2025-2026 Global Report on Biosynthetic Ingredients in Health Supplements Dietary Supplements and EU Compliance

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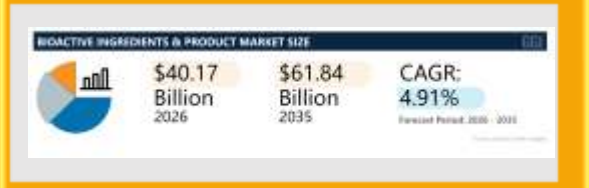
Table of Content

01 Overview and Trends of the Global Biosynthetic Ingredient Market

1.1 Rapid Market Growth

Synthetic biology technology is profoundly reshaping the global health supplement/dietary supplement ingredient industry. **The global market size for bioactive ingredients and products was US$38.29 billion in 2025, and is projected to reach US$40.17 billion in 2026, growing to US$61.84 billion by 2035, with a CAGR of 4.91% during the forecast period of 2026-2035.** Globally, over 63% of consumers choose products with additional nutritional and health benefits, and consumer demand is shifting comprehensively from "basic nutrition" to "functional optimization."



1.2 Industry Paradigm Shif

The health supplement raw material sector underwent a significant paradigm shift in 2025-2026. If antioxidants were the protagonist in 2025, **then regulators and metabolites will dominate in 2026**—they are no longer merely "free radical scavengers," but directly participate in the body's signaling pathways and microecological construction. Biosynthetic ingredients are rapidly penetrating the market along three main tracks:

Cellular Energy and Anti-aging: Mitochondrial activating/protective ingredients such as NMN, PQQ, and ergothioneine are leading the way, with longevity science moving from a niche geek community to the mainstream consumer market.

Precision Gut Health: Microbiome-regulating ingredients such as HMOs and AKK postbiotics are emerging, evolving from "supplementing bacteria" to "cultivating bacteria + precise regulation."

Cognitive and Emotional Health: Adaptogens and nootropic ingredients are the fastest-growing categories, with continued explosive growth in demand from working professionals and students.

1.3 Synthetic biology dominates the supply of high-end raw materials

Synthetic biology continues to play a vital role in the production of high-end functional ingredients. According to CIRS statistics, of the 68 novel food products approved in the EU since 2020, 16 are derived from synthetic biology, accounting for 23.5%. The core advantages of biosynthesis—**high purity, sustainability, lack of seasonal and geographical limitations, and controllable costs**—make it the mainstream technological route for functional food ingredient innovation globally.

1.4 Cross-border compliance becomes a core competitive advantage

In 2025-2026, the FDA approved a number of new ingredients (NDIs) with high innovation and strong scientific evidence, covering probiotics, plant extracts, microalgae, new peptides, and specialty nutrients. At the same time, the EU's approval process for novel foods accelerated significantly – the EFSA issued 28 scientific opinions on novel foods throughout 2025.

02 Summary of Global Biosynthetic Component Categories

2.1 Antioxidant and Anti-aging Products

2.1.1 Ergothioneine (EGT)

Ergothioneine is the only natural antioxidant in the world that possesses a specific transmembrane transport protein (OCTN1). **It can precisely penetrate cells and mitochondria, exerting multiple effects such as scavenging free radicals, inhibiting inflammation, and protecting mitochondria. Its potential applications cover anti-aging, liver protection, cardiovascular health, and medical aesthetics.**
The efficient production of synthetic biology has significantly reduced the cost of ergothioneine, enabling it to move from a niche, high-end ingredient to industrial applications.
By 2025, ergothioneine had become one of the most watched star ingredients in the health supplement industry, and its sales increased by more than 2.6 times year-on-year in early 2026.

2.1.2 Pyrroloquinoline quinone (PQQ)

PQQ is a novel redox cofactor that promotes mitochondrial regeneration, protects nerve cells, and has powerful antioxidant functions. PQQ can be biosynthesized through microbial fermentation. In anti-aging compound products, it is often used in combination with NMN and ergothioneine to cover different aging pathways and build a multidimensional anti-aging combination.
In Q4 of 2025, PQQ was submitted as a Novel Food application in the European Union as an amendment to an already approved substance.

2.1.3 Resveratrol

Resveratrol is a natural polyphenol antioxidant **with functions including activating Sirtuin, anti-inflammatory properties, and cardiovascular protection.**
In 2022, the European Union officially approved resveratrol as a novel food through a biosynthetic route (using Saccharomyces cerevisiae as the production strain) (Regulation (EU) 2022/672), paving the way for its compliant use as a dietary supplement ingredient.

2.1.4 Coenzyme Q10

Coenzyme Q10 is a key component of the mitochondrial respiratory chain. Its biosynthesis and production are mainly achieved through microbial fermentation. The selection of high-yield strains combined with metabolic regulation technology has enabled efficient industrialization, and it has become a competitive product for Chinese enterprises.
Key benefits: Metabolic support, heart health, antioxidant and anti-aging, sexual and fertility support.
Coenzyme Q10 is legally marketed as a dietary supplement ingredient in the European Union, primarily governed by Food Supplements Directive 2002/46/EC and the General Food Safety Regulation (EC) No 178/2002. In Denmark, Coenzyme Q10 is the only officially approved dietary supplement product for the prevention and treatment of Coenzyme Q10 deficiency.

2.1.5 Astaxanthin

Astaxanthin is one of the strongest natural antioxidants in nature, with anti-inflammatory, **vision-protecting, and anti-aging effects on the skin. Synthetic biology techniques can utilize microalgae (such as Haematococcus pluvialis) or engineered strains to biosynthesize astaxanthin,** achieving high-purity industrial-scale production.

02 Summary of Global Biosynthetic Component Categories

2.1 Antioxidant and Anti-aging Products

2.1.6 S-acetyl-L-glutathione (SAG)

Biosynthetic route: Acetylation modification (derived from glutathione synthesized through microbial fermentation or enzymatic methods).
Core efficacy: A highly efficient oral glutathione precursor, solving the problem of low oral bioavailability of native glutathione; antioxidant, free radical scavenging, liver protection and detoxification, and anti-aging effects.
Global trend: Since 2025, global application activity has significantly increased, penetrating from high-end skincare to oral beauty and liver protection. On September 19, 2025, EFSA issued Public Advisory Document PC-1620, proposing formal approval of SAG as a novel food.

2.1.7 Spermidine

Biosynthetic route: Microbial fermentation (using engineered bacteria) / wheat germ extraction and enrichment.
Core efficacy: Induces autophagy, clears aging and damaged organelles; animal studies show it can extend lifespan, improve cardiovascular health, provide neuroprotection, and regulate immunity.
Global trend: Synthetic biology technology is overcoming production capacity bottlenecks and is moving from niche research circles to mass health consumption, with significant growth expected in longevity clinics and high-end supplement channels in Europe and the US in 2025–2026. **Regarding EU compliance, "wheat germ extract rich in spermidine" has been approved for marketing as a Novel Food; however, purified spermidine (free base) derived from fermentation has not yet been approved on a large scale as a monomeric component.**

02 Summary of Global Biosynthetic Component Categories

2.2 NAD+ precursors (core anti-aging ingredients)

2.2.1 β-Nicotinamide mononucleotide (NMN)

NMN is a direct precursor to coenzyme I (NAD+) and **has shown significant potential in cellular energy metabolism and anti-aging research, making it a star ingredient in dietary supplements.**
Biosynthesis (enzymatic catalysis) is currently the mainstream production method, utilizing enzyme preparations such as nicotinamide phosphoribosyltransferase (NAMPT). This method offers mild reaction conditions, high specificity, and product purity exceeding 99%.

2.3 Human milk oligosaccharides (HMOs)

2.3.1 2'-Fucosyllactose (2'-FL), 3-Fucosyllactose (3-FL), lactose-N-tetrasaccharide (LNT), sialyllactose (3'-SL, 6'-SL)

Human milk oligosaccharides (HMOs) are important bioactive components in breast milk, promoting the colonization of beneficial bacteria (such as Bifidobacteria), inhibiting pathogenic bacteria, and supporting the development of the infant's immune system. HMOs represent one of the most successful applications of synthetic biology in the food industry. **Currently, nearly 20 HMO products from different strains have been approved as novel food products in the European Union. HMOs are the category with the most approved products among synthetic bio-based novel food products.**

02 Summary of Global Biosynthetic Component Categories

2.4 Functional Sugars

2.4.1 D-Allulose

D-Allulose is a rare hexose ketose with 70% the sweetness of sucrose and only 10% of its calories. **It possesses physiological functions such as regulating blood sugar, lowering lipids, and anti-oxidation, making it suitable as a sugar substitute for people with diabetes and those trying to control their blood sugar.** In July 2025, the National Health Commission of China officially approved D-allulose produced by enzymatic conversion and microbial fermentation as a new food ingredient. **This marked the first new food ingredient product in China whose production process involves genetically modified microorganisms, signifying the "first year" of the application of synthetic biological ingredients in China's food industry.**

2.4.2 Tagatose

Taggart sugar is a rare sugar with a low glycemic index and a sweetness close to sucrose**, making it suitable as a functional sweetener in sugar-reducing formulations.** Achieving its efficient biosynthesis through synthetic biology techniques provides a new option for natural sweetening solutions.

2.4.3 N-acetylneuraminic acid (Sialic acid)

N-acetylneuraminic acid is the core active ingredient in bird's nest, known for its benefits such as promoting brain development and enhancing immunity. Its biosynthesis through microbial fermentation significantly reduces production costs, allowing it to transition from a high-end tonic to a mainstream nutritional supplement.

2.4.4 D-ribose

D-ribose is a pentose sugar widely found in the cell nucleus and mitochondria, **which can directly participate in ATP synthesis and accelerate energy regeneration.** Human clinical trials in marathons have revealed the core benefits of D-ribose: **reducing exercise-induced myocardial and skeletal muscle damage, protecting myocardial function, regulating redox balance, reducing the risk of inflammation, improving exercise endurance, and accelerating fatigue recovery.**

02 Summary of Global Biosynthetic Component Categories

2.5 Amino acids and their derivatives

2.5.1 γ-Aminobutyric acid (GABA)

GABA is an inhibitory neurotransmitter that has functions such as relieving anxiety, improving sleep, and regulating mood. GABA synthesized through microbial fermentation is highly pure and safe, and is widely used in sleep aids and mood health supplements.
In Q4 of 2025, Bloomage Biotech submitted an application to EFSA for GABA as a novel food product.

2.5.2 5-Hydroxytryptophan (5-HTP)

5-HTP is a precursor to serotonin (5-HT), which has the effects of regulating mood, improving sleep, and suppressing appetite. Its biosynthesis can be industrialized through fermentation by engineered strains, and it has been included in the R&D pipelines of several synthetic biology companies since 2025.

2.5.3 Ectoine

Ectoin is a compatible solute with effects such as protecting cell membranes, anti-inflammation, and protection against ultraviolet damage. Ectocin, produced through biosynthesis, is widely used in the repair and anti-inflammatory applications of health supplements and skincare products.

2.5.4 D-3-hydroxybutyric acid (Betaic acid)

Endogenous neural regulatory molecules represent a major breakthrough in synthetic biology for brain health. Endogenous molecules such as D-3-hydroxybutyric acid, prepared using synthetic biotechnology, can safely and effectively regulate sleep and mood.

2.5.5 S-Adenosyl-L-methionine (SAMe)

SAMe is an important methyl donor in the body, with effects such as improving mood and protecting joints and the liver. SAMe produced by biosynthesis (microbial fermentation) has been industrialized.
In early 2025, SAMe-DT, independently developed by Jincheng Biotechnology, successfully passed the NDI certification of the US FDA, becoming the first company in China to obtain this certification.

2.5.6 Phosphatidylserine

Neuroprotective ingredient. Phosphatidylserine exerts its cognitive protective effects by regulating cortisol levels, relieving anxiety, and promoting neuronal repair. It is used in synergy with ingredients such as L-theanine in sleep aids and brain health products.

2.5.7 β-Alanine

β-alanine is a precursor to carnosine synthesis and prolongs the duration of high-intensity exercise by buffering the decrease in intramuscular pH.
β-alanine has been included in the list of new food additives approved by the National Health Commission.

02 Summary of Global Biosynthetic Component Categories

2.6 Polypeptides, vitamins, lipids, and others

2.6.1 Hydroxytyrosol

Hydroxytyrosol is the core antioxidant component of olive oil, possessing excellent antioxidant and anti-inflammatory properties, and showing promising potential in cardiovascular protection and anti-aging.
Its green and efficient production can be achieved through synthetic biology technology.

2.6.2 Vitamins (such as vitamin K2 and vitamin D3)

Vitamin K2 has achieved an industrial leap through synthetic biology technology**. Its core functions encompass six dimensions: bone health (activating osteocalcin to precisely deposit calcium in the bone matrix, significantly increasing bone density, as confirmed by a 2025 study in *Osteoporosis International*)**; cardiovascular protection (activating the matrix Gla protein MGP, reducing coronary artery calcification scores; daily intake of 45 μg MK-7 can reduce coronary heart disease mortality); cellular energy metabolism (transferring electrons in the inner mitochondrial membrane, improving the efficiency of ATP synthesis in skin cells); and also has immune regulation (inhibiting the NF-κB pathway), oral health, and coagulation support effects.

2.6.3 Algal Oil DHA

DHA is an important structural fatty acid for the brain and retina, playing a vital role in the development of the nervous system in infants and the maintenance of cognitive function in adults.
Algal oil DHA produced through fermentation by microorganisms such as Schizochytrium has become one of the world's leading sources of DHA.
In 2025, several Schizochytrium oil products received new food approval or revised approval in the European Union.

2.6.4 Inositol

Inositol is an important component of cell signaling and has functions such as supporting nervous system function, improving metabolic syndrome, and promoting oocyte maturation. **Its biosynthesis via microbial fermentation has entered the industrialization stage.**

2.6.5 β-glucan

β-glucan is a polysaccharide with immunomodulatory functions that can be produced through biosynthesis techniques (such as fungal fermentation) and **is widely used in immune support and gut health products.**

02 Summary of Global Biosynthetic Component Categories

2.6 Polypeptides, vitamins, lipids, and others

2.6.6 Urolithin A (UA)

Urolithiasis A is hailed as a "mitochondrial scavenger," capable of clearing aging and dysfunctional mitochondria (mitochondrial autophagy), thereby improving muscle endurance and cognitive function. Its growth rate has exceeded 300%. Its biosynthesis and production are currently a hot research topic**.**

2.6.7 Estrol

Estrol possesses estrogen-like biological activity and is naturally derived from plants such as soybeans, formed through a complex biosynthetic pathway**. Its estrogen-like regulatory effects give it unique value in menopausal women's health supplements.**

2.6.8 Palmitoylethanolamide (PEA)

Neurosoothing factor. PEA is a naturally occurring fatty acid amide substance in human cells. It can effectively inhibit mast cell degranulation by regulating the inflammatory response and sensitivity of the nervous system, thus alleviating menopausal-related neurological discomfort. LadyPEA® formulation combines PEA with standardized saffron extract azron® (standardized to 3.5% Lepticrosalides®), supported by more than nine clinical studies at a 28mg dose.

2.6.9 AKK inactivated bacteria (pasteurized Akkermansia)

AKK bacteria are one of the core symbiotic bacteria in the human gut, accounting for approximately 1%–5% of the gut microbiota in healthy individuals, and are closely related to metabolic homeostasis and intestinal integrity**. Inactivated AKK bacteria achieve multi-dimensional health interventions by targeting and regulating the intestinal mucosa, metabolic pathways, and immune balance: metabolic regulation and weight management, intestinal barrier strengthening, immune regulation, and healthy aging**.
AKK bacteria have been fully authorized as a Novel Food in the EU; on February 23, 2026, the applicable population was expanded from adults to those aged 12–18 years ((EU) 2026/391). The safety of use in pregnant and lactating women remains undetermined, and they cannot use this product.

2.6.10 Vitamin D2 Mushroom Powder

Vitamin D2 (ergocalciferol) is one of the two main forms of vitamin D; **It promotes intestinal absorption of calcium and phosphorus, maintaining serum calcium and phosphorus homeostasis; supports bone mineralization and bone density maintenance, preventing rickets and osteoporosis; participates in immune regulation, supporting innate and adaptive immune function; and also plays an important regulatory role in muscle function, cardiovascular health, and cell differentiation.**
Vitamin D2 mushroom powder, as a novel food ingredient, is mainly used in the fields of food fortification and dietary supplements, providing vitamin D supplementation for vegetarians and general consumers.
At the regulatory level, vitamin D2 mushroom powder has been fully authorized in the three major markets of the United States, Canada, and the European Union, but the Chinese market still lacks clear regulations on the addition of D2 mushroom powder to ordinary food products. 。

02 Summary of Global Biosynthetic Component Categories

Summary table of major biosynthetic components

Ingredient name	Main effects	Typical biosynthetic pathways	Main application scenarios
Ergothioneine (EGT)	Mitochondrial targeted anti-oxidation, anti-aging, and anti-inflammatory effects	Microbial fermentation	Anti-aging, liver protection, cardiovascular health, skin care
PQQ	Promotes mitochondrial regeneration, neuroprotection, and antioxidant effects	Microbial fermentation	Anti-aging and cognitive health
Resveratrol	Activates Sirtuin protein, anti-inflammatory, and cardiovascular protective	Microbial fermentation (Saccharomyces cerevisiae)	Anti-aging, cardiovascular
Coenzyme Q10	Mitochondrial energy metabolism, antioxidant, heart protection	Microbial fermentation	Cardiovascular health, anti-fatigue
Astaxanthin	Powerful antioxidant, anti-inflammatory, and vision-protective properties	Microalgae/engineered bacteria fermentation	Antioxidant, skin care, eye health
NMN	NAD+ precursor, anti-aging, energy metabolism	Enzyme catalysis/microbial fermentation	Anti-aging, NAD+ boosting
HMOs (2'-FL, etc.)	Promotes beneficial bacteria and provides immune support	Fermentation by engineered bacteria	Infant nutrition and gut health
D-Allulose	Blood sugar regulators, low-calorie sweeteners	Enzymatic conversion/microbial fermentation	Controlling blood sugar and losing weight
GABA	elieve anxiety and improve sleep	Microbial fermentation	Emotional health and sleep aid
Ectoine	Cell protection, anti-inflammatory, anti-UV	Microbial fermentation	Skin care, anti-inflammatory

Ingredient name	Main effects	Typical biosynthetic pathways	Main application scenarios
Hydroxytyrosol	Antioxidant, anti-inflammatory, cardiovascular protection	Microbial fermentation/enzyme catalysis	Cardiovascular and anti-aging
Vitamin K2	Bone health and cardiovascular protection	Microbial fermentation	Bone health, cardiovascular
Algal oil DHA	Nervous system development and cognitive function	Microalgae fermentation (Schizochytrium)	Infant nutrition and brain health
5-Hydroxytryptophan	Regulates mood and improves sleep	Microbial fermentation	Emotional health, sleep
Sialic acid	Brain development, immunity	Microbial fermentation	Infant nutrition and immunity
Tagatose	Low glycemic sweeteners	Microbial fermentation/enzyme conversion	Reduced sugar recipe
Inositol	Nervous system, metabolic regulation	Microbial fermentation	Metabolic health, PCOS
β-glucan	Immune regulation	Fungal fermentation	Immune support
Bisabolol	Anti-inflammatory and soothing	Microbial fermentation	Skin care, anti-allergy
SAMe	Mood improvement, joint protection	Microbial fermentation	Emotional health, joint health

03 Global Popular Biosynthetic Ingredients: Efficacy and Trends

3.1 Science of Anti-aging and Longevity

Anti-aging is currently the largest and fastest-growing sector. The global anti-aging market reached $73 billion in 2024 and is projected to exceed $140.94 billion by 2034 (CAGR 6.8%). In the first half of 2025, China's oral anti-aging market exceeded 22 billion yuan, with a growth rate of 35%, contributing 15% to the overall industry growth.
The market is characterized by "mainstream consolidation and emerging explosive growth": NMN still holds a core position with sales of 1.2 billion yuan, but its growth rate has slowed from 68% to 35%; while ergothioneine, thanks to breakthroughs in synthetic biology technology and a 90% reduction in costs, achieved sales of 850 million yuan in the first half of the year, a surge of 600% year-on-year, becoming a phenomenal ingredient. Although the PQQ market size is only 420 million yuan, its growth rate is as high as 180%, and it is rapidly penetrating the market.

3.2 Emotional and Sleep Health

The mental health supplement market is growing rapidly at a CAGR of 11.4%, becoming a necessity in an era of intense competition. Synthetic biology technology offers a new non-pharmacological intervention option in the mood and sleep sector.

3.3 Brain and Cognitive Health

The global brain health supplement market reached $6.74 billion in 2025 and is projected to grow to $7.24 billion in 2026.
It covers the needs of all age groups, from improving the attention of teenagers to intervention for cognitive decline in the elderly.

3.4 Gut Health Balance

The probiotic health food sector is steadily expanding at an annual growth rate of 21%, with the Chinese market size reaching 13.8 billion yuan in 2024.
Beyond live bacteria preparations, postbiotics driven by synthetic biology technology are becoming the most innovative direction in the gut health field.

3.5 Women's Health Management

The women's health sector contributed 13% of the market growth with a growth rate of 26.0%, and has undergone a profound transformation from "general supplementation" to "precise care throughout the entire life cycle".

3.6 Sports Nutrition Management

The sports nutrition sector benefits from the expansion of the fitness population and the pursuit of scientific training management, with synthetic biological components demonstrating significant value in improving athletic performance and post-exercise recovery.

04 Overview of the EU Compliance System

4.1 Core Regulatory Framework

The EU has a multi-tiered regulatory system for biosynthetic ingredients in health supplements/dietary supplements.

Regulations	Scope of application	Core Requirements
Regulation (EU) 2015/2283	Novel Food	Ingredients not consumed in large quantities in the EU before May 15, 1997, must undergo EFSA safety assessment and EC approval before being marketed.
Directive 2002/46/EC	food supplements	The regulations specify the list of vitamins and minerals that can be used and the labeling requirements.
Regulation (EC) No 1924/2006	Nutrition and health claims	All functional claims must be scientifically evaluated by EFSA and approved by the EC.
Regulation (EC) No 178/2002	General Food Law	Food safety responsibility, traceability, and risk prevention principles

4.2 Important Updates in 2025

The new EFSA guidelines strengthen requirements for products derived from synthetic organisms.
On February 1, 2025, the new versions of the "Administrative Guidelines for Novel Foods" and "Scientific Requirements Guidelines" issued by EFSA officially came into effect, setting forth clearer and stricter requirements for the data submitted for products of synthetic biological origin.

These requirements include:
Strain safety assessment: It is necessary to clarify the genetic stability of the engineered strain and the removal status of antibiotic resistance genes.
Production Process Description: Complete record of the entire fermentation, purification, and refining process.
Nanomaterial Risk Assessment: If the ingredients involve nanoscale particles, additional nanomaterial safety data must be submitted.
Microbial Contamination Control: Establish a full-chain microbial quality control system from raw materials to finished products.
Allergen Assessment: Conduct a comprehensive assessment of potential allergic risks.

4.3 Compliance Path Selection

For biosynthetic ingredients, the main pathways for their marketability in the EU are as follows:

Novel Food Application Pathway: Applicable to ingredients that were not consumed in large quantities in the EU before May 15, 1997 (such as NMN, ergothioneine, sialic acid, HMOs, etc.), and must pass EFSA safety assessment and EC approval**.**
Existing ingredient pathways: Ingredients that have been used in the EU food supply for a long time (such as Coenzyme Q10) can be directly marketed as dietary supplement ingredients.
Third Country Traditional Food Pathway: Applicable to ingredients with a traditional consumption history of over 25 years in a third country, enjoying a simplified declaration process.
Substantial equivalence pathway: If an ingredient is substantially equivalent to an already approved Novel Food ingredient, it can be quickly approved through an amendment application.

4.4.1 Authorized ingredients

4.4 Summary of Biosynthetic Ingredients Used in Health Products/Dietary Supplements

Overview of EU Novel Food Compliance Status for Biosynthetic Ingredients (—2026) and Explanation of Status Labels:

Authorized: Approval for novel food or non-novel products has been completed, and the product can be used legally.

Under Assessment/Partial: The EFSA is reviewing the application or has granted approval in a specific form, but full market access has not yet been implemented.

Restricted/Grey Zone: Areas with special restrictions or compliance risks due to regulatory uncertainty.

Element	Synthesis process	Core efficacy	Representative brand raw materials	EU compliance status	Authorized Dosage/Remarks
L-Ergothioneine	Microbial fermentation/chemical synthesis	Naturally rare sulfur-containing amino acids enter mitochondria via the OCTN1 transporter to clear ROS, exhibiting a dual mechanism of direct antioxidant activity and upregulation of antioxidant enzyme expression through the KEAP1-NRF2 pathway, thus protecting mitochondrial function.	ErgoActive® （Blue California）	✅ Approved by Novel Foods in 2017 (EU 2017/1281), and its use was expanded to include beverages, cereal bars, and other general food products in 2018.	Adults ≤30 mg/day, children over 3 years old ≤20 mg/day (food supplement); excluding pregnant and lactating women.
PQQ (disodium pyrroloquinoline quinone)	Microbial fermentation (Hyphomicrobium denitrificans CK-275), purity ≥99.0%	Cellular-level mitochondrial activator promotes mitochondrial biosynthesis (PGC-1α pathway), supporting cognitive function and metabolic health.	BioPQQ™ （MGC）	✅ Approved by Novel Foods in 2018 (EU 2018/1122)	≤20 mg/day (excluding adults, pregnant and lactating women); EFSA has determined that the safety profile is acceptable.
Microbial-derived trans-Resveratrol	Microbial fermentation (yeast/engineered bacteria)	Antioxidant, anti-inflammatory, cardioprotective, and neuroprotective effects; exerts anti-aging effects by activating the SIRT1 pathway.	Veri-te™ （Evolva）、Resvida® （DSM）	✅ The 2022 revision of the implementing regulation (EU 2022/672) clarifies the specifications for trans-resveratrol of microbial origin.	In 2022, it officially obtained authorization from Novel Foods to be legally marketed in the EU as a food supplement ingredient.
Vitamin K2 (MK-7)	Natto fermented with Bacillus subtilis and extracted using supercritical CO_2, achieving an all-trans purity of ≥99.9%.	Activating osteocalcin guides calcium deposition to bones rather than blood vessels, preventing osteoporosis and vascular calcification.	vitaMK7® (Kappa/Danone), MediQ7® (GF Fermentech), RiviK2® (Richen)	✅ It has obtained EU Novel Food Certification + GRAS	All brands are authorized by Novel Food and have obtained multiple international certifications such as USP, GRAS, and Non-GMO.

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Element	Synthesis process	Core efficacy	Representative brand raw materials	EU compliance status	Authorized Dosage/Remarks
HMOs (human milk oligosaccharides, 8 types have been approved)	Microbial precision fermentation (genetically engineered E. coli/yeast)	It promotes the proliferation of beneficial gut bacteria (especially Bifidobacteria), inhibits pathogenic bacteria, enhances intestinal barrier function, and improves immune function and cognitive development.	CARE4U® (DuPont/IFF), etc.	✅ Several products have been approved by Novel Food.	Approved for: 8 types including 2'-fucosylated lactose (2'-FL), 3-fucosylated lactose (3-FL), lactose-N-tetrasaccharide (LNT), and lactose-N-neotetrasaccharide (LNnT); Synthetic biology dominates 90% of the market.
Reduced Coenzyme Q10 (Ubiquinol)	Coenzyme Q10 was extracted by yeast fermentation and then hydrogenated and reduced.	A key component of the mitochondrial electron transport chain, involved in ATP production; its highly bioactive form directly scavenge free radicals and protects lipids from oxidative damage.	Kaneka Ubiquinol™	✅ EFSA approved, allowing the use of food supplements.	Adults ≤300 mg/day; the EU has approved several health claims, including "helps with normal energy metabolism".
Haematococcus pluvialis oleoresin rich in astaxanthin	Haematococcus pluvialis was cultured and then extracted using supercritical CO_2.	One of nature's most powerful natural antioxidants, it protects skin from UV damage, supports eye health, and relieves muscle damage after exercise.	AstaReal® （AstaReal AB）	✅ Authorized by Novel Foods, the product is expected to have its scope of application expanded to include dairy analogues, fruit juices, etc., according to a safety opinion issued by EFSA in December 2025.	Do not consume other supplements containing astaxanthin esters on the same day; do not use for infants under 3 years old.
Lutemax 2020 (Lutein)	Marigold flower extract (natural source, not confirmed by Novel)	Provides all three types of lutein (lutein, RR-zeaxanthin, and RS-zeaxanthin) needed by the macula in a 5:1 dietary ratio to protect against blue light damage.	Lutemax 2020 （OmniActive）	✅ It will receive EU Non-Novel Status confirmation in 2025, allowing it to be used as a food supplement.	It must not be added to infant formula for children aged 0-12 months.

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Overview of EU Novel Food Compliance Status for Biosynthetic Ingredients (—2026) and Explanation of Status Labels:

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🔴 **Restricted/Grey Zone:** Areas with special restrictions or compliance risks due to regulatory uncertainty.

4.4.2 🟡 Evaluation in progress / Partial approval

Element	Synthesis process	Core efficacy	Representative brand raw materials	EU compliance status	Authorized Dosage/Remarks
NMN (β-nicotinamide mononucleotide)	Bio-enzymatic catalysis/microbial fermentation	NAD+ is a key precursor involved in energy metabolism, DNA repair, and mitochondrial function, and is one of the most thoroughly researched and commercially successful raw materials in the field of anti-aging.	Uthever® NMN (EffePharm)	🟡 In July 2025, EFSA initiated a safety assessment (PC-1537) with Shanghai Shangke Biotechnology Co., Ltd. as the applicant. Uthever® was the first to complete the public consultation phase and entered the final review by EFSA, and is expected to obtain the first certification.	The application limit is approximately 300-500 mg/day; in May 2026, EFSA published its scientific opinion on the safety assessment, concluding that it is safe under certain conditions, and formal approval is imminent.
Spermidine	Microbial fermentation (synthesis using engineered bacteria) / wheat germ extraction and enrichment	Inducing autophagy to clear aging and damaged organelles; animal studies show it can prolong lifespan, improve cardiovascular health, provide neuroprotection, and regulate immunity.	spermidineLIFE® （TLL The Longevity Labs）	🟡 "Wheat germ extract rich in spermidine" has been approved for marketing as a novel food product; however, purified spermidine (free base) derived from fermentation has not yet been approved on a large scale as a monomeric component.	Currently, the only clearly defined EU compliance pathway is for "wheat germ extract" to be marketed as a novel food product.
S-acetyl-L-glutathione (SAG)	Acetylation modification (derived from glutathione synthesized by microbial fermentation or enzymatic methods).	This orally administered, highly efficient glutathione precursor solves the problem of low oral bioavailability of native glutathione; it also has antioxidant properties, scavenges free radicals, protects the liver and detoxifies, and delays skin aging.	(Multiple Chinese companies are positioning themselves in the raw material supply sector)	🟡 In September 2025, EFSA issued Public Consultation Document PC-1620, proposing approval as a novel food; the target population is adolescents aged 10 years and adults.	The maximum daily dosage is set at 300 mg; it can be used in food supplements and foods for special medical purposes.
Yellow tomato extract (containing Phytoene/Phytofluene)	Non-photosensitive yellow tomato enrichment extraction	Colorless carotenoids provide endogenous photosensitivity and improve skin appearance.	PhytofLORAL® （IBR）	✅ EFSA will publish its scientific opinion on the safety assessment in May 2025.	Adults ≤100 mg extract/day (equivalent to approximately 0.4 mg lycopene)

4.4.3 Restricted/Grey Zone:

4.4 Summary of Biosynthetic Ingredients Used in Health Products/Dietary Supplements

Overview of EU Novel Food Compliance Status for Biosynthetic Ingredients (—2026) and Explanation of Status Labels:

Authorized: Approval for novel food or non-novel products has been completed, and the product can be used legally.

Under Assessment/Partial: The EFSA is reviewing the application or has granted approval in a specific form, but full market access has not yet been implemented.

Restricted/Grey Zone: Areas with special restrictions or compliance risks due to regulatory uncertainty.

Element	Synthesis process	Core efficacy	EU compliance status	风险说明
Melatonin	Chemical synthesis	Regulate your circadian rhythm (sleep-wake cycle), shorten sleep onset time, and alleviate jet lag.	In 2010–2011, EFSA approved limited health claims (relief of jet lag: ≥0.5 mg/day; shortening of sleep latency: ≥1 mg/day), but the EU as a whole does not regulate it as a food ingredient; some member states (such as Sweden and Norway) classify it as a prescription drug at all dosages, and even supplements legally available abroad cannot be mailed into the EU.	Companies entering the EU market must undergo country-by-country classification verification; there are dual classification risks associated with products being classified as both "supplements" and "medicines," resulting in highly inconsistent compliance pathways.
Synthetic Lycopene）	Chemical synthesis	Antioxidant, protects cardiovascular and prostate health	Synthetic lycopene is not permitted for use in food in Japan and Europe; currently, European law only allows the use of naturally derived lycopene as a food coloring agent.	Synthetic products are not accepted by the EU; companies must use naturally derived sources. Toxicity research data on synthetic lycopene is still insufficient.
α-Lipoic acid (ALA, R-type preferred)	Chemical synthesis (mostly R/S racemic mixtures)	This "universal antioxidant" possesses both water-soluble and fat-soluble antioxidant capabilities, can recycle vitamins C and E, and enhance glutathione synthesis.	They often operate in individual member state markets via the "other substances" route, lacking a unified EU authorization for novel food products.	Lacking full EU authorization, compliance status varies from country to country, requiring verification on a country-by-country basis before entry; many companies adopt regional online sales strategies, clearly labeling products as "non-therapeutic use."
Sodium Hyaluronate	Microbial fermentation (Bacillus subtilis/Streptococcus equi, etc.)	Skin moisturizing, improves skin hydration, lubricates joints; approved in multiple countries for use as an oral beauty and joint health supplement.	Many countries (Japan, South Korea, the United States, China, etc.) have approved its addition to food supplements; however, in 2012, the EFSA rejected health claims for oral hyaluronic acid skincare, citing a lack of human clinical trials to support the claim.	It can be marketed as a food supplement ingredient, but it cannot claim a causal relationship with skin protection; it can be used in compliance with regulations, but the scope for health claims is extremely limited.

05 Trends and Recommendations

Technology-driven compliance: Synthetic biology technology has not only reduced the production cost of high-value ingredients (ergothioneine has dropped from hundreds of thousands of yuan/kg to tens of thousands of yuan), but has also promoted the global compliance process. Ingredients produced using biosynthetic pathways are more competitive in Novel Food approval due to their high purity, strong batch consistency, and lack of chemical residues.

Accelerated approvals coexist with stringent requirements: In early 2026, EFSA released an updated version of its New Food Administrative Guidelines, aiming to standardize material requirements, improve the scientific rigor and transparency of the application process, and help companies achieve compliance more efficiently. However, in practice, the application for novel food still places extremely high demands on the scientific data package submitted by companies, and the costs are considerable.

The strategic value of the data protection period: Newly authorized components can enjoy a 5-year data protection period, during which other companies are not allowed to directly use the original applicant's proprietary data. This provides a considerable market exclusivity window for the first companies to obtain certification.

Stricter Enforcement of Health Claims: Since 2025, the EU has intensified its enforcement of health claim compliance (including social media KOL marketing). Companies must strictly comply with (EC) No 1924/2006 and may only use approved claims listed in the Authorisation Register. Significant Category Differentiation: HMOs are the most mature and diverse category of biosynthetic sources approved in the EU (17 varieties have been approved). NMN is in a critical window of approval, while ergothioneine and sialic acid are undergoing preliminary validation in the cosmetics sector, and compliance in dietary supplements is progressing.