Assessment of EU regulatory landscape in a global context

SEAMARK DELIVERABLE 10.3

SUBMARINER Network for Blue Growth EEIG

This project has received funding from the European Union's Horizon Europe research and innovation programme under Grant Agreement No 101060379. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or The Research Executive Agency. Neither the European Union nor the granting authority can be held responsible for them.

SEAMARK DELIVERABLE 10.3: ASSESSMENT OF EU REGULATORY LANDSCAPE IN GLOBAL CONTEXT

Kim Anderle[1], Frederick Bruce[1], Efthalia Arvaniti [1], Ólavur Gregersen[2]

[1]SUBMARINER Network for Blue Growth EEIG, Berlin, Germany, [2]Ocean Rainforest Sp/F, Tórshavn, Faroe Islands

Abstract

This regulatory assessment analyzes the EU's current regulatory framework for macroalgae, focusing on seaweed cultivation, processing, and product development. Bioactive beta-glucans, pig feed supplements, and eco-friendly alginates are key products under scrutiny.

In November 2022, the EU proposed 23 actions to facilitate the growth of a sustainable seaweed industry. These actions aim to enhance governance, improve the business environment, bridge research gaps, and raise social awareness.

Despite its potential, the European seaweed industry faces systemic challenges. Europe's historical reliance on wild seaweed harvesting cannot meet growing demand. To invigorate the industry, a transition to sustainable farming practices is essential.

This report identifies significant regulatory barriers hindering market expansion for seaweed products, especially beta-glucans, pig feed, and green alginate. It proposes measures to eliminate policy barriers, fostering innovation and growth.

Key Findings

- Beta-Glucans: Unclear novel food status and strict health claim requirements impede seaweed-derived beta-glucans market entry, hindering innovation.
- Pig Feed: Regulatory hurdles, including lengthy EU authorization processes and cross-border harmonization issues, limit innovation in climate-positive animal feed.
- Green Alginate: Consumer perception affects alginate's acceptance. Regulatory consistency across regions is vital for market exploitation.
- Cultivation: Streamlining cultivation regulations is vital. Recommendations include custom licensing procedures, subsidies, and harmonized transnational regulations.

Recommendations for Regulatory Reform

To overcome policy barriers and promote industry growth:

- Simplify Licensing: Standardize and expedite licensing for seaweed farms.
- Expedite Authorization: Speed up authorization processes while ensuring transparency and harmonization.
- Clear Guidance: Develop precise regulatory guidance for macroalgae.
- Support Innovation: Provide targeted support, subsidies, and infrastructure funding, especially for SMEs.
- Foster Collaboration: Encourage international collaboration and alignment with global standards.

Future Outlook

Despite regulatory challenges, the European algae industry shows promise. Evolving consumer preferences and increased awareness offer opportunities. With regulatory reforms and stakeholder collaboration, the industry can thrive, fostering a sustainable and circular economy.

OPEN ACCESS

Edited by:
Kim Anderle, SUBMARINER Network for Blue Growth EEIG, Berlin, Germany

Reviewed by:
Ólavur Gregersen Ocean Rainforest Sp/F, Faroe Islands; Efthalia Arvaniti and Maya Miltell SUBMARINER Network for Blue Growth EEIG, Berlin, Germany

Document Status: *Finalised*
Dissemination Level: *PU – Public*

Due Date: *30.09.2023*
Submission Date: *04.10.2023*
Accepted Date: *04.10.2023*
Updated date: *08.07.2024*
Deliverable Reference: *D10.3*

Work Package / Task:
10 / T10.5 Assessment of EU Regulatory Landscape in a global context

Total number of pages (incl. annexes):
30

Keywords:
algae, macroalgae, seaweed, beta-glucan, feed, cosmetics, regulation,

LIST OF FIGUR

LIST OF ABBREVIATIONS

Abbreviation	Description
ADI	Aquaculture Disaster Insurance
ASC	Aquaculture Stewardship Council's
CAP	Common Agricultural Policy
CCM	Collaborative Cost Management
CPNP	Cosmetic Products Notification Portal
CSR	Corporate Social Responsibility
DOC	Department of Commerce
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
ESG	Social and Governance
FDA	Food & Drug Administration
FFDC	Federal Food, Drug, and Cosmetic Act
FOSHU	Oversees Foods for Special Health Uses
GFCO	Gluten-Free Certification Organisation
GIG	Gluten Intolerance Group
GMO	Genetically Modified Organism
GRAS	Generally Regarded as Safe
INCI	International Nomenclature of Cosmetic Ingredients
LCAs	Life Cycle Assesments
MHLW	Ministry Of Health, Labour, and Welfare
MoCRA	Modernization of Cosmetics Regulation Act
MOF	Ministry of Oceans and Fisheries
NGO	Non-Governmental Organizations
NMPA	National Medical Products Administration
NOAA	National Oceanic and Atmospheric Administration

PIF	Product Information Files
PMDL	Pharmaceutical and Medical Devices Law
R&D	Research and Development
SABs	Seaweed Aquaculture Beds
SAMR	State Administration for Market Regulation
SSbD	Safe-and-Sustainable-By-Design
UPOV	Union for the Protection of New Varieties of Plants
USDA	U.S. Department of Agriculture
VET	Vocational Education and Training

CONTENTS

INTRODUCTION

In Europe, seaweed has emerged as a promising and sustainable resource with a wide range of applications across various industries including food, cosmetics, biomaterials, and nutraceuticals as a sustainable, healthy, and environmentally friendly product. The cultivation of this species holds the potential to ameliorate overarching global predicaments, encompassing matters that extend beyond consumption, including aspects related to human health, agriculture, coastal management, and its role in fostering a sustainable circular and blue bioeconomy.[7] Their potential as a renewable feedstock in latter mentioned industries has attracted significant interest worldwide. The European Union (EU) recognizes the importance of harnessing the economic and environmental benefits of macroalgae, however, to date represents less than 1 % of the world's production.[5]

The world is experiencing climate change, and several reports have shown that seaweeds are an efficient CO_2 sink.[27,58] Seaweed aquaculture beds (SABs) provide ecosystem services similar to those seaweed beds existing in the wild. The use of SABs for potential CO_2 mitigation has been established, with commercial seaweed production in China, India, Indonesia, Japan, Malaysia, the Philippines, the Republic of Korea, Thailand, and Vietnam, and it is also in the developmental stage in Australia and New Zealand.[11] Seaweed farming is no doubt an aquaculture endeavour that can be socially and economically sustainable; socially and environmentally sustainable; and economically and environmentally sustainable.[12] Every stakeholder has an important role along the value chain to make it sustainable.

The successful exploitation and upscaling of seaweed products are contingent upon navigating a complex regulatory landscape and a lack of governmental support through subsidies, grants, and funding for infrastructure.[7,39] The industry needs to upscale first production volumes and reduce production costs in order to support the budding algae start-up and product market and ultimately make the industry economical. Understanding the existing EU regulations governing seaweed cultivation, processing, product development, marketing, and associated policy instruments is essential for stakeholders and large investors seeking to capitalize on this burgeoning industry and take the risk at this stage.

Unlike other aquacultures, such as finfish farming, seaweed cultivation often lacks specific and targeted regulations, operating instead under more generalized and loosely formulated laws. This lack of clear and tailored legislation extends to other parts of the seaweed value chain, significantly impeding the growth of the algae sector in Europe. Manufacturers of ingredients, final products, and primary producers involved in harvesting and cultivation of algae are all impacted by the existing rules, making the industry's growth and development challenging.

The regulatory complexity also manifests in lengthy licensing processes for seaweed farms and obstacles in product development and marketing efforts. Moreover, the awareness of seaweed's potential remains in its infancy, adding additional pressure to the expansion of the value chain. This nascent stage of development in Europe calls for in-depth and widespread knowledge dissemination to raise awareness among public authorities and relevant stakeholders, ultimately bridging the legislative gap and unlocking its immense potential benefits.

Within the SeaMark project, this report at hand aims to shed light on the existing legislative gaps throughout the seaweed value chain in Europe, making a comparative analysis with international regions such as China, the USA, and others. Focusing on the project's three flagship products as case studies: bioactive beta-glucans, pre- and probiotic pig feed supplements, and eco-friendly alginates, the analysis will reveal the regulatory disparities hindering their optimal exploitation and integration into markets. By bringing attention to these vital regulatory aspects, the report seeks to foster a conducive environment for the seaweed industry's growth, enabling it to realize its potential as a sustainable, healthy, and environmentally friendly resource across multiple sectors.

BACKGROUND

The development of algal cultivation is gaining momentum with multiple policy statements at both European and national levels advocating its potential across various applications. Within the European Union, five types of legal acts are adopted, including binding acts like Regulations, Directives, and Decisions, as well as non-binding ones like Recommendations and Opinions. These legal acts play a crucial role in shaping the regulatory landscape for algal cultivation.

At present, there is very limited seaweed production in Europe and other parts of the world outside of Asia and as such it is considered a new and emerging sector in these regions.[8,9] However, initiatives such as Seaweed for Europe[64], the Safe Seaweed Coalition[59] and the upcoming EU4Algae[22] (the latter part of the EU From Farm to Fork strategy)[15] highlight the interest in boosting production (and consumption) of seaweed in the EU with a potential market value of €9.3 billion and production of >8 million tonnes of fresh weight by 2030.[27]

Despite the growing interest, the regulatory framework surrounding seaweed aquaculture in Europe faces challenges and gaps. Several papers and reports have assessed specific aspects of the algae industry and highlighted regulatory complexities, including licensing processes, sustainable farming practices, personnel training, marine space availability, and social acceptability issues.[7,14] Various European countries have yet to establish specific regulations for seaweed aquaculture, leading to regional inconsistencies and hindering industry growth. This introduction provides an

overview of the existing policies and regulations related to algal cultivation, acknowledging the need for coherent and harmonized legal frameworks to foster sustainable and responsible development in this promising industry. Multiple policy statements at the European and national levels advocate the development of algal cultivation across a range of uses.

The mission of the SeaMark project is to produce twelve innovative seaweed-based products and develop new ways of treating macroalgae through fermentation and biotransformation.

SeaMark will deploy a range of mechanical, physicochemical, and enzymatic pre-processing and fractionation techniques combined with chemical, enzymatic, or microbial conversion refinery techniques to generate a diversity of value-added products for multiple industries from food to feed, cosmetics, pharmaceutical, and fine chemicals.

The successful conclusion of the project will help substantiate strategic decisions by policymakers, industrial stakeholders, and potential investors through dedicated webinars, workshops, and reports.

The project expects to achieve impact through the development of 12 marketable products covering market segments in protein feed, human food ingredients, food with health-promoting effects, pharmaceuticals, and biomaterials (**Error! Reference source not found.**). SeaMark will also have an impact on European entrepreneurship and industry through a "Blue Economy Entrepreneurship" webinar for a marine macroalgal biorefinery with competitive business models and a go-to-market strategy that includes life cycle assessments (LCAs), and environmental- and socio-economic impact assessments throughout the value chain.

The SeaMark project will make significant progress in the valorisation of seaweed biomass, with environmental and societal impacts that leave a legacy beyond the project term. SeaMark will ensure that stakeholders understand the scientific, economic, and societal value of SeaMark for the whole of Europe.

OBJECTIVES

The primary objectives of this regulatory assessment are threefold:

1. To identify key regulatory hurdles hindering the market exploitation and upscaling of seaweed products in the EU, with a specific focus on three crucial categories: beta-glucans, pig feed, and green alginate. By conducting a comprehensive analysis, we aim to highlight the specific challenges and opportunities associated with each category.

2. To raise awareness among target groups, including national and transnational policymakers, about the regulatory bottlenecks currently impeding the growth of the European algae industry. By highlighting these obstacles, we aim to promote informed decision-making and facilitate dialogue towards more effective and supportive regulatory frameworks.

3. To propose policy recommendations and engagement strategies aimed at removing barriers to innovation, improving market access, and accelerating the upscaling of the European algae industry. By providing actionable insights, we seek to foster an enabling regulatory environment that stimulates investment, promotes sustainable practices, and positions the EU as a global leader in the macroalgae sector.

METHODOLOGY

Task 10.3 applies a combination of rigorous desk research, encompassing an extensive review of existing literature, reports, scientific studies, and relevant EU legislation and supplemented by stakeholder surveys and industry interviews to gather report data. In addition, comparable regulatory frameworks outside the EU were analysed to provide a comprehensive comparative analysis. By synthesizing and evaluating the gathered information, we aim to identify gaps, challenges, and best practices in the EU regulatory landscape. The findings of this assessment are derived from a holistic examination of the macroalgae market, regulatory

			Products*	Biomass Source			Applications			Innovation action					Assessments											
Product number	Partners involved	Work Packages	*Products are added to three categories based on technical readiness level (TRL) and also the supply chains: (F) = Flagship products, (I) = Innovation products, and (R)=reference products	*Saccharina*, the Faroe Islands	*Saccharina*, France	*Ulva*, Portugal	** Scientific validation of bioactivity / Product documentation / Enzymatic refining of macroalgal polysaccharides to added value products ***A medical device is any article that is used to diagnose, prevent, mitigate, treat, or cure disease or other conditions (e.g. dressings for wound healing)	TRL Start	TRL End	Breeding	Cultivation	Pre-processing	Processing	Scientific validation**	Supply chain	Value chain analysis	Techno-economic assessment	Socio-economic assessment	Eco-system service	Life Cycle Assesment	Market analysis	Regulatory investigation	Go to market strategy	Business Model Canvas
P1		3+6	**Bioactive beta-glucans (F)**	x			Nutraceutical & cosmeceutical	5	7	FO	FO	x	x	x	x	x	x	FO	FO	x	N/C	x	x	x
P2	OCE	3+6	**Bioactive fucoidan (I)**	x			Nutraceutical & cosmeceutical	6	7	FO	FO	x	x	x	x			FO	FO		N/C		x	
P3		3	**Bio-packaging materials (I)**	x			Packaging, etc.	5	7	FO	FO	x	x		x			FO	FO				x	
P4		3	**Fibre & protein food ingredients (R)**	x			Food	6	8	FO	FO	x	x		x			FO	FO					
P5	FEX	4	**Pig feed supplement (F)**	x			Pigs feed	7	9	FO	FO	x		x	x	x	x	FO	FO	x	Pf	x	x	x
P6		4	**Meat replacer product (I)**	x		x	Meat replacer, food	7	9	FO	FO	x		x	x			FO	FO			x	x	
P7		5+6	**Green alginate (F)**		x		Food texture & cosmetic texture	5	8		FR	x	x	x	x	x	x	FR	FR	x	A	x	x	x
P8		5+6	**Designer alginates (I)**		x		Cosmetic texture & medical device***	5	7		FR	x	x	x	x			FR	FR		A		x	
P9	ALG	5	**Fucoidan extraction with enzymes (I)**		x		Feed & cosmetics	5	7		FR	x	x		x			FR	FR		C/A		x	
P10		5	**Mineral concentrates (R)**		x	x	Food & feed	4	7	PT	PT	x	x		x									
P11		5	**Proteins (R)**			x	Food & feed	5	7	PT	PT	x	x		x									
P12		5+6	**Bioactive oligosaccharides (R)**			x	Nutraceuticals & medical device	4	6-7		PT	x	x	x	x						N			
								Total cases:		2	3	12	10	7	12	3	3	2	2	3	4	4	8	3

A=Alginate products C = cosmetic products N=Nutraceuticals Pf = Pig feed
FO=Faroe Islands FR=France PT=Portugal.

Figure 1: 12 Seamark products. Source: SeaMark project Grant Agreement ID: 101060379

frameworks, and the perspectives of key stakeholders. The insights presented in this report are intended to inform evidence-based decision-making and foster constructive dialogue between policymakers, industry stakeholders, and researchers.

OVERVIEW OF THE GLOBAL MACROALGAE MARKET

GLOBAL MARKET TRENDS AND OPPORTUNITIES

The global seaweed industry is estimated to be worth €8.1 billion per year, with a significant portion of aquatic plant production being seaweed.[8] In 2017, global production of aquatic plants reached 32.9 million tonnes, with 96.6% harvested from aquaculture.[13] Asia, led by China and Indonesia, dominates seaweed production, while Spain, France, and Ireland have the highest number of macroalgae companies in Europe.[65]

The Seaweed for Europe roadmap envisions a European seaweed industry worth €0.9-2.7 billion by 2030, driven by increasing demand for sustainable solutions.[27] According to Future Market Insights, the global seaweed market reached a value of US $6.73 billion in 2021, with a 7.0% CAGR from 2018 to 2022.[26] Most European seaweed companies direct their biomass production to food (36%), food-related uses (15%), and feed (10%).[20] The industry is striving to overcome barriers such as technological, regulatory, and market-related challenges to enhance production.

The European seaweed market is valued at €840 million, but supply does not meet demand, leading to significant imports. Europe is considered the most start-up-friendly region for seaweed, with investments in downstream processing and biorefinery. In 2017, nearly 36 million tonnes of algae were produced globally, with the EU accounting for only 0.2%.[9] Despite being a major importer, Europe's demand for seaweed products is set to reach €9 billion by 2030, driven by food, cosmetics, pharmaceuticals, and energy production.[27] Seaweed's versatility and various applications make it a valuable resource for sustainability efforts in the transition to a circular economy, due to fast growth, provision of ecosystem services, and no fresh water or fertiliser inputs.

To enhance competitiveness in global value chains, SeaMark aims to follow the 'high road' strategy, focusing on innovation, increased productivity, and enhanced quality, resulting in price-competitive products for commercial uptake.

THE SEAMARK FLAGSHIP PRODUCTS' MARKET POTENTIAL

BETA GLUCAN

The total nutraceutical ingredients market is expected to grow to $7.5 billion by 2028 with a 7% CAGR.[29] The total cosmetic industry is expected to grow to $51.6 bn with a 5.6% CAGR by 2030.[53] Although Oceanium isn't currently in the market with bioactive beta-glucan, the growth rate of the beta-glucan market is 7,7% CAGR.[26] Key opportunities in this market is to validate health claims and to identify and validate positive health effects that are different from competitors. To read more specifics on the strengths and weakness of Beta-glucan market application for industry partners refer to deliverable 7.1 by NOFIMA.

"GREEN" ALGINATES

Alginates are applied in a variety of industries for various end-use applications. The texturiser market primarily relies on animal-derived gelatins, and there is a lack of sustainable texturisers sourced from marine origins in the current market. Although pectin serves as the main plant-based alternative, its availability is contingent on the supply of fruit by-products.[10] Many existing alternative products on the market are produced using heavy chemical processes which are unsustainable in the long-term. Estimates indicate that the total market demand for regular alginate exceeds 12,000 tons.[65]

In Europe, *Laminaria hyperborea* biomass is primarily targeted for alginate production, supplying approximately 25% of the world's alginate manufacturing.[24,55,61] Exploring opportunities to develop eco-friendly extraction techniques that reduce or eliminate the use of chemicals in their production process would increase the overall sustainability of alginates sourced from macroalgae. Such advances hold the potential to obtain organic certification for seaweed-based products, which in turn would increase consumer confidence and social acceptance. To read more specifics on the strengths and weakness of green alginates market application for industry partners refer to deliverable 7.1 by NOFIMA.

CO-FERMENTED PIG FEED

Seaweed biomass has found diverse applications, including its use in feed for both marine and terrestrial organisms. Recent research findings have underscored the favourable impact of seaweed in mitigating enteric methane emissions from cattle, as elucidated by multiple studies.[35,42,57] Notably, species such as Ascophyllum nodosum find extensive utilization as feed components for both livestock and companion animals[7,33,] while Saccharina latissima has been successfully incorporated into animal feed formulations.[53] Furthermore, kelp meals are a common inclusion in abalone feed, particularly observed in European countries like Ireland.[48]

Nevertheless, it is crucial to acknowledge that the present cost and production scale of seaweed-derived protein for feed applications do not yet rival alternative protein sources such as soy. Although seaweed exhibits promise, it currently lags behind due to its higher production cost and environmental footprint. As production scales increase and refining of processing methods progresses, seaweed biomass is anticipated to secure a more substantial foothold in the feed applications market in the foreseeable future.[18] According to the World Bank report (2023) prebiotic additives market, such as seaweed, was worth $9.7 billion in 2022.[65]

SeaMark, as the sole producer of fermented seaweed feed supplements in the Western world, aims to validate positive health effects, potentially unlocking significant opportunities for FermentationExperts. The ability to use health claims would allow them to differentiate their products from competitors and enhance their market position. Furthermore, expansion into other market segments, such as the fish feed industry, pet food industry, and various types of animal farming, presents promising avenues for growth. By increasing the number of farmers who can test and use their product, SeaMark partners could further boost their sales, especially given the high rate of repurchase observed among their customers.

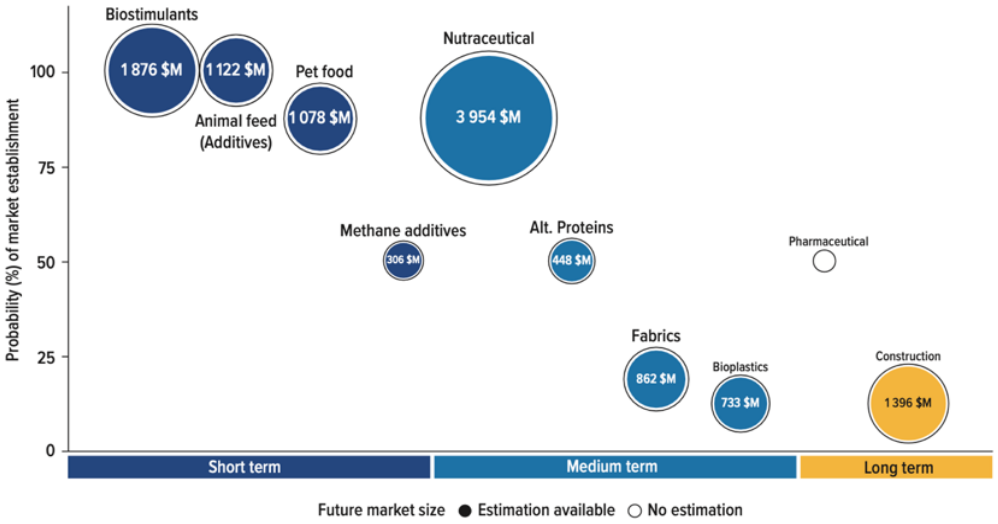

Figure 2: Predicted seaweed market size by 2030 ($ millions) with the chance of market establishment indicated by color on a high-level market horizon timeline. Figure sourced from World Bank report 2023[65]

Considering the existing disparity in production capacities between Europe and Asia, the SeaMark consortium focuses on low-volume, high-value applications (nutraceuticals, food) with higher volumes for lower-value products (e.g. biomaterials, feed). These have been recognized recently in the World Bank report as the most promising short-term markets for seaweed. It's worth noting that while higher-value applications like pharmaceuticals hold potential, they are not actively pursued within the project due to the substantial costs associated with medical trials, which fall outside the project's financial and temporal scope. This strategic positioning sets the stage for a comprehensive examination of EU regulations and their impact on seaweed cultivation across diverse product categories.

EUROPEAN REGULATORY LANDSCAPE

In the following section, the report touches on the main regulations and certifications governing the value chain with specific focus on the three SeaMark flagship products. A full list of all regulations associated with each category is listed in the appendix.

SEAWEED CULTIVATION AND HARVESTING REGULATIONS

While there is no specific EU-wide legislation dedicated solely to macroalgae cultivation, existing regulations related to marine spatial planning, environmental impact assessments, and aquaculture licensing apply to seaweed farming activities. Member states may have multiple (sometimes conflicting) national regulations governing seaweed cultivation and harvesting. These cover the selection of species; rules for genetically modified organism (GMO) use and procedures for organic production. These have been identified and described fully in the Interreg BSR GRASS project report.[30]

The main EU legislations relevant to seaweed aquaculture are listed below.[30] Barbier et al. (2019) summarise the mentioned EU regulations and appoint the main challenges of applying these legislations on seaweed aquaculture as described below.

- Maritime Spatial Planning Directive 2014/89/EU
- Marine Strategy Framework Directive 2008/56/EC
- Water Framework Directive 2000/60/EC
- Alien Species Regulation 1143/2014/EU
    - along with the Regulation on Aliens Species in Aquaculture 2007/708/EC
- Habitats Directive 92/43/EEC
- Regulation on Organic Production 2018/848/EU:
    - Part III lays down the rules to be followed in all stages of production, preparation, and distribution production of organic algae. An environmental assessment that is appropriate to the production unit shall be required for any new operators applying for organic production and producing more than 20 tonnes of aquaculture products per year. The content of the environmental assessment shall be based on Annex IV to Directive 2011/92/EU.

Currently, France is the only European country with an authorised list of seaweed species for aquaculture.[25] Scotland has also issued a Seaweed Cultivation Policy Statement,[31] but without specifying particular species. It is imperative to choose seaweed species or strains that are indigenous or non-invasive to the local waters to prevent ecological disruptions. Some member states have implemented lists to prohibit the cultivation of potentially invasive seaweed species that could harm native ecosystems. However, these lists are outdated and vary across member states.

ALIEN SPECIES

To enhance the governance of non-indigenous seaweed species in the domain of aquaculture, it is advisable to institute both national and regional inventories of economically significant alien species and subsequently assess their ecological risks.[14] The Alien Species Regulation (1143/2014/EU),[30] still has gaps with regard to harmonisation across member States on listed invasive alien species. In the event that any of these species are identified as potentially jeopardizing indigenous ecosystems, their inclusion in a comprehensive EU-level roster of species should be warranted. Prior to granting official authorization for their cultivation, it is imperative that an expert committee undertakes a thorough evaluation of the prospective environmental ramifications associated with non-native species and the introduction of species previously absent from local ecosystems. This evaluation process should be mandatory before companies receive legal or financial support.

GENETIC MODIFICATION, HYBRIDISATION AND SELECTIVE BREEDING

Crossbreeding or hybridisation of seaweed species in the aquaculture industry requires further in-depth research and strict regulation. Currently, there are no specific rules or guidelines governing crossbreeding practices in the EU to safeguard native species and prevent the introduction of GMOs. The Nagoya Protocol (511/2014) regulates species usage, however, this regulation still needs to be fully developed, as clarification is needed with regards to the situation of cultivated genera and the protection of genetic resources.

Cultivating genetically modified seaweed may be subject to stringent regulations in Europe, guided by regulations such as Directive 2001/18/EC and Regulation (EC) No. 1829/2003. These regulations oversee the intentional release of GMOs into the environment and the commercialisation of GMO products. Utilising genetically modified seaweed for cultivation purposes may necessitate comprehensive risk assessments, extensive monitoring, and specific permissions from national authorities or the European Food Safety Authority (EFSA).

The hybridisation and selective breeding of seaweed for cultivation represents a "softer" approach with promising potential to enhance yields and bolster resilience against the challenges posed by climate change. By carefully crossbreeding and selecting seaweed varieties that exhibit desirable traits such as faster growth rates, increased disease resistance, and improved nutrient utilization, researchers can create hybrids that are better suited for evolving environmental conditions. This strategic manipulation of genetic diversity aims to harness the natural adaptive abilities of seaweed, enabling it to thrive in changing oceanic environments. As a result, this approach not only boosts productivity but also contributes to the sustainable management of marine resources, offering a path towards securing our coastal ecosystems in the face of climate uncertainties.

PROCESSING, PRODUCT DEVELOPMENT AND FOOD SAFETY STANDARDS:

The EU has regulations in place to ensure the safety, quality, and traceability of seaweed products during processing and manufacturing stages. These regulations encompass food safety standards under the General Food Law and Novel Food Regulation, hygiene requirements under the Regulation on Food Hygiene, and good manufacturing practices.

The EU Novel Food Regulation is a regulatory framework that governs the authorization and safety assessment of novel foods within the European Union market. Novel foods are those that were not commonly consumed in the EU prior to May 15, 1997. This regulation aims to ensure the safety of new and innovative food products while maintaining consumer protection and transparency.[54]

The EU Novel Food Regulation sets out the procedures and requirements for placing novel foods on the EU market. It mandates that any novel food or food ingredient must undergo a safety assessment before it can be legally marketed. The safety assessment evaluates factors such as composition, nutritional value, potential allergenicity, and any potential risks to consumer health.

The EFSA plays a crucial role in this process by providing scientific opinions on the safety of novel foods. These opinions help inform the decision-making process for authorizing the novel food. If a novel food receives a positive safety assessment and is authorized under the Novel Food Regulation, it can be legally marketed within the EU. The regulation also includes provisions for labelling and traceability of novel foods to ensure consumer awareness and facilitate food safety monitoring.

FOOD AND FEED

In many legal and standardisation processes, food and feed come together and the same documentation applies to both sectors. In fact, 2003 EU along with many international institutions, developed strategies to implement cross-sectoral collaboration to implement the One Health concept that recognises that human health is tightly connected to the health of animals and the environment, for example that animal feed,

human food, animal and human health, and environmental contamination are closely linked.[41]

Given that in the EU, the consumption of algae as food was not significant before 1997,[37] only a few species are considered traditional foods. Most species are considered novel foods and have to be authorised in accordance with the relevant Regulation (Regulation (EU) 2015/2283), regardless of whether they are being used as foods or food additives. This is often considered one of the main regulatory barriers for new producers since only a small number of species is currently authorised.[52] The authorisation process, managed by the EFSA can last several years and the average cost is between 50,000 and 200,000 euros.[39]

HEAVY METALS

Commission Recommendation (EU) 2018/464 encourages EU Member States to monitor the presence of arsenic, cadmium, lead, and mercury in seaweed, halophytes, and products containing seaweed. Recommendation 2018/464 does not indicate specific regulatory thresholds for seaweed that Member States should adopt. The Recommendation observes that maximum allowable limits for lead, cadmium, and mercury have already been established for various foodstuffs, including some seafood, by Commission Regulation (EC) No. 1881/2006 in 2006.

The European Union's regulatory framework currently lacks a clear differentiation between harmless organic arsenic and toxic inorganic arsenic levels in seaweed. This oversight not only poses a substantial challenge for producers of seaweed-based products but also places consumers at potential health risks.

Organic arsenic, which naturally occurs in various marine organisms, is deemed safe for consumption. In contrast, inorganic arsenic is highly toxic, carrying severe health concerns. The EFSA offers guidance on maximum allowable levels of inorganic arsenic in various food items,[17] which indirectly influences the regulation of arsenic in seaweed-based products.

The absence of specific regulations addressing this differentiation creates the inadvertent risk of consumers consuming seaweed products with elevated inorganic arsenic levels, thereby undermining efforts to ensure their safety. Furthermore, this ambiguity poses a significant challenge for producers, making it difficult for them to guarantee that their products meet safety requirements. This situation can lead to compliance issues and potential reputational damage for producers.

As the demand for seaweed-based products continues to rise, establishing a clear regulatory distinction is imperative to safeguard public health, protect consumer interests, and provide producers with the necessary guidelines to ensure product safety and compliance with EU standards.

France was the first European country to establish a specific regulation concerning the use of seaweeds for human consumption as non–traditional food substances. Twenty-one species of macroalgae and three species of microalgae are authorized as vegetables and condiments by French authorities. These authorities have implemented permissible thresholds for heavy metals in authorized species.

Table 1: France's Legal limit for heavy metals in seaweed

France's Legal Limits for Heavy Metals in Seaweed	
Heavy metal	**Maximum level (mg/kg dry weight)**
Inorganic Arsenic (As)	3.0
Cadmium (Cd)	0.5[62]
Mercury (Hg)	0.1
Lead (Pb)	5.0
Tin (Sn)	5.0

FEED ADDITIVES

The approved input substances for animal feed within the European Union, encompassing algae meals, algae oil, and extracts, are specified in Commission Regulation 68/2013. The permissible thresholds for harmful contaminants in animal feed are outlined in Directive 2002/32/EC. In the context of macroalgae-based feed materials, specific maximum limits have been established in the above directive. Additionally, if requested, the feed operator is obligated to demonstrate that the inorganic arsenic content is less than 2 mg/kg. As for lead, cadmium, and mercury, the maximum allowable levels in feed materials in general are 10 mg/kg, 1 mg/kg, and 0.1 mg/kg, respectively, as per Directive 2002/32/EC.[40] EU regulatory requirements for the use of macroalgae in feed have been fully described in the Interreg GRASS project and products.[54]

COSMETICS

Regulation 1223/2009/EC on cosmetic products contains the basic EU rules on cosmetics, the regulations have been described in detail by Lähteenmäki-Uutela at al. (2021). A centralized procedure exists for the notification of all cosmetic products intended for the EU market. Manufacturers and importers are required to submit notifications through the EU portal known as the Cosmetic Products Notification Portal (CPNP). Their legal obligations encompass conducting safety assessments, maintaining comprehensive product information files (PIF), and promptly reporting any significant adverse effects. Within this framework, there are definitive lists categorizing ingredients as acceptable, restricted, or prohibited. For comprehensive details on these regulations, the EU's Cosmetic Ingredient database, CosIng (accessible at https://ec.europa.eu/growth/tools-databases/cosing/index.cfm), serves as a valuable resource. Furthermore, guidelines for defining natural and organic cosmetic ingredients are provided by ISO 16128-1:2016, while ISO 16128-2:2017 outlines quality criteria for both ingredients and finished products in this domain. By adhering to these

protocols, manufacturers and importers ensure compliance with EU cosmetic product regulations while aiming to meet consumer expectations and safety standards. It is worth noting that laws around misleading customers are far less stringent in a B2B scenario and in B2B marketing. Unlike legislation relating to sales and marketing to consumers, it does not prohibit other commercial practices which may mislead by act of omission.

The International Nomenclature of Cosmetic Ingredients (INCI) names are systematic names internationally recognised to identify cosmetic ingredients. They are developed by the INC and published by the PCPC in the *International Cosmetic Ingredient Dictionary and Handbook*, available electronically as *INCI*.[51] There are many benefits to a uniform system of labelling names for cosmetic ingredients. INCI names provide a standardised and systemic name for cosmetic ingredients allowing dermatologists, formulation scientists and cosmetic companies a reliable method to track the ingredients they are using. INCI names are generally required by all companies buying cosmetic ingredients. An INCI name for a cosmetic ingredient does not imply that the substance is safe for use as a cosmetic ingredient, nor does it indicate that its use as a cosmetic ingredient complies with the laws and regulations of any country. INCI names do not imply standards or grades of purity.[40] INCI registration will be required before marketing SeaMark products to the cosmetic market. In a similar vein, it's important to note that ISO standards do not possess the authority of laws. However, when a business chooses to adopt an ISO standard and incorporates it into product labelling, it establishes a binding agreement between the seller and the consumer.

HEALTH CLAIMS

EU regulatory requirements for nutrition and health claims have been fully described in the Interreg GRASS project[54] and by Lähteenmäki-Uutela at al. (2021).[40] All nutrition and health claims made in commercial communications, including among other things generic advertising of food and promotional campaigns, must be supported by an authorisation from the EU. Nutritional claims, such as mineral or dietary fibre contribution may be available to a number of SeaMark products as will iodine health claims relating to thyroid function. Nutrition claims follow Commission Regulation (EC) No 1924/2006. Health claims, linking food and health, are harmonized under EU regulation, listed in Commission Regulation (EU) No 432/2012 and Commission Regulation (EU) No 957/2010.[40] The EU requirements for health claims are demanding, and communicating preliminary evidence to consumers is not possible. In the US, for example, in addition to authorised health claims based on significant scientific agreement, 'qualified' health claims are allowed that are supported by a less demanding level of scientific evidence. Obtaining approval for health claims within the EU is a demanding process that places a substantial burden on business owners in terms of time and resources. To date, two health claims have been applied for macroalgae based on *Lithothamiion* coralloids and seaweed fibres, which were both not authorised by the EFSA due to insufficient substantiation of claims. Hence, a simpler marketing approach for macroalgae health foods and health-boosting dietary supplements involves focusing solely on nutritional claims.

CERTIFICATIONS

The SeaMark products are eligible for specific certification schemes which will help support market acceptance, provide transparency and consumer confidence, and prove quality and safety, while demonstrating a commitment to meeting the expectations of specific consumer groups. This can lead to increased consumer trust and loyalty, potentially driving higher sales and market success. Kosher or halal certifications and compliance to their rules can be of similar economic advantage to macroalgae producers. Several Kosher certification agencies exist. Halal certification is country-related. Other types of certification include the Aquaculture Stewardship Council's (ASC) Seaweed Standard and the UK Soil Association's organic standards for seaweed.

The EU Regulation 1169/2011 requires the European Commission to set out rules for the voluntary labelling of foods as "suitable for vegans" and/or "suitable for vegetarians." Vegan and Vegetarian Certification are available through the European Vegetarian Union (EVU) (https://www.euroveg.eu/ consulted on 13/04/2021). Additionally, Gluten Free Certification, such as by The Gluten-Free Certification Organisation (GFCO) is a program of the Gluten Intolerance Group (GIG). Unlike other certifications which only audit record-keeping, GFCO reviews the manufacturer's products and ingredients, and individually tailors testing requirements based on risk. Lastly, the European Union has an organic certification scheme that covers various agricultural products, including seaweed. The EU Organic Certification ensures that products meet certain standards and regulations for organic production, handling, and labelling.

FLAGSHIP PRODUCTS

BETA-GLUCAN

Beta-glucans from yeast[3] and Paramylon beta-glucan from *Euglena gracilis* have novel food status.[63] Beta-glucan from *S. Latissima* does not hold novel foods approval, therefore an application to the EFSA will be required before these products can be sold in the EU and UK. Several macroalgae species are used as nutraceutical extracts and food supplements. In the General Food Law, food supplements are considered as foodstuff and their maximum levels of toxic contaminants are controlled by the Commission Regulation (EC) No. 1881/2006. Many food supplements are considered novel foods and require an authorisation by the EFSA. Commission Regulation (EU) 2017/2470 contains a list of authorised novel foods including authorised food supplements. As of the present, the inclusion of novel food products derived from macroalgae is limited, with only two instances of acceptance recorded: fucoidan extracts sourced from *Fucus vesiculosus* and *Undaria pinnatifida*. These approvals pertain specifically to their

utilization in food supplements.[68] Therefore, again here beta-glucan would need to be approved for use in food supplements if used in nutraceuticals.

"GREEN" ALGINATE

Across historical contexts, macroalgae have found multifaceted applications as agents for thickening and gelling in the compositional design of additives within a broad spectrum of industries, spanning the domains of food, cosmetics, and nutraceuticals. In the EU, the management of food additives is subject to stringent oversight under Regulation (EC) No. 1333/2008. This comprehensive regulatory framework includes a catalogue of authorized food additives, which notably encompasses those derived from macroalgae, identified by alphanumeric codes ranging from E400 to E407a. The specific origin, composition, and usage of these accepted additives are further detailed in Commission Regulation (EU) No. 231/2012. The Interreg GRASS project provides a comprehensive description of the EU regulatory requirements for food additives.[54] In 2022 the EFSA recommended that the limits for some of the impurities of toxic elements for additives be revised, specifically E406 (agar).[16] Under these regulations, alginates derived from *S. latissima*, particularly E401 to E404. Alginic acid from brown seaweeds (*Phaeophycea*), are accepted as permissible additives. These regulations ensure that the usage of macroalgae-derived additives in food products complies with safety and quality standards set by the EU.

CO-FERMENTED PIG FEED

The authorized feedstock components within the EU, encompassing algal meals, algae-derived oils, and extracts, are delineated in Commission Regulation 68/2013. EU regulatory requirements for the use of macroalgae in feed have been fully described in the Interreg GRASS project and products.[54] The maximum level of arsenic in macroalgae feed materials, 40 mg/kg for macroalgae meal and macroalgae-derived feed materials for livestock.[37,40]

MARKETING AND LABELLING REGULATIONS

Seaweed products marketed within the EU for both feed and food must comply with EU regulations on product labelling and advertising. These have been fully described in the Interreg GRASS project report on the algae product regulatory landscape, and by the Multi-Str3am project report.[30,44,54] These regulations aim to provide consumers with accurate and transparent information about the product's origin, composition, nutritional content and potential allergens such as in the EU Food Information to Consumers Regulation (EU) No. 1169/2011.

Additionally, specific claims related to health benefits, organic certification and sustainability must be supported by scientific evidence and comply with EU regulations on nutrition and health claims. According to Regulation (EC) No. 1924/2006, only claims that are on the list of permitted nutrition claims or authorised health claims may be used. Being limited to these specific health claims is a major obstacle in terms of marketing the product, especially within the EU.

The EU Cosmetics Regulation also includes a set of strict rules for labelling, which must be present on the product container, packaging, or, if not possible given space restrictions, in an enclosed leaflet. This EU Cosmetics Regulation also sets the principles for claims that manufacturers can make on their packaging.

GREENWASHING AND MISLEADING INFORMATION

Greenwashing and net-zero carbon claims have come under scrutiny in recent years, leading the European Commission to propose a new Green Claims Directive on 22nd March 2023.[32] According to the proposed rules, companies will be required to substantiate their environmental claims using life cycle assessments and provide transparent and honest communication with consumers. Phrases like 'net zero', 'carbon neutral', and 'eco-friendly' would be banned in advertisements and packaging labels unless they can be verified with relevant and credible data.

EU ECOLABEL

In the EU, products and services that demonstrate a reduced environmental impact across their entire lifecycle can be labelled with the EU Ecolabel. This label is aimed at consumers, but its use is voluntary, and its adoption appears to have slowed down in recent years.[21]

POLICY INSTRUMENTS AND SUPPORT MEASURES

The EU has implemented policy instruments and support measures to promote the development and growth of the macroalgae industry. These include research and innovation funding programs, such as Horizon Europe, that support projects focused on seaweed cultivation techniques, product development, and process optimisation. Furthermore, regional and national authorities within the EU provide support through grants, subsidies, and capacity-building initiatives aimed at fostering innovation, knowledge transfer, and market development in the macroalgae sector.

While the EU regulatory landscape for macroalgae is evolving, challenges persist in terms of regulatory fragmentation, lack of harmonisation, and the need for clearer guidelines and standards. Streamlining regulations, aligning practices across member states and fostering dialogue between industry stakeholders and policymakers are crucial for removing regulatory barriers, promoting innovation, and accelerating the growth of the European algae industry.

COMPARATIVE PERSPECTIVE

REGULATORY LANDSCAPE IN NON-EU COUNTRIES

To provide a comprehensive assessment of the global regulatory landscape concerning macroalgae, it is crucial to compare the European situation with that of non-EU countries. This comparison covers cultivation, processing, marketing and policy instruments. Several countries outside the EU have developed specific regulations and frameworks to facilitate the growth of their macroalgae industries. Adopting similar regulations and frameworks may be beneficial to the growth of the European macroalgae sector and accelerate upscaling to meet production and climate targets by 2030.

UNITED STATES

In 2020, the United States government published the Federal Activities Report on the Bioeconomy: Algae, which provided a comprehensive overview of the regulatory oversight governing the cultivation, application, utilisation, and production of algal biomass.[46] This report highlights the involvement of four major federal agencies responsible for overseeing the algae industry: the U.S. Environmental Protection Agency (EPA), Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), and the Department of Commerce (DOC) along with the National Oceanic and Atmospheric Administration (NOAA) Fisheries.

SEAWEED CULTIVATION AND HARVESTING

Despite the existence of a well-defined regulatory framework, establishing algae farms remains a complex endeavour, particularly in coastal states. The process involves navigating through permitting requirements from various agencies, leading to cumbersome paperwork. However, to address this issue, in 2020, Sea Grant published a report that inventoried state laws impacting commercial seaweed aquaculture.[45] Similarly, in 2021, NOAA released a report focusing on seaweed aquaculture leasing and permitting requirements on a state-by-state basis, providing valuable insights into the current situation. [47]

Some states, such as Maine, have implemented special limited-purpose permits to support new seaweed and shellfish farmers. These permits allow for a one-year lease on a 400-square-foot site, and around 750 such sites are currently operational. This approach facilitates small-scale experimentation and risk limitation, fostering growth in the state's aquaculture industry. The hope is that more states will adopt similar small-scale permit systems to encourage the entry of aspiring farmers. Thanks to these reports and efforts, the U.S. seaweed farming industry has experienced significant growth in recent years, with numerous farms operational in waters across New England, the Pacific Northwest, and Alaska.

PROCESSING, PRODUCT DEVELOPMENT AND FOOD SAFETY

In general, depending on how a food product is handled, processed, and distributed, different regulatory agencies may require permits, registration, or authorization to operate.

FOOD AND FEED

Besides licensing, an additional challenge lies in the current regulatory status of seaweed by the FDA, which does not classify it as a food, seafood, nor vegetable. Instead, seaweed is categorised as a spice due to its historical consumption as a dried product in small quantities. With respect to the sale of seaweed in its whole form as a food product, there are no federal regulations or guidance. All facilities that manufacture, process, package, and/or store processed food and beverages in the US must register with the FDA. The FDA current regulations are helpful to seaweed aquaculture operations seeking to sell their product for use as a food additive, but they do not apply to the sale of seaweed in its whole form. States have the authority to fill this regulatory gap. However, states often rely on federal frameworks when developing their own laws and regulations related to food safety. These frameworks are either treating seaweed as a General Food Product under the 21 CFR part 117,[13] as a seafood under the Seafood Hazard Analysis Critical Control Point (HACCP) or as a plant under the Product Safety Rule.[34] Without federal guidance, states are independently developing regulatory programs to address the needs of the emerging industry in their states. Rooted in this uncertainty is the decision agencies must make regarding whether to regulate seaweed as a seafood (like fish or shellfish) or as a plant. This decision has regulatory implications, as it may affect which governmental entity regulates the seaweed product. A full description of these frameworks and implications has been described by Janasie (2023).[34]

In the United States, products derived from seaweed are typically regarded as GRAS (generally recognised as safe), meaning they do not require pre-market authorisation. However, the FDA retains the authority to take regulatory action if it deems a product to be unsafe. As outlined in sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act),[23] any substance intentionally added to food is considered a food additive and is subject to pre-market review and approval by the FDA, unless it is generally recognised, among qualified experts, as being safe for its intended use or is exempt from the definition of a food additive.[69] GRAS status is essential for all food ingredient products and nutraceuticals before they can be sold in the US. The GRAS classification means that SeaMark products such as beta-glucan can be sold in the US, but not yet in Europe.

FEED ADDITIVES

In the United States, the FDA is responsible for regulating animal feed and pet food. To be approved for use as a feed additive, products must be shown to be safe not only for farm

animals to consume but also for humans to eat animals that consumed the feed.

HEAVY METALS

At the federal level, all food for human consumption is subject to the Federal Food, Drug, and Cosmetic Act (FDCA).[69] The U.S. Food & Drug Administration (FDA) administers the FDCA and sets levels for the maximum amount of contaminants (arsenic, cadmium, lead, and mercury) in food (general) and bottled water.[38] The FDA currently regulates iodine levels in kelp only when that kelp is used in food additives.[2] The rule only applies to dehydrated, ground products prepared from *Macrocystis pyrifera, Laminaria digitata, Laminaria saccharina*, and *Laminaria cloustoni,* and the agency has prescribed its legal thresholds in this context by reference to the age and physiological state of consumers targeted by the product's labelling.

COSMETICS

The Federal Food, Drug and Cosmetics Act contains the basic U.S. rules on cosmetics. Furthermore, it lays down the criteria for the justification of claims used in cosmetics marketing stating that it is not possible to claim any therapeutic actions. In addition, the Modernization of Cosmetics Regulation Act of 2022 (MoCRA)[1] is a significant piece of legislation aimed at updating and enhancing the regulation of cosmetics in the U.S. This act addresses the need for a more robust and science-based regulatory framework to ensure the safety and efficacy of cosmetic products. Among other provisions, MoCRA added section 607 to the Federal Food, Drug, and Cosmetic Act (FFDC Act), establishing requirements for cosmetic product facility registration and product listing. Section 607(a) of the FFDC Act requires every person who owns or operates a facility that "engages in the manufacturing or processing of a cosmetic product for distribution in the United States" to register each facility with FDA. Section 607(c) of the FFDC Act requires that for each cosmetic product, the responsible person must submit to FDA "a cosmetic product listing."[56] Existing products and facilities will have to be registered by December 29, 2023. After this date, new facilities must be registered within 60 days after first engaging in activity and new cosmetics products must be registered within 120 days after marketing in the US. Biennial updates are required for facility registration and annual updates for product listing. Meaning for the beta-glucan produced in SeaMark a registration will be necessary.

MARKETING AND LABELING

Packaged food must be labelled in accordance with the Federal Food, Drug and Cosmetics Act, the Federal Fair Packaging and Labelling Act, and the Uniform Packaging and Labelling Regulation.

For any cosmeceutical products specific labelling has been updated by the MoCRA regulation.

Most recently in 2023, the first patent has been approved for seaweed-blended bread flour in the US. Sea & Flour, which integrates seaweed into the commercial baking process - thereby increasing protein content and lowering sodium compared to standard breads – was awarded the patent which will help to bring seaweed into mainstream consumption in everyday products, further justifying the upscaling of production.

POLICY INSTRUMENTS AND SUPPORT MEASURES

In the USA, certain states like Maine and California have introduced specific incentives to promote the algae industry. For example, the California Energy Commission offers grants and tax incentives to algae-based biofuel companies to encourage the development and commercialisation of renewable energy from algae. Additionally, ARPA-E has $25 million in funding for the MARINER program, which focuses on expanding the use of macroalgae as a renewable feedstock for biofuel and energy production. The program aims to enhance macroalgae yield and expand into offshore environments, potentially producing up to 2% of U.S. primary energy consumption by 2050.

Despite seaweed being recognised as generally safe, numerous regulatory barriers continue to impede the growth of the seaweed industry in the US. Nonetheless, there is a strong drive to address these challenges, evident in the recent reports published by NOAA and Connecticut Sea Grant. Additionally, initiatives such as those by GreenWave, which focuses on developing practicality in seaweed farming and best practices for regulating seaweed as human food, as supported by Connecticut Sea Grant, are striving to overcome these obstacles.

ASIA

From the 1950s to the mid-2010s, the Chinese national and provincial governments have consistently promoted the development of the seaweed industry through various means, such as policies, financial support, funding initiatives, designated onshore and offshore farming areas and access to freshwater resources. Asian countries, in general, have demonstrated a greater level of government support through subsidies and regulations for the advancement of their seaweed sectors.

SEAWEED CULTIVATION AND HARVESTING

One key factor contributing to industrial development in Asia is the acknowledgement and implementation of hybridisation and crossbreeding practices. For example, in China, the crossbreeding of *Saccharina japonica* has been extensively utilised in cultivation due to its relative immunity to inbreeding depression, which arises from a reduction in genetic variability.

The rapid growth of the kelp aquaculture industry has been facilitated by advancements in seedling-rearing and "autumn sporeling-rearing" technologies in Asia. Korea's involvement in the International Union for the Protection of New Varieties of Plants (UPOV) began in 2002, and in 2012, the plant variety

protection system was extended to include seaweeds, providing legal recognition and intellectual property rights for new plant varieties in 74 countries. Subsequently, the Korean government initiated the certification of seaweed varieties in 2012.

The production of novel kelp varieties has been made possible through the development of innovative culture techniques, significantly reducing time, cost, and labour intensity compared to conventional breeding methods. As a result, this kelp species has become the primary commercial seaweed crop in China, covering over 40,000 hectares and boasting an annual production of approximately one million tons in dry weight.

In China, the Aquaculture Disaster Insurance (ADI) scheme was introduced in 2007 to safeguard sea farmers from natural disasters, reducing investment risks associated with seaweed farming. The implementation of ADI has encouraged seaweed farmers to promptly report disease outbreaks and remove damaged infrastructure. Consequently, the government has gained a more accurate understanding of the economic damage caused by such outbreaks, leading to increased funding for research and development in disease identification and management. This has accelerated the development of eco-friendly treatment methods for algal diseases as seaweed farmers receive more information and tailored solutions.

PROCESSING, PRODUCT DEVELOPMENT AND FOOD SAFETY

In both China and Japan, regulations pertaining to seaweed processing exhibit a lesser degree of stringency when compared to the EU or the U.S.

In Japan, the Ministry of Health, Labour, and Welfare (MHLW) oversees foods for special health uses (FOSHU), which includes products derived from seaweed. Seaweed-based products meeting FOSHU standards are permitted to claim specific health benefits on their packaging and advertising. In addition, the Japan Fisheries Agency (JFA) regulates seaweed cultivation, providing guidelines for sustainable practices encompassing cultivation, harvesting, and environmental protection.

HEAVY METALS

Japan's Ministry of Health, Labour, and Welfare oversees the standards for heavy metals in food and food additives.[60] The only food the NSGLC found in its review with a heavy metal standard is rice: the legal limit for cadmium in rice is 0.4 ppm.

COSMETICS

In Japan, cosmetic products are regulated under the Pharmaceutical and Medical Devices Law (PMDL) by the Ministry of Health, Labour, and Welfare serving as the relevant authority. In China, three major authorities oversee regulations related to cosmetic products: the State Administration for Market Regulation (SAMR), the National Medical Products Administration (NMPA), and the General Administration of Customs (GAC).

POLICY INSTRUMENTS AND SUPPORT MEASURES

Asian countries like China and Indonesia have implemented market development programs to stimulate the growth of the algae industry. For instance, the Chinese government has initiated marketing campaigns to raise awareness about the nutritional and environmental benefits of algae-based products, encouraging greater consumer acceptance and market penetration. Similarly, Indonesia has implemented programs to promote the export of algae-derived products to international markets, thereby expanding the global reach of their algae industry. The Japanese government's Ministry of Education, Culture, Sports, Science and Technology (MEXT) has provided substantial funding to universities and research institutions for conducting studies on algae cultivation techniques, genetic improvement, and novel product development. Similarly, South Korea's Ministry of Oceans and Fisheries (MOF) has established research grants to support research projects focused on sustainable seaweed cultivation and biotechnology.

The aquaculture industry in Asia has experienced substantial growth, largely attributed to strong government involvement and support. However, it is noteworthy that regulations concerning seaweed processing in this region exhibit a lower level of stringency compared to the European Union or the United States. As a consequence, a larger number of farmers have been able to enter the industry, resulting in increased seaweed biomass production. Nevertheless, this comparatively relaxed regulatory environment may have implications for the long-term economic potential of Asian seaweeds, particularly when targeting European or American markets. The global demand for sustainable and organic products is on the rise among consumers in these regions. Consequently, the less stringent regulatory practices in Asia may pose challenges when attempting to meet the high standards and preferences of these discerning markets in the future. To maintain competitiveness and capitalise on growing demand, it would be prudent for Asian seaweed producers to consider aligning their practices with sustainable and organic requirements embraced by European and American consumers.

IDENTIFICATION OF KEY DIFFERENCES AND COMPETITIVE ADVANTAGE

Key action points should be considered at policy level:

1. Develop custom licensing procedures to facilitate new entrants to the industry
2. Develop subsidies under the Common Agricultural Policy (CAP) or similar program to support new farmers
3. Push through EFSA approval of more algae species, including food and feed additives
4. Develop standardised frameworks to monitor and quantify environmental impacts and justify subsidies
5. Develop support measures and industry catalysts in the form of advertising/awareness campaigns, diverse educational programmes and decentralised infrastructure
6. Facilitate capacity-building activities in and between national governmental bodies to co-develop common processes and transfer basic knowledge between institutions, ensuring cross-institutional compatibility and monitoring

Through the comparative perspective, several key differences in regulatory frameworks between the EU and non-EU countries can be identified. These differences may confer a competitive advantage to certain regions or provide insights into best practices for the European algae industry. Some key aspects to consider include:

- **Licensing and permits:** The U.S. is similar to the EU when it comes to licensing procedures and regulations for seaweed cultivation and harvesting, which are also fragmented and regulated by various agencies. However, a big difference in the licensing and regulation for farming in the U.S. is the very active engagement from a select few agencies pushing change and establishing clear roadmaps even though fragmentation exists, thereby making it easier for farmers to enter the industry. Due to less stringent licensing regulations and high governmental support in the form of subsidies, the Asian market currently is still the dominant player in the algae industry.

- **Novel food regulations:** The EU Novel Food Regulation imposes stringent requirements for introducing new seaweed-based ingredients and novel food products, potentially creating barriers to innovation and market access compared to non-EU countries with less stringent regulations. The question is then whether the origin and quality standards of the imported product can be guaranteed, especially in changing environmental conditions. Stricter regulations and quality demands from the market value chain could reduce the likelihood of importing much seaweed from low-cost countries, as European businesses must be sure of the quality of the raw material. The expectation in Europe is that more regulation on safety and environment will be implemented, which will require more robust and/or standardised sampling and testing procedures to guarantee safety and quality.

- **Cosmetic regulation:** The centralized and evidence-based procedural approach, coupled with unhindered product mobility among EU member states, establishes a definitive regulatory framework conducive to cosmetics enterprises. The EU's regulatory competence in the cosmetics domain is meticulously delineated, earning Europe the appellation of an "unchallenged regulatory authority." Other nations frequently emulate the EU's inventory and regulations in this sphere.[6,66]

- **Environmental regulations:** Non-EU countries may have well-defined environmental impact assessment procedures and guidelines for sustainable seaweed cultivation, offering a competitive advantage in terms of traceability, environmental stewardship and eco-certifications. These in turn benefit companies' Environmental, Social and Governance (ESG) and Corporate Social Responsibility (CSR) obligations.

- **Support measures:** In Asia, countries like Japan and South Korea have allocated significant research funding to support algae-related research and development. These incentives help to create a conducive environment for algae entrepreneurs and foster industry growth. These tailored support measures provide Asia and the USA with a competitive advantage in the algae industry, fostering innovation, economic growth, and market expansion. The EU, while also offering support, may need to consider similar targeted initiatives to remain competitive in the global algae market and stimulate sufficient social awareness and acceptance to drive demand, since macroalgae is not as well established in Europe as a traditional food as in Asia.

Understanding these key differences and competitive advantages can inform policy discussions within the EU and help to identify areas for regulatory improvement, harmonisation, and collaboration. It can also facilitate knowledge exchange between the EU and non-EU countries to foster innovation, create market opportunities, and enhance the competitiveness of the European algae industry on a global scale.

KEY REGULATORY HURDLES

The key hurdles in EU today concern seaweed cultivation and market entry. In numerous countries, the lack of coordinated planning among agencies and authorities leads to decisions being made based on individual departmental responsibilities. This complexity is exacerbated in certain countries (e.g., Italy, Israel, Cyprus) where the involved agencies are not specifically dedicated to aquaculture but have broader mandates, such as food production, resulting in a wider range of competencies and experiences but lacking adequate expertise in aquaculture.[4]

Within the European Union, concerns regarding licensing, regulation, and the protracted duration required to obtain permissions have been recognised since at least 2009.[36] A major contributing factor is the involvement of multiple agencies, causing ambiguity over their respective responsibilities. Legislative frameworks related to aquaculture are often fragmented and dispersed, making information challenging to locate, available in various formats and frequently accessible only in the national language of the respective country. Consequently, aquaculture producers face significant difficulties in comprehending and navigating complicated and unclear regulations, leading to increased time and financial resources spent on identifying applicable rules and ensuring compliance.[19]

A survey conducted by Gjertsen et al. (2020) among coastal planners in Norway revealed that 85% of municipalities expressed unsatisfactory knowledge regarding algae farming. Although authorities may not necessitate a high level of expertise in specific species and production systems, they do require a basic understanding of relevant subject areas to make informed decisions regarding aquaculture development. Consequently, the lack of planning competence, as discussed by Gjertsen et al., represents a significant barrier to the emergence and growth of the aquaculture industry.

The European seaweed aquaculture industry has the potential to achieve significant growth if farms become more accessible and supported with subsidies, as observed in Asian countries. The ease of establishing farms and the availability of financial support significantly contribute to the industry's growth and competitive position in the market. Currently, the lack of high biomass volumes is the main hurdle to producing European seaweed products at an industrial scale. In the same way that agriculture and energy subsidies were a mechanism devised in the post-war period to guarantee energy and food security, the mix of European subsidies should be reviewed and redistributed to divest from harmful industries such as oil, gas or beef, and transferred to climate-positive industries such as renewable energy and low-trophic aquaculture, which are comparatively cheaper and contribute more not only to energy- and food security, but crucially to job-, nutrition- and climate security.

Finally, market entry barriers – especially related to the Novel Food regulation – must be urgently addressed and alleviated at the European level to allow the industry to gain rapid traction by 2030. This goes hand-in-hand with environmental monitoring and safety testing, as well as rolling out measures to reduce unwanted contaminants. These aspects can be streamlined by applying stricter regulations on upstream causes of contamination, such as agricultural run-off, oil spillages and removal of munitions from potential cultivation sites.

BETA-GLUCANS: REGULATORY CHALLENGES AND MARKET OPPORTUNITIES

Beta-glucans, bioactive compounds found in macroalgae, hold substantial market potential in pharmaceuticals, nutraceuticals, and functional foods industries. However, exploiting this potential faces several regulatory challenges. While beta-glucans from oats, yeast, mushrooms, and *Euglena* have obtained EFSA novel foods approval and US GRAS status, seaweed-derived beta-glucans lack such approvals. Consequently, comprehensive regulatory dossiers must be prepared for both U.S. GRAS and EFSA to facilitate market entry.

The EFSA novel foods approval process is both cost-intensive (approximately €2-3 million) and time-consuming (usually spanning 2 years), necessitating careful consideration in commercialisation plans. The unique properties of laminarin beta-glucan from kelp offer new market opportunities, yet they require validation through health claim substantiation trials. Partner in SeaMark Oceanium (OCE)'s participation in a clinical trial testing beta-glucan for cognitive decline management presents the potential to unlock a large market for seaweed-derived beta-glucan, demanding the completion of an information file with a product safety evaluation.

Regulatory considerations also extend to specific markets, such as cosmetic use of beta-glucan. Compliance with the EU Regulation on cosmetic products (EC No. 1223/2009), EU REACH (Registration, Evaluation and Authorisation of Chemicals) (EC No. 1907/2006), Commission Regulation on claims in cosmetic products (EU No. 655/2013), and relevant local or national laws is essential for cosmeceutical applications. Notably, in B2B scenarios, laws concerning misleading customers are less stringent, allowing for commercial practices that may mislead through omission.

Moreover, pursuing international standards like ISO 16128 for natural and organic ingredients and products adds further complexity to regulatory considerations. In conclusion, addressing these regulatory challenges is critical for the successful commercialisation of beta-glucans from seaweed and unlocking their market potential across multiple industry sectors.

Key challenges for the market exploitation of beta-glucans from *S. latissima* include:

1. **Novel Food Status:** Beta-glucans derived from *S. latissima* are not currently considered novel food, necessitating a rigorous authorisation process. The complexity and time-consuming nature of this process can hinder innovation and impede market entry for beta-glucan products.

2. **Health Claim Substantiation**: Making specific health claims related to the benefits of beta-glucans requires strict compliance with EU regulations on nutrition and health claims. Companies seeking to market beta-glucan products must provide scientific substantiation and adhere to specific criteria, presenting challenges in obtaining approval for health claims. Clinical trials often cost upwards of one million Euros and can take longer than the average European project duration. The process can therefore only be undertaken by large companies or government institutions.

CO-FERMENTED PIG FEED: REGULATORY CHALLENGES AND MARKET OPPORTUNITIES

A specific issue addressed by this product is the use of fermented pig feed to improve animal health without resorting to antibiotics or zinc. The recent EU regulations (2019/6 and 2019/4) prohibit the routine use of antibiotics in farmed animals, allowing for metaphylaxis use only in high-risk situations where no alternative treatments are available. Consequently, achieving good animal health across the EU requires avoiding routine antibiotic use and adopting alternative approaches such as pre- and probiotic functional feeds, which can be achieved through innovative techniques such as fermentation.

However, despite the potential benefits, there are limitations in selling such products within the EU due to restrictions on making health claims. The regulatory landscape surrounding seaweed-based ingredients in pig feed poses challenges for market exploitation. The cost and complexities of registering and obtaining regulatory approval for a new feed additive can be considerable, making it particularly challenging for small or medium-sized enterprises to navigate these expenses. These regulatory requirements represent significant hurdles for the successful market penetration of seaweed-based pig feed.

Key challenges for the market exploitation of *S. latissima* seaweed-based pig feed include:

1. **EU Authorisation Processes:** Seaweed-based ingredients used in pig feed may necessitate authorisation under the EU feed legislation, involving safety assessments and compliance with labelling and compositional requirements. The authorisation process can be intricate and time-consuming, posing obstacles to the successful market entry of innovative, climate-positive feed ingredients.

2. **Transnational Regulatory Harmonisation:** The lack of harmonisation in feed regulations across EU member states can create barriers to market entry. Feed ingredients authorised in one country may not be automatically accepted in others, leading to a fragmented market. Streamlining and harmonising regulatory requirements would facilitate wider market access and create new opportunities for feed ingredient manufacturers, promoting innovation and fair competition with more established products and ingredients.

"GREEN" ALGINATE: REGULATORY CHALLENGES AND MARKET OPPORTUNITIES

Green alginate, a polysaccharide derived from macroalgae, presents promising potential in diverse industries, including pharmaceuticals, cosmetics, and food. In Europe, alginate is classified as a food additive and is assigned an E number. Despite being added at very low dosages, hydrocolloids such as alginate are sometimes perceived as "artificial" due to their intentional extraction from seaweed biomass, leading consumers to view them as unnatural. In terms of regulatory barriers, no major obstacles exist since alginate, when used in food or cosmetics, is considered a food additive (labelled as E401 to E404) and as alginate from brown seaweed in the cosmetic industry in China. Notably, alginates have been approved by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) as the safest food additives, primarily due to their unique properties in food applications. As such, alginate holds considerable promise for various industrial applications, with its safety profile well-established by regulatory authorities.

The "green" alginate developed in the SeaMark project offers the competitive advantage of applying a less harsh chemical process of extraction. This will in turn benefit buyers of the biomass who are looking to optimise the sustainability and traceability of their products. This will be backed up by life cycle assessments of the flagship SeaMark products under Work Package 9 (Ecosystem Services & Life Cycle Assessment).

Key challenges for the market exploitation of green alginate from *S. latissima* include:

1. **Consumer Perception:** Addressing the perception of alginate as "artificial" due to its extraction from seaweed, which impacts consumer acceptance.

2. **Regulatory Consistency:** Ensuring alignment with regulatory classifications and standards for alginate across different regions and industries.

AWARENESS AND COMMUNICATION

IDENTIFYING TARGET GROUPS AND STAKEHOLDERS

Seaweed products are increasingly gaining popularity in Northern Europe, not just in Far East gastronomy, but also in the retail market. They are available as salads (both loose and packed with various flavours), dried products including snacks, and innovative multi-ingredient and clean-label products. Additionally, dietary supplements based on seaweed are widely accessible and increasingly popular.

Consumer research conducted during the GRASS project reveals that 26% of consumers in the Baltic Sea Region have already consumed seaweed, primarily as an ingredient in sushi. However, only a quarter of consumers (23%) have tried seaweed in other forms, such as salads, soups and snacks. A significant portion (34%) of consumers express interest in trying seaweed food products.[70]

Furthermore, more than 30% of consumers in the region recognise seaweed as having exceptional health properties. Considering the consumer's growing interest in locally-sourced products, the market potential for seaweed food products in the Baltic Sea Region is considerable.[70]

To address regulatory bottlenecks effectively, it is essential to identify key target groups and stakeholders who can influence regulatory decision-making and support policy changes. These groups may include:

- National policymakers
- Transnational policymakers
- Industry associations
- Research institutions and academia
- Consumer organisations

RAISING AWARENESS OF REGULATORY BOTTLENECKS

To enhance policy and foster innovation within the European algae industry, it is imperative to raise awareness about specific regulatory barriers and their impacts on the industry. This can be achieved through active engagement with target groups via workshops, conferences and consultations, providing a platform for discussion and dissemination of information concerning regulatory challenges. Facilitating dialogue and knowledge exchange among policymakers, industry representatives and research institutions can foster a better understanding of these hurdles.

Furthermore, it is essential to develop targeted awareness campaigns aimed at educating stakeholders, including policymakers, industry professionals and consumers regarding the regulatory complexities faced by the macroalgae industry. Utilising diverse communication channels, such as websites, social media, and industry publications, can help extend the reach of these campaigns to a broader audience. It is also beneficial to showcase successful examples of other countries or regions that have implemented supportive regulatory frameworks for the macroalgae industry, sharing compelling case studies and success stories to demonstrate the potential socioeconomic benefits of alleviating regulatory bottlenecks.

As seen in the EU4Algae initiative, such awareness-raising efforts have been well-received by members who express a desire for more regulatory endorsement. Recognising that regulations and licensing frameworks are rooted in available scientific evidence, it is essential to regularly review state-of-the-art information and identify knowledge gaps requiring attention to support the sustainable development of the aquaculture sector.[43,50] The dynamic nature of aquaculture and its high level of innovation present challenges in comprehensive, robust regulation, but it can also be facilitated by regulatory innovation, such as the introduction of specific regulation for low-trophic, zero-input aquaculture.[49] By proactively addressing regulatory obstacles and keeping abreast of advancements in the field, the European algae industry can create a conducive environment for growth and progress.

POLICY RECOMMENDATIONS AND ENGAGEMENT STRATEGIES

Policy recommendations to support the growth of seaweed production in a scientifically grounded manner:

1. **Monetise Ecosystem Services:** Seaweed farms' ecosystem services, such as carbon and nitrogen uptake, can be quantified and traded as credits with companies or municipalities seeking to offset CO_2 or nutrient emissions. The example of oyster nitrogen credits in the Chesapeake Bay shows the potential for recognizing macroalgae cultivation and wild harvesting as compensation measures, fostering innovation in multi-trophic biocircular systems. Additionally, incorporating seaweed additives in animal feed, such as fermented seaweed for pigs, can reduce methane emissions and decrease the need for antibiotics, opening possibilities for income through tradeable offsets.

2. **Introduce Tax Schemes and Trade Agreements:** Tax schemes that prioritise environmental criteria can incentivise sustainable products. The EU can influence VAT rate categories, while tax rates are determined at the Member State level. Trade agreements with other countries or trade blocks could adopt criteria favouring sustainable products while limiting imports of unsustainable or lower quality ones. Divesting subsidies from carbon-.intensive raw material production can further enhance the competitiveness of more sustainable alternatives.

3. **Harmonise Inter-departmental and Transnational Regulations:** Encouraging harmonisation of regulations across EU member states ensures a level playing field for the algae industry. Policymakers at both national and EU levels should engage in policy dialogues, exchange knowledge, and develop evidence-based recommendations for regulatory reforms. Collaborative efforts among industry stakeholders, research institutions, and policymakers will foster the sharing of best practices and joint development of recommendations for regulatory improvements.

4. **Encourage Pilot Projects and Demonstration Sites:** Establishing pilot projects and demonstration sites that demonstrate the economic, environmental, and social benefits of macroalgae cultivation, processing, and product development will garner public and large industry support. Such initiatives can influence policymakers and raise awareness among consumers and producers of the advantages of algae-based products.

REMOVING POLICY BARRIERS

ADDRESSING REGULATORY CHALLENGES AND GAPS

SEAWEED CULTIVATION

To overcome policy barriers and facilitate the market expansion and upscaling of seaweed products, addressing the identified regulatory challenges is of paramount importance. While stringent licensing standards are necessary to ensure sustainability, quality and safety, the current licensing process remains a significant barrier to entry. The application process is lengthy, often exceeding several years, with unclear pathways and involvement of multiple stakeholders. To aid seaweed farmers in navigating this process, support and funding could be provided, building on existing resources such as the Seaweed for Europe/EU4Algae Licensing Toolkit. Boosting capacities of local and national authorities may expedite the process. Implementing a one-stop-shop for license applications at the national level could streamline the process, offering efficient and transparent licensing procedures while considering species-specific impacts.

Key Points – Seaweed cultivation

1. Licensing standards necessary for sustainability, quality, and safety.
2. Lengthy, unclear, and involves multiple stakeholders.
3. Support and funding for seaweed farmers needed.
4. Capacity building for authorities may speed up the process.
5. Consider implementing a one-stop-shop for licenses at the national level.

PROCESSING, PRODUCT DEVELOPMENT & HEALTH CLAIM SUBSTANTIATION

The current EFSA novel foods approval process is not only time-consuming but also imposes a substantial financial burden, averaging around €2-3 million, with an approximate two-year duration for completion. To streamline this process and expedite the introduction of innovative food products to the market, it is imperative to initiate a thorough review of the novel foods approval system. Enhancing the capacity of EFSA to efficiently conduct the necessary tests and approvals is a crucial step, which could involve allocating dedicated resources such as a specialized task force. Furthermore, there is a growing need to include the most common seaweed species in the list of approved additives, particularly in functional food and feed sectors, including the rapidly expanding vegan and alternative protein markets. To gain substantial support, it is essential to foster collaboration among large companies, allowing for shared cost management through collaborative cost management (CCM) approaches and cooperative structures such as Producer Organisations. Additionally, exploring public-private partnerships to pool resources could prove beneficial in navigating the complexities of the novel foods approval process, ultimately fostering innovation and market growth.

Key Points – Processing, product development & health claim

1. EFSA's novel foods approval process is time-consuming and costly.
2. A review of the approval system is crucial to expedite innovation.
3. Inclusion of common seaweed species in approved additives needed.
4. Collaboration with large companies for cost management.

RISK ASSESSMENT, QUALITY CONTROL & STANDARDISATION

Investing in research and development (R&D) plays a pivotal role in advancing risk assessment methodologies tailored to the unique characteristics of macroalgae products. This strategic investment is not only vital for the industry's growth but also imperative for safeguarding consumers by ensuring accurate safety evaluations. The need for such R&D efforts was underscored during the EU4Algae WG4 meeting held in April 2023, where it was evident that risk assessments in the feed industry were facing a considerable gap. This gap, particularly concerning the introduction of new species and usages in the market, calls for urgent attention. To bridge this gap and set high safety and sustainability standards, it is proposed that the EU establish comprehensive measures. These measures include the development of EU-level standards through a straightforward yet robust EU certification scheme, exemplified by the "safe-and-sustainable-by-design" (SSbD) framework created by the European Commission for evaluating the safety and sustainability of chemicals and materials. Furthermore, a broader EU-wide LCA framework for all seaweeds, or individual seaweed species, is recommended to comprehensively evaluate their environmental impact. In addition, to ensure inclusivity and transparency, involving non-governmental organizations (NGOs) and consumer associations in the formulation of these standards and frameworks is essential. This collaborative approach will not only enhance the credibility of assessments but also foster trust among consumers and stakeholders alike, paving the way for a safer and more innovative macroalgae industry.

Key Points- Risk Assessment, quality control & standardisation

1. R&D crucial for tailored risk assessment of macroalgae products.
2. Proposal for EU-level standards through SSbD framework.
3. Recommendation for EU-wide LCA framework.
4. Involvement of NGOs and consumer associations for transparency.

GUIDANCE AND COMMUNICATION

To foster the responsible growth of the macroalgae industry, it is imperative to establish clearer regulatory guidance that extends beyond cosmetics. Tailored regulations specific to different sectors, including food, feed, and cosmetics, should be developed to account for the unique characteristics of macroalgae and their derivatives. A key challenge lies in the lack of clarity regarding market access regulations for various algae species, highlighting the pressing need for regulatory coherence in this domain. Addressing this issue can be facilitated through dedicated tools provided by responsible authorities, such as EFSA, which can guide companies through the regulatory processes. Moreover, increasing the capacity of EFSA or establishing a dedicated task force focused on macroalgae-related regulations would expedite this effort. Public information campaigns can play a pivotal role in dispelling industry myths and misinformation, while training courses for member states would help build the capacities of local and national authorities to formulate seaweed-specific or low-trophic aquaculture regulations in alignment with EU guidelines. Lastly, the involvement of NGOs and consumer associations in this regulatory development process will contribute to a more inclusive and transparent framework that ensures both industry growth and consumer safety.

Key Points – Guidance and communication

- Clearer and tailored regulatory guidance needed for responsible macroalgae industry growth.
- Lack of clarity in market access rules for algae species.
- Use dedicated tools like EFSA to guide companies.
- Consider increasing EFSA capacity or creating a task force.
- Training for member states on seaweed-specific regulations.
- Involve NGOs and consumer associations for transparency and safety.

PROMOTING INNOVATION AND MARKET ACCESS

FUNDING & BUSINESS DEVELOPMENT

Continued funding for research and development across various aspects of seaweed cultivation, processing, and product innovation is essential to drive advancements and improve market accessibility for seaweed products, especially in removing regulatory barriers. However, to achieve this, greater emphasis must be placed on directing governmental funding towards farms in the form of subsidies and grants, as these incentives play a critical role in promoting growth and development in the industry. Furthermore, supporting value-added applications of seaweed products through financial aid, technical assistance and market insights will encourage product diversification, expanding the array of seaweed-derived offerings and bolstering the industry's competitiveness.

To facilitate the progress of small and medium-sized enterprises (SMEs) within the sector, tailored support programs should be developed. These initiatives should focus on assisting SMEs in navigating complex regulatory requirements, accessing funding opportunities, consumer acceptance and entering new markets. Providing guidance on effective marketing strategies, and conducting market research will be vital components of these support programs, empowering SMEs to thrive in the dynamic seaweed market. Additionally, providing test bed facilities for start-ups to test and demonstrate their innovations in a low-risk environment would further encourage entrepreneurship and innovation within the industry.

An undervalued catalyst of business development is education. Tertiary education is too academic, elitist and research-focused to achieve widespread societal impact. Instead, learnings from the seaweed industry should be integrated into primary, secondary and VET (vocational education and training) levels from teaching materials to volunteering opportunities, apprenticeships, community colleges and professional training, education is a key driver of upskilling, innovation and social acceptance, the impact of which should not be underestimated. This can be achieved by specific funding calls focusing on education in cooperation with national and local authorities, and funding for schools, community colleges, charities and social services to co-develop educational offers. Successful examples of these educational offers can be found in the United States with the Algae Foundation, Algae Technology Educational Consortium and GreenWave, as well as in third countries from Tanzania to India. By driving social acceptance through education, a critical mass will be achieved which can apply pressure on local, national and transnational authorities to accelerate regulatory reform.

COLLABORATIVE APPROACHES AND INTERNATIONAL COOPERATION

To effectively address regulatory barriers at the global level and facilitate the growth of the European algae industry, a collaborative and internationally coordinated approach is essential. Key strategies include promoting knowledge exchange and best practices with countries beyond the EU. This involves establishing networks, organising workshops and participating in international conferences to facilitate the sharing of expertise and lessons learned.

Aligning EU regulations with relevant international standards and guidelines (e.g. United Nations FAO, ISO) is crucial for facilitating trade and market access. Engaging in discussions and negotiations at international fora ensures that regulatory frameworks keep pace with the evolving needs of the global algae industry.

Encouraging research collaboration between EU research institutions and international counterparts allows for joint efforts to tackle scientific challenges, share research findings, and promote innovation in the macroalgae sector. Establishing research partnerships, joint projects, and knowledge-sharing platforms fosters a collective effort to advance the industry. This is to an extent well covered by the current EU programmes and project portfolio. These projects should substantiate claims for the benefits of macroalgae cultivation and increase pressure on regulators to accelerate regulatory reform and remove market barriers.

By implementing these strategies and embracing collaborative approaches, the EU can effectively remove policy barriers hindering innovation, improve market access and accelerate the growth of the European algae industry. This contributes to the development of a sustainable and competitive macroalgae sector, positively impacting various industries and supporting the transition towards a more sustainable and bio-based economy.

CONCLUSION

KEY FINDINGS

Through a comprehensive assessment of the EU regulatory landscape in a global context, our analysis reveals several significant findings. The regulatory environment governing macroalgae cultivation, processing, product development, marketing, and policy instruments within the EU is intricate and poses substantial challenges to facilitate market exploitation and upscaling of seaweed products. Specific regulatory hurdles pertinent to beta-glucans, pig feed and green alginate have been identified, encompassing issues related to novel food status, national authorisation processes and inter-departmental as well as transnational harmonisation.

"GREEN" ALGINATE

In terms of regulatory barriers, no major obstacles exist for alginates As such, alginate holds considerable promise for various industrial applications, with its safety profile well-established by regulatory authorities. The "green" alginate developed in SeaMark can therefore be used as a good practice example of where regulation can facilitate economic growth.

CO-FERMENTED PIG FEED

For pig feed, the regulatory landscape surrounding seaweed-based ingredients poses challenges due to restrictions on using health claims. This limits companies' ability to sell their products within the EU. Moreover, the cost and complexities of registering and obtaining regulatory approval for a new feed additive can be considerable, making it particularly challenging for small or medium-sized enterprises to navigate these expenses. These regulatory requirements represent significant hurdles for the successful market penetration of seaweed-based animal feed.

BETA-GLUCAN

Although *S. lattisima* is a novel food (having been consumed before 15th May 1997), beta-glucans derived from *S. lattisima* are not currently considered novel food, necessitating a lengthy authorisation process before they can be put on the market. The complexity and time-consuming nature of this process can hinder innovation is impeding market entry for beta-glucan products, while other countries such as the United States benefit from these health products. Moreover, making specific health claims related to the benefits of beta-glucans requires strict compliance with EU regulations on nutrition and health claims, adding to the regulatory challenges and costs for companies seeking to market such products. As things stand, seaweed-derived beta-glucan must undergo a safety assessment before it can be legally marketed. The safety assessment evaluates factors such as composition, nutritional value, potential allergenicity and any potential risks to consumer health.

CULTIVATION

Finally, a significant challenge in the seaweed industry is the streamlining of regulation for cultivation. It is recommended that each member state establishes an official Seaweed Cultivation Policy Statement, akin to the one in Scotland, but with more comprehensive information on specific species, and local socioeconomic and environmental risk factors. Moreover, the inclusion of a detailed roadmap including timelines and delegation of responsibilities is essential to gain a comprehensive understanding of the legal framework, with concrete actions to enable the growth of the industry. This is deemed by industry advocates as crucial and urgent in order to achieve the Mission Ocean goal to restore European waters by 2030.

Therefore, raising awareness of these specific regulatory bottlenecks among various stakeholders, including policymakers, industry representatives and consumers, becomes imperative to drive regulatory reforms and establish an enabling environment for market exploitation. Clearly, there is a shared interest in achieving more straightforward, streamlined and transparent licensing systems. However, the aquaculture industry is multifaceted, subject to diverse regulations and involves a multitude of stakeholders with varying interests that necessitate a multi-actor approach to ensure overall social acceptance and long-term impacts.

RECOMMENDATIONS FOR REGULATORY REFORM

Based on the identified regulatory challenges, the following recommendations can be proposed to address policy barriers and promote the growth of the European algae industry:

Recommendations for regulatory reform:

1. **Streamline and Standardise Processes:** Simplify the licensing process for seaweed farms by building capacities of national regulatory bodies to accommodate applicants. Reducing the number of consulted organisations and consolidating consultations into a unified, inter-departmentally cross-compatible application procedure will expedite this process.

3. **Expedite the Authorisation Process for Seaweed-based Ingredients and Products:** Ensuretransparency, clear guidelines, and harmonisation across EU member states.

4. **Provide Regulatory Clarity:** Provide clear guidance and a comprehensive roadmap on regulatory requirements for seaweed cultivation, processing and product development, considering the unique characteristics of macroalgae and their derivatives. Focus on addressing regional-specific needs at the bioregional scale, including guidance on genetic diversity and strain cultivars.

5. **Promote Innovation and Market Access:** Support research and development initiatives, encourage product diversification and implement targeted support programs to assist small and medium-sized enterprises (SMEs), business support organisations and educational institutions in navigating regulatory requirements and accessing new markets. Governmental subsidies, grants and funding for infrastructure are crucial to incentivise participation and mobilise both public and private investment.

6. **Create an Enabling Environment through Collaboration:** Foster international cooperation, knowledge exchange and alignment with international standards to facilitate cross-compatible trade and market access for European algae products, promoting growth and strengthening competitiveness.

FUTURE OUTLOOK FOR THE EUROPEAN ALGAE INDUSTRY

The future outlook for the European algae industry is promising, despite the existing regulatory challenges. With the right regulatory reforms and supportive policies, the seaweed industry can thrive and become a key driver in building a sustainable and bio-based economy. However, it is essential to acknowledge that the European farmed seaweed industry is still in its early stages and faces significant risks of failure. Many companies are currently in the pre-revenue phase or not generating profits, with some having already faced closure. To achieve success, the industry needs to operate at a large scale comparable to other agri-foods sectors, e.g. through the formation of producer organisations, group purchasing organisations and vertical integration, which require cooperation, capacity building and grassroots activism as well as commercial investment and policy support.

The removal of policy barriers will open up market opportunities for seaweed products like beta-glucans, pig feed and green alginate, leading to increased market exploitation and growth in the EU, as well as more sustainable industries and societal well-being. The growing demand for climate-positive health products such as vegan foods are strong indicators for growth scalability. Continuing to confirm positive environmental outcomes through research and innovation will further justify technological advancements in seaweed cultivation, processing, product development, and subsidies, unlocking new opportunities and applications in a positive feedback loop.

As customer preferences shift towards plant-based ingredients and food products in tandem with increased awareness of the benefits of macroalgae-based products, the European algae industry can play a crucial role in supporting the transition towards a regenerative, circular economy. To achieve this, capacity building, regulatory reforms and international cooperation are vital. The EU has the potential to become a global leader in the algae industry, shaping international standards, influencing best practices and fostering innovation for decades to come. Policymakers, industry stakeholders, researchers and consumers must work together to establish an enabling regulatory environment that supports the growth and upscaling of the European algae industry. This collaborative effort will pave the way for a more prosperous and sustainable future for the algae industry in Europe.

BIBLIOGRAPHY

1. *117 Congress U.S.A.* (2023). Hentet fra Congress. Gov: https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf
2. 172.365., S. 2. (2023). *Code of Federal Regulation Title 21*. Hentet fra FDA: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.365
3. Agostoni, C. V.-T. (2011). Scientific Opinion on the safety of'yeast beta-glucans' as a Novel Food ingredient. *EFSA JOURNAL, 9(5).*
4. Alexander, K. A. (2015). The implications of aquaculture policy and regulation for the development of integrated multi-trophic aquaculture in Europe. . *Aquaculture, 443,* , 16.
5. Araújo, R. V. (2021). Current status of the algae production industry in Europe: an emerging sector of the blue bioeconomy. . *Frontiers in Marine Science*.
6. Bach D, N. A. (2010). Governing lipitor and lipstick: capacity, sequencing and power in international pharmaceutical and cosmetics regulation. . *Rev Int Polit Econ 17(4)*, 665–695.
7. Barbier, M. C. (2019). *PEGASUS. Phycomorph European Guidelines for a sustainable Aquaculture of Seaweeds, .* Roscoff: COST ACTION FA1406. Horizon 2020 Framework Programme of the European .
8. Buschmann, A. H.-G. (2017). Seaweed production: overview of the global state of exploitation, farming and emerging research activity. *European Journal of Phycol*.
9. Campbell, I. M. (2019). The environmental risks associated with the development of seaweed farming in Europe-prioritizing key knowledge gaps. . *Frontiers in Marine Science*, 6.
10. Chandel, V. B. (2022). Current advancements in pectin: Extraction, properties and multifunctional applications. . *Foods, 11(17)*, p.2683.
11. Chung, I. &. (2014). Mitigation potential of seaweed aquaculture beds in Asia-Pacific countries. *Paper presented at World Aquaculture 2015 Guangzhou.* China.
12. *Circular Ecology*. (2016). Hentet fra Sustainable development: www.circularecology.com/sustainability-and-sustainable-development.html#.WBZjJ4WcHg8
13. *Code of Federal Regulation Id. §§ 117.4, 117.5.* (2015). Hentet fra eCFR System: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117
14. Cottier-Cook, E. N. (2016). *Safeguarding the future of the global seaweed aquaculture industry. Policy Brief. .* Canada: United Nations University.: Hamilton, .
15. Dujardin, B. F. (2023). Dietary exposure to heavy metals and iodine intake via consumption of seaweeds and halophytes in the European population. *EFSA Journal, 21(1), e07798.*
16. EFSA. (2009). EFSA Panel on Contaminants in the Food Chain. Scientific Opinion on arsenic in food. . *EFSA Journal.* , 7:1351. 10.2903/j.efsa.2009.1351.
17. Emblemsvåg, J. K. (2020). Strategic considerations for establishing a large-scale seaweed industry based on fish feed application: a Norwegian case study. *J. Appl. Phycol. 32*, 4159–4169. doi: 10.1007/s10811-020-02234-w.
18. Engle, C. R. (2013). Competitiveness of US aquaculture within the current US regulatory framework. . *Aquaculture Economics & Management, 17(3)*, 251-280.
19. European Commission (2022). Commission Communication COM/2022/0592. Towards a Strong and Sustainable EU Algae Sector. Available online at https://oceans-and-fisheries.ec.europa.eu/publications/communication-commission-towards-strong-and-sustainable-eu-algae-sector_en (accessed May, 2023).
20. *EU Ecolabel*. (2023). Hentet fra European Comission: https://environment.ec.europa.eu/topics/circular-economy/eu-ecolabel-home_en
21. *EU4Algae*. (2023). Hentet fra Maritime Forum: https://maritime-forum.ec.europa.eu/en/frontpage/1727
22. *Federal Food, Drug and Cosmetics Act* . (2023). FDA: https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act
23. Fisheries, D.-G. f. (09. 02 2022). *European Comission launches platfrom to promote production and use of algae.* Ocean and fisheries European Comission: https://oceans-and-fisheries.ec.europa.eu/news/european-commission-launches-platform-promote-production-and-use-algae-europe-2022-02-09_en
24. Frangoudes, K. (2011). Seaweeds fisheries management in France, Japan, Chile and Norway. . *Cah. Biol. Mar. 52*, 517–525.
25. Frank., K. (2020). Seaweed Aquculture – An assessment of the legal and managmant structure on seaweed farming in Icland.
26. *Future Market Isights*. (2023). Future Market Insights: http://www.futuremarketinsights.com/reports/beta-glucans-market
27. Gallagher, J. B. (2022). Seaweed ecosystems may not mitigate CO2 emissions. *ICES Journal of Marine Science*, 79(3), 585-592.
28. Gjertsen, A., Bay-Larsen, I., Bjørkhaug, H., & Vangelsten, B. V. (2020). Access to areas for algae cultivation in Norway. *Marine Policy, 115, 103853.*
29. *Global Market Insights*. (2023). Hentet fra Gminsights: https://www.gminsights.com/industry-analysis/nutraceutical-ingredients-

market?gclid=EAIaIQobChMIn4-EuMC4gAMVg5KDBx2LLws2EAAYASAAEgIeFfD_BwE
30. Gómez, T. a.-U. (2021). European and National Regulations on Seaweed Cultivation and Harvesting. Growing algae Sustainably in the Baltic Sea"(GRASS) and "Sustainable Cultivation of Seaweed"(SUSCULT) Project Report.
31. Government, S. (2017). *Seaweed Cultivation Policy Statement.* Edinburgh: The Scottish Government.
32. *Green Claims*. (2023). Hentet fra European Comission: https://environment.ec.europa.eu/topics/circular-economy/green-claims_en
33. Holdt, S. L. (2011). Bioactive compounds in seaweed: functional food applications and legislation. *J. Appl. Phycol. 23,*543–597. doi: 10.1007/s10811-010-9632-5.
34. Janasie, C. M. (2023). Federal Food Safety Framework: Where does Seaweed Fit In? *Journal of Food Law & Policy*, 18(2).
35. Kinley, R. D., Martinez-Fernandez, G., Matthews, M. K., de Nys, R., Magnusson, M., & Tomkins, N. W. (2020). Mitigating the carbon footprint and improving productivity of ruminant livestock agriculture using a red seaweed. *J. Clean. Prod. 259*, 120836. doi: 10.1016/j.jcle.
36. Lane, A. H. (2009). *Evaluation of the Impact of" A strategy for the Sustainable Development of European Aquaculture"* COM (2002) 511 Final.
37. Le Bras, Q. R. (2014). Etude de la consommation des algues alimentaires en France. . *Programme IDEALG Phase 1. Etude nationale (Doctoral dissertation, Agrocampus Ouest: Rennes).*, p.13.
38. *Lead in Food, Foodwares, and Dietary Supplements*. (2023). FDA: https://www.fda.gov/food/environmental-contaminants-food/lead-food-foodwares-and-dietary-supplements
39. Leinemann, F. &. (2019). European Union legislation and policies relevant for algae. *Grand Challenges in Algae Biotechnology*, p.583.
40. Lähteenmäki-Uutela, A. R.-G. (2021). European Union legislation on macroalgae products. *Aquaculture International*, pp.487-509.
41. Mackenzie, J. S. (2019). The One Health approach—Why is it so important? *Tropical medicine and infectious disease*, 4(2), 88.
42. Maia, M. R. (2016). The potential role of seaweeds in the natural manipulation of rumen fermentation and methane production. *Sci. Rep. 6*, 32321. doi: 10.1038/srep32321.
43. Mather, C. & Fanning, L. (2019). Social licence and aquaculture: towards a research agenda. *Marine Policy, 99,*275-282.
44. Multi-Str3am. (2021) *Report on the regulatory landscape for microalgae biomass valorisation across market applications.* 2020: Instituto de Biologia Experimental e Tecnológica (iBET). Hentet fra https://www.czeder.cz/pdf/en/17-multistr3am.pdf
45. Nichols., A. (2019). *INVENTORY OF STATE LAWS AFFECTING COMMERCIAL SEAWEED AQUACULTURE.* Sea Grant.
46. None, N. (2020). *Federal activities report on the bioeconomy: algae (No. DOE/EE-2009). US Department of Energy (USDOE).* Washington DC: Office of Energy Efficiency and Renewable Energy (EERE).
47. NOAA. (2021). *State by state summary of seaweed aquaculture leasing/permitting requironments.* Hentet fra media fisheries noaa: https://media.fisheries.noaa.gov/2021-09/Report-State-by-State-Summary-of-Seaweed-Aquaculture-Leasing-Permitting-Requirements-2021.pdf
48. O'Mahoney, M. R. (2014). Towards sustainable feeds for abalone culture: evaluating the use of mixed species seaweed meal in formulated feds for the Japanese abalone, Haliotis discus hannai. *Aquaculture 430*, 9–16.
49. Osmundsen, T. C. (2017). Fish farmers and regulators coping with the wickedness of aquaculture. *Aquaculture Economics & Management, 21(1)*, 163-183.
50. Ouzzani, M. H. (2016). Rayyan—a web and mobile app for systematic reviews. *Systematic reviews, 5,* 1-10.
51. *Personal Care Products Council*. (2023). personal care council: https://www.personalcarecouncil.org/resources/inci/
52. Probst, L. F. (2015). *Sustainable safe, and nutritious food: New nutrient sources.* Bruss. Belg: Eur. Comm.
53. *Prophecy Market Insights*. (2023). Globenewswire: https://www.globenewswire.com/news-release/2023/03/14/2626738/0/en/Cosmetics-Market-worth-US-665-18-Billion-2030-with-a-CAGR-of-5-30-BY-PMI.html
54. Rahikainen, M. a. (2020). Macroalgae as food and feed ingredients in the Baltic Sea region–regulation by the European Union. *Report of the Interreg project Growing Algae Sustainably in the Baltic Sea,* pp.1-20.
55. Rebours, C., Marinho-Soriano, E., Zertuche-González, J. A., Hayashi, L., Vásquez, J. A., Kradolfer, P., & Robledo, D. (2014). Seaweeds: an opportunity for wealth and sustainable livelihood for coastal communities. *J. Appl. Phycol. 26*, 1939–1951. doi: 10.1007/s10811-0.
56. *Registration and Listing of Cosmetic Products Facilities and Products.* (2023). FDA: https://www.fda.gov/media/170732/download
57. Roque, B. M. (2019). Effects of the macroalgae Asparagopsis taxiformis on methane production and rumen microbiome assemblage. *Anim. Microb. 1*, 1–14.
58. Ross, F. W., Boyd, P. W., Filbee-Dexter, K., Watanabe, K., Ortega, A., Krause-Jensen, D., & Macreadie, P. I. (2023). Potential role of seaweeds in climate change mitigation. *Science of the Total Environment*.
59. *Safe seaweed coalition*. (2023). Global Seawead coalition: https://www.safeseaweedcoalition.org

60. *See Standards for Food and Additives.* China: MINISTRY OF HEALTH, LABOUR, AND WELFARE. (translated by
61. AI Language DeepL June. 15, 2023)
62. Stévant, P. R. (2017). Seaweed aquaculture in Norway: recent industrial developments and future perspectives. *Aquacult. Int. 25*, 1373–1390. doi: 10.1007/s10499-017-0120-7.
63. The French Agency for Food, E. a. (u.d.). ANSES makes recommendations to limit cadmium exposure from consumption of edible seaweed. FRENCH AGENCY FOR FOOD, ENVTL. & OCCUPATIONAL HEALTH & SAFTEY .
64. Turck, D. B.-E. (2023). Safety of water lentil protein concentrate from a mixture of Lemna gibba and Lemna minor. *EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA)*.
65. Vincent, A. S. (2020). Hidden champion of the ocean: Seaweed as a growth engine for a sustainable European future. *Seaweed for Europe*, 60.
66. World Bank . (2023). Global Seaweed: New and Emerging Markets Report: http://hdl.handle.net/10986/40187 License: CC BY-NC 3.0 IGO."
67. Zakaria, Z. (2015). Regulation of cosmetics: what has Malaysia learnt from the European system? *J Consum Policy 38*, 39–59.
68. CSS (Conseil Supérieur de la Santé). Opinion on the Substancail Equivalence of Focodian focodian extracted from Undaria pinnatifida and Fucodian Extracted from Fucus versiculosus. European Parliament.
69. Sidley Austin LLP - Diane C. McEnroe, E. M. (2023). Spotlight: food and cosmetic safety in USA. *The Law Reviews*.
70. GRASS. (2021). Synthesis Report Benefits, risks and opportunities of macroalgae cultivation, harvesting and use at local, regional, national and transnational level. Interreg Baltic Sea Region.

APPENDICES

LIST OF EU REGULATIONS AND DIRECTIVES

This appendix provides a comprehensive list of EU regulations and directives relevant to the macroalgae industry.

CULTIVATION AND HARVESTING:

- Maritime Spatial Planning **Directive 2014/89/EU**
- Marine Strategy Framework **Directive 2008/56/EC**
- Water Framework **Directive 2000/60/EC**
- Alien Species **Regulation (EU) No 1143/2014**
  - along with the Regulation on Aliens Species in Aquaculture **2007/708/EC**
- Habitats **Directive 92/43/EC**
- Regulation on Organic Production **2018/848/EU:**
  - Part III lays down the rules to be followed in all stages of production, preparation, and distribution production of organic algae. An environmental assessment that is appropriate to the production unit shall be required for any new operators applying for organic production and producing more than 20 tonnes of aquaculture products per year. The content of the environmental assessment shall be based on Annex IV to Directive 2011/92/EU.
- Nagoya Protocol **Regulation (EU) No 511/2014**
- Release of GMO into environment **Directive 2001/18/EC**

FOOD:

- General Food Law **Regulation (EC) No 178/2002**
- Novel Food **Regulation (EU) 2015/2283**
  - Concerns the placing on the market within the Community of novel foods or novel food ingredients **Regulation (EC) No 258/97**
  - Novel Food Catalogue **(EU) 2017/2470**
- Food Contaminants **Regulation (EC) No 1881/2006**
  - Maximum residue levels of pesticides in food and feed defines a maximum level for mercury **(EC) No 396/2005**
  - Monitoring of metals and iodine in seaweed, halophytes and products based on seaweed **Recommendation COM (EU) 2018/464**
- Food hygiene **Regulation (EC) No 852/2004**
  - Guidelines on the Requirements of Food Hygiene Legislation: **FSA (2006)**
- On Microbiological Criteria for Foodstuffs **Regulations (EC) No 2073/2005**
- A Guide for Food Businesses (food standards agency 2008) **Food Safety Act 1990**
- On materials and articles intended to come into contact with food **Regulation (EC) No 1935-2004**
- Regulation (EEC) No 320 of 2003
- Genetically modified food and feed **Regulation (EC) No 1829/2003**

FOOD ADDTIVES:

- Food additives **Regulation (EC) No 1333/2008**
  - Origin of additives **Regulation (EU) No 231/2012**
- Food additives authorized for use in foodstuffs intended for human consumption **Directive 89-107 EEC**
- The Food Additives (England) Regulations 2009

HEALTH CLAIMS FOOD

- Nutritional Claims **Regulation (EC) No 1924/2006**
  - Nutrition Information **Regulation (EU) No 1169/2011** (recomedned daily allowance) Amendment of above
- Health Claim Commission **Regulation (EU) No 432/2012** and Commission **Regulation (EU) No 957/2010**

GLOBAL FOOD SAFETY INITIATIVE CERTIFICATION (FOOD SAFETY AND QUALITY):

- BRCGS
- Canada GAP
- Efi
- Freshcare
- FSSC 22000
- Global Gap
- SQF
- IFS

PRODUCT CERTIFICATION:

- Halal Certification
- Kosher Certification
- Organic Certification
- Vegan Certification
- Vegetarian Certification
- Gluten Free Certification

LABELING:

- On the common organisation of the markets in fishery and aquaculture products **Regulation (EU) No 1379-2013 of 11 Dec 2013**
- Organic macroalgae production **Regulation (EC) No 710/2009**
- Production and labelling of organic algae **Regulation (EU) 2018/848**
- Nutrition Information **Regulation (EU) No 1169/2011**

FEED:

- Catalogue of feed materials **Regulation (EU) No 68/2013**
- Feed Additive **Regulation (EC) No 1831/2003**
- Feed Contaminants **Directive 2002/32/EC**
- Feed Hygiene **Regulation (EC) No 183/2005**
- On the placing of the Marketing and use of feed **Regulation (EC) No 767/2009**
- Genetically modified food and feed **Regulation (EC) No 1829/2003**

FEED LABELING:

- Amending Regulation (EU) No 68/2013 on the Catalogue of feed materials **Regulation (EU) 2022/1104)**

COSMETICS:

- Basic EU rules on cosmetics **Regulation (EC) No 1223/2009**
- EU cenrilized notification of products on **CPNP** with legal responsibility
- EU's Cosmetic Ingredient database, **CosIng**
- Claims in cosmetics **Regulation (EU) No 655/2013**
- The EU REACH **Regulation (EC) No 1907/2006**