THE BLUE BIOREFINERY

Engineering Marine Bioactives for Food and Nutraceutical Applications

Astaxanthin, Fucoidan and Algal Biomass: From Molecular Identity and Extraction Technology to Human Evidence, Industrial Scale-Up and European Food Law

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Abstract

Marine and microalgal ingredients occupy an increasingly important position in the development of functional foods and nutraceuticals. Yet the term “algal bioactive” conceals a remarkably heterogeneous set of biological entities: intracellular carotenoids accumulated under environmental stress, structurally diverse sulfated polysaccharides from brown seaweeds, proteins and pigments extracted from cyanobacterial or microalgal biomass, and oils manufactured under controlled fermentation or phototrophic conditions. Their industrial potential cannot be inferred from their common marine origin. This critical interdisciplinary review compares astaxanthin-rich *Haematococcus pluvialis* materials, fucoidans from selected brown seaweeds, and related algal ingredient platforms across molecular characterization, cultivation, extraction, formulation, analytical release, human evidence, contaminant management and European food law. A randomized 2026 trial of *H. pluvialis*-derived astaxanthin (6 mg/day, eight weeks, 44 participants) reported an improvement in minimal erythema dose, while a 2025 three-arm trial of a *Saccharina latissima* fucoidan-rich extract (91 participants, 90 days) described microbiome-related changes; neither finding supports unrestricted clinical or consumer-health claims for other materials. EFSA’s 2025 favourable opinion on a proposed extension of use of an astaxanthin-rich oleoresin illustrates the separation between scientific safety assessment and the subsequent legal act of authorization. The EU novel-food list already contains source- and process-specific entries for certain fucoidan extracts from *Fucus vesiculosus* and *Undaria pinnatifida*, which cannot be extrapolated to all sulfated algal polysaccharides. The review proposes an industrial design framework integrating structural identity, dose-specific human evidence, process mass balance, finished-food stability, exposure assessment, sustainability and claim eligibility. A profitable blue biorefinery must sell more than biomass or a generic narrative of naturalness: it must deliver a reproducible, traceable, legally admissible ingredient whose defined performance survives the transition from cultivation to the consumer’s finished food.

Keywords: *marine biotechnology; microalgae; Haematococcus pluvialis; astaxanthin; fucoidan; brown seaweed; sulfated polysaccharides; biorefinery; supercritical carbon dioxide; photobioreactor; novel food; iodine; arsenic; EU food law; clinical substantiation*.

1. A marine resource becomes a food ingredient only after it acquires an identity

The apparent simplicity of the seaweed ingredient market is deceptive. A dried macroalgal powder, a standardized carotenoid-rich oleoresin and a purified fucose-containing sulfated polysaccharide may all be described in commerce as marine-derived or algal. They differ, however, in botanical identity, manufacturing history, molecular composition, gastrointestinal exposure, technological behavior and their position under European law. Their common source does not establish functional equivalence; even two extracts obtained from the same organism may belong to different regulatory and biological categories.

This distinction matters because industrial enthusiasm frequently advances along an unreliable inferential sequence. An organism produces a metabolite under laboratory conditions. The metabolite displays antioxidant, immunological or microbiological activity in a selected model. A supplier creates an extract and gives it a consistent commercial name. The resulting food is then described as though its biological effect were already characterized in humans. In reality, each step changes what has been demonstrated. Cell-free antioxidant activity is not physiological antioxidant protection, a taxonomic shift is not a clinical benefit, and a legally authorized food ingredient is not automatically entitled to a health claim.

The contemporary opportunity is nonetheless substantive. Microalgal cultivation permits controlled intervention in nutrient supply, illumination, temperature, carbon dioxide, salinity and cell density. Brown seaweed can yield several different fractions, including alginate, fucoidan-rich materials and other components, if processing is planned around a coherent separation strategy. Advances in filtration, membrane processing, cell disruption and selective extraction can convert once poorly characterized biomass into ingredients with more reproducible specifications. Work published during 2026 has clarified both the promise and unresolved industrial bottlenecks of these platforms (Chen et al., 2026; El-Sheekh et al., 2026).

In this review, the term *blue biorefinery* describes a production system in which algal or marine biomass is characterized and fractionated to maximize useful, lawful product streams while accounting for resource consumption and residual material. It does not imply that every biomass source is environmentally superior or that every recovered fraction qualifies for food use. This review is a critical narrative synthesis, not an original clinical trial or a registered systematic review. Its evidence and legal cut-off is november 2026.

2. Two ingredient families, two fundamentally different molecular problems

2.1. Astaxanthin is a defined carotenoid within a variable commercial material

Astaxanthin is an oxygenated C40 carotenoid, or xanthophyll, whose hydroxyl and keto groups confer physicochemical characteristics distinct from non-oxygenated carotenoids. It is hydrophobic, sensitive to light and oxidative conditions, and may occur in free, monoesterified or diesterified forms. Stereochemistry, ester distribution, lipid environment and the analytical basis used to express total astaxanthin matter when comparing products. An oleoresin specified as “10% astaxanthin” is not described adequately by that number alone: the extraction route, ester profile, stability, residual components and method of quantification determine whether one product is equivalent to another for a particular purpose.

The microalga *Haematococcus pluvialis* accumulates astaxanthin as a protective response to adverse environmental conditions. Commercial cultivation often separates a biomass growth phase from a pigment induction or accumulation phase. The first favours cellular multiplication; the second may sacrifice growth rate to increase intracellular product concentration. Consequently, maximization of pigment percentage within cells is not necessarily equivalent to maximum kilograms of saleable astaxanthin per reactor volume and year. Chen et al. (2026) emphasize the trade-off among biomass formation, metabolic regulation, operational stress and downstream extraction.

The thick, resilient cell wall of pigment-rich *Haematococcus* cells is a particular process obstacle. Without sufficient disruption, extraction recovery may remain poor even when intracellular astaxanthin content appears high. Aggressive cell rupture, meanwhile, can expose pigments to oxygen, heat, metal surfaces or light and may alter quality. The material supplied to formulators is therefore the result of a coupled biological and physical manufacturing system, not simply harvested algae.

2.2. Fucoidan denotes a heterogeneous family rather than one molecular structure

Fucoidan is a collective term applied to fucose-containing sulphated polysaccharides associated principally with brown seaweeds. Such materials vary in monosaccharide composition, chain length, linkage architecture, sulphate density and sulphate position, branching, acetylation, uronic-acid content, residual alginate and phenolic components. Species, environmental conditions, harvest timing, pretreatment, extraction pH and purification modify the profile. Indeed, the ratio of fucose to sulphate or the label “fucoidan 85%” cannot establish molecular equivalence between preparations.

This is not a minor analytical inconvenience. Polysaccharide chain architecture governs hydration, viscosity, ionic interactions, resistance to processing, potential microbial substrate use and interaction with proteins or mucosal systems. High-molecular-weight fractions and low-molecular-weight derivatives may exhibit different in-vitro activities; selective depolymerization can change both accessibility and biological effects. El-Sheekh et al. (2026) and subsequent structure–function literature accordingly emphasizes distributional measurements rather than a single average molecular weight or bulk sulphate assay.

A further complication is that an extract can include other biologically active molecules. Polyphenols, alginates and residual minerals may contribute to laboratory observations, especially when purification is incomplete. Assigning an effect to “fucoidan” without demonstrating which fractions are present can misidentify the active exposure. For mechanistic research, extracts should be characterized sufficiently to distinguish a polymer-specific hypothesis from the combined action of a mixed seaweed fraction.

3. Cultivation and wild harvest create different forms of variability

Phototrophic microalgal cultivation offers substantial process control but does not eliminate biological variation. Photobioreactors can reduce contact with uncontrolled environments and allow close monitoring of temperature, pH, illumination and nutrient supply. Their economics depend on reactor design, light penetration, fouling, culture density, energy input, cleaning requirements and seasonal conditions. Open ponds offer a different capital and operational profile, with greater exposure to environmental variability and potential contamination. The appropriate comparison is productivity and compliance per unit of saleable product, not the theoretical photosynthetic efficiency of an organism.

A controlled culture is also an ecological system. Competitive organisms, bacteriological contamination and changes in strain performance can alter metabolite yields. The quality system should distinguish source-culture authentication, strain banking, production inoculum controls and routine batch release. If a producer introduces strain-selection or genome-editing strategies, the change may affect the process and regulatory identity; it cannot be treated purely as a yield optimization without examining the finished material.

Macroalgal harvesting has a different risk profile. Seaweed composition varies with species, life stage, geography, season, water chemistry and processing delay after collection. Wild-harvest claims require evidence of sustainable stock management and geographic traceability. Cultivated macroalgae may offer improved control of site and harvest schedule, but aquaculture itself can create environmental impacts and supply risks. A geographically diversified sourcing strategy may increase resilience while complicating uniformity unless strict input specifications and fractionation controls are established.

For both systems, commercial traceability should connect the collected biological material to the manufactured lot. The minimum data chain includes verified species or strain, location or production unit, harvest date, culture or marine conditions, pre-processing interval, drying regime, extraction parameters and final batch analytical results. Without this chain, a supplier may deliver consistent-looking powder while silently shifting molecular performance or contaminant exposure.

4. Biorefinery engineering: yield, integrity and mass balance

It is attractive to describe supercritical carbon dioxide, pulsed electric fields, enzymatic extraction and membrane filtration as “green” technologies. Their scientific value, however, derives from selectivity and process performance under defined conditions. Environmental claims require a separate life-cycle analysis. Supercritical CO_2 extraction, for example, can avoid the residual-organic-solvent concern associated with some conventional solvent systems, but it does not by itself eliminate thermal exposure, energy consumption, oxidation, co-extraction of non-target compounds or all process-related risks. Pressure, temperature, solvent-to-feed ratio, pretreatment, co-solvent use when relevant and solvent recovery must be specified.

For astaxanthin, upstream growth and induction are followed by harvest, dewatering, drying or stabilization, disruption, extraction, concentration and protected packaging. Recovery and bioavailability are distinct optimization targets. A process may obtain high analytical recovery while yielding a poorly dispersible ingredient that performs weakly in a beverage. Conversely, a technologically attractive water-dispersible preparation may require emulsifiers or carriers that alter the regulatory composition and must be declared as appropriate.

For fucoidan, the initial problem is separation of a highly heterogeneous, water-soluble polymer fraction from alginate, laminarin, mineral salts, pigments and phenolics. Hot water, dilute acid and enzyme-assisted extraction offer different balances between recovery, structural preservation and cost. Membrane ultrafiltration, precipitation and chromatography may enrich selected fractions, but each step changes molecular-weight distribution and product yield. Excessively harsh conditions can cleave chains or modify sulphate groups; selectively removing low-molecular-weight species may improve one analytical attribute while losing another biologically relevant fraction. The optimal route depends on an explicit product specification, not the ambition to extract the highest possible mass.

A complete biorefinery mass balance should quantify dry biomass input, recovered target fractions, water use, extraction aids, losses, residual streams and product that meets specification. Under a circular-economy model, secondary fractions may have commercial value, but only if their intended market and legal status are separately validated. Calling an output a by-product does not create an exemption from food safety or new-food legislation.

Table 1. Key design contrasts between algal bioactive platforms

Dimension	Astaxanthin-rich microalgal oleoresin	Fucoidan-rich brown-seaweed extract	Industrial implication
Chemical class	Lipophilic xanthophyll within an oleoresin	Heterogeneous sulfated polysaccharides	Different analytical and formulation methods
Source control	Cultivated microalga and stress induction	Species, marine geography and season	Different upstream critical attributes
Main extraction difficulty	Resistant cell wall; oxidative and photo-stability	Separation of polymers, salts, alginate and phenolics	Distinct process controls and purification losses
Product identity	Astaxanthin content, ester/stereoisomer profile, carrier	Fucose, sulfate, molecular-weight distribution, co-extractives	A single assay percentage is insufficient
Typical formulation barrier	Water dispersibility, oxygen and light	Viscosity, taste, salt load, protein interaction	Matrix-specific stability testing
Clinical evidence	Selected controlled human trials on defined preparations	Selected human trials measuring microbial or other outcomes	Results cannot be transferred indiscriminately
EU legal control	Specific authorized novel-food material and uses	Specific source/process entries for certain extracts	Verify the exact entry before commercial launch

The contrasts in Table 1 are technical categories and do not authorize any specific commercial material.

5. Analytical identity must survive extraction, storage and formulation

A premium food ingredient should have an analytical fingerprint appropriate to its chemical class. For astaxanthin-rich oleoresins, validated chromatographic methods can establish identity, total carotenoid content, ester distribution and relevant degradation products. Analytical protocols should state whether hydrolysis is performed, how results are calculated and which reference substances are used. A result from one laboratory cannot be compared mechanically with another if one method measures unhydrolyzed esters and the other expresses all forms as free astaxanthin equivalents.

Oxidative stability should be assessed through the entire manufacturing chain. The key question is not simply whether the pigment remains visible, but whether the target compound and related fractions remain within validated acceptance limits during intended storage and after inclusion in the finished food. Exposure to oxygen, light, temperature, transition metals and interfaces may produce changes. The oil carrier, packaging oxygen permeability, protective atmosphere and manufacturing hold times should therefore enter the stability program.

For fucoidan, no single routine test resolves molecular heterogeneity. A defensible release system should combine species and extraction provenance, fucose or other monosaccharide composition, sulphate content, molecular-weight distribution using a suitable chromatographic approach, moisture, ash, mineral profile, microbial quality and relevant contaminants. FTIR can help identify functional groups; NMR and more discriminating fractionation may be needed for development and reference-grade characterization. In routine industrial supply, a validated set of surrogate measurements can then be correlated with the deeper reference profile, but the correlation should be demonstrated rather than presumed.

Batch-to-batch variability matters especially when biological activity is part of the technical proposition. If a study used a defined high-sulfate fraction while commercial supply changes to a material with another chain distribution, the evidence bridge must be addressed. The appropriate statement may be that the new material

is chemically related, not clinically equivalent. Ingredient qualification is therefore continuous rather than complete when the first certificate of analysis is issued.

6. The human evidence: relevant results with narrow boundaries

6.1. A 2026 astaxanthin trial and the meaning of a skin endpoint

Sekikawa, Li and Izumi (2026) examined the effect of *H. pluvialis*-derived astaxanthin in a randomized, double-blind, placebo-controlled parallel trial among 44 healthy Japanese participants, with 22 assigned to each group. The intervention supplied 6 mg/day for eight weeks. The investigators evaluated minimal erythema dose (MED), skin-related measurements and selected hair outcomes, and reported an increase in MED together with a reduction in subjective hair dryness. The study provides a plausible signal of interest for further investigation in a defined population and time horizon.

The finding cannot be read as a demonstrated reduction in skin-cancer incidence, a replacement for ultraviolet protection, an approved EU claim or evidence of efficacy for every astaxanthin source and formulation. MED is a measurable physiological response under standardized irradiation conditions; it is not a general measure of long-term clinical protection. The limited study size, single population, selected dose and relatively short treatment period should inform any assessment of external validity. Consumer claims concerning protection from UV damage require a separate legal assessment, irrespective of whether a trial reports a positive endpoint.

The metabolic and dermatological literature on carotenoids also presents an analytical challenge. An ingredient may affect biomarkers of oxidative stress, tissue carotenoid status or inflammatory pathways without demonstrating that a specified food changes a clinically meaningful outcome. Biomarkers should be distinguished from risk reduction, and even statistically significant differences should be interpreted in terms of effect size, baseline risk and relevance to the proposed product.

6.2. A 2025 fucoidan intervention and what microbiome endpoints show

Garcia et al. (2025) reported a randomized, double-blind, placebo-controlled, three-arm trial of a *Saccharina latissima* fucoidan-rich extract in 91 healthy adults. Participants received 125 mg twice daily, 500 mg twice daily or placebo for 90 days. The trial's principal focus was microbial composition determined by 16S rRNA sequencing, with additional analyses and tolerability assessment. The authors reported dose-associated microbial diversity and taxonomic changes, and an increase in predicted functional pathways associated with short-chain fatty-acid biosynthesis. In-vitro colonic simulations provided complementary observations.

The study's strengths include its controlled design, defined interventions and explicit microbiome measurements. Its principal limitation for commercial communication is endpoint interpretation. A predicted microbial metabolic pathway is not a direct measurement of host physiological benefit, and even a measured change in microbial composition cannot establish disease prevention or durable health improvement. The trial is not a generic validation of every fucoidan-rich material: its results are tied to the defined *Saccharina* extract, dose, population and methods. Critically, the existence of a clinical trial does not establish that the exact *Saccharina* ingredient enjoys EU market authorization under the entries applicable to different seaweed species.

The authors' characterization of beneficial microbial taxa should therefore be translated carefully. Microbial ecology is context-dependent; the direction of a taxon shift is not an invariant clinical verdict. Further work should incorporate well-defined clinical or functional endpoints such as gastrointestinal symptoms, bowel function, markers of barrier function where validated, or other prospectively chosen outcomes, rather than using compositional differences as a universal proxy for health.

6.3. An evidence hierarchy for translational decisions

For either ingredient class, the most common conceptual error is compression of the evidence chain. Demonstration of a chemical constituent is followed by an in-vitro activity, a human biomarker and a marketing claim as though these were interchangeable degrees of the same observation. They are different experiments that answer different questions. A formulation developer should distinguish molecular identity, delivery in the food matrix, gastrointestinal availability, mechanism of action, measured human response and legally authorized communication.

Table 2. Interpretation of selected human findings

Study	Controlled exposure	Supported observation	Unsupported extrapolation
Sekikawa et al., 2026	6 mg/day *H. pluvialis* astaxanthin; 8 weeks; 44 healthy adults	Change in MED and some reported subjective outcomes in the studied conditions	Prevention of skin disease; an EU-approved UV-protection claim; equivalence to sunscreen
Garcia et al., 2025	*Saccharina latissima* extract, 125 or 500 mg twice daily; 90 days; 91 adults	Selected microbiome-associated responses and tolerability in this preparation	Guaranteed clinical gut benefit for all fucoidans; EU authorization of an unrelated extract
EFSA NDA Panel, 2025	Safety assessment of a specified *Haematococcus* oleoresin and proposed additional food uses	Safety conclusion under modeled exposure assumptions	Commercial authorization automatically granted by EFSA; permission for an unrestricted health claim

No new clinical data from INTABIOTECH are represented in this table.

7. Food-matrix engineering changes the exposure

An algal ingredient selected based on its composition must eventually function in a finished food. This transition is sometimes treated as a minor formulation step, but it can alter physical and chemical exposure sufficiently to undermine the rationale for the ingredient. A lipophilic oleoresin may be readily incorporated in a capsule filled with oil while proving difficult in a clear acidic beverage. Conversely, a water-soluble sulphated polysaccharide may be straightforward to disperse yet produce unwanted viscosity, mineral taste or precipitation when combined with proteins.

For astaxanthin, the engineering problem includes particle or droplet size, lipid-carrier composition, emulsion stability, light exposure, oxygen availability, pH and thermal history. Nano-emulsion, microemulsion and encapsulation approaches may increase apparent dispersion or physical stability, but the terminology must be applied correctly; a small droplet size alone does not establish improved human bioavailability. Emulsifiers and carrier systems must themselves be lawful for the intended food category. If a new delivery material or particle-engineering process changes the identity of the ingredient, additional novel-food questions may arise.

For fucoidan, matrix pH, ionic strength, calcium or other multivalent ions, protein charge and competing hydrocolloids can govern rheology and phase stability. Its sulphate groups confer polyelectrolyte behaviour. The same extract may be acceptable in a diluted beverage and unsuitable in a concentrated high-protein formulation; a polymer that performs technologically as a stabilizer also raises questions about its functional role and regulatory classification in that product. Source-specific novel-food authorization does not automatically permit arbitrary additive use.

Finished-product validation should separate chemical retention from functional retention. Astaxanthin measured by chromatography after pasteurization may survive analytically while its sensory properties deteriorate owing to other ingredients. Fucoidan content may appear stable while chain scission alters viscosity or fermentability. The relevant specification therefore includes both finished-product composition and the specific performance that justified inclusion.

8. Three application environments expose different failure modes

8.1. An acidified functional beverage

Consider a proposed 250 mL fruit-based beverage incorporating an astaxanthin-containing dispersion and, potentially, a characterized algal polysaccharide. The research targets might be stable colour, acceptable taste, low sedimentation, no visible ring formation, and ingredient identity preserved through an appropriate pasteurization or equivalent process. This is a conceptual research application, not a formula represented as authorized or commercially available.

A scientifically sound pilot would first determine whether the exact astaxanthin material is lawful in the intended beverage category. The 2025 EFSA opinion on extension of use specifically addressed certain new food categories; a favourable safety conclusion must be checked against the later Commission authorization record, its date of effect and any conditions. If the necessary entry is absent, commercial work should not assume that an ordinary supplement authorization covers beverages. Only after legal feasibility is established should a full sensory and stability development proceed.

The formulation study should record pH, titratable acidity, soluble solids, oxygen, droplet distribution, sedimentation, colour parameters, pigment retention and packaging light transmission. Process trials should compare pre- and post-treatment material and follow real-time storage at realistic temperatures. An observed change in antioxidant capacity in the bottle would not independently justify a consumer health claim.

8.2. A powder or stick-pack supplement

A dry blend reduces some aqueous instability problems but introduces mixing uniformity, humidity and oxygen exposure. For low-dose pigments, segregation and dosing accuracy deserve particular attention. A product nominally containing a few milligrams of astaxanthin per serving may exhibit unacceptable unit variability if the premix is poorly engineered. Testing only bulk blend composition can conceal dose variation among individual sachets or capsules.

A fucoidan-rich supplement creates a different problem: the specific authorized ingredient, serving size and population restrictions must be checked alongside mineral and contaminant exposure. The mass printed on the label should distinguish total extract from the assayed polymer fraction. The manufacturer should not present a 500 mg crude extract as 500 mg purified fucoidan unless the analytical data demonstrate that equivalence.

8.3. A cocoa, confectionery or protein-containing matrix

Fat-continuous confectionery can accommodate certain lipophilic pigments more readily than a clear drink, but the ingredient may affect flavour release, colour and oxidation. Cocoa powders already contain analytically important metals and polyphenols, creating the need to avoid assuming that an algal active is the sole source of a measured response. A protein-enriched beverage or bar may additionally contain ingredients that complex with charged seaweed polymers and change texture over shelf life.

Such applications may be commercially useful only when the ingredient serves a clear sensory, technological or nutritional function that can be supported independently. Adding a marine extract purely to obtain a differentiated product story can increase cost and regulatory risk without improving the finished food. A platform approach should prioritize applications in which the material’s measurable attributes solve a customer-defined problem.

9. Safety and contaminants are inseparable from the marine source

Marine organisms interact with environments containing naturally occurring and anthropogenic contaminants. Brown seaweed may accumulate iodine and certain metals; their concentrations can vary substantially by species, harvest site, season and post-harvest processing. Consequently, a certificate declaring merely

“heavy metals compliant” is inadequate if it does not identify which analytes were assessed, on what analytical basis, and against which applicable category-specific legal limits.

Total arsenic and inorganic arsenic must not be conflated. The toxicological relevance of inorganic arsenic differs from that of several organic arsenic species, and methods capable of arsenic speciation may be needed for the material and intended use. Similarly, iodine is an essential nutrient at appropriate intake, but excessive exposure is relevant to thyroid physiology, particularly among susceptible consumers. Specification design must consider the cumulative contribution from other foods and supplements, not only the isolated ingredient concentration.

Commission Recommendation (EU) 2018/464 calls for monitoring metals and iodine in seaweed, halophytes and products based on seaweed. Regulation (EU) 2023/915 establishes legally binding maximum levels for specified contaminants and food categories. These instruments have different legal functions: a monitoring recommendation is not a generally applicable numerical maximum level, while a maximum level for a specifically defined supplement category must not be projected onto every type of seaweed ingredient. In particular, a limit relevant to supplements containing a high proportion of dried seaweed does not constitute a blanket maximum for every processed or fractionated extract. The applicable consolidated text and food category govern each case.

Microbial safety also deserves attention. Fresh or insufficiently stabilized biomass may deteriorate before extraction. Processing waters, downstream filtration systems and drying operations can introduce risks independently of initial harvest quality. For microalgal cultivation, authentication and contamination monitoring are critical because an unexpected organism may produce a materially different biomass. A complete safety program therefore links source control, water quality, processing, final microbiology, contaminant analysis and traceability.

The potential presence of microplastics, marine pollutants or other emerging contaminants may warrant risk-based investigation for particular origins and products; however, the mere capacity to detect a particle does not establish a universal legal threshold or human-health risk. Analytical method validation, exposure estimation and toxicological relevance must precede sweeping claims.

10. Europe’s legal architecture: species, process, intended use and claims

European food law does not authorize “algae” as a universal ingredient family. Regulation (EU) 2015/2283 requires assessment of food or ingredients lacking a significant history of consumption in the Union before 15 May 1997, subject to the precise scope and exceptions of that Regulation. Commission Implementing Regulation (EU) 2017/2470 establishes the Union list of authorized novel foods and the relevant conditions and specifications. An ingredient isolated from a traditional food may still require examination when its composition, production process or level of exposure differs materially from historically consumed material.

Astaxanthin-rich oleoresin. The Union list contains a specific authorized novel food derived from *Haematococcus pluvialis*, with later changes to conditions of use and specifications, including Commission Implementing Regulations (EU) 2023/1581 and 2024/1026. The entries cannot be treated as authorizing astaxanthin from all organisms, with any purity or in all finished-food categories. EFSA’s 2020 safety assessment used an acceptable daily intake (ADI) of 0.2 mg/kg body weight/day in interpreting total exposure, while the legal conditions for marketed preparations must be read from the applicable authorization entry. A scientific ADI is not itself a recommended dose or permission for every age group.

The 2025 EFSA NDA opinion concerning an extension of use for an oleoresin containing approximately 10% astaxanthin is particularly instructive. The Panel considered the proposed use in dairy analogues, including beverage whiteners, and fruit juices, modelling background dietary exposure and possible intake from supplements. It concluded that the proposed novel food was safe under stated assumptions and conditions, while identifying potential exceedance of the ADI when supplement exposure was combined for certain younger populations. This scientific opinion does not, by itself, amend the Union list. Authorization must be

confirmed in a subsequent Commission act before the new use is implemented commercially (EFSA NDA Panel, 2025).

Fucoidan extracts. The Union list includes source-specific entries for extracts from *Fucus vesiculosus* and *Undaria pinnatifida*, linked to detailed descriptions, product specifications and permitted categories. These entries identify defined extraction methods and compositional ranges. They cannot be used to argue automatically that all fucoidans are conventional food ingredients or that a *Saccharina latissima* trial material is legally covered. A supplier should establish exact taxonomic source, extraction conditions, specifications, supply identity and proposed use. The applicable legal entry must be checked in its consolidated form before marketing.

Food additives and claims. Some algae-derived materials may have a distinct authorization as food additives for specific technological purposes. Such authorizations and new-food status are not interchangeable, and the existence of an E number for an alginate, colouring or other substance does not allow indiscriminate use of every related extract. Regulation (EC) No 1333/2008 and its category-specific annexes apply where an additive function is involved. Regulation (EU) No 1169/2011 governs consumer-facing ingredient and nutrition information. Regulation (EC) No 1924/2006 and the EU Register govern nutrition and health claims; promising skin, immune or microbiome results do not create a right to advertise those effects.

A final EU market decision must therefore answer at least five separate questions: Does the exact material have a lawful food status? Does the source and manufacturing process match an authorized specification? Is the intended food category and use level permitted? Is the final food safe and correctly labelled? Is the proposed claim independently authorized and compliant with its conditions? No positive answer to one question substitutes for the others.

Table 3. EU regulatory decision points for a marine ingredient project

Question	Primary legal or scientific source	Required result	Invalid assumption to avoid
Is the ingredient authorized?	Regulation (EU) 2015/2283; Union list 2017/2470	Exact source, process, specification, uses and applicable conditions	“All seaweed extracts are traditional”
Is an astaxanthin food use covered?	Current novel-food entry; Regulations 2023/1581, 2024/1026; later Commission acts if any	Authorized population, category, dose and label conditions	“An EFSA opinion is a market authorization”
Does the fucoidan source match?	Union-list entries for specified *Fucus* and *Undaria* extracts	Species and manufacturing equivalence	“A clinical trial with *Saccharina* authorizes *Saccharina*”
Is an additive used lawfully?	Regulation (EC) No 1333/2008; specifications	Food category, technological function, levels, purity	“The whole material family has an E number”
Are contaminants controlled?	Regulation (EU) 2023/915; risk-based specifications; Recommendation 2018/464	Applicable maxima, iodine and metal profile, exposure	“One generic seaweed limit applies to everything”
May the benefit be claimed?	Regulation (EC) No 1924/2006; EU health-claim register	Exact authorized wording and conditions	“A positive study permits a health claim”

11. The biorefinery sustainability question is empirical

Algal production is frequently presented as inherently sustainable because some systems require relatively little arable land and can incorporate carbon dioxide into biomass. Those features are relevant, but they do not complete an environmental assessment. Photobioreactor lighting, pumping, temperature control, culture cleaning, dewatering, freeze-drying, extraction energy, solvent recovery, transportation and waste treatment can dominate the life-cycle profile of a high-purity ingredient. A process claiming to use waste carbon dioxide is not necessarily a net carbon removal process if downstream energy or the eventual fate of the carbon is ignored.

The functional unit should be defined as a kilogram of ingredient meeting a particular specification and, where necessary, delivering a specified functionality in a finished food. Comparing one kilogram of wet algae with one

kilogram of a purified conventional ingredient would be meaningless. For a fucoidan-rich extract, the value chain should include the harvest yield, percentage recovered, quality of residual fractions, energy required for water removal and destination of process effluent. For astaxanthin, it should consider the total production cycle including the high-stress pigment phase and the losses incurred during disruption and purification.

Co-product valorisation can improve a mass and economic balance, but it also increases the complexity of quality controls. Protein, oil, pigment and polysaccharide fractions extracted from the same biomass may require separate manufacturing conditions and different legal assessments. The circular-economy argument is strongest when it is supported by reproducible yields, measured environmental inventories and real markets for the residual streams, not by a hypothetical list of possible applications.

12. Industrial translation: a structured R&D platform

A company developing marine-derived ingredients should begin with a market and technical brief rather than an abstract request to produce “the most bioactive algae extract”. The brief should specify the intended population, food category, manufacturing process, nutritional or technological objective and the lawful consumer message that may eventually be possible. It should state which measurements would justify continued investment, and which findings would stop a particular application.

The program can be organized into linked qualification stages. The first establishes legal identity and source authenticity: species, strain where applicable, harvest and process, current Union-list conditions, contamination risks and representative batch specifications. The second establishes chemical and physicochemical quality, including deeper characterization of a small set of reference lots. The third evaluates compatibility with the intended product matrix and processing conditions. The fourth measures stability, food safety, sensory acceptance and exposure. Only when a scientifically coherent physiological hypothesis remains should an appropriately designed human intervention be considered; clinical trials must be powered for the intended endpoint rather than a convenient intermediate biomarker.

For biological activity screening, in-vitro models should be employed to explore mechanism and narrow candidate selection. They should not be used to replace human evidence. A fucoidan sample that alters cytokine production in a cell system must still pass questions of gastrointestinal exposure and safety. An astaxanthin emulsion that increases apparent bio-accessibility in simulated digestion must still demonstrate that this translates to a relevant human outcome if such an outcome is proposed as a commercial differentiator.

The analytical program should be multi-batch. Testing only one carefully optimized extraction batch risks confusing a desirable material with a reproducible manufacturing platform. Replicate lots should be produced under realistic scale and process conditions; validation should be separated by batch and raw-material origin. This distinction is especially important if data-analysis methods or machine learning are subsequently used to optimize extraction or predict quality. A model that sees nearly identical samples from the same batch during training and validation may overestimate generalizability.

Table 4. Minimum industrial evidence package

Domain	Suggested documentation and measurements	Decision supported
Source and procurement	Authenticated species/strain, origin, date, cultivation or harvest controls	Is the biological raw material reproducible and traceable?
Molecular identity	Appropriate chromatography, astaxanthin profile or fucoidan structure fingerprint	Is the supplied material comparable with the studied ingredient?
Process engineering	Mass balance, extraction yield, degradation products, recovery and energy	Does the method produce a saleable material at scale?
Safety	Specified metals, arsenic speciation as needed, iodine, microbiology, contaminants	Is exposure acceptable for the proposed use?

Domain	Suggested documentation and measurements	Decision supported
Formulation	pH, thermal response, dispersion, interactions, sensory and packaging	Does the ingredient survive the finished product?
Clinical evidence	Registered primary outcomes, dose, population, comparators, tolerance	Is the intended physiological proposition substantiated?
EU compliance	Novel-food entry, additive status, labelling, claims conditions	Can the exact material and finished food be legally marketed?
Sustainability and cost	LCA with functional unit; throughput, waste, cost of compliant finished ingredient	Is the project economically and environmentally credible?

13. A model applied-development case: astaxanthin for a beverage platform

Assume a prospective industrial customer wishes to develop a fruit-containing beverage with a standardized carotenoid fraction and a nutritional story relating to marine biotechnology. The temptation is to select an attractive target amount of astaxanthin and solve its dispersion problem. A more defensible initial action is to determine whether the selected ingredient is legally permitted in that beverage category under the Union list in force on the planned launch date. EFSA's positive 2025 opinion provides a scientific basis for considering an expanded use but does not substitute for confirmation of the actual Commission authorization.

If legal feasibility is confirmed, the laboratory study can compare two or three commercially documented astaxanthin preparations using the same analytical basis for pigment content. A reference formula should be fixed for acidity, fruit solids, flavour and thermal process. Investigators would then vary only the targeted delivery-system components within permissible limits, measuring pigment recovery, particle distribution, turbidity, sedimentation and colour. Sensory work should address possible marine notes and interactions with the intended fruit profile rather than presuming that astaxanthin is flavour-neutral.

A preliminary manufacturing study could involve standardized heating, filling and packaging conditions, with sampling before processing, immediately after processing and throughout storage. Oxygen ingress and light exposure should be quantified. An ingredient that appears stable in a sealed laboratory vial may degrade faster under commercial filling, distribution or repeated refrigeration cycles. The development endpoint would be a defined shelf-life and composition specification, not a broad claim that the beverage improves antioxidant defences.

A parallel fucoidan project would require a separate legal and scientific brief. A particular *Fucus* or *Undaria* extract that matches an authorized entry may be assessed for a permitted category, while a *Saccharina* material should not be treated as interchangeable because of a favourable trial. If the latter is chosen for its specific clinical evidence, its EU status must be established for that exact material before commercialization. The two cases together demonstrate why a common marine sourcing narrative cannot replace ingredient-specific development.

14. Economic strategy: differentiation through documentation and function

The supply economics of marine ingredients rewards technical discipline. A kilogram of low-cost biomass is not a kilogram of active ingredient; a high pigment content at harvest is not a high extraction recovery; and a high-purity extract with uncertain market eligibility is not a commercially deployable product. Procurement teams should compare compliant output cost and supply reliability at the actual target grade, including quality-control burdens, rejected lots, logistics and storage conditions.

For a supplier serving European food and nutraceutical companies, the strongest differentiated offering may be a small portfolio of fully characterized grades tied to specific matrices and regulatory pathways. One astaxanthin grade could be optimized for an authorized supplement presentation; another may be investigated for a beverage application if legally permitted. A fucoidan grade could be defined for controlled research on

gastrointestinal exposure, but its label and market position must be separated from unsupported generic claims. The technical dossier is part of the product's value, not an administrative appendix.

The strategic opportunity for INTABIOTECH lies in formulation, analytical evaluation and evidence-based ingredient selection, potentially in cooperation with specialized cultivation and extraction operators. This is a proposal for an industrial research direction, not a claim that INTABIOTECH currently manufactures or clinically validates the specific ingredients examined. The company could create value by qualifying suppliers, selecting legally admissible grades, formulating around matrix constraints, coordinating independent verification and supporting clients with structured technical documentation.

The threshold for accepting an ingredient should be simple but demanding identity must be traceable; safety must be evaluated for real exposure; efficacy language must match the level of human evidence; food processing must preserve the relevant quality; and economic performance must justify scale. This approach remains valid whether the ingredient originates in a photobioreactor, a seaweed aquaculture site or a managed marine harvest.

15. Discussion: an advanced supply chain should reduce uncertainty, not obscure it

Marine biotechnology has moved beyond the era when a colourful extract or a promising microbial experiment could reasonably be presented as a complete innovation proposition. The field now offers better bioprocess understanding, improved analytical methods and increasingly sophisticated clinical experiments. At the same time, those advances make simplistic ingredient narratives less defensible. A defined molecular profile, stability after processing and an exposure-specific legal identity have become essential to credible differentiation.

The strongest evidence in this review is not distributed uniformly. Astaxanthin has a chemically defined core molecule and selected controlled human trials, though interpretation depends on formulation and endpoint. Fucoidan is structurally heterogeneous, with promising mechanistic research and preparation-specific human studies, but substantial uncertainty about cross-extract equivalence. Algal biomass as a category is wider still. These distinctions should determine the sophistication of the corresponding product specifications and claims, not be concealed under a common "marine wellness" label.

Regulatory asymmetry reinforces the point. The existence of authorized entries for certain *Haematococcus* materials and specific fucoidan extracts is commercially valuable because a lawful route can be identified. Yet those authorizations operate through species, manufacturing specifications, intended categories and conditions of use. They are not endorsements of a biological mechanism or permissions to make any attractive health claim. Nor does an EFSA opinion resolve the final Commission authorization step.

A realistic blue biorefinery will therefore be evaluated by how reliably it controls variation. Can the operator demonstrate that seasonal changes do not alter the critical sulfate distribution of a fucoidan fraction beyond specification? Can pigment yield be increased without imposing unacceptable oxidative losses? Can a finished drink maintain its analytical identity throughout shelf life? Can the supplier show that the available evidence concerns the exact commercial material? These are the questions that distinguish an industrial platform from a collection of experimental extracts.

16. Conclusions

Marine and microalgal biotechnology can support a new generation of food ingredients, but the opportunity is conditioned by the same rigor that governs any sophisticated ingredient platform. Biological origin is only the beginning of product identity. Molecular characterization defines what has been recovered; process engineering determines whether recovery is reproducible; formulation establishes how the ingredient is delivered; human evidence determines what physiological propositions are supportable; and European law decides the legitimate market route and communication.

The 2026 astaxanthin literature and recent fucoidan research justify further work, particularly where production design and analytical specification are linked to explicit human or technological endpoints. Neither family warrants generic claims of metabolic, immune or dermatological benefit. The commercially relevant achievement is a finished ingredient whose exact source, structure, process, safety, quality and lawful intended use can be independently demonstrated. For INTABIOTECH and its industrial partners, the blue-biorefinery opportunity should be approached as a platform for controlled formulation and verified evidence—not as an exception to the requirements of food science and food law.

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Editorial note. *This critical review integrates published evidence and independently reasoned industrial and legal analysis. The applied-development cases are research proposals rather than experiments reported as performed by*

INTABIOTECH. European legal descriptions reflect the sources checked up to 18 November 2026 and must be rechecked against the consolidated legislation and exact ingredient authorization before commercial implementation.

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