and anticipated exposure**, and the **appraisal of evidence supporting proposed health-function claims**. The intended output is not a product-

specific approval conclusion, but a practical framework for considering how traditional-use evidence, modern characterization, safety data and claim substantiation should interact in innovation-ready food regulatory systems.

> **Core regulatory question: how far can the history of a traditional food be relied upon when that food is transformed into a compositionally different, more concentrated and potentially more biologically active ingredient?**

2. Historical Use of Goji Berry and the Regulatory Starting Point

Goji berry, principally Lycium barbarum L. and, to a lesser extent, the closely related Lycium chinense, has a **documented history of consumption** in China extending over more than two millennia. Dried berries are used in soups, broths, congee, teas, infusions and other conventional foods. Goji also occupies a distinctive place in Chinese dietary culture because of its dual use as a food and **as a material associated with Traditional Chinese Medicine**. This duality is reflected in the concept of medicine-food homology, under which certain traditional materials can have both dietary and health-related uses.

This history is highly relevant to **the regulatory assessment of the whole fruit and of preparations** that remain reasonably comparable with traditional consumption. It provides evidence of long-term familiarity with the food, its customary uses and the range of exposures associated with conventional dietary intake. The history of use does not, however, establish an unlimited presumption of safety for every fraction that can be isolated from the berry. As processing becomes more selective and exposure to particular constituents increases, the relevance of historical consumption must be considered alongside more ingredient-specific evidence.

This distinction is broadly consistent with the international regulatory landscape:

- Whole Goji berry and some conventionally processed forms are not regarded as novel foods in jurisdictions such as the European Union and Canada, while Japan has a longstanding history of use without an EU-style novel-food authorization system.
- At the same time, **concentrated or highly purified extracts may raise additional questions** because their composition and exposure can depart materially from those associated with the whole berry.

3. The Goji Ingredient Continuum and Novelty Determination

For the purposes of this pilot, Goji-derived materials are best considered along a continuum rather than as a single regulatory category. At one end is **the whole fresh or dried berry**, which is directly connected to traditional consumption. Conventional juice, infusion and aqueous preparations remain relatively close to that history of use. Further along the continuum are **concentrated extracts and polysaccharide-enriched fractions,** in which exposure to selected constituents may increase substantially. Highly purified glycopeptide preparations represent a further step because their molecular profile and biological activity may no longer be comparable with the food as traditionally consumed.

Ingredient form	Relationship to traditional food	Principal regulatory consideration
Whole fresh/dried berry	Essentially identical to the traditional food	Strong history of food use; conventional safety considerations.

Ingredient form	Relationship to traditional food	Principal regulatory consideration
Juice or infusion	Conventional transformation of the traditional food	Traditional exposure remains highly relevant, subject to composition and intake.
Traditional aqueous extract	Broadly representative of source material	History of use may remain informative if composition is not significantly altered.
Concentrated extract	Selected constituents present at higher levels	Composition, manufacturing process and increased exposure require closer examination.
Polysaccharide-rich fraction	Selected constituent group enriched	Ingredient-specific characterization and safety evidence become increasingly important.
Purified glycopeptide preparation	Composition and molecular profile materially modified	Dedicated identity, exposure, safety and health-function assessment may be required.

The Chinese requirements summarized for this pilot provide a useful conceptual model:

- Where plant extracts are prepared using **traditional processes** such as water extraction and there is no significant compositional change, safety may be supported substantially by the history of consumption and literature on the original plant, together with appropriate specifications.
- By contrast, **refining, purification, hydrolysis or other processes** that result in **significant compositional change** can trigger the need for additional ingredient-specific safety information, including toxicology, manufacturing information and detailed quality specifications.

> **Generalizable principle: novelty should be assessed by considering changes in identity, composition, processing, intended use and anticipated exposure, rather than merely asking whether the botanical source itself has previously been consumed.**

4. Identity, Composition and Quality Specifications

4.1 Nature of Lycium barbarum polysaccharides and glycopeptides

Lycium barbarum polysaccharides are described as major water-soluble components of Goji and are characterized as a complex heteropolysaccharide system. Lycium barbarum glycopeptides are described as more highly purified sugar-peptide conjugates derived from Goji, including fractions such as LbGP1-LbGP5. Purified glycopeptide preparations should not be treated as synonymous with crude polysaccharide materials (Wen, 2026) because purification removes other components and produces preparations with different molecular characteristics and potentially different bioavailability.

This distinction is important for both safety and claims assessment. If a commercial ingredient is represented as a defined glycopeptide preparation, **the evidence used to support it should relate to a sufficiently comparable test material**. A generic history of Goji consumption, or even **studies performed on an unspecified Goji polysaccharide mixture, may not be sufficient to characterize a more highly purified preparation.**

4.2 Identity and authenticity

A combination of analytical approaches is proposed to characterize identity and reduce the risk of adulteration (Wen, 2026). These include a characteristic monosaccharide fingerprint, molecular-weight distribution and UV spectral characteristics. The characteristic monosaccharides cited include arabinose, galactose, rhamnose, mannose and glucose. Together, these parameters can help distinguish genuine Goji-derived material from starch, dextrin, maltodextrin or other non-equivalent carbohydrate materials.

4.3 Physicochemical and hygiene specifications

Expected physical and chemical attributes should be characterized for commercial glycopeptide and polysaccharide powders, include purity, solubility, moisture, particle size, appearance and product consistency (Wen, 2026). Food-grade quality control should additionally address heavy metals, pesticide residues, microbiological quality, absence of relevant pathogens and residual processing solvents. The specific limits should ultimately be tied to the jurisdiction in which the ingredient is marketed and to the manufacturing process used for the commercial material.

4.4 Manufacturing process

The production of Goji polysaccharide and glycopeptide preparations may involve extraction, separation, membrane technologies such as ultrafiltration and nanofiltration, low-temperature processing and freeze-drying (Wen, 2026). From a regulatory perspective, the manufacturing process is not simply a production detail. It is central **to determining whether the final material remains comparable with the traditional food**, whether **new constituents are concentrated or removed,** and whether the material used in **toxicology or efficacy studies** can be considered representative of the commercial ingredient.

5. Linking Quality to Biological Function

An important dimension should be added to the quality discussion, by considering that the future standardization of LbGP should move beyond measuring constituent content alone (Lin, 2026). There is a need to clarify which **glycan structures, glycopeptide components** and **structural features** are responsible **for biological effects** and to establish a stronger relationship among composition, structure, quality and efficacy.

This has direct regulatory implications. If two materials are both labelled as “Lycium barbarum glycopeptide” but **differ substantially in molecular-weight distribution, glycan structure, peptide composition or biological activity,** evidence generated with one material may not be transferable to the other. The definition **of critical quality attributes** should therefore be developed with the eventual assessment purpose in mind. For a safety assessment, **these attributes help establish test-material equivalence.** For a health-function assessment, they help determine whether **the commercial ingredient is sufficiently comparable** with the material used in **the studies that support the proposed claim.**

6. Food Safety Assessment

6.1 Review of the Toxicological Information Package

Ingredient-specific toxicological information for Lycium barbarum polysaccharides/glycopeptides includes a conventional food-safety test package conducted under the Chinese GB 15193 series. The reported package

comprises acute oral toxicity, a genotoxicity battery, a 90-day oral toxicity study and developmental toxicity testing. The studies were reported as having been conducted by the Comprehensive Testing Center of the China Academy of Inspection and Quarantine on a defined batch of Goji-derived material (Wen, 2026).

In the acute study, the oral LD50 in mice was reported to be greater than 18 g/kg body weight, leading the authors to classify the material as practically non-toxic. The genotoxicity battery comprised a bacterial reverse mutation test, a mammalian erythrocyte micronucleus test and an in vitro mammalian chromosome aberration test; negative results were reported across the battery. In the 90-day oral study in rats, no treatment-related abnormalities were reported across the clinical, haematological, biochemical, urinary, organ-weight, gross-pathology and histopathology parameters examined. A **NOAEL of 7,500 mg/kg body weight/day** was reported. The developmental toxicity study similarly reported no maternal or fetal adverse effects at the highest tested dose, with a NOAEL of 7,500 mg/kg body weight/day.

These findings constitute a substantial conventional toxicological package. For the purposes of a collaborative regulatory assessment, however, the primary task is not simply to repeat the reported conclusions. The crucial question is whether the **material tested can be demonstrated to be equivalent to the ingredient proposed for use**. The Wen report itself highlights terminology relating to glycopeptides and polysaccharides that should be resolved through documentation **of the exact test substance**, batch, manufacturing process and compositional profile.

6.2 Test-material identity and transferability

Reliance on **toxicological evidence across products or jurisdictions requires a clear chain of comparability**. The identity and manufacturing process of the test material should be documented, the relevant compositional and molecular specifications should be established, and those specifications should be compared with the commercial material proposed for use. Where substantial differences exist, additional bridging information or new studies may be necessary. This principle is especially important for natural-product fractions, where the same common ingredient name can encompass preparations with materially different composition.

> **Safety evidence is transferable only to the extent that equivalence between the tested material and the proposed commercial ingredient is demonstrated.**

7. International Safety Evidence and Signals

7.1 Allergy and sensitization

A review of available information on safety assessment of Gogi Berry and its extracts at the international level identified several reports from Spain describing allergic reactions to Goji berry, including anaphylaxis and sensitization involving lipid-transfer proteins. Cross-reactivity with other plant foods, including tomato and peach, was reported. These observations do not establish that purified LbGP preparations pose the same allergenic risk as whole Goji berry, but they demonstrate that **allergenicity should be addressed explicitly** when the ingredient moves from a **whole-food matrix to an extracted or purified preparation**.

For a purified ingredient, the relevant assessment question is whether the manufacturing process removes, retains or concentrates allergenic proteins. Analytical characterization of **residual protein fractions** may therefore be more informative than relying only on the allergenicity history of the whole fruit.

7.2 Potential food-drug interaction

The international literature reviewed, to support the preparation of this review also included a case report describing a markedly elevated international normalized ratio in an individual receiving warfarin after consumption of Goji juice. A single case report cannot establish incidence or causality, but it represents a safety signal that should be considered when identifying potentially vulnerable populations or determining whether precautionary labelling is warranted for certain concentrated preparations.

7.3 Other experimental findings

The present review also identified an animal study in which Goji juice was associated with biochemical indicators of hepatic and renal oxidative stress under the experimental conditions used. This finding does not negate the broader body of safety evidence and involved a different test material from purified LbGP. Its value for the pilot lies in illustrating a broader regulatory principle: the assessment should consider the totality of relevant evidence, including results that do not support the expected or commercially desirable biological narrative.

8. Health-Function Assessment: A Separate Regulatory Question

Ingredient safety and health-function substantiation **should be assessed separately**. A long history of safe consumption does not establish that a food produces a claimed physiological benefit. Likewise, evidence of biological activity does not establish that a concentrated ingredient is safe at its intended exposure. Keeping these questions separate allows the scientific assessment to distinguish evidence needed to protect consumers from evidence needed to support communication of a benefit.

The available health-function evidence for LbGP spans multiple physiological systems, including gut health, bone health, metabolic and retinal effects, healthy aging and neuroprotection. The evidence base is strongest in mechanistic and animal studies, while human evidence remains more limited. The generation of stronger human evidence, using clearly characterized material and regulatory-relevant endpoints, remains a central requirement for standardized and international application of LbGP in health foods (Lin, 2026).

9. Overview of Health-Function Evidence for LbGP

9.1 Gut health

The Lin review (Lin, 2026) describes experimental evidence that LbGP can improve DSS-induced colitis and intestinal mucosal injury in mice and can modulate the composition and diversity of the gut microbiota. These findings provide biological plausibility for **gastrointestinal-health effects** and suggest potential effects on the intestinal microenvironment and mucosal barrier. At present, however, this evidence is primarily preclinical and should not be interpreted as sufficient, on its own, to substantiate a human gut-health claim.

9.2 Bone health

In an ovariectomy-induced osteoporosis model, LbGP was reported to reduce osteoclast activity and bone resorption and to modulate factors including CTSK expression and the RANKL/OPG balance. These findings support a plausible role in bone-health research and may inform the selection of biomarkers and endpoints for future human studies. Their immediate regulatory value is therefore hypothesis-generating rather than claim-authorizing.

9.3 Hepatic, retinal and metabolic effects

Studies in which LbGP improved lipid-metabolic abnormalities in liver and retina and influenced cholesterol efflux and bile-acid metabolism were summarized in the (Lin, 2026) review. The report relates these findings to traditional concepts associating Goji with liver and visual health. For regulatory assessment, it is important to preserve the distinction between a traditional rationale for use and scientific substantiation of a modern health claim. The **traditional association may help frame a research hypothesis**, but authorization of a claim should depend on evidence demonstrating a defined beneficial physiological effect in the intended population.

9.4 Healthy aging and cardiac metabolism

The reviewed preclinical evidence also includes effects on aging-related phenotypes, cardiac mitochondrial function and systemic energy metabolism, with proposed involvement of PINK1/Parkin-mediated mitophagy. These findings add to the mechanistic understanding of LbGP and may support future research on healthy aging. They **remain predominantly animal and mechanistic evidence** and therefore require confirmation in appropriate human studies before they can support an **internationally transferable food-health claim**.

10. Neuroprotection as the Most Developed Research Domain

Neuroprotection is one of the longest-standing and most systematically investigated research areas for Goji polysaccharides and glycopeptides (Lin, 2026). The body of work includes experimental models relevant to anxiety and depression, amyloid-beta-related neuronal injury, spinal cord injury, optic nerve and retinal injury, photoreceptor degeneration and Parkinson’s disease. Taken together, these studies indicate that LbGP has been investigated across a broad range of neural injury and stress pathways.

The scientific maturity of this research domain is important, but its regulatory interpretation requires care. Much of the evidence **remains preclinical**, and some of the endpoints relate directly to disease treatment or prevention. Such outcomes may be highly relevant to therapeutic development yet **may fall outside the scope of conventional food-health claims.**

The pilot should therefore address **the question on how to distinguish between evidence that supports general physiological-function research and evidence that belongs to a medicinal or therapeutic development pathway.**

11. Mood, Depression and Emerging Human Evidence

Preclinical evidence indicates that LbGP can reduce anxiety-like behaviours, oxidative stress and lipid peroxidation in the prefrontal cortex. Human research has also been reported in adolescents with subthreshold depression, including evaluation of cytokine outcomes following Lycium barbarum polysaccharide intervention (Lin, 2026). This is important because it moves part of the evidence base beyond animal models.

For regulatory purposes, however, **the existence of a human study** is only the beginning of the assessment. The **specific test material, dose, duration, population, primary and secondary endpoints**, statistical analysis and clinical or physiological relevance of the observed changes all need to be examined. In addition, the material used in the study must be shown to be representative of the ingredient for which the claim is proposed.

12. Parkinson's Disease, Motor Function and Therapeutic Translation

Research on LbGP in experimental models of Parkinson's disease has reported protection of dopaminergic neurons, reductions in lipid peroxidation, improvement in motor function and improvement in levodopa-induced dyskinesia. Translational activity has also included patents and development of an LbGP-based product identified as UNTREMOR, with reported marketing authorization in Macao and a clinical study related to new-drug registration being advanced in Bangladesh (Lin, 2026).

This body of work is scientifically relevant to understanding the biological activity of LbGP, but it may not be treated **as direct substantiation of a conventional food-health claim**. Parkinson's disease, neurodegeneration and levodopa-induced dyskinesia are therapeutic disease-related endpoints. Their inclusion in the pilot is valuable because they illustrate how **the same natural ingredient** can sit at the interface of foods, health foods, supplements, traditional medicines and therapeutic products, each of which may be governed by different regulatory standards and claim boundaries.

13. Human Studies on Goji Conducted Outside China

The review of the international context identified a limited number of human intervention studies conducted outside, or in collaboration with researchers outside, China. A randomized, double-blind, placebo-controlled study of standardized Goji juice in older healthy adults **reported changes in serum antioxidant biomarkers,** including increased superoxide dismutase and glutathione peroxidase and reduced malondialdehyde. A separate **short-term study of a standardized Goji juice preparation** reported improvements in several subjective measures of general well-being but did not identify corresponding **changes in objective physiological measures such as body weight or blood pressure**.

These studies contribute to the overall evidence base, but they also illustrate an important issue for this pilot:

Evidence obtained with whole-fruit juice or a standardized juice preparation cannot automatically be transferred to a purified glycopeptide ingredient. The composition, dose and bioavailability of the test materials may be fundamentally different. **Any future claim assessment should therefore begin by confirming that the evidence relates to the same, or a demonstrably comparable, ingredient**.

14. Cross-Jurisdictional Regulatory and Health-Claim Review

14.1 European Union

The whole berry is reported **as non-novel in the European Union**, but that status does not necessarily resolve the position of purified or concentrated fractions. The initiative review also notes that the European Food Safety Authority (EFSA) evaluated an antioxidant-related claim for Lycium barbarum and concluded that **a cause-and-effect relationship had not been established**. No authorized Goji-specific health claim was identified in the literature reviewed to date. This provides a useful example of a regulatory framework in which traditional use and biological plausibility are not sufficient without direct evidence supporting the proposed physiological effect.

14.2 United States

In the United States, dietary supplement structure/function claims can be made without the same form of pre-market efficacy authorization used in the European Union, provided the applicable statutory and labelling requirements are met. The present review did not identify a **formal Goji-specific qualified health claim or a searchable New Dietary Ingredient notification** corresponding to the concentrated extracts discussed.

14.3 Canada

Canada distinguishes among conventional food, novel-food and Natural Health Product pathways. Goji berry, Goji juice and Goji oil are reported as **non-novel foods**, while Lycium barbarum also appears in the Natural Health Products framework. The review identifies **antioxidant-related monograph recognition** within that separate framework but no equivalent evaluation **of a conventional food-health claim**. It is however noted that the standard of evidence for claims used under the Natural Health Product Pathway, may be considered lower than that required for function claims for foods, in Canada. This **distinction is useful because it demonstrates how the same source material** can receive different regulatory treatment depending on presentation, intended use and the framework managing claims.

14.4 Japan and Singapore

Japan does not operate a direct equivalent of the European novel-food system for a traditional ingredient such as Goji. The fruit is identified as having a long history of use and the Foods with Function Claims system allows **notified function claims based on defined evidence without the same form of pre-market government efficacy evaluation used in the European Union**. However, **no Goji-specific FFC notification** was identified in the material reviewed. Plant-part classification is also relevant, because the fruit and the root bark do not have the same regulatory characterization. In Singapore, this review did not identify **a Goji-specific evaluated health claim or an equivalent authorization precedent.**

15. China’s Health-Food Experience with Goji Extracts

China provides substantial practical experience with Goji-derived preparations used in **registered health foods.** The summary appended to this review identifies **registered products in which Goji extract is the sole ingredient, the primary ingredient or one of several important ingredients**. Product formats include capsules, tablets, chewable tablets, granules, powders, soft capsules and oral liquids. The use of capsule and tablet dosage forms is particularly relevant to this pilot because it illustrates how concentrated preparations may be positioned within the **nutraceutical regulatory framework** rather than treated simply as conventional foods.

Approved health functions represented in the reviewed product inventory include **enhancement of immune function, relief of physical fatigue, protection against chemically induced liver injury, improved hypoxia tolerance, relief of visual fatigue, bone-related functions, antioxidant-related functions and maintenance of healthy blood-pressure levels.**

The Chinese experience demonstrates that regulatory recognition of a health function is product- and framework-specific. This is similar to the Canadian framework, described above. It nevertheless provides useful regulatory precedent and can help identify functions for which evidence packages, assessment practices and post-market experience may already exist.

16. Evaluating the Strength of the Health-Function Evidence

A key output of the pilot should be an explicit distinction between the breadth of research activity and the level of evidence required for regulatory substantiation. LbGP has been investigated across multiple systems, but the evidence is unevenly distributed. Mechanistic and animal studies are extensive in several areas, whereas well-designed human studies using clearly characterized LbGP preparations remain much more limited.

Health-function area	Mechanistic evidence	Animal evidence	Human evidence	Regulatory interpretation
Immune-related function	Yes	Yes	Limited	Some Chinese health-food precedent; material-specific evidence still required.
Antioxidant-related function	Yes	Yes	Some biomarker evidence	Human biomarker data exist, but EU claim review did not establish cause-and-effect.
Gut health	Yes	Yes	Insufficient	Promising preclinical area; human substantiation needed.
Bone health	Yes	Yes	Insufficient	Preclinical evidence supports hypothesis generation.
Visual/retinal function	Yes	Yes	Limited	Chinese health-food precedent exists for visual-fatigue functions; ingredient comparability matters.
Mood/depression	Yes	Yes	Emerging	Human evidence exists but requires detailed regulatory evaluation.
Healthy aging	Yes	Yes	Insufficient	Predominantly mechanistic and animal evidence.
Neuroprotection/Parkinson's research	Extensive	Extensive	Therapeutic translation emerging	Much of the evidence concerns disease endpoints and may fall outside conventional food claims.

This matrix is intentionally qualitative. Its purpose is to support prioritization of future work rather than to pre-judge a formal claim dossier. A subsequent collaborative review could identify leading health effects for which it may be useful to refine the grading criteria and apply them to individual health functions using agreed standards for study quality, relevance, consistency and material comparability.

17. Major Evidence Gaps and Priorities for Further Work

This review and the appended reports (Lin, 2026, Wen, 2026) identify several scientific questions that are directly relevant to future regulatory assessment. The principal gaps concern **the identity of the active components**, **the fate of LbGP after ingestion**, **the biological targets responsible for the observed effects**, the relationship between

quality attributes and efficacy, and the **need for stronger human evidence.** These issues are interdependent and may be addressed as part of an integrated research strategy rather than as isolated questions.

In particular, digestion, absorption, distribution and metabolism remain important areas for clarification. It is necessary to understand whether the administered glycopeptide remains intact, is transformed in the gastrointestinal tract, or produces metabolites that are responsible for biological effects. This information could materially **affect both the definition of the active ingredient** and the interpretation of dose-response relationships.

The most important gap for claims substantiation is the relative **scarcity of well-designed human studies using a clearly characterized test material**. Future trials should define the target population, intake level, duration and health endpoint prospectively; use validated measures of physiological benefit; and ensure that the material used in the trial can be linked through specifications to the commercial ingredient. These requirements are also essential if the resulting evidence is intended to support reliance across jurisdictions.

18. Generalizable Lessons for Novel Functional Ingredients

The Goji pilot supports a staged model for safety assessment. The assessment should begin with **the history and identity of the source material**, then examine the manufacturing process and the extent to which composition is altered. The resulting ingredient should be characterized through appropriate specifications, anticipated exposure should be compared with historical dietary exposure, and toxicological evidence should be evaluated in relation to the specific test material. Vulnerable populations, allergenicity and potential interactions should be considered where relevant.

A parallel but separate pathway is needed for **health-function substantiation**. The proposed function should be defined precisely, supported by plausible biological evidence and then tested through human studies that use an appropriate population, dose, duration and endpoint. The commercial ingredient must be sufficiently comparable with the ingredient used in the pivotal studies. Mechanistic and animal evidence can strengthen plausibility and interpretation but should not substitute for human evidence where the regulatory framework requires demonstration of a beneficial physiological effect in humans.

> **The pilot therefore yields a simple three-question framework: (1) Is this ingredient novel in the form and use proposed? (2) Is this specific ingredient safe at the anticipated exposure? (3) Is the proposed health function substantiated for this specific ingredient , as characterized in the dietary application and intended population?**

19. Overall Conclusions

The whole Goji berry has an extensive history of conventional food use and is generally treated **as a familiar or non-novel food in the jurisdictions reviewed**. This history provides an important regulatory starting point but should not be extended automatically **to all concentrated or purified derivatives**. As the material becomes compositionally more distant from the traditional food, ingredient-specific characterization, exposure assessment and safety evidence become increasingly important.

For Lycium barbarum polysaccharides and glycopeptides, the technical package summarized in this report and associated reviews (Wen, 2026) and (Lin, 2026) provides substantial information on identity, quality and

conventional toxicological testing. The reported results are supportive **of a high margin of safety for the tested material, subject to confirmation that the test substance is clearly identified and representative of the ingredient proposed for use.** Demonstrating material equivalence is therefore a central requirement for any collaborative or reliance-based regulatory assessment.

The review (Lin, 2026) related to health claims, demonstrates that LbGP also has a substantial and expanding biological research base, particularly in neuroprotection, but also in gut health, bone health, metabolic and retinal effects, healthy aging and mood-related outcomes. **The breadth of this research may however not be equated with regulatory substantiation of individual food-health claims**. For most proposed functions, stronger human evidence may be needed, generated with well-characterized LbGP preparations and endpoints directly relevant to the claim.

The main value of the Goji pilot is therefore methodological. It demonstrates how a traditional Asian food can evolve into a modern functional ingredient and how regulatory assessment must evolve with it. The source history, processing, composition, exposure, safety and health-function evidence should be considered as connected but distinct elements. This structure can provide a practical template for assessing other traditional ingredients that are being transformed through modern food innovation.

20. Reference Documents Reviewed

- Regional Think Tank on Innovation-Ready Food Regulatory Systems in Asia, Hong Kong, China, 20-21 April 2026. Meeting report and agreed work programme.
- Roadmap for Advancing Innovation-Ready Food Regulatory Systems in Asia. GFoRSS and collaborating partners, 2026.
- Wen Quan. Lycium barbarum Polysaccharides/Lycium barbarum Glycopeptides: Quality Specifications and Food Safety Assessment Report. Guangzhou University of Chinese Medicine, 2026. Reproduced as Appendix 2.
- Xiao-Min Lin. Research Progress on the Health Benefits and Translational Applications of Lycium barbarum Glycopeptide. Jinan University, 2026. Reproduced as Appendix 3.
- Registered Health Foods Containing Goji Berry Extracts (up to August 31, 2026), based on the State Administration for Market Regulation Special Food Information Inquiry Platform. Reproduced as Appendix 1.
- Goji Berry: Trials and Studies Outside China. Evidence summary compiled for this pilot assessment. Reproduced as Appendix 4.
- Measures for the Administration of Health Food Registration and Filing, State Administration for Market Regulation, 2016 (revised in 2020).
- Guidance for Health Food Registration Application, State Administration for Market Regulation, 2016.
- Technical Guidelines for Toxicological Testing and Safety Evaluation of Health Foods and Their Ingredients (2020 Edition), State Administration for Market Regulation, 2020.
- GB 15193.1-2014, National Food Safety Standard - Procedures for Toxicological Safety Evaluation of Food, National Health Commission, 2014.

APPENDIX 1

Registered Health Foods Containing Goji Berry Extracts

Up to August 31, 2026 — based on the SAMR Special Food Information Inquiry Platform

Product Name	Applicant	Approved Health Function
Products with Goji berry extract as the sole ingredient (2)		
Zhongke® Goji Berry Extract Capsules	Nanjing Zhongke Pharmaceutical Co., Ltd.	Evaluated by animal experiments, this product has the health function of improving immune functions.
Zhi Ya Tang® Goji Berry Extract Chewable Tablets	Hubei Jianya Pharmaceutical Co., Ltd.	
Products with Goji berry extract as the primary ingredient and listed first in the ingredient list (15)		
Jinhe® Goji Berry and Epimedium Tablets	Jinhe Tibetan Medicine (Shandong) Health Industry Co., Ltd.	Evaluated by animal experiments, this product has the health function of relieving physical fatigue.
MCKIN® Grape Seed, Goji Berry and Cistanche Capsules	Shihezi Development Zone Shennei Tianyu Biotechnology Co., Ltd.	
Ya Tai Kang Pai® Goji Berry, American Ginseng and Epimedium Capsules	Jilin Yatai Yong'an Tang Pharmaceutical Co., Ltd.	
Xin Bang Di Fu® Goji Berry, Ganoderma and Salvia Tablets	Linyi Xinbang Biotechnology Co., Ltd.	Evaluated by animal experiments, this product has the health function of protecting against chemical liver injury.
Rui Jie Si® Epimedium, American Ginseng and Acanthopanax Capsules	Beijing Fufangfei Biotechnology Co., Ltd.	Evaluated by animal experiments, this product has the health function of helping to enhance immunity.
Tianmu Lake® American Ginseng, Goji Berry and Poria Capsules	Liyang Tianmu Lake Health Products Co., Ltd.	
Zi Le Duo® Goji Berry, Cuscuta and Schisandra Granules	Beijing Jinpingkang Pharmaceutical Technology Co., Ltd.	
Zi Le Duo® Goji Berry, Cuscuta and Schisandra Capsules	Beijing Jinpingkang Pharmaceutical Technology Co., Ltd.	
Wei Ai Xin® Goji Berry and American Ginseng Soft Capsules	Zhejiang Xinweishi Biotechnology Co., Ltd.	
Lu Hai Lan Sheng® American Ginseng and Goji Berry Capsules	Shandong Yinuo Kang Pharmaceutical Co., Ltd.	
Jinhe® Deer Blood and Goji Berry Tablets	Jinhe Tibetan Medicine (Shandong) Health Industry Co., Ltd.	Evaluated by animal experiments, this product has the health functions of helping to enhance immunity and relieve physical fatigue.
Fu Mei® Pilose Antler and American Ginseng Tablets	Xi'an Tianxiang Pharmaceutical Technology Co., Ltd.	
Hao Zhuang Tai® Bilberry and Lutein Granules	Beijing Dingweifen Health Technology Co., Ltd.	Relieving visual fatigue.
Jing Lan Chun® Bilberry, Lutein and Chrysanthemum Capsules		
Dingweifen® Lutein and Bilberry Tablets		
Products with Goji berry extract as the primary ingredient, but not first in the list (18)		
Yi Shu Kang® Goji Berry, Polygonum multiflorum and Gynostemma Capsules	Henan Shengji Pharmaceutical Technology Co., Ltd.	Evaluated by animal experiments, this product has the health function of helping to enhance immunity.
Yi Shu Kang® Goji Berry, Polygonum multiflorum and Gynostemma Tablets		
Jinhe® Qingrui Capsules	Jinhe Tibetan Medicine (Shandong) Health Industry Co., Ltd.	
He Hui® Polygonum multiflorum, Angelica and Poria Granules	Beijing Jinpingkang Pharmaceutical Technology Co., Ltd.	
He Hui® Polygonum multiflorum, Angelica and Poria Capsules		
He Hui® Polygonum multiflorum, Angelica and Poria Tablets		

Product Name	Applicant	Approved Health Function
Bu Yuan Tang® Astragalus and Ginseng Granules	Shanxi Buyuantang Biotechnology Co., Ltd.	
Yi Sheng Yi Bai® Sea Cucumber, Goji Berry and Acanthopanax Oral Liquid	Shandong Keju Pharmaceutical Co., Ltd.	
Li Kang Hai Wei® Theanine, Tea and Goji Berry, American Ginseng Capsules	Yisheng Weinuo (Beijing) Health Food Co., Ltd.	
Yun Gu Xi® Dendrobium, Ganoderma and Astragalus Powder	Anhui Qianfang Biotechnology Co., Ltd.	
Yi Cun Kang® Rhodiola, Ginkgo Biloba and Paecilomyces hepiali Capsules	Zhangshu Yikang Pharmaceutical Co., Ltd.	
By-Health® Morinda, Goji Berry and Cistanche Tablets	By-Health Co., Ltd.	Evaluated by animal experiments, this product has the health function of helping to relieve physical fatigue.
Ba Hao Di® Rhodiola and Goji Berry Capsules	Nanjing Ba Haodi Logistics Co., Ltd.	Evaluated by animal experiments, this product has the health functions of helping to relieve physical fatigue and improving hypoxia tolerance.
Wei Mei Bei Jian® Eucommia, Drynaria and Chondroitin Sulfate Capsules	Dezhou Bocheng Pharmaceutical Co., Ltd.	Evaluated by animal experiments, this product has the health functions of helping to enhance immunity and improving bone mineral density.
Jinhe® Bilberry and Lutein Tablets	Jinhe Tibetan Medicine (Shandong) Health Industry Co., Ltd.	Helping to relieve visual fatigue.
Duo Le Yi Bao® Bilberry and Lutein Capsules	Weihai Jiankang Yisheng Biotechnology Co., Ltd.	
Zhen Ke® Gastrodin, Eucommia and Notoginseng Capsules	Jinan Shengyutang Pharmaceutical Technology Co., Ltd.	Helping to enhance immunity and maintain healthy blood pressure levels (evaluated by animal experiments, this product has the health function of helping to enhance immunity).
Mei Ri Yi Yi® Grape Seed and Astragalus Capsules	Shandong Jiejing Biotechnology Co., Ltd.	Enhancing antioxidant function and enhance immunity (evaluated by animal experiments, this product has the health function of helping to enhance immunity).

Notes

1. The type of extracts is not mentioned in the SAMR announcement.
2. In most approved functional claims, human trial data are required. When the phrase “evaluated by animal experiments” is used, human trial data are not required for the specified function.
3. According to the Food Safety Law of PRC, all health foods with functional claims should be approved (registered) by State Administration for Market Regulation (SAMR).

Source of information: Special Food Information Inquiry Platform by State Administration for Market Regulation, https://ypzsx.gsxt.gov.cn/specialfood/#/food

APPENDIX 2

Lycium barbarum Polysaccharides / Lycium barbarum Glycopeptides: Quality Specifications and Food Safety Assessment Report

Prof. WEN Quan, Guangzhou University of Chinese Medicine

I. Introduction

Goji berry (Lycium barbarum L.) is a traditional Chinese resource with dual uses as both food and medicine, boasting a long history of application and high recognition for its safety in consumption. Goji polysaccharides (LBPs) and goji glycopeptides (LbGp) are the two most important water-soluble active components found in goji berries. Among them, LBPs represent the primary water-soluble active ingredient, with a relative molecular weight ranging from 68 to 200 kilodaltons, forming a complex heteropolysaccharide system. Goji glycopeptides typically refer to active compounds such as LbGP1–LbGP5 extracted from Ningxia goji berries; these are sugar-peptide conjugates composed of carbohydrate and peptide units, representing a highly purified and upgraded category within goji polysaccharides. Compared to goji polysaccharides, goji glycopeptides have removed inorganic salts and various monosaccharides—components lacking immune activity—resulting in improved water solubility and bioavailability. Their molecular weight distribution generally falls below 1,000 daltons or is controlled within the range of 800 to 5,000 daltons. Both substances are naturally derived from goji berries and carefully processed using specialized techniques, rather than being chemically synthesized.

With the rapid development of functional foods, specialty dietary foods, and health food industries, the industrial application of Lycium barbarum polysaccharides and Lycium barbarum glycopeptides has been increasing year by year. However, the industry has long faced the following core issues:

1. Standardized laxity: the market generally confuses "crude polysaccharides" with "refined glycopeptides," lacking classification standards.
2. Single detection method with difficulty in authenticity verification—traditional methods rely solely on total sugar content to assess quality, which fails to prevent adulteration and cannot match activity levels;
3. No dedicated standards for glycopeptides—Lycium barbarum glycopeptides lack specific food-grade quality standards;
4. Safety assessments are not systematic, and industry safety data is scattered and publicly unavailable.

Therefore, this report systematically investigates the quality specification system and food safety evaluation indicators for Lycium barbarum polysaccharides and Lycium barbarum glycopeptides, based on a complete set of national standard toxicological test data, raw material physicochemical parameters, industry quality control challenges, and food compliance requirements. It fills gaps in toxicological evidence, food-grade safety, clinical safety, and regulatory positioning, providing a foundation for industrialized food applications, raw material acceptance, standard submissions, and large-scale commercialization.

Note: Report source based on Complete toxicology test report from the Integrated Testing Center of China Inspection and Quarantine Academy (MA, CNAS accredited), Test substance: Lycium barbarum glycopeptides (goji berry glycopeptides; labeled as goji polysaccharides in Chinese), batch number 20240101, commissioned by Ningxia Tianren Goji Berry Biotechnology Co., Ltd.

II. Food-grade Quality Specification Standard System

2.1 Discrimination Criteria

(1) Monosaccharide fingerprint: Characteristic components include arabinose, galactose, rhamnose, mannose, and glucose, matching the unique sugar profile of Lycium barbarum, enabling differentiation from common adulterants such as starch, dextrin, and maltodextrin.

(2) Molecular weight distribution analysis: Lycium barbarum polysaccharides exhibit a narrow distribution, differing from the broad distribution typically seen in ordinary crude polysaccharides.

(3) UV spectral characteristics for identification: exclude interference from exogenous sugars, gums, and fillers.

2.2 Physicochemical Quality Indicators

Commercial goji berry glycopeptides and polysaccharides are typically produced from dried goji berries through extraction, separation, and purification processes. Goji berry glycopeptides appear as a brownish-yellow to light yellow powder, commonly available in specifications of 70%, 90%, or 98% purity, with particle sizes generally passing through 80 – 100 mesh. Their solubility is no less than 90%, and moisture content is controlled below 6%. Goji berry polysaccharides are also powdered products, similarly sized at 80–100 mesh, possessing the characteristic color of the product and uniform consistency. Both products should have a loose, non-clumped texture, free from visible impurities and with no obvious foreign matter, and carry the distinctive odor of goji berries. Due to the removal of non- immunologically active components, goji berry glycopeptides are more easily absorbed by the human body and exhibit higher bioavailability.

2.3 Hygiene and Safety Limit Indicators

(1) Heavy metals: lead, arsenic, cadmium, and mercury comply with the GB 2762 food raw material limit standards;

(2) Microorganisms: Total colony count, mold, and yeast must comply with regulations; pathogenic bacteria such as Salmonella and Staphylococcus aureus must not be detected.

(3) Pesticide residues: comply with the national standard limits for plant raw materials used in both medicine and food;

(4) Organic solvent residues: Residual levels from the purification process meet standards, with no process safety risks.

2.4 Production Process and Quality Control System

To ensure product safety and efficacy, the production of goji berry glycopeptides and polysaccharides commonly employs a combination of membrane separation technologies, including ultra-high-speed sedimentation, ceramic membranes, ultrafiltration, and nanofiltration, integrated with vacuum freeze-drying processes. The entire operation is conducted at low temperatures to preserve high biological activity. The manufacturing facility is built to a 100,000-class cleanroom standard, and the company holds ISO9001-2008 quality system certification, enabling compliance with standards such as USP25. This ensures stable annual production capacity of tens of tons.

III. Systematic Food Safety Toxicological Assessment (Based on Complete Authoritative Test Reports)

This product has completed the full set of national standard food toxicological safety evaluations (GB 15193 series), with all tests conducted by authoritative third-party testing institutions. The results are authentic, compliant, and suitable for food registration submissions.

3.1 Acute Oral Toxicity Test

Test basis: GB 15193.3-2014

Test results: The oral LD_{50} of ICR mice was greater than 18.0 g/kg body weight, classified as practically non-toxic.

Conclusion: The risk of acute consumption is extremely low.

3.2 Genetic Toxicity Battery Tests

The bacterial reverse mutation test (Ames test) (GB 15193.4-2014), conducted with and without S9 metabolic activation system using TA97a, TA98, TA100, TA102, and TA1535 strains, yielded negative results in all cases, indicating no mutagenic effect. The mammalian erythrocyte micronucleus test (GB 15193.5-2014) yielded a negative result, indicating that the test substance does not induce chromosomal damage. In vitro mammalian cell chromosome aberration test (GB 15193.23-2014): Regardless of whether the S9 metabolic system was added, there was no statistically significant difference in chromosome aberration rates between each dose group and the negative control group, resulting in a negative outcome. Integrated genotoxicity conclusion: Lycium barbarum polysaccharides do not cause gene mutations and pose no risk of chromosomal damage.

3.3 90-Day Subchronic Oral Toxicity Test (GB 15193.1-2014)

SD rats were administered the test substance orally via gavage for 90 consecutive days, with multiple dose groups established, along with a recovery period satellite study. No treatment-related abnormalities were observed in animal body weight, food consumption, feed efficiency, ophthalmic examination, complete blood count, blood biochemistry, or urinalysis. Gross examination, organ coefficients, and histopathological sections of all major organs revealed no treatment-related toxic lesions. No adverse effect level observed (NOAEL) = 7,500 mg/kg body weight Conclusion: Long-term continuous intake does not result in chronic accumulation toxicity and poses no risk of organ damage.

3.4 Teratogenicity Test (GB 15193.14-2015)

SD rats were administered the drug orally by gavage daily from day 6 to day 15 of pregnancy at doses of 1.875, 3.750, and 7.500 g/kg body weight. Maternal animals: no abortions, no vaginal bleeding, no maternal toxicity or death; normal weight gain during pregnancy. Fetal examination: No abnormalities were observed in fetal survival rate, external development, skeletal development, or organ development. Conclusion: NOAEL = 7,500 mg/kg body weight; no potential teratogenic risk observed.

3.5 Toxicology Summary Conclusion

Lycium barbarum polysaccharide: Acute toxicity is non-toxic; the full set of genotoxicity tests is negative; 90-day subchronic toxicity study shows no toxicity; no teratogenic effects; toxicological data meet the high safety standard for food ingredients.

> *Note: Lycium barbarum polysaccharide peptide is a refined and upgraded component of Lycium barbarum polysaccharides, and this toxicological data provides significant reference value for the safety assessment of Lycium barbarum polysaccharides.*

IV. Special Assessment on Long-Term Consumption Safety

4.1 Long-term Consumption Safety Conclusion

(1) A 90-day subchronic study demonstrated that long-term continuous intake causes no hepatic or renal accumulation toxicity, no organ damage, and no metabolic impairment.

(2) Fully negative for genotoxicity, with no carcinogenic or mutagenic risk upon lifelong and long-term consumption;

(3) Non-teratogenic, no reproductive toxicity, mild metabolism, and high tolerance;

(4) The raw material is a purified component of Lycium barbarum, which is both medicinal and edible, with no drug toxicity targets, making it suitable for long-term continuous consumption.

4.2 Dose Safety Summary

Long-term, continuous, and regular consumption within the recommended product dosage range is supported by sufficient, reliable, and traceable food safety evidence.

V. Comprehensive Evaluation Conclusion

5.1 Stable and controllable quality: Lycium barbarum polysaccharides and Lycium barbarum glycopeptides can establish comprehensive food-grade quality specifications, effectively eliminating issues such as adulteration and batch inconsistency.

5.2 Safe and sufficient for long-term consumption: The complete set of national standard toxicological tests confirms it is non-toxic, non-accumulative, non-genotoxic, and non-reproductive toxic, making it safe for long-term use at conventional doses.

5.3 Complete compliance system: Clearly defined target and non-target populations, dosage, consumption methods, and label instructions, fully meeting requirements for food registration, enterprise standard submission, and functional food development;

5.4 High scientific research and industrial value: suitable for collaborative regional research, studies related to the health industry, and high-end transformation of food-medicine homology outcomes.

VI. Outlook

With comprehensive quality standards and complete toxicological safety data, Lycium barbarum polysaccharides and Lycium barbarum glycopeptides can achieve further standardization, normalization, and industrial development. Clearly defined dosage levels and target populations provide a solid foundation for the marketization, standardization, and international promotion of products, thereby driving high-quality development of the premium deep-processing industry for goji berries.

Note: All toxicological data in this report are derived from the MA/CNAS test reports issued by the Comprehensive Testing Center of China Academy of Inspection and Quarantine, Report No.: CAIQS0025001889001 series.

APPENDIX 3

Research Progress on the Health Benefits and Translational Applications of Lycium barbarum Glycopeptide

Xiao-Min Lin, Jinan University

1. Background

Ningxia wolfberry (Lycium barbarum L.) is a representative food–medicine homologous resource in China, with a long history of consumption and broad applications for health maintenance. With advances in modern separation, analytical, and biomedical technologies, multiple bioactive constituents of wolfberry, including polysaccharides, glycopeptides, carotenoids, phenolic compounds, and phenylpropanoid aliphatic amides, have been increasingly investigated. Among these constituents, Lycium barbarum polysaccharides and glycopeptides represent an important group of water-soluble bioactive components that have been studied relatively systematically. Over years of research, Lycium barbarum glycopeptide (LbGP) has accumulated substantial experimental evidence in multiple areas, including gut health, bone health, metabolic regulation, healthy aging, and neuroprotection. These findings provide a scientific basis for the further development of LbGP as a functional ingredient in health foods and other high-value wolfberry- derived products.

2. Multi-System Health Benefits of LbGP

Current studies suggest that LbGP can influence multiple tissues and physiological processes, demonstrating a broad spectrum of potential health benefits.

In terms of gut health, LbGP has been shown to ameliorate DSS-induced colitis and intestinal mucosal injury and to modulate the composition and diversity of the gut microbiota in mice[1]. These findings suggest that LbGP may support gastrointestinal health by improving the intestinal microenvironment and maintaining mucosal barrier integrity. In terms of bone health, studies using an ovariectomy-induced osteoporosis model showed that LbGP reduced osteoclast activity and bone resorption and modulated CTSK expression and the RANKL/OPG balance[2]. These findings indicate the potential value of LbGP in maintaining bone health during aging. With regard to hepatic–retinal protection, LbGP has been reported to improve lipid metabolic abnormalities in the liver and retina and to regulate cholesterol efflux and bile acid metabolism[3]. From the perspective of modern metabolic research, these findings provide experimental support for the traditional concept of wolfberry in “Clearing the Liver and brightening the eyes.” In the context of healthy aging and cardiac protection, LbGP improved several aging-related phenotypes, cardiac mitochondrial function, and systemic energy metabolism in aged animals. These effects may involve the maintenance of mitochondrial quality control through PINK1/Parkin-mediated mitophagy[4]. Collectively, these studies suggest that the health-related effects of LbGP are not restricted to a single tissue or physiological function. Instead, they may involve multiple biological processes, including inflammatory regulation, metabolic homeostasis, lipid homeostasis, and cellular stress responses. From the perspective of health food development, LbGP therefore has a relatively broad research foundation and may offer opportunities for the development of products addressing different health needs.

3. Neuroprotection as a Long-Standing and Systematically Investigated Research Direction of LbGP

Among the various health-related effects of LbGP, neuroprotection is one of the areas with a relatively long research history and a substantial body of accumulated evidence. Academician Kwok-Fai So has long been engaged in research on neurobiology, neural injury, and neural regeneration. Over the course of this long-term research, Academician So

and collaborating teams have conducted extensive studies on the neuroprotective effects of Lycium barbarum polysaccharides and glycopeptides, resulting in a systematic body of publications, monographs, and intellectual property.

Current evidence indicates that the neuroprotective effects of LbGP involve multiple conditions, including anxiety and depression, neurodegenerative injury, spinal cord injury, and optic nerve and retinal injury. In chronic stress models, LbGP improved anxiety-like behaviors and reduced oxidative stress and lipid peroxidation in the prefrontal cortex[5]. In depression-related studies, both animal and human studies have provided supportive evidence[6, 7]. Neuroprotective effects have also been observed in models of amyloid-β-related neuronal injury[8] and spinal cord injury[9].

Protection of the optic nerve and retina represents another important component of this research field. Studies have evaluated LbGP in optic nerve inflammation and injury[10], retinal ischemia–reperfusion injury[11], and photoreceptor degeneration[12], showing that LbGP can reduce neural injury and improve associated visual functions. Overall, long-term research has generated a substantial body of scientific evidence supporting the neuroprotective effects of LbGP and its potential value for nervous system health.

4. LbGP in Parkinson’s Disease and Related Motor Complications

While Academician Kwok-Fai So’s team has conducted long-term research on wolfberry-derived bioactive components and neuroprotection, Professor Rong-Rong He’s team has focused extensively on the pathogenesis of Parkinson’s disease (PD) and interventions using traditional Chinese medicine and natural products, with particular attention to oxidative stress, membrane phospholipid peroxidation, and dopaminergic neuronal injury.

Building on a long-standing collaboration between the two teams, further systematic studies have been conducted to investigate the protective effects and translational potential of LbGP in PD. PD is a common neurodegenerative disorder characterized primarily by degeneration of the nigrostriatal dopaminergic system and reduced brain dopamine levels, and it requires long-term disease management. Previous studies by the team identified neuronal membrane lipid peroxidation as an important pathological process affecting dopaminergic neuronal homeostasis. On this basis, the effects of LbGP were evaluated in multiple experimental models of PD. The results showed that LbGP improved motor function, reduced dopaminergic neuronal loss in the substantia nigra, and decreased lipid peroxidation in neural tissues[13].

Long-term management of PD also faces the challenge of motor complications associated with levodopa therapy. After prolonged levodopa treatment, some patients gradually develop motor fluctuations and levodopa-induced dyskinesia (LID). To address this issue, the team further evaluated LbGP in multiple LID models representing different pathological backgrounds. LbGP consistently reduced abnormal involuntary movement scores across these models, demonstrating a reproducible improvement in dyskinesia-related phenotypes. Taken together, these studies have established a connected body of experimental evidence in PD, ranging from the protection of dopaminergic neurons to the improvement of long-term levodopa- related motor complications. These findings provide a scientific basis for further evaluation of the potential value of LbGP in brain health and for subsequent translational development.

5. Translational Development and International Applications

With the continued accumulation of functional and mechanistic evidence, LbGP research has progressively advanced toward intellectual property protection and product translation. Multiple patents have been filed covering the preparation of LbGP and its applications in neuroprotection, anxiety, neuropathic pain, and Parkinson’s disease-related motor complications.

In the translational development of PD-related research, Professor He's team and Academician So's team have further promoted the development of UNTREMOR (developed using LbGP as its key active ingredient). The product has received marketing authorization in Macao, and a clinical study related to new drug registration is currently being advanced in Bangladesh. In parallel, the related research has been incorporated into the National Key R&D Program of China, supporting the internationalization of traditional Chinese medicine in Belt and Road countries across Southeast and South Asia. Given the multi-system research evidence accumulated for LbGP, its future applications may extend beyond therapeutic development. Further exploration is warranted in functional foods and health products targeting brain health, gut health, bone health, healthy aging, and other health-related needs.

6. Key Issues to Be Addressed

Although a substantial body of functional research has been accumulated for LbGP, several key scientific questions remain to be addressed in order to further support standardized product development and international applications.

a. Which key components and structural features determine the health benefits?

LbGP is a naturally derived and structurally complex bioactive system. Further studies are needed to clarify the relationships among different glycan structures, glycopeptide components, structural characteristics, and biological activities.

b. What happens to LbGP after ingestion in terms of digestion, absorption, distribution, and metabolism?

Particular attention should be given to whether LbGP undergoes structural transformation in the gastrointestinal tract, which components can be absorbed, and which metabolites or molecular forms are ultimately responsible for its biological effects in vivo.

c. Through which tissues, cells, and biological processes does LbGP exert its health-promoting effects?

Current evidence indicates that LbGP affects multiple systems. Further studies are therefore needed to determine whether different health-related effects share common responsive tissues, cell types, and biological mechanisms.

d. How can a robust relationship among composition, structure, quality, and efficacy be established?

Future quality control should not focus solely on constituent content. It is also necessary to define the relationships between critical quality attributes, biological activity, and health benefits, thereby establishing a quality evaluation system that is more closely linked to biological function.

e. How can stronger human evidence be generated to support the standardized and international application of LbGP in health foods?

Much of the current evidence on the functional effects of LbGP is still derived from experimental studies. Future work should include well-designed human studies targeting specific health functions, with clear definitions of target populations, intake levels, and measurable health endpoints. Such evidence should also be aligned with the food regulatory frameworks of different countries and regions.

7. Conclusions and Perspectives

Over years of research, LbGP has accumulated a relatively systematic body of evidence covering multi-system health functions, neuroprotection, and translational development. Future studies should further strengthen the scientific evidence base by addressing its bioactive components, in vivo fate, mechanisms of action, quality– efficacy relationships, and human evidence. Through coordinated efforts across scientific research, standardization, industry,

and regulation, the health value of LbGP can be further clarified, supporting its development into a quality-controlled and functionally characterized ingredient with potential for international application in functional foods and health products.

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APPENDIX 4

Goji Berry: Trials and Studies Outside China

Evidence summary compiled for this pilot assessment

1. Human studies

Clinical studies

United States / China — Lycium barbarum (goji) juice improves in vivo antioxidant biomarkers in serum of healthy adults (Amagase, Sun & Borek, 2009).

A 30-day randomized, double-blind, placebo-controlled trial in 50 healthy adults aged 55–72. The LBP-standardized juice ("GoChi") significantly increased serum superoxide dismutase (+8.4%) and glutathione peroxidase (+9.9%), and reduced malondialdehyde (-8.7%) relative to placebo. While the authors and funding are US-based, the study population consisted of Chinese adults.

Case studies

United States — Probable interaction between Lycium barbarum (Goji) and warfarin (Rivera et al., 2012).

They describe the case of a 71-year-old Ecuadorean-American woman who was taking warfarin and was hospitalized for a markedly elevated, indeterminate international normalized ratio (INR) after consumption of goji juice. After discontinuation of the goji juice and warfarin, the patient was treated with phytonadione, and her INR decreased to 2.6 over 2 days.

Spain — Anaphylaxis associated with the ingestion of Goji Berries (Lycium barbarum) (Ballarin et al., 2011)

They describe 2 cases of allergic reaction, 1 of which was an anaphylactic reaction, after Goji berry ingestion. A Goji berry extract was manufactured and immunochemically characterized. The patients were skin prick tested with a battery of common aeroallergens including mites, epithelia, and molds. Individuals were also skin prick tested with food allergens, including Goji berries. A positive skin prick test and specific immunoglobulin (Ig) E to Goji berry was detected in both cases. Serum samples recognized a 9-kDa band, probably related to lipid transfer proteins (LTPs). Cross-reactivity with tomato was analyzed by inhibition studies, which showed that the 9-kDa band was totally inhibited by the tomato extract. This study describes the first 2 cases of allergic reaction following Goji berry ingestion. LTPs seem to be involved in allergic sensitization to Goji berries, as evidenced by cross-reactivity with tomato.

Spain — Goji berries (Lycium barbarum): Risk of allergic reactions in individuals with food allergy (Larramendi et al., 2011)

They recruited 30 additional plant food–allergic individuals in Spain during 3 months in 2010. Skin tests to Goji berries were positive in 24 patients (77%): 5 symptomatic patients and 19 asymptomatic patients. Positivity to Goji berries was associated with positivity to peach peel and to the panallergen nonspecific lipid transfer protein (LTP). Nearly half of the patients reported symptoms (45%), but 89% of the skin test–positive patients had never eaten Goji berries. Specific immunoglobulin E to Goji berries were detected in all cases, and several individuals recognized 2 protein bands in the immunoblot. Addition of LTP to sera mostly inhibited immunoglobulin E binding to an LTP-like band, suggesting a role for this panallergen in sensitization to Goji berries.

Spain — Recently introduced foods as new allergenic sources: Sensitisation to Goji berries (Lycium barbarum) (Carnes et al., 2012)

566 individuals, with respiratory or cutaneous symptoms were skin-prick tested with goji berries extract. Thirty three were positive (5.8%). 94% were sensitised to other allergens. Specific IgE to GB, peach, tomato and nut-mix was measured. Thirteen individuals from 24 available sera (54.2%) had positive specific IgE. 92.3% of goji berry positive patients were positive to peach. Seven individuals recognised 8 bands and six recognised a 7 kDa band. This band was identified as a lipid transfer protein by MS/MS. Cross-reactivity was demonstrated with tomato, tobacco, nutmix, Artemisia pollen and purified Lyc e 3 and Pru p 3.

Neuroprotection, cognition, and mood

United States - A randomized, double-blind, placebo-controlled, clinical study of the general effects of a standardized Lycium barbarum (Goji) Juice, GoChi (Amagase & Nance, 2008).

This study is presented by its authors as the first study reported from outside China that examined the general effects of the orally consumed goji berry, Lycium barbarum, as a standardized juice (GoChi; FreeLife International LLC, Phoenix, AZ) in healthy adults over 14 days. Results clearly indicate that daily consumption of GoChi for 14 days increases subjective feelings of general well-being, but with no measurable effect on objective physiological parameters (weight, blood pressure, etc.).

2. In vivo studies (animal models)

Subchronic toxicology

Brazil — Impact of Goji Berry Juice on Redox Status in Wistar Rats: A Subchronic Toxicity Assessment (de Freitas Rodrigues et al., 2026).

Over 28 days, at goji juice doses equivalent to typical human consumption, female rats showed no change in body weight or food intake, but the researchers observed:

- elevated hepatic transaminases (a marker of liver stress),
- increased reactive species generation in the liver and kidneys,
- imbalanced antioxidant defenses and damage to lipids/proteins,
- kidney damage (increased Bowman's space).

The authors conclude that goji juice, even at typical consumption doses, may have a pro-oxidant rather than antioxidant effect in certain organs — a finding that meaningfully complicates the usual commercial narrative around the fruit's "antioxidant" properties.

Neuroprotection, cognition, and mood

Turkey — Anxiolytic, antioxidant, and neuroprotective effects of goji berry polysaccharides in ovariectomized rats (Pehlivan Karakaş et al., 2020).

In ovariectomized rats (a menopause model), high-dose goji polysaccharides (LBP, 200 mg/kg) reduced anxious behavior, increased antioxidant enzyme activity along with serotonin and BDNF levels in the hippocampus, and decreased the count of TUNEL-positive cells (an apoptosis marker). A follow-up study by the same team (Soytürk et al., 2023) found similar effects on depression-like behavior, with increased serum superoxide dismutase and decreased malondialdehyde (an oxidative stress marker).

Mexico — The treatment of Goji berry improves the neuroplasticity of the prefrontal cortex and hippocampus in aged rats (Ruíz-Salinas et al., 2020).

In 18-month-old rats, goji administration (3 g/kg for 60 days) improved dendritic morphology and recognition memory, with reduced reactive astrogliosis and apoptosis markers (caspase-3) in the prefrontal cortex and hippocampus.

Cardio- and nephroprotection

Bulgaria — Cardio- and nephroprotective effects of fractions isolated from Lycium barbarum in models of cardio- and nephrotoxicity in rats (Georgiev et al., 2022/2023, Biotechnology & Biotechnological Equipment).

Three goji fractions (pectin-free, polysaccharide, and a 1:1 combination) were tested in male Wistar rats against doxorubicin (chemotherapy)-induced cardio- and nephrotoxicity. All three fractions significantly reduced markers of cardiac damage (creatine kinase, LDH, AST) and renal damage (creatinine, urea, uric acid) compared to animals treated with doxorubicin alone.