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AlgaePro BANOS

STANDARDISATION GUIDELINES & PRODUCT REGISTRATION ROADMAP

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LIST OF ABBREVIATIONS

Abbreviation	Description
APB	AlgaeProBANOS
CO	Confidential
D	Deliverable
d.m.	Dry matter
DEM	Demonstrator
DoA	Description of the Action
DoW	Description of Work
EC	European Commission
EU	European Union
GA	Grant Agreement
KER	Key Exploitable Result
M	Month
ML	Maximum levels
MS	Member states
PTE	Potentially Toxic Element
PU	Public
QC	Quality Control
RASFF	Rapid Alert System for Food and Feed
SEN	Sensitive
SME	Small and Medium Enterprises

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ABSTRACT

Macro- and microalgae are versatile and sustainable renewable resources with high potential for use in various product applications. Algae can be sustainably produced and are a key part of the European efforts towards making the blue economy carbon neutral. This report is an **information point for producers and product developers** and aims to support algal businesses by providing guidelines and summarising relevant information, including European regulations, product claims, relevant certificates and trade barriers for algae and algal products in the following categories: food, food additives and food supplements, feed ingredients and plant biostimulants. The goal is to facilitate market access by providing a roadmap for the AlgaeProBANOS pilots.

Key take away results

- Key information was summarised for the following algal applications: food, feed ingredients, nutraceuticals, fertilisers, and biostimulants.
- Regulations exist to harmonise practices within various aspects of the value chains and ensure consumer safety and sustainable practices.
- Although several regulations apply to algal production, future regulations and European guidance should include microalgal production as well as levels of acceptable contaminants and iodine in algal food and feed products.
- Product claims, including health claims and green claims, can be used as part of product marketing strategies and are especially vital for food supplements.
- Certifications and labels make it visible to consumers that products are made according to environmental and social standards. Relevant standards include EU organic, Seaweed from Norway, MarinTrust, Friend of the Sea, and ASC-MSC Seaweed standard.
- The most important legal factors posing innovation and market access barriers for the exploitation of algae include health claims, novel food regulations and other barriers related to trade.

ALGAE PRO BANOS SYNOPSIS

AlgaeProBANOS (APB) is an innovation project, co-funded by the European Union through the Horizon Europe programme under project number 101112943. APB brings together 26 expert and industry partners and affiliated entities from the Baltic and North Sea area, to accelerate product development and market access for sustainable algae solutions, in line with the objectives of the Mission Ocean. Partners include start-ups, SMEs, research organisations and innovation experts. The overarching objective of APB is to demonstrate market accessibility and presence of sustainable solutions and innovative algae products in the Baltic and North Seas. It is geared towards the development of innovative and sustainable algae-based products, with a keen focus on meeting the growing market demands in this sector. The project is set to run from April 2023 to March 2027, with a total budget of €12,027,291. The core mission of APB is to support the development and market accessibility of algae-based products, aiming to position the EU as a global leader in this domain. This initiative strives to not only foster industry growth but also support coastal societies and stimulate local economies. It is part of the broader Blue Mission BANOS lighthouse initiative, which is dedicated to fostering a carbon-neutral and circular blue economy across the Baltic and North Seas. APB is supporting the launch of six business pilots, aiding SMEs and startups to introduce eight innovative algae-based products into the market. These products span various sectors including food, feed, nutraceuticals, textiles, cosmetics, and plant biostimulants. The project places a significant emphasis on sustainability, with the algae used in these products sourced from the Baltic and North Sea or from recycled resources. The development process involves iterative circular loops, ensuring the products meet high standards of quality, efficiency, and sustainability. APB is not just about product development; it is about creating an ecosystem that supports the entire value chain, from biomass producers to consumers. The project will develop digital tools and platforms to support industry needs, create market strategies tailored to each pilot, and construct a comprehensive Algae Accelerator to aggregate knowledge, develop solutions, and provide guidelines and training to industry stakeholders.

1. INTRODUCTION

Macro- and microalgae are versatile and sustainable renewable resources with high potential for use in various product applications, such as food, feed, nutraceuticals, cosmetics, textiles, fertilisers, and biostimulants. Algae can be cultivated without drinking water, arable land, or added mineral fertilisers and pesticides. Seaweed cultivation can also have the additional benefit of improving the marine environment. However, algae utilisation has yet to be fully exploited. To change this, European Commission released a Communication in 2022, in which it proposes 23 actions to create opportunities for the industry to help algae grow into a robust, sustainable and regenerative sector capable of meeting the growing EU demand. In addition, the European Commission has set up the EU Mission "Restore our Ocean and Waters" with a 2030 target that aims to protect and restore the health of our ocean and waters through research and innovation, citizen engagement and blue investments. To implement the Mission objectives, it is divided into lighthouse areas, and the Baltic and North Sea (BANOS) Lighthouse's objective is to make the blue economy carbon neutral. One of the implementation actions of Mission Ocean BANOS lighthouse is the AlgaeProBANOS project, with a mission to accelerate the development of sustainable and innovative algae-based products in the Baltic and North Sea.

This report aims to support algal businesses by providing guidelines and summarising relevant information, including certificates, product claims, potential legal barriers, and European regulations for micro- and macroalgae products. The goal is to facilitate more accessible certification and market access by providing a roadmap summarizing relevant information for the AlgaeProBANOS pilots. The EU regulations are in place to secure the health and safety of consumers and the environment. At the same time, certifications are often voluntary schemes that are positive/enablers for entering the market. Not all regulations will be relevant for all raw materials and/or products, and we have focused on summarising those that are important for the AlgaeProBANOS pilots.

Disclaimer: EU regulations and limits, certifications, and documents for specific claims are constantly evaluated and can be changed. This report includes the regulations in place by September 2024.

2. SPECIFIC REQUIREMENTS FOR EACH PRODUCT CATEGORY

In AlgaeProBANOS, six pilots use macro- and microalgae to produce 8 products. Two **microalgae** pilots, Power Algae and Algiecel, produce their microalgae in **autotrophic** mode, using CO_2 as their main carbon source. Autotrophic cultivation uses the photosynthetic pathway to produce the desired bioproducts. **Macroalgae** pilots Vetik, Sjy, OceanBASIS, and Origin by Ocean base their products on cultivated seaweed (Sjy and oceanBASIS), wild harvested seaweed (Vetik), and seaweeds washed from marine environments on coasts (Origin by Ocean). **Seaweeds** refer to large multicellular algae that grow underwater, typically in the sea or attached to rocks. Seaweed can be divided into three groups based on pigmentation: **red algae** (Rhodophyta, e.g., *Furcellaria lumbricalis*), **green algae** (Chlorophyta, e.g., *Ulva* spp.), and **brown algae** (Phaeophyceae, e.g., kelp species such as *Saccharina latissima*).

2.1 Algae production

2.1.1 Macroalgae production in open waters

To ensure "good practice" in seaweed cultivation, it should be performed with minimal negative impacts (sustainable) and maximum positive impacts (restorative or regenerative) on the surrounding environment. Minimising negative impact includes actions such as selecting local indigenous species, taking precautions on optimal scaling and monitoring of a farm, and use of farm equipment and production processes that minimise environmental footprint and overall disturbance and pollution levels caused from production activities. For wild harvesting, local species should be harvested in a sustainable way, meaning that harvesting should have a minimum impact on local population and surrounding biodiversity status. Currently, this is only described for organic seaweed production (summarised herein).

Generally, aquaculture production falls under the jurisdiction of national authorities (MSP siting, licensing and permits, monitoring), while the European Commission's role is to harmonise processes and develop standards at EU level. Two recent reports summarised the status of European legislation (Anderle et al, 2023; Gómez & Lähteenmäki-Uutela, 2022). Gómez & Lähteenmäki-Uutela (2022) write: «*In Europe, seaweed aquaculture is still at an early stage. The same applies to the legislation of this activity. The EU and individual European countries lack seaweed-specific legislation, apart from the EU rules on organic seaweed (see below). The main pieces of EU legislation related to seaweed aquiculture are the Maritime Spatial Planning Directive 2014/89/EU, the Marine Strategy Framework Directive 2008/56/EC, the Water Framework Directive 2000/60/EC, the Alien Species Regulation 2014/1143/EU along with the Regulation on Aliens Species in Aquaculture 2007/708/EC, the Habitats Directive 92/43/EEC, and the Regulation on Organic Production 2018/848/EU.*» The report also included specific regulations in Baltic and Nordic countries. Specific requirements and legislation for Norway, the Faroe Islands and Iceland are summarised in the ALGET 2 report, whereas the report by Anderle et al. (2023) includes a comparison between European and overseas countries (the US and Asia).

To operate, companies require a licence permit to start algae cultivation or wild harvesting. The process of obtaining a licence is often complicated, interrupted, costly and time-consuming and differs across EU Member States (MS). To assist companies in accelerating the licensing process, Seaweed for Europe compiled general and country-specific information and resources to guide future farmers through their licensing process. The so-called Licensing Tool was recently expanded during the EU4Algae project and there is a plan to expand the Licensing Toolkit to all 27 EU member states. The Licensing Toolkit can be found here.

Specific EU regulations exist to guide good practices for both cultivation and harvesting, as listed below:

- Regulation (EU) 2018/848 on organic production and labelling of organic products
- Commission Implementing Regulation (EU) 2021/1165 authorising certain products and substances for use in organic production and establishing their lists
- UN Convention on the Law of the Sea - basic protections and standards of behaviour, covering pollution and basic sustainability principles

2.1.2 Microalgae cultivation (on land)

While relevant information and guidelines for good practices for seaweed cultivation are already available, these are still scarce for microalgae production in tanks on land. Moreover, whenever any regulation for microalgae exists, it is included in the national aquaculture regulations, and no stand-alone document at the EU level exists contemplating regulations exclusively for microalgae.

Nevertheless, there is an indication that guidelines will be developed to help Member States facilitate the implementation of algae farms in their territory within the current aquaculture regulations (European Commission,

2022). Relevant documents on the topic will become available on Key documents | EU Aquaculture Assistance Mechanism (europa.eu).

Moreover, in 2014, the EnAlgae project put together a thorough document on "Regulations and Permitting concerning algal cultivation in North-West Europe" (Parker et al., 2014). While these might not be up to date, they still provide some examples of how Member States addressed this matter in the past, which can serve as a guide for the setup of novel algae farms in the EU.

2.2 Food

Food manufacturing must be performed in such a way that the food produced is safe to consume. To achieve this, several measures need to be taken concerning microbiology/hygiene, process control, and raw material constituents. Raw material quality, processing method and conditions, and storage conditions are all important for the final food safety and quality. The EU regulation on food is implemented by the European Food Safety Agency (EFSA), and the list below provides an overview of relevant regulations.

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Council Directive for testing migration of plastic materials intended to come into contact with foodstuffs (82/711/EEC)
- Regulation (EU) 2015/2283 on novel foods

Specific regulations for Norway, the Faroe Islands and Iceland are summarised in the ALGET 2 report. Also, European regulations and a comparison with US and Asia was prepared in the Seamark project.

2.2.1 Legislation on potentially toxic elements (PTEs)

Macro- and microalgae have many constituents associated with a healthy diet. However, they also contain constituents that should be limited, including potentially toxic elements (PTEs), a term that commonly refers to arsenic, cadmium, lead, mercury, and iodine. Maximum levels (MLs) of inorganic arsenic, cadmium, and lead in various foodstuffs are set in the EC Regulation 2023/915 on contaminants in foodstuffs. The content of cadmium and lead in food supplements from seaweed is included in this law. In addition, mercury in algae and prokaryotes is limited by Commission Regulation (EU) 2018/73. Apart from these limits, no MLs are currently set for any PTEs in seaweed. Some maximum residue levels of pesticides on algae are provided in Regulation (EC) 396/2005. Regulated constituents and their limits are summarised in **Table 1**, and the regulations applicable for PTEs in seaweed are summarised in Commission Recommendation (EU) 2018/464. Sampling must be conducted according to Commission Regulation (EC) No 333/2007.

There is, however, reason to believe that further specific regulations for seaweed, on a general European level, will come in the near future. Commission Recommendation (EU) 2018/464 (5) states that: "*Seaweed and halophytes form an increasingly important contribution to the consumption patterns of certain EU consumers. Therefore it is necessary to assess whether the contribution of arsenic, cadmium, iodine, lead and mercury from seaweed and halophytes to the total exposure of these substances, would necessitate the establishment of MLs for arsenic, cadmium and lead for these commodities or the amendment of the MRL for mercury for algae and prokaryotic organisms or any action to be taken related to the exposure to iodine from these products*."

Two European countries have their additional regulations concerning PTEs, namely France and Germany. France (CEVA) has proposed maximum allowable limits for all PTEs, including arsenic, lead, mercury, cadmium, and iodine (CEVA, 2019). In Germany, the Federal Institute for Risk Assessment is of the opinion that seaweed products with a content of > 20 mg/kg pose a health risk and should therefore not be allowed on the market as food (BfR, 2007). This is much lower than the regulation practised in France (≤2000 mg/kg dw). A recent review article summarised available data for health effects of excessive iodine consumption from seaweed (in a food context), including a

modelling exercise with various inclusion levels of iodine in foods and the outcome on iodine status (Blikra, Aakre et al., 2024).

Furthermore, there is an ongoing dispute on the classification of the bioavailability of inorganic forms of arsenic, and to distinguish from organic forms of arsenic. Currently, there are efforts of DG SANTE with MS authorities to update the maximum levels of "inorganic" arsenic (Seamark project).

The recently published report "A Nordic approach to food safety risk management of seaweed for use as food" (Hogstad et al., 2022) summarises the status for regulations of hazards in seaweed well: *"There is little specific legislation on food safety of seaweed, such as maximum levels (MLs) for actual food hazards. This is the status globally, including the EU. Discussions are ongoing regarding the need for more regulation on food safety in seaweed, both in the EU and in Codex Alimentarius. However, general legislation on food applies for all types of food, including seaweed. Regulation (EC) No 178/2002 lays down the basic principles to protect human health and consumer interests. Article 14 in this regulation refers to general food safety requirements and stipulates that food must not be placed on the market if it is not safe to consume*."

2.2.2 Allergens

When the immune system reacts to certain foods, it is referred to as a **food allergy**. The **allergen** is the food or food component (typically proteins) which elicit the allergic response. General information about food allergies, from a consumer's perspective, is found here.

A list of acknowledged allergens, according to European Commission, can be found in Annex II of Regulation (EU) No 1169/2011.

2.2.2.1 Allergens amongst ingredients

The European Commission requires the provision of allergen information on both prepacked and non-prepacked foods when allergens are intentionally incorporated in foods, namely when they are ingredients. Ingredients are defined as follows (Regulation (EU) No 1169/2011): "*any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as 'ingredients'*". General information on food labelling in the EU, including labelling of allergens, can be found here, and this Commission Notice contains further details. See also the Scientific opinion on the evaluation of allergenic foods and food ingredients for labelling purposes (EFSA NDA, 2014).

2.2.2.2 Cross-contamination

The European Federation of Allergy and Airways states the following on their website: "The European Union Regulation on the provision of food information for consumers, that entered into force in 2014, identifies a list of 14 allergens that need to be labelled (eggs, milk, fish, crustaceans, molluscs, peanuts, tree nuts, sesame seeds, cereals containing gluten, soybeans, celery and celeriac, mustard, lupin and sulphites). (…) In the case of products that may have been in contact with other allergens accidentally, something called **cross-contamination**, producers can choose to voluntarily indicate the risk of a presence of an allergen. Cross contamination may be caused during food production (when using the same production machines) while transporting and storing food, and during food preparation (due to allergens on a surface or an object)."

TABLE 1. LIMITS FOR THE PRESENCE OF POTENTIALLY TOXIC ELEMENTS IN FOOD, NUTRACEUTICALS, AND FEED ACCORDING TO EUROPEAN REGULATION.

CATEGORY	SUBCATEGORY	TOTAL ARSENIC	INORGANIC ARSENIC	CADMIUM	MERCURY	LEAD	IODINE
FOOD	Food ingredients from algae (EC[1])	-	-	-	0.01 mg/kg	-	-
	Seaweeds[2] (CEVA, 2019)	3 mg/kg	-	0.5 mg/kg	0.1 mg/kg	5 mg/kg	2000 mg/kg
	Dried algae food products (BfR, 2007)	-	-	-	-	-	20 mg/kg
GENERAL FOOD, FORMULATIONS, EXAMPLES (EC[3])	Salt	-	-	-	0.01 mg/kg	-	-
	Fruit juices[4]	-	0.020 mg/kg	-	-	0.03 mg/kg	-
	Drinks for young children[5]	-		-	-	0.020 mg/kg	-
	Infant formulae (liquid)	-	0.010 mg/kg	-	-	0.010 mg/kg	-
	Infant formulae (powder)	-	0.020 mg/kg	-	-	0.020 mg/kg	-
	Baby food	-	0.020 mg/kg	0.04 mg/kg	-	-	-
NUTRACEUTICALS (EC[3])		-	-	3.0 mg/kg if at least 80 % dried seaweed, else 1.0 mg/kg	0.10 mg/kg	3.0 mg/kg	-
FEED (EU[6])	Ingredients from algae	40 mg/kg	2 mg/kg[7]	1 mg/kg[8]	0.1 mg/kg	10 mg/kg	-
	Complete feed	10 mg/kg	2 mg/kg[7]	0.5-2 mg/kg[9]	0.1-0.3 mg/kg[10]	5 mg/kg	-

[1] **Regulation (EU):** Maximum levels of mercury in and on products: http://data.europa.eu/eli/reg/2018/73/oj
[2] Note: "in vegetable or condiment form"
[3] **Regulation (EC):** Maximum levels of contaminants in food and supplements: http://data.europa.eu/eli/reg/2023/915/2024-07-22
[4] Note: Other than exclusively from berries and small fruits, incl. mixtures
[5] Note: Incl. fruit juices
[6] **Regulation (EC):** Undesirable substances in animal feed: http://data.europa.eu/eli/dir/2002/32/2019-11-28
[7] Note: Measured and reported upon request
[8] Note: Applies to feed materials of "vegetable origin"
[9] Note: Depending on the consuming species (sheep, fish, pet, etc.)
[10] Note: No regulation given for complete feed. These values apply for compound feed, depending on consuming species.

2.2.2.3. Seaweed allergenicity

For seaweed harvested or cultivated in marine habitats, the main concern is potential cross-contamination by species like **molluscs**, **crustaceans**, and **fish**, which may grow on or live near seaweeds and therefore could end up in the products. Ongoing research has found such cross-contamination to be low (e.g. in the SusKelpFood project), but the presence and levels of contaminants depend on factors like harvesting time, ocean basin, ocean temperature, and seaweed species. It is also possible that cross-contamination may increase by production year, as new invasive species (e.g. skeleton shrimp) may emerge and multiply. However, this is, to our knowledge, not documented. The current European Union legislation does not cover allergens that enter accidentally in the food (cross-contamination). Many food manufacturers include "may contain" labelling, but these practices are not regulated or harmonised.

Recent publications highlight that micro- and macroalgae contain substances which could cause allergenic reactions (e.g. James et al., 2023), however, the research within this field is still limited, and algae are not part of the list with 14 acknowledged allergens with mandatory labelling.

In summary, these legal references are most relevant:

- Regulation (EU) No 1169/2011 on the provision of food information to consumers
- Commission Notice relating to the provision of information on substances or products causing allergies or intolerances

This publication from the EFSA journal is advised for further in-depth reading of allergenicity risk assessment, taking the seaweed *Palmaria palmata* as an example (Garciarena et al., 2022).

2.2.3 Novel food regulation

As simply stated by the European Algae Biomass Association, the Novel Food Status Catalogue is "a tool to check if a product can be put on the EU market as food or food supplement, or it has to be authorised by the EU because it is Novel and as such has to pass a safety assessment" (EABA, 2024). In 2024, more than 20 new algae species were published to the EU non-novel food Catalogue, opening the doors for more algae food products to go to the market, without the need for costly novel food authorisation processes. There are now more than 60 algae-based entities in the catalogue, including whole biomass of species of micro- and macroalgae, and derived products (extracts, oils).

The novel food regulation requires a pre-market authorisation of foods or ingredients "not consumed in the EU to a significant degree as a food before 15 May 1997" (Regulation (EU) 2015/2283).

Selected macroalgae with "not novel in food" status: *Saccharina latissima, Alaria esculenta, Palmaria palmata, Laminaria hyperborea, Chondrus crispus, Sargassum fusiforme, Porphyra sp., Fucus sp., Ulva sp., Undaria pinnatifida* and *Saccharina japonica.* Some species of interest have "novel food" status, including *Furcellaria*, and *Vertebrata lanosa*.

Selected microalgae with "not novel in food" status: *Chlorella pyrenoidosa, Chlorella sorokiniana, Chlorella vulgaris,* and *Spirulina major.*

In addition to species, extracted components from algae also need to be listed or approved as "not novel" to enable use as food in the EU.

- The new novel food catalogue can be found here
- As part of the EU4Algae initiative, a new platform for New Algae For Food (NAAF) has been launched
- See also further information on EFSA's website

2.3 Feed ingredients

Feed ingredients greatly influence an animal's health and welfare but can also influence the environment and consumer food safety. For example, feed distributed but not consumed in aquaculture can influence the surrounding waters. Nutritional compounds and contaminants can be passed on to consumers through the production of animals. It is therefore vital that feedstuff is regulated with this in mind.

For seaweed used in feed, some maximum levels of undesirable substances (contaminants) are listed in Directive (EC) No 2002/32/EC on undesirable substances in animal feed. Apart from these, general regulations apply. These are summarised in Table 1. The UK applies the same regulation as the EC.[11]

According to Commission Regulation (EU) 2022/1104, for algae products used as feed, the iodine content must be declared if it is above 100 mg/kg, in addition to crude fat, crude protein and crude ash.

To produce feed from algae, these regulations are a good place to start reading:

- A comprehensive overview of animal feed and EC regulations
- Regulation (EC) No 767/2009, on the market and use of feed
- Regulation (EC) No. 183/2005 on feed hygiene requirements

2.4 Textiles

Seaweed extracts as additives in textile finishings are not regulated except if claims are driven to antimicrobial (that is regulated in the EU by ECHA BPR and EPA in the US) or any other health-related claims.

2.5 Biostimulants

Biostimulants are products (chemical substances, microorganism cultures, or mixtures of compounds or materials) that stimulate natural plant nutrition processes that either impact nutrient use efficiency, abiotic stress tolerance, quality characteristics, and/or nutrient availability within the soil/rhizosphere, independently of the product's nutrient content (EU VO219/1009, NVN-CEN/TS 17700-1:2022).

As of 2016, the global biostimulant market has a size of 1,448 million EUR, whereas the EU seaweed-based biostimulant sector accounts for approx. 13% of the global market (Noordzeeboerderij, 2018). After recent developments, the main EU regulation that is in principle applicable to these products is the new Regulation (EC) 2019/1009 on Fertiliser Product Regulation (FPR). These products have now been excluded from the scope of EC 1107/2009 applicable to plant protection products (or PPPs) and applications for plant resistance against abiotic stress (NEN, 2021).

FPR regulation can be followed in two ways: (1) at EU market level, obtaining CE marking; or (2) at Member State national market level, without CE marking and complying thus only with local regulations. For EU compliance, plant biostimulants should comply with the requirements stated for the Product Function Category (PFC) 6 on microbial/non-microbial "plant biostimulants" as follows:

- Stimulating plant nutrition processes independently of the product's nutrient content by aiming to improve one or more of the following: (a) nutrient use efficiency; (b) tolerance to abiotic stress; (c) quality of traits; (d) availability of confined nutrients in the soil or rhizosphere;
- Not exceeding contaminant limit values of Cd (1.5 mg/kg d.m.), hexavalent Cr (2 mg/kg d.m.), Pb (120 mg/kg d.m.), Hg (1 mg/kg d.m.), Ni (50 mg/kg d.m.), inorganic As (40 mg/kg d.m.);

[11] https://www.legislation.gov.uk/eur/2013/1275 and https://www.legislation.gov.uk/eur/2015/186

- Having Cu and Zn contents of less than 600 and 1500 mg/kg d.m., respectively;
- Complying with the effects claimed on the label for the plants specified thereon;
- Complying with the quality criteria for experimental validation as defined by the latest EU CEN (see NVN-CEN/TS 17700-1:2022, for a detailed overview of requirements).

Additionally, non-microbial plant biostimulants should also comply with two more requirements:

- Not consisting of a microbial plant biostimulant (meaning a microorganism or consortium thereof as specified in the component material categories (CMC) 7 of microorganisms (Part II, Annex II, EU 2019/1009);
- Not exceeding the pathogen limits established for PFC 6(B) for *Salmonella* spp. and *Escherichia coli* or *Enterococcaceae*.

An algae-based biostimulant product would, in principle, be classified under CMC 2 "Plant, plant parts or plant extracts", which includes algae. However, to comply with CMC 2, the product must have been derived from a process that can include only cutting, grinding, milling, sieving, sifting, centrifugation, pressing, drying, frost treatment, freeze drying, or extraction with water or supercritical CO_2 extraction. If other processes are used, the algae biostimulant might still be used according to the FPR as long as the process is described in another CMC. For instance, if acid hydrolysis is performed, the obtained extract can be classified as CMC 1 "Virgin material substances and mixtures". The same is valid for an algae material having undergone enzymatic hydrolysis.

Finally, a biostimulant product must comply with the requirements of the PFC and CMC categories that apply to the product through a conformity assessment. For this, three procedural modules may apply (European Commission, 2022):

- Module B – EU type examination;
- Module C – Conformity to type based on internal production control;
- Module D1 – Quality assurance of the production process.

These assessments require a notified body (see Annex IV, EU 2019/1009, for more information).

Labelling of the biostimulant products should also include:

- Physical form;
- Production and expiry date;
- Application method(s); (foliar, seed treatment, soil drench)
- Effect claimed for each target plant; and
- Any relevant instructions related to the efficacy of the product, such as soil management practices, incompatibility with other products, etc.

2.6 Food additives & supplements

Algae, with their natural ingredients and untapped potential, are gaining increasing interest for investigation of value-added products (The future of the EU algae sector; Global seaweed new and emerging markets report 2023), which leads to algae farming and algal biorefinery becoming one of the next big trends, not only for the food and feed industry (Food 2030 pathways for action), but also for human health and wellbeing, particularly in the food supplement sector.

The increasing prevalence of chronic diseases, also known as non-communicable diseases, responsible for 74 % of global deaths annually (WHO, 2023), is driving the boom in the so-called "nutraceutical" market, in which products marketed as "nutraceuticals" target and address customers´ needs for healthy ingredients. Despite research and development challenges,[12] seaweed-based nutraceuticals provide, due to their high value, attractive mid-term market entry opportunities up to USD 3.9 billion worldwide by 2030 (World Bank, 2023). Regulatory complexities, however, may impact market expansion. This chapter will guide you through the registration of nutraceuticals as food supplements in the EU.

2.6.1 EU regulations and guidelines

According to EU Vocabularies, "nutraceutical" is one of the used forms of the concept "functional food", which is defined as "*food that provides medical or health benefits*". At the time of writing this report, the regulatory framework for nutraceuticals was complex due to the lack of dedicated EU regulations and guidelines specifically addressing nutraceuticals. If a product is marketed as a nutraceutical in the EU but does not make any medical claims or has no pharmacological effects, it must comply with EU legislation on foods (Section 2.2) or be categorised as food supplements.

Table 2 outlines the definitions of "foods" and "food supplements". Of note, food supplements are regulated as foods, not as drugs. Therefore, when communicating their health benefits to consumers, it is important to know that foods or food supplements cannot refer to the prevention, treatment, or cure of human diseases (Regulation 1169/2011). The following text will focus on nutraceuticals that provide physiological health effects rather than medical benefits.

2.6.1.1 EU Safety Standard

Given that nutraceuticals fall under the broad EU regulation of foods/food supplements, which are subject to food safety regulations, ensuring the safety of these products and avoiding harmful effects on human health becomes the foremost criteria. Therefore, compliance with the general food safety requirements (Regulation (EC) No 178/2002) and maximum levels for certain contaminants in food, including heavy metals and natural toxins, are essential and crucial (Commission Regulation (EU) 2023/915; Council Regulation (EEC) No 315/93; Contaminants; see also Section 2.2).

The scientific evaluation of the safety is conducted by the European Food Safety Authority (EFSA). You should also pay attention to the tolerable upper intake levels of minerals and vitamins in food to avoid any health risks caused by excessive consumption (EFSA, 2023). In addition, if a substance, extract, isolate, or ingredient used in food (including food supplements) lacks a history of safe use in the EU before 15 May 1997, a novel food approval will be required to enter the EU market (Regulation (EU) 2015/2283; see also Section 3.3.1).

2.6.1.2 EU Quality standards and specific requirements

The quality of nutraceuticals relies on their beneficial effects on human health. Therefore, the specific requirements for registering nutraceuticals in the EU are as follows: the proposed new health benefit must be scientifically substantiated in line with Regulation (EC) No 1924/2006. A comprehensive quality dossier is required to support the health claim (Section 2.6.2; Section 3.1.1). Health claims must adhere to the general and specific requirements outlined in this Regulation (No 1924/2006).

[12] Research Topic: technological advancements for enhancement of high-value nutraceutical co-products in algae

TABLE 2. DEFINITION AND REGULATORY FRAMEWORK OF FOODS AND FOOD SUPPLEMENTS IN THE EU.

Category	Definition	Regulatory framework
Foods	'*Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans*'	General Food Law Regulation 178/2002
Food supplements	'*A subset of foods meaning foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with nutritional or physiological benefits to supplement a normal diet. They may be sold as capsules, lozenges, tablets and sachets or in bottles*'	- The same regulations as for foods - Specific regulation: Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements - Also see EFSA´s guidance, and food supplements

Only claims that are authorised and included in the list of authorised claims specified in Articles 13 and 14 of this Regulation (No 1924/2006) can be used for commercial communications (labelling, presentation, or advertising) of food products, including food supplements and nutraceuticals. When applying for authorisation of a health claim, the applicant must specify the nutraceutical, describe the health relationship, propose the wording of the claim, and define the conditions of use (for further details, see Section 3.1.1).

In addition to general labelling requirements regulated for foods (Regulation 1169/2011), requirements for food supplement labelling are as follows (Directive 2002/46/EC):

- '*the nutrients and substances that the foodstuffs contain*';
- '*recommended daily consumption with a warning as to not exceed that dose*';
- '*no substitute for a balanced, varied diet*'; and
- '*advice to store the product out of reach of young children* '

Specifically for health claims, business operators must provide the following mandatory information in the labelling, presentation, or advertising to consumers (Decision 2013/63/EU):

- *'A statement indicating the importance of a varied and balanced diet and a healthy lifestyle';*
- *'The quantity of the food and pattern of consumption required to obtain the claimed beneficial effect';*
- *'Where appropriate, a statement addressed to persons who should avoid using the food'; and*
- *'An appropriate warning for products that are likely to present a health risk if consumed to excess'.*

2.6.2 Scientific substantiation of health claim

Validation of bioactivity is a critical quality requirement and is of central importance in substantiating proposed claims. Macroalgae contain various bioactive substances (e.g., polyphenols, polysaccharides, etc.) that are potentially beneficial to human health and, therefore, have attracted attention in the nutraceutical market (Tavares et al., 2023). Below, using an example of fucoidans, a type of polysaccharide found in brown algae that are gaining increasing importance due to its health-promoting properties and is also the focus of one of the APB pilots, we

explain the key points to be considered for validating bioactivity in terms of „characterisation of the claimed effect“ and „identification of pertinent scientific data“ in order to apply for the authorisation of a health claim (EFSA Panel on Dietetic Products & Allergies, 2021; Regulation 1924/2006).

First, it is necessary to determine what kind of beneficial physiological effects the nutraceutical may have, as there are different categories of health claims (see Section 3.1.1). Taking fucoidans as an example: numerous studies demonstrate that fucoidans offer great potential health benefits by targeting crucial signalling pathways or modulating metabolic and immunological processes, potentially leading to a reduced risk of chronic, particularly age-related, diseases, as reviewed by e.g. Apostolova et al. (2020), and Dörschmann and Klettner (2020). In this context, a proposed health claim is based on the beneficial physiological effects of fucoidans on reducing a disease-related risk factor.

2.6.2.1 Characterisation of the claimed effect

The claimed effect needs to be clarified, and the following requirements need to be provided in an application for authorisation of disease risk reduction claims (EFSA Panel on Dietetic Products & Allergies, 2021):

- '*the risk factor(s) for the development of the human disease*';
- '*how the specific risk factor can be assessed in vivo in humans*';
- '*the disease to which the risk factor relates*';
- '*the criteria used for the diagnosis of the disease*';
- '*evidence that the relationship between the risk factor and the development of the disease is biologically plausible*'; and
- '*evidence from human studies that a reduction of the risk factor reduces the disease incidence*'.

This points out the importance of human studies in understanding how the consumption of the nutraceutical will prospectively impact the proposed disease risk factor, which is linked to evidence of reduced disease incidence. Such studies are essential for scientifically substantiating the proposed claim, as the claimed effect must be demonstrated in humans. In this case, if there is evidence that human intervention involving specified fucoidans can reduce the proposed risk factor related to the disease, it would be sufficient for scientific substantiation.

Additionally, studies other than human studies (e.g. preclinical studies) can give valuable insights into biological plausibility and mechanisms supporting the relationship between the nutraceutical and the claimed effect. They also aid in screening the most promising nutraceutical(s) during early product development.

2.6.2.2 Identification of pertinent scientific data

The EFSA Panel on Dietetic Products and Allergies (2021) states that: “*pertinent human studies are an absolute requirement for the scientific substantiation of health claims, and pertinent human efficacy studies are at the top of the hierarchy that informs decisions on substantiation*”. Therefore, a systematic and comprehensive review of published human studies that are relevant to that proposed health claim has to be provided in the application (EFSA, 2010).

Taking fucoidans as an example: fucoidans from seaweeds are considered a group of chemically heterogeneous sulphated polysaccharides that may exert different bioactivities depending on a variety of factors as reviewed by e.g. Ale et al., 2011, and Jayawardena et al., 2022. Therefore, fucoidans used in a pertinent study identified should be the same fucoidans to which the claim is made or be representative of the key characteristics of fucoidans (e.g. molecular weight distribution, degree of sulphation, fucoidan purity, algae species, etc.) that may be responsible for

the effect claimed in the health claim application. Otherwise, they may not be comparable and may not provide information for decisions on substantiation.

Furthermore, the study should show that specific, comparable, or representative fucoidans affect the proposed disease risk factor reduction in the proposed target population when consumed under the proposed conditions of use. The study's methodologies (e.g. method of measuring outcome variables, method of participant recruitment, statistical analyses, etc.) should follow eligible criteria. Moreover, a list of relevant unpublished human studies and the procedure for identifying these studies should be provided to the same extent.

In summary, in addition to the reliability of identified studies in terms of design, quality, and methodology, pertinent data should provide convincing evidence that the nutraceutical exerts the claimed effect, and the human studies provided for substantiation purposes must meet the following criteria (here taking fucoidans as an example):

- whether the fucoidans used in the study comply with the characterised specifications of fucoidans for which the claim is made;
- whether outcome variables investigated in the study (e.g. health markers, specific bioactivity properties, etc. based on proposed wording) are measured using valid (or established) methods and are appropriate for assessing the claimed effect;
- whether the study group in the study is representative of the target population (in principle, subjects without disease or without medication) of the claim; and
- how the conditions of use (daily dose and consumption pattern) in the study relate to the conditions of use proposed for the claim.

Information on the scientific requirements for health claims relating to specific areas (such as functions of the nervous system) is outlined in specific EFSA guidance documents. The role of EFSA and the link to the documents can be found in Section 3.1.1. Based on the scientific data submitted, one of the following three possible evaluation conclusions will be published in EFSA´s scientific opinion:

- '*A cause and effect relationship has been established between the consumption of the food/constituent and the claimed effect.*'
- '*The evidence provided is insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect.*'
- '*A cause and effect relationship has not been established between the consumption of the food/constituent and the claimed effect.*'

In addition, EFSA will also deliver its opinion on the following two points:

- 'if the food/constituent is sufficiently defined and characterised (e.g. based on the provided manufacturing process and the composition information)'; and
- 'if the claimed effect is defined and is a beneficial physiological effect for the target population and can be demonstrated in vivo in humans'.

The scientific opinion issued by EFSA will be delivered to risk managers who will make the decision on whether the proposed health claim will be authorised or not (for further details, see Section 3.1.1).

3 GENERAL CERTIFICATION AND PRODUCT LABELLING

3.1 Claims

With the emergence of algae-based products, applying strategies, such as a brand marketing strategy, to differentiate themselves and stand out in a crowded and competitive market can greatly increase their visibility.

General information about nutrition and health claims can be found here.

3.1.1 Health claims

A key strategy in the healthy food sector is to target health claims and communicate the product's health benefits to consumers. Authorised health claims enhance product credibility and differentiate it from competitors' products lacking such claims. While this unique selling point offers a marketing advantage, initial challenges are inevitable, particularly given the strict regulations on health claims. This chapter will help you understand what a health claim is and guide you through the process, enabling you to explore this topic in depth.

3.1.1.1 Understanding health claims

According to EU rules, **health claim** means: "*any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health*" (Regulation 1924/2006). Different categories of health claims can be submitted by applicants for approval (Table 3). Authorised health claims can be found in the Register by setting the "Claim Status" filter to "Authorised". Authorised claims without usage restrictions (filter "Protection of proprietary data granted" to "No") can be used by anyone, provided the conditions of use are met. The EU has published a practical Q&A documentation on the list of permitted health claims.

When communicating health benefits to consumers, it is essential to know that health claims cannot refer to preventing, treating, or curing human diseases (Regulation 1169/2011). Health claims must comply with Regulation 1924/2006 to ensure consumer protection and fair competition. Before initiating scientific studies to substantiate a new health claim, thoroughly read this key regulation and other relevant documents (as indicated below) to avoid unnecessary investments and expenses and to ensure that discipline becomes your greatest ally.

„We must all suffer from one of two pains: the pain of discipline or the pain of regret. The difference is discipline weighs ounces while regret weighs tons."

- Jim Rohn

3.1.1.2 Regulatory framework and guidance

After understanding the definition and the categories of health claims, the following options may be considered:

- Using an authorised health claim from the EU Register list, provided the product meets the conditions of use (note that the right to use the claim is not exclusive to the use of the applicant and the business operator is responsible for avoiding overpromising or making exaggerated statements);
- Applying for the modification of an authorised health claim;
- Applying for the authorisation of a new health claim. The focus below will be on this authorisation procedure.

Health claims must be substantiated by scientific evidence and easily understood by consumers. Therefore, after an application for authorisation is submitted via the E-submission Food Chain platform (ESFC) and its validity is verified by the national competent authority of a Member State, it is forwarded to the European Food Safety Authority (EFSA) for a thorough scientific assessment and its opinion on provided data and proposed wording for the claim. To ensure food safety and build public trust in line with Transparency Regulation (EU) 2019/1381, applicants are required to notify studies in the pre-submission phase; failure to do so may invalidate the application or delay the EFSA´s risk assessment process.

According to the general principle of proactive disclosure and transparency (Art. 38, 39-39e of General Food Law Regulation 178/2002), applications will be made publicly accessible on the OpenEFSA portal once declared valid. However, applicants can request confidential treatment, if they can demonstrate that disclosure significantly harms their interests (Art. 39(2) of Regulation 178/2002). This requires submitting a confidentiality request, a non-confidential version with confidential elements blackened, and a confidential version. Of note, the non-confidential version may be revised based on EFSA´s confidentiality decision, including potential rejection of one or more confidentiality requests (Art. 39-39e of Regulation 178/2002). A public consultation with third parties will then be launched via OpenEFSA public consultations. If the confidentiality request is partially or fully rejected, the applicant may state their view or withdraw the application.

EFSA´s role is to provide independent scientific advice to regulatory decision-makers. After EFSA issues its opinion, the final decision on authorisation, including the wording of the claim and the conditions/restrictions of use, is made by risk managers (the European Commission and the Member States). Negotiations with risk managers for alternative wording of the claim are possible. EFSA has created guidance for applicants on preparing and submitting applications to ensure high-quality dossiers (Supplementary Table 1). Therefore, starting the process from this entry point is recommended.

3.1.1.3 Scientific basis and practical application

After determining the applicable health claim category, consider whether the proposed health claim is based on the essentiality of nutrients or not. Note that data requirements vary (Table 4). Ensure the application includes all pertinent scientific data (both published and unpublished data, data in favour and not in favour) which are relevant to that proposed health claim.

In an application for the authorisation of a health claim, the following key data must be provided:

- The food/constituent for which the health claim is made needs to be clearly specified and sufficiently characterised including information related to manufacturing process, stability or shelf-life, and characteristics, particularly those characteristics which may influence the claimed effect.
- The relationship between the food/constituent in question and the claimed effect needs to be clearly described, including identification of outcome variable(s) used to assess the claimed effect *in vivo* in humans, the measurement methods, and mechanisms by which the food/constituent could exert the claimed effect.
- A proposal for the wording of the health claim needs to be included.
- The conditions of use need to be defined, including target population, and quantity and consumption pattern required to obtain the claimed effect.

TABLE 3. CATEGORIES AND EXAMPLES OF HEALTH CLAIMS SUBMITTED FOR APPROVAL (ART.: ARTICLE OF REGULATION 1924/2006).

Category	Submitted under	Referring to	Example
Art. 13(5)	Art. 18	General function claims that a nutrient or food ingredient can influence the maintenance of normal human health or performance, or support weight control, other than those referring to Art. 14.	Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow (link) Claims referring to Art. 13(1) see Regulation 432/2012 establishing a list of permitted health claims made on foods, other than those referring to Art. 14
Art. 14(1)(a)	Art. 15	Reduction of a risk factor related to a disease	A combination of artichoke leaf dry extract standardised in caffeoylquinic acids, monacolin K in red yeast rice, sugar-cane derived policosanols, procyanidolic oligomers from French maritime pine bark, garlic dry extract standardised in allicin, d-α-tocopheryl hydrogen succinate, riboflavin and inositol hexanicotinate reduces blood LDL-cholesterol concentrations. High LDL-cholesterol is a risk factor in the development of coronary heart disease (link) At the time of writing this report, data protection has been granted for this claim in terms of restriction of use of the claim in favour of the applicant for 5-years with the expiry date on 10/04/2028
Art. 14(1)(b)	Art. 15	Children's development and health	Essential fatty acids are needed for normal growth and development of children (link)
Art. 13(5) or Art. 14	Art. 19	Modification of an existing authorised health claim	Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow (link) In this claim example, the conditions of use of the claim were modified (for capsules or tablets)

TABLE 4. DATA REQUIREMENTS FOR IDENTIFICATION OF PERTINENT SCIENTIFIC DATA IN AN APPLICATION.

Category	Data requirements
Claims based on the essentiality of nutrients	- '*Evidence regarding the essential role of nutrients in metabolism and the clinical signs of deficiency should be provided.*' - '*Procedure for identifying the evidence of nutrient essentiality should be depicted.*'
Claims other than those based on the essentiality of nutrients	- '*Human studies are essential for substantiating health claims related to food constituents.*' - '*Animal or model system data can support but not replace human evidence.'* - *'A systematic review of relevant published studies is necessary to demonstrate balanced evidence.*' - '*Procedure for identifying relevant unpublished human studies should be depicted.*'

Consistency is crucial across various aspects: from the application process and manufacturing to food/constituent characteristics, analytical data, study findings, and effect reproducibility (within and across studies). Additionally, consider batch-to-batch variability and stability. Keep in mind that each application allows only one relationship between a food/constituent and a single claimed effect. Nevertheless, applicants can propose multiple formulations of the same food/constituent within a single application, as long as scientific evidence supports all proposed formulations.

EFSA´s scientific and technical guidance (EFSA, 2021) provides details on the application structure, including administrative data, public summary, and technical dossier. Thoroughly studying this guidance, particularly the technical dossier section, to understand necessary data for compiling the application is recommended, as is learning from relevant EFSA's scientific opinions (available in the OpenEFSA portal and EFSA Journal) to ensure the submission meets the highest scientific standards and the claimed effect is well-supported by scientific evidence. Also, remember to check for any additional national requirements specific to your Member State.

3.1.2 Green claims

Positive impacts from cultivation could be achieved if measures are taken to allow for environmental benefits such as improving nutrient density (reducing nitrogen) in surrounding waters, or the macroalgae can act as shelters for e.g. breeding fish. Other examples of proposed sustainability within algae businesses include:

- Microalgae for nutrient sequestration from industrial waste streams
- Harvesting of invasive macroalgal species

For sustainable products, it is beneficial, from a marketing perspective, to communicate the environmental performance of the product across the production life cycle to consumers. However, currently, no regulations of how such claims can be made exist, making it difficult for consumers to know which products and brands to trust.

The European Commission has developed a proposal (currently under negotiation with the European Council) on a new Green Claims Directive that aims to regulate environmental claims across the value chain life cycle, including communication of claims to prevent greenwashing and encourage consumer trust, and to regulate how green claims can be substantiated. They have proposed a new law with "new criteria to stop companies from making misleading claims about environmental merits of their products and services". The directive proposal announcement can be found here.

The key measures of the law are as follows: "To ensure consumers receive reliable, comparable and verifiable environmental information on products, the proposal includes 1) clear criteria on how companies should prove their environmental claims and labels; 2) requirements for these claims and labels to be checked by an independent and accredited verifier and 3) new rules on governance of environmental labelling schemes to ensure they are solid, transparent and reliable."

The Directorate-General for Environment presented the new proposal at the Working Group meeting on Green Claims (video recording available), organised by the SUBMARINER Network. The meeting also included discussions with end-users on how Green Claims affects blue bioeconomy companies including algae product developers.

Furthermore, the EU4Algae Stakeholder Forum is planning to deliver two synthesis reports this year on the topic of environmental footprint (substantiation of Algae Green Claims) for various algae product categories, also analysing needs for a standard LCA methodology for assessing algae Green Claims.

3.2 Certificates

In addition to the statutory regulatory arrangements that companies must follow, several other certifications and labels are available for algae production and products. Such claims can, for example, make it visible to consumers that products are made according to environmental and social standards. European consumers and retailers are increasingly putting pressure on companies to ensure this.

The websites (link following each logo) provide information about the requirements and application processes for the different certifications.

3.2.1 EU organic

The European Union's organic logo gives a coherent visual identity to organic products produced in the EU. This makes it easier for consumers to identify organic products and helps farmers market them across the entire EU.

The organic logo can only be used on products certified as organic by an authorised control agency or body. This means they have fulfilled strict conditions on how they must be produced, processed, transported, and stored in compliance with EU regulations (2018/848 and 2021/1165).

EU Organic Agriculture regulation (EC No 2018/848) certifies agricultural products, processed agri-food products, feed and pet food, aquaculture products, **algae and microalgae** (spirulina), and yeasts.

3.2.2 Seafood from Norway/ Seaweed from Norway

"Seafood from Norway" is a generic trademark that producers of Norwegian seafood can use in marketing and on product packaging for goods to be traded outside Norway.

3.2.3 MarinTrust

MarinTrust is a programme "dedicated to marine ingredient production factories, allowing them to gain recognition for their sourcing and production of marine ingredients". MarinTrust describes Marine ingredients as "nutritious natural products derived from marine

organisms such as fish, krill, shellfish, and **algae**. They are used mainly for aquafeed (75%), land animal feed, pet food, and human consumption as health supplements".

3.2.4 HACCP

To ensure food safety, HACCP, or Hazard Analysis and Critical Control Points, is crucial in algae production. This systematic approach identifies potential biological, chemical, and physical hazards throughout the production process. Producers can effectively monitor and control these hazards by establishing Critical Control Points (CCPs). Implementing HACCP in algae production involves assessing risks associated with harvesting, processing, and storage. For instance, contamination from water sources or improper handling can pose significant risks. By adhering to HACCP principles, algae producers can enhance product safety, comply with regulatory standards, and protect consumer health, thereby promoting sustainable practices in the industry. The European Commission mentions HACCP as part of their legislation on food hygiene. More information about HACCP can be found here:

- Food Standards Agency (UK)
- Food and Drug Administration (US)
- The ALGET 2 report includes guidelines for internal control and HACCP in a seaweed context

3.2.5 Friend of the sea

Friend of the Sea is currently a project of the **World Sustainability Organization**, an international NGO whose mission is to promote environmental conservation.

"Friend of the Sea is a certification standard for products and services that respect and protect the marine environment. The certification awards sustainable practices in Fisheries, Aquaculture, Fishmeal, and omega-3 Fish Oil".

3.2.6 ASC-MSC Seaweed Standard

The Seaweed Standard sets several requirements for seaweed harvesting and farming practices. Environmentally, seaweed operations must show that they actively minimise their impact on the surrounding natural environment. Seaweed operations must be managed responsibly and socially. "Producers must care for their employees, work with the local community, and be good and conscientious neighbours. The standard applies globally to all locations and scales of seaweed operations, including harvesting wild populations and farmed seaweed production".

It refers to scientific understanding and industry best practices and conforms to international norms of good conduct, including the United Nations FAO Guidelines for Ecolabelling and ISEAL Codes of Good Practice. Read about the ASC MSC Seaweed Standard in the brochure to learn more about the standard.

3.2.7 Other relevant certificates

To show you meet social standards, consider FLO Fairtrade certification or meet FairForLife standards.

Other food safety certification schemes that may be relevant are the FSSC 22000, International Food Standard (IFS) and/or British Retail Consortium (BRC), and sometimes also GLOBALG.A.P. Depending on the end market, other buyers also require your seaweed products to be HALAL-certified or Kosher-certified.

3.3 Trade barriers

Different countries have varying regulations regarding the use of algae and algae products. Barriers can include regulatory challenges such as the Novel food regulation, and market-related barriers.

3.3.1 Market-related barriers

All trade barriers reported to DG TRADE which affect EU exports to non-EU countries can be found here.

Currently, the only mention of algae is the export of algae and agar from Morocco, which is "subjected to an export licence within the limit of quotas, allegedly for environmental reasons".

My Trade Assistant provides information about which tariffs, taxes, duties, requirements and trade barriers might apply.

A study carried out on behalf of the CBI Ministry for Foreign Affairs addresses the challenges of entering the European market for seaweed.

3.3.2 Food export list: necessary for export to some foreign countries

Some foreign food safety authorities require certification of certain exported food products in the form of publicly available lists of establishments eligible for export.[13]

More information about listing of non-EU establishments can be found here.

3.3.3 Exporting seaweed from the EU to non-EU countries

The European Commission has compiled a Guide for export of goods, which can be found here.

The guide includes step by step information on **identifying suitable markets** and how to find potential buyers. Information about **export conditions in the EU** including how to export, who can export, and how to register as an exporter is also included. Export of some food products and plants might be restricted and in need of licence or authorisation. More information can be found here in the TARIC Consultation and EU Sanctions Map. Food and agricultural products must often adhere to health and hygiene requirements and may require health certificates (see Guide for export of goods). The guide also includes steps on the **preparation of the sale and organising transportation.** Countries often have mandatory requirements for the packing and labelling of certain products, usually related to public safety, health and environmental concerns. Other liabilities, like if the seller or the buyer will be responsible for expenses related to transportation and loading costs, customs clearance, etc., should be included in contracts**.** More information regarding **which documents are needed for customs clearance in the EU and in the export market** can be found here**: Taxation and Customs Union - European Commission (europa.eu)**. Export declarations might include information about the origin of the product(s), the destination and value of the products, and customs and commodity codes that apply.

3.3.4 Importing seaweed to the EU

According to the Ministry of Foreign Affairs, to enter the European market for seaweed, you must meet the mandatory requirements set by the European Union.

[13] Food Export Lists | FDA

Based on the General Food Law (EC No 178/2002), the Rapid Alert System for Food and Feed (RASFF) was established to allow food safety authorities to exchange information on health risk derived from food or feed. The RASFF includes all EU members states in addition to Norway, Iceland, Lichtenstein and Switzerland. For algae products, high content of iodine in dried seaweed, or cadmium found in seaweed used as feed ingredients are usual causes for flags in the RASFF.

SUMMARY

This document provides a comprehensive overview of necessary regulations, relevant guidelines, useful certifications and regulatory barriers to facilitate market access for algae-based products. It forms a roadmap for registering several micro- and macroalgae products, especially food, feed, biostimulants, and nutraceuticals, focusing on ensuring consumer health and environmental protection. The present work is part of the Horizon Europe funded project AlgaeProBANOS, which aims to accelerate the development of sustainable and innovative algae-based products in the Baltic and North Sea.

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SUPPLEMENTARY TABLE ON HEALTH CLAIM APPLICATIONS

SUPPLEMENTARY TABLE 1. HEALTH CLAIM APPLICATION NAVIGATOR INCLUDING PRACTICAL GUIDE AND REGULATORY FRAMEWORK.

Link	Content
EFSA's glossary	Definition of a health claim
Health claims in general	List of guidance, EU framework & FAQ
Guidance documents	Including key regulations: - Regulation 1924/2006 on nutrition and health claims made on foods - Regulation 353/2008 establishing implementing rules for applications for authorisation of health claims - amending Regulation 1169/2009 establishing implementing rules for applications for authorisation Including key guidance documents to consult: - Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 3) (update 2021): the general principles for applications and a common format for the technical dossier - General scientific guidance for stakeholders on health claim applications (Revison 1) (update 2021): the general approach for the evaluation of health claim applications - Administrative guidance for the processing of applications for regulated products (update 2021) - EFSA´s Catalogue of support initiatives during the life-cycle of applications for regulated products (update January 2024) Specific guidance on the scientific requirements in specific areas: - functions of the nervous system, including psychological functions - muscle function and physical performance - bone, joints, skin and oral health - appetite ratings, weight management, and blood glucose concentrations - the immune system, the gastrointestinal tract and defence against pathogenic microorganisms - antioxidants, oxidative damage and cardiovascular health
Transparency regulation	Mandatory notification of studies and requirement of a pre-application ID in the pre-submission phase for regulated products according to the Transparency regulation (EU) 2019/1381 Please also see - Decision of the Executive Director of EFSA laying down the practical arrangements on pre-submission phase and public consultations - Questions and answers on the EFSA practical arrangements

E-Submission food chain platform	The EU e-submission system for applicants to create, submit and manage applications of regulated products including video tutorial
Competent authorities	List of competent authorities of the Member States within the framework of Regulation 1924/2006
Health claims application procedure	A simplified figure showing the process from application submission to publication Other useful figures summarising key steps and main players in the authorisation process and key scientific aspects (Figure 1 and Figure 2 in General guidance)
Parma Summer School	Useful presentations such as „Scientific evaluation of health claims made by EFSA“ (recording and presentation slides)
EFSAchannel	EFSA’s youtube videos and webinars related to health claims by searching „health claim“ within the channel