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INNOAQUA PROJECT

A legal analysis of the reuse of aquaculture effluents, fish processing waste, and algae biomass

LAND-BASED rearing of marine Pearl Oysters in India

Mediterranean Marine Finfish Aquaculture Demonstration Centre (MMF-ADC)

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On the cover

Inset 1: Algae culture

Inset 2: Drum bio/filter, courtesy of Landing Aquaculture

Insets 3, 4 and 5: Fish waste courtesy of Leitat Technological Center

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INNOAQUA : Legal pathways, regulatory gaps, and compliance requirements for the reuse of aquaculture effluents, fish processing waste, and algae biomass.

The INNOAQUA project is taking land-based aquaculture forward by integrating sustainable practices such as Recirculating Aquaculture Systems (RAS) and Integrated Multi-Trophic Aquaculture (IMTA). These systems promote a circular economy by repurposing fish farming effluents and by-products into valuable resources, including algae-based food ingredients, nutraceuticals, and food contact materials.

This article is based on a deliverable of the INOAQUA project, authored by Bruna Gomes Maia, Greet Smets & Patrick Rüdelsheim of PERSEUS BV, a 3Bio company, partner in the project. It provides a comprehensive review of the EU's regulatory landscape relevant to the INNOAQUA innovations. It identifies legal pathways, regulatory gaps, and compliance requirements for the reuse of aquaculture effluents, fish processing waste, and algae biomass.

Traditional land-based aquaculture results in the release of wastewater and sludge that is directly deposited in the seas and rivers, which causes their eutrophication . By using circular technologies instead, these fractions previously considered waste are repurposed rendering in-land aquaculture more sustainable when compared to those practiced offshore. Scientific and technological advancements do not occur in isolation from society. As a result, INNOAQUA places significant emphasis on assessing relevant legislation, pinpointing gaps and obstacles, and recommending regulatory adjustments to facilitate these innovations.

Within the EU, there is no specific legislation dedicated to aquaculture. Instead, the sector is governed by a multitude of policies and regulatory frameworks of water, waste, environmental protection, and human and animal health, which are implemented through directives or regulations. These directives are transposed into national laws, allowing for potential variations between Member States. Furthermore, existing legislation predominantly addresses traditional single-species monocultures, with specific regulations related to IMTA are virtually non-existent.

The primary objective of INNOAQUA is to enable the reutilization of substances and materials that, within a linear economic model, would typically be discarded into the environment. The report on which this article is based undertook a comprehensive analysis of the existing regulatory framework governing aquaculture, waste management, wastewater treatment, animal by-products, and algae. Additionally, it examined the health and safety requirements necessary for placing in the market food products and food contact packaging derived from aquaculture production.

Part 1. Aquaculture in the EU regulatory framework

This section provides brief summaries of the policies, regulations, and strategies governing aquaculture within the EU, demonstrating its objective to ensure that aquaculture activities contribute to long-term environmental sustainability, thereby achieving economic and social benefits for society.

Common Fisheries Policy Regulation

Regulation (EU) No. 1380/2013 lays down provisions concerning the Common Fisheries Policy (CFP), aiming to ensure that fishing and aquaculture activities are environmentally sustainable in the long-term and are managed in a way that is consistent with the objectives of achieving economic, social and employment benefits, and of contributing to the availability of food supplies. It covers the conservation of marine biological resources and the management of fisheries and fleets exploiting such resources. It also covers measures on markets and financial tools in support of the implementation of the CFP, fresh water biological resources, aquaculture, and the processing and marketing of fisheries and aquaculture products.

The CFP outlines a general framework and does not specifically regulate aquaculture. It encourages the promotion of the sustainable development of the European aquaculture sector through a coordinated strategy, based on the elaboration of a multiannual national strategy plan for aquaculture by Member States. This disposition is in line with the European Green Deal.

Green Deal and Farm to Fork Strategy

In 2019, the European Union introduced the Green Deal, a comprehensive strategy aimed at addressing climate and environmental challenges. The European Commission outlined its commitment to this initiative in a detailed document, emphasizing the need for a sustainable and inclusive transition towards a greener economy. The Green Deal serves as a roadmap for achieving climate neutrality by 2050, promoting clean energy, enhancing biodiversity, and fostering a circular economy. It also aims to reduce pollution, ensure sustainable food systems, and support green innovation, ultimately striving to create a healthier and more resilient environment for future generations.

As part of the Green Deal, the Farm to Fork Strategy seeks to minimize the environmental footprint of the food processing and retail sectors by addressing transport, storage, packaging, and food waste. Food production methods should adopt climate-friendly practices while enhancing efficiency. This strategy also emphasizes the use of sustainable packaging and the development of innovative food and feed products, such as algae-based seafood.

Strategic guideline for a more sustainable and competitive EU aquaculture

In 2021, the Commission adopted a new strategic guideline for a more sustainable and competitive EU aquaculture for the period 2021 to 2030 . These guidelines are aligned with the European Green Deal and the Farm to Fork Strategy, aiming to make the aquaculture sector more competitive, efficient, and sustainable. The guidelines also call for the development of organic aquaculture and other aquaculture systems with lower environmental impact, such as energy-efficient RAS, IMTA, as well as the diversification to lower-trophic species (molluscs and other invertebrates and algae and herbivore fish).

The guidelines mention that access to space and water and regulatory complexity are the main challenges of the aquaculture sector in the EU. It recognises that national regulations are complex, and that the licensing process is unpredictable regarding time, involving multiple authorities. As a possible solution for the regulatory complexity, the guideline suggests streamlining national legislation, by adopting a single piece of legislation that gathers all relevant aspects and ideally enacted by a single national aquaculture entity responsible for coordination, planning, licensing and monitoring of aquaculture activities.

And for other areas, the guidelines offer potential solutions to increase the diversification of aquaculture products; enhance consumer acceptance of the products; ensure a good skill base for production and provide an enabling environment for investment in innovative solutions.

The EU's strategy sets a path for aquaculture to become resilient, competitive, and globally recognized for sustainability and quality. Implementation of the guidelines – by the Commission, Member States and the Aquaculture Advisory Council - are supported by the EC Aquaculture Assistance Mechanism.

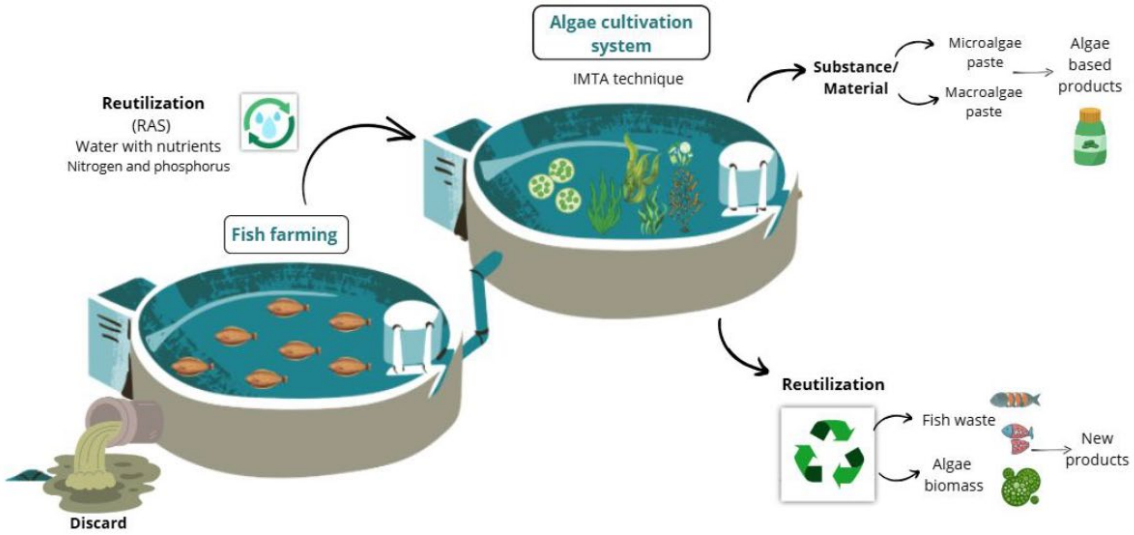

Figure 1: Simplified scheme of aquaculture using RAS and IMTA techniques

Towards a Strong and Sustainable EU Algae Sector

In 2022, the EU Commission released a Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions entitled "Towards a Strong and Sustainable EU Algae Sector" . The document emphasized the role of macroalgae (seaweed) and microalgae farming in contributing to achieving several objectives of the European Green Deal (e.g. decarbonisation, zero pollution, circularity, the preservation and restoration of biodiversity, the protection of ecosystems and the development of environmental services). Algae can provide sustainable food and feed products and bio-based packaging.

The Communication recognized that improvements needed to be made in the governance framework and legislation in this area. Algae and seaweed aquaculture were subject to EU and national regulatory requirements and the sector could benefit from a more coherent approach. An example would be to facilitate the obtention of algae farming licenses.

Furthermore, the Communication supported the development of innovative equipment to increase productivity in the algae sector and the quality of algae-based products. Also, downstream processes, e.g. after extracting active components, biorefineries for the treatment of the entire biomass of macroalgae and microalgae should be developed instead of wasting the rest of the biomass.

In conclusion, The EU's regulatory framework for aquaculture seeks to balance environmental sustainability, economic viability, and societal benefits. Through a combination of policies—including the Common Fisheries Policy, the Green Deal, the Farm to Fork Strategy, and strategic guidelines—the EU aims to create a resilient and competitive aquaculture sector. Emphasizing innovation, ecosystem preservation, and streamlined governance, these regulations lay the foundation for sustainable growth. However, regulatory challenges, such as complex licensing procedures and fragmented national regulations, remain obstacles to sectoral development and require coordinated efforts for simplification and harmonization. By addressing challenges such as licensing complexity, consumer awareness, and diversification, the EU strives to enhance aquaculture's role in food security, climate adaptation, and environmental conservation. Continued collaboration among stakeholders and targeted investments will be essential in realizing these ambitious goals.

Part 2. Utilisation of material derived from aquaculture production

Integrated fish farming and algae cultivation systems are in line with the European Union's goal to advance sustainable aquaculture. INNOAQUA's objective is to harness water, fish waste, and algae biomass to produce nutritious food while minimizing environmental impact. This approach aims to stimulate economic growth, create employment opportunities, reduce pollution, protect ecosystems, and combat climate change.

Transitioning from a linear economy to a circular model, however, presents certain challenges.

Utilization of aquaculture effluents

One of the employed techniques within the integrated fish farming and algae cultivation system involves the reutilization of water from fish farming for algae cultivation. RAS systems allow the control of culture conditions and the collection of fish waste. Aquaculture effluents contain dissolved and suspended solids, along with nutrients such as phosphorus (P) and nitrogen (N), derived from fish excretion, faeces, and uneaten feed. These nutrients can act as fertilizers in algae cultivation systems. **However, due to the origin and composition of aquaculture effluents, they may be classified as waste, wastewater, or animal by-products. This classification is crucial as it determines the specific legal conditions for their use.**

The Waste Framework

Before examining the various scenarios in which effluents from aquaculture might be classified as waste, it is important to highlight that this perspective is rooted in a traditional "input-output" model. However, with the adoption of RAS and IMTA, the circulating water—along with its nutrients and other components—is considered an integral part of the system. As such, it does not meet the definition of waste, which is typically described as a "substance or object which the holder discards or intends or is required to discard." Therefore, only the small volume of surplus effluent that is periodically discharged from the system could potentially be classified as waste.

The Waste Framework Directive (Directive 2008/98/EC) (WFD) governs issues around waste in general in the EU. This WFD lays down measures to protect the environment and human health by preventing or reducing the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use. Commission Decision 2000/532/EC established a single Community list which integrated the list of waste and the list of hazardous waste previously scattered over different Directives and Decisions. This European Waste Catalogue (EWC) simplifies and clarifies waste classification across Member States. It provides the technical implementation Article 7 of WFD, which mandates the creation of a list of waste and the classification of hazardous waste.

Table 1: Selection of wastes identifications as indicated in the EWC, potentially relevant for aquaculture.

02	Wastes from agricultural, horticultural, hunting, fishing and aquacultural primary production, food preparation and processing
0201	*Primary production wastes*
020102	Animal tissue waste
020106	Animal faeces, urine and manure (including spoiled straw), effluent, collected separately and treated off-site
020199	Waste not otherwise specified
0202	*Wastes from the preparation and processing of meat, fish and other foods of animal origin*
020202	Animal tissue waste
020203	Material unsuitable for consumption or processing
020204	Sludges from on-site effluent treatment
020299	Waste not otherwise specified

The specifications selected in Table 1 confirm that effluents from aquaculture are considered waste in this framework.

On the other hand, Article 2 §1 excludes from the scope of the WFD faecal matter and straw and other natural non-hazardous agricultural or forestry material used in farming, forestry or to produce energy from such biomass through processes or methods which do not harm the environment or endanger human health. This exclusion might be relevant to aquaculture effluents because it highlights that similar materials, if used in aquaculture processes that do not harm the environment or human health, might also be excluded from strict waste regulations. This can simplify regulatory compliance for aquaculture operations, provided they meet the necessary environmental and health safety standards.

Other materials are expressly excluded from the scope of the WFD (Article 2 §2) to the extent that they are regulated by other EU regulations. Those exclusions relevant to the INNOAQUA project are wastewater and animal by-products including processed products covered by Regulation (EC) No 1774/2002, except those which are destined for incineration, landfilling or use in a biogas or composting plant.

In Article 5, the WFD defines by-products as a substance or object, resulting from a production process, the primary aim of which is not the production of that item. (Note: these "by-products" are distinct from "animal by-products" which will be covered below). Member States must ensure that by-products meet certain conditions: (a) they are certain to be used further; (b) they can be used directly without additional processing beyond normal industrial practices; (c) they are produced as part of the production process; and (d) their further use is lawful and meets all relevant product, environmental, and health protection requirements without causing adverse impacts.

For the INNOAQUA project, as the effluent resulting from fish farming is not considered the primary aim of the production, it might be classified as a by-product. In a RAS or IMTA they are produced as part of the aquaculture production process, and they are certain to be used further without additional processing beyond normal industrial practices. However, there may be uncertainty of the lawful use and the relevant product, environmental, and health protection requirements may not have been defined.

Furthermore, **the WFD concept of "end-of-waste", specifies the possibility of certain waste materials to cease to be classified as waste and become products or secondary raw materials**. According to Article 6 of the directive, waste can achieve non-waste status if it meets detailed criteria aiming to protect the environment and human health while promoting the efficient use of natural resources. They include (a) permissible waste input materials for recovery operations, (b) allowed treatment processes and techniques, (c) quality criteria for end-of-waste materials, including pollutant limits, (d) management system requirements for compliance, quality control, self-monitoring, and accreditation, (e) a requirement for a statement of conformity.

Member States must ensure that waste which has been recycled or recovered is no longer considered waste if it is intended for specific uses; there is a market or demand for it; it meets the technical requirements and relevant legislation and standards; and its use will not cause negative environmental or human health impacts. Again, if the effluent resulting from fish farming is considered waste, it might be eligible for redirecting as a recycled product, providing that all indicated conditions are being met.

However, approaches to recognise end-of waste status differ between Member States. In some, a designated institution such as the Environment Ministry or the Environment Agency is responsible for deciding whether end-of-waste status is applicable or not. In others, local or regional authorities take such decisions, or alternatively, the responsibility is with the industry to self-declare, with inspections carried out by the competent enforcement authorities.

Reuse of wastewater

Regarding wastewater reuse, Regulation (EU) 2020/741 applies to the reuse of treated urban wastewater for agricultural irrigation. According to the definition established in Article. 2 of Directive 91/271/EEC, 'urban wastewater' means domestic wastewater or the mixture of domestic wastewater with industrial wastewater and/or run-off rainwater. Hence, as aquaculture effluents do not contain domestic waste, they are not considered urban wastewater and, therefore, this regulation is not applicable.

Animal by-products

Animal by-products (ABPs) are materials derived from animals that are not intended for human

consumption. These include parts of slaughtered animals like skin, bones, blood, fat, and offal, as well as bodies of animals that died on farms, pet animals, and materials produced by animals such as manure, eggshells, feathers, and wool. ABPs are categorized based on their risk level: Category 1 (high risk), Category 2 (intermediate risk), and Category 3 (low risk). Proper handling and processing of ABPs are essential to prevent the transmission of diseases and to utilize their nutritional and energetic value effectively.

Regulation EC 1069/2009 and Commission Regulation 142/2011 set down controls on the safe use and disposal of animal-by products to safeguard public and animal health but allow exemptions in certain circumstances. More specifically, it lays down rules as regards the safe treatment, and the processing or transformation of animal by-products into derived products.

In aquaculture, several components are derived from animals and not intended for human consumption, including faeces, excretory products and fish scales. **Article 2 (2)(k), of the ABP Regulation establishes that the Regulation shall not apply to excrement and urine other than manure and non-mineralised guano.** To understand if aquaculture effluents containing fish excrement would be considered 'manure', it is important to analyse the definition provided by the same regulation **(Article 3 (20)): "manure" means any excrement and/or urine of farmed animals other than farmed fish, with or without litter.**

Since aquaculture waste is not classified as manure under the ABP Regulation, some EU member states have prohibited its use as fertilizer and instead regulate it as sludge (see below). In this context, it is also important to mention that although fish sludge is a product suitable to be used as fertiliser, the use of this type of sludge as fertiliser is excluded from the EU Fertilising Products Regulation (EU) No. 2019/1009.

Use of sludge in agriculture

In certain countries, aquaculture waste has been classified as sludge and is subject to regulation under Council Directive 86/278 concerning the use of sewage sludge in agriculture. According to Article 2 of the mentioned Directive, sludge means:

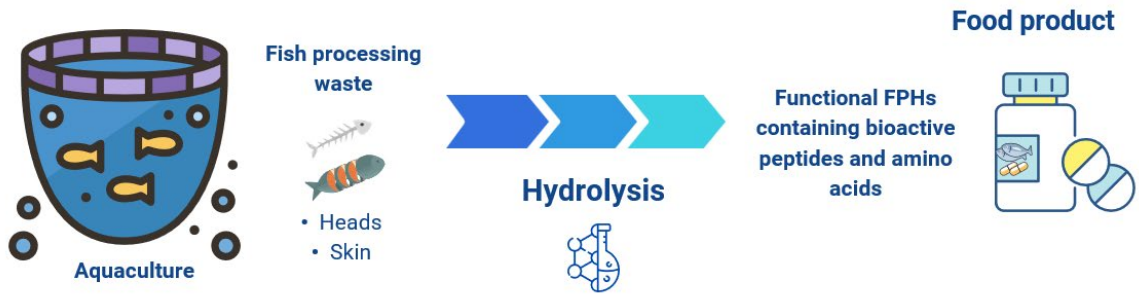

Figure 2 : Simplified scheme of reutilization of fish by-product from in-land aquaculture.

I. residual sludge from sewage plants treating domestic or urban wastewaters and from other sewage plants treating wastewaters of a composition similar to domestic and urban wastewaters;

II. residual sludge from septic tanks and other similar installations for the treatment of sewage;

III. residual sludge from sewage plants other than those referred to in (i) and (ii) (...)

Article 3 sets forth that the aforementioned sludge can only be used in agriculture in accordance with the requirements of the Directive. The Directive specifies some requirements, such as the values for concentrations of heavy metals in soil to which sludge is applied, concentrations of heavy metals in sludge and the maximum annual quantities of such heavy metals which may be introduced into soil intended for agriculture. Moreover, according to Art. 6, sludge shall be treated before used in agriculture, however, Member States may authorize the use of untreated sludge if it is injected or worked into the soil.

Regarding the use of the sludge, Article 7 sets forth that Member States shall prohibit the use of sludge or the supply of sludge for use on:

- grassland or forage crops if the grassland is to be grazed or the forage crops to be harvested before a certain period has elapsed. This period, which shall be set by the Member States taking particular account of their geographical and climatic situation, shall under no circumstances be less than three weeks;
- soil in which fruit and vegetable crops are growing, with the exception of fruit trees;
- ground intended for the cultivation of fruit and vegetable crops which are normally in indirect contact with the soil and normally eaten raw, for 10 months preceding the harvest of the crops and during the harvest itself.

This classification of the possible uses limits the potential applications of aquaculture effluents, specifying the types of cultures on which they can be utilized. Furthermore, it imposes stringent safety and monitoring standards that are pertinent to sludge derived from urban wastewater, but not necessarily applicable to RAS.

At the Workshop on Nutrients in Aquaculture and Fisheries, organized by the European Sustainable Phosphorus Platform in Bergen, Norway, on June 11, 2025, a representative from DG SANTE of the European Commission stated that aquaculture sludge is not specifically defined by name, but it is considered an animal byproduct. It might fall within Category 2 material referred to in Article 9(h) of Regulation n. 1069/2009. The representative recommended that the industry should prepare a material for the European Food Safety Authority (EFSA) scientific assessment. Depending on the outcome, new and specific rules for the use of aquaculture sludge may be set out in implementing the Regulation (EU) N. 142/2011.

Utilization of fish processing waste

Fish processing waste, such as fish heads and skin, is often discarded as a byproduct of aquaculture. However, this nutrient-rich material has the potential to be repurposed into functional food ingredients. The INNOAQUA Project aims to explore legal pathways for reusing this material in compliance with current regulations.

Animal by-products

According to Article 10 of the ABP Regulation (EC 1069/2009), the following products are included in Category 3 material (low risk):

- aquatic animals, and parts of such animals, except sea mammals, which did not show any signs of disease communicable to humans or animals
- animal by-products from aquatic animals originating from establishments or plants manufacturing products for human consumption

Article 14 mentions the possible uses of animal by-products classified in Category 3, which seem relevant for the cases evaluated by INNOAQUA:

- processed, except in the case of Category 3 material which has changed through decomposition or spoilage so as to present an unacceptable risk to public or animal health, through that product, and used:
  - for the manufacturing of feed for farmed animals other than fur animals
  - for the manufacturing of feed for fur
  - for the manufacturing of pet food
  - for the manufacturing of organic fertilisers or soil improvers,
- used for the production of raw petfood,
- composted or transformed into biogas;
- in the case of material originating from aquatic animals, ensiled, composted or transformed into biogas;
- used as a fuel for combustion with or without prior processing;
- used for the manufacture of derived products and placed on the market.

Derived products include cosmetic products (Directive 76/768/EEC), active implantable medical devices (Directive 90/385/EEC), medical devices (Directive 93/42/EEC), in vitro diagnostic medical devices (Directive 98/79/EC), veterinary medicinal products (Directive 2001/82/EC), and medicinal products (Directive 2001/83/EC). For each of the manufacturing uses and the production of raw petfood, the placing on the market must meet specific conditions that are further described in dedicated Articles.

Considering that the ABP in question is fish processing waste and that the purpose is to enable it to be processed through a hydrolyzation process to become a

derived product to be used as a food ingredient, it does not fit in any of the specific product types mentioned above. In this case, Article 36 may apply which covers the placing on the market of derived products, other than those already referred to. Such derived products not intended for use for the feeding to farmed animals or for application to land from which such animals are to be fed; nor for feeding to fur animals. Operators must ensure the control of risks to public and animal health by safe sourcing (Article 37); safe treatment where safe sourcing does not ensure sufficient control (Article 38) or verifying that the products are only used for safe end uses where safe treatment does not ensure sufficient control (Article 39).

Once it is established that fish processing waste can be legally reutilized to produce a derived product, the producer must comply with health and safety regulations regarding the process of production and the final product.

Processing fish waste as food

Commission Regulation (EU) No. 142/2011 lays down implementing measures for the public and animal health rules for ABP and derived products laid down in Regulation (EC) No. 1069/2009. Detailed provisions concern the disposal and use of ABP and derived products. Annex IV of the Commission Regulation sets out the General Processing Plants Requirements. Annex VIII, chapters I and II, specifies the requirements for collection, transport and identification.

Regulation (EC) No 852/2004 on the hygiene of foodstuffs sets general hygiene rules for food businesses across the EU. It requires food premises to be clean, well-maintained, and designed to support hygiene, including proper ventilation, lighting, drainage, and pest control. Facilities must allow easy cleaning, prevent contamination, and provide adequate space and temperature control.

Once the food is authorized to be placed on the EU market, in addition to the hygiene measures of the production process, food business operators must observe the requirements regarding the food. One of them is Commission Regulation (EC) No 2073/2005, which lays down the microbiological criteria for certain microorganisms and the implementing rules to be complied with by food business operators when implementing general and specific hygiene measures. For fishery products, the main concern is the limit of the levels of histamine.

Another important regulation is the Commission Regulation (EU) 2023/915, which establishes the

Figure 3 : Authorisation procedure for novel foods.

maximum levels for certain contaminants in food, such as cadmium, mercury, dioxins, and PCB (polychlorinated biphenyls) for fishery products.

In the case of the use of fish peptides as food supplements, this is also applicable.

General Food Law

The EU General Food Law, Regulation (EC) No. 178/2002, aims at ensuring a high level of protection of human health and consumer interest. The regulation applies to all stages of production, processing, and distribution of food. According to the definitions, food means “any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans”. Food shall be deemed to be unsafe if it is considered unfit for human consumption or injurious to health. The regulation establishes that the food and feed businesses are responsible for ensuring that food and feed satisfy all the requirements of food law. It also establishes an independent agency responsible for scientific advice and support, the European Food Safety Authority (EFSA).

In the EU, food supplements, such as bioactive peptides and amino acids derived from fish, are regulated as foods. Directive 2002/46/EC harmonizes the rules across EU Member States for the marketing of food supplements, aiming to protect consumer health and ensure fair trade within the internal market. It defines food supplements as concentrated sources of nutrients—such as vitamins and minerals—marketed in dose form (e.g., capsules, tablets, liquids). The Directive establishes a positive list of permitted vitamins and minerals and sets requirements for labelling, including the nutrient content, recommended daily intake, and warnings not to exceed the stated dose. It prohibits misleading claims, such as suggesting that supplements can prevent or cure diseases or that a balanced diet is insufficient. National authorities may require notification of new products and can restrict or ban supplements that pose health risks, informing the European Commission and other EU countries accordingly.

Novel Food

Under EU food law, any food that was significantly consumed within the European Union before 15 May 1997 is not subject to safety assessment or authorization before being marketed. However, Regulation (EU) 2015/2283—commonly known as the Novel Food Regulation—defines “novel foods” as those that were not consumed to a significant degree in the EU prior to that date. These novel foods must undergo a safety evaluation, receive authorization from the EFSA, and be included in the Union List of authorized novel foods before they can be placed on the EU market.

The regulation defines ten categories of novel foods, including those derived from new sources (e.g., insects, algae), produced using innovative processes (e.g., nanotechnology), or with altered molecular structures. For cases in which it is difficult to determine the status of novel foods, the Commission Implementing Regulation (EU) 2018/456 delineates the procedural steps for the consultation process.

The Novel Food Status Catalogue is a non-binding online database maintained by the European Commission. It provides guidance on whether specific foods or food ingredients are considered novel under the Novel Food Regulation. The Catalogue includes as an example "peptide extract from hydrolysed parts of Pacific cod (*Gadus macrocephalus*)" and indicates that it is considered a novel food. It can therefore be assumed that bioactive peptides derived from fish (such as salmon or sole) are subject to the Novel Food Regulation.

The latest version of the Union's list of novel foods includes only a fish peptide from *Sardinops sagax* (technical description included as Table 2) as a novel food ingredient. This ingredient is marketed as VALTYRON®, a clinically tested bioactive peptide for reducing pre and mild hypertension, obtained from sardine muscle protein hydrolysate.

Nutrition and Health claims in food products

General labelling provisions are contained in Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. Directive 2000/13/EC generally prohibits the use of information that would mislead the purchaser or attribute medicinal properties to food. Regulation 1924/2006 lays down specific provisions concerning the use of nutrition and health claims concerning foods to be delivered as such to the consumer. This Regulation should apply to all nutrition and health claims made in commercial communications, including inter alia generic advertising of food and promotional campaigns.

There are different procedures managed by the Commission for the various types of claims, with regard to their authorisation. A public EU Register of Nutrition and Health Claims lists all permitted nutrition claims and all authorised and non-authorised health claims, as a source of reference and so that full transparency for consumers and food business operators is ensured.

In conclusion, the reuse of fractions traditionally classified as waste faces regulatory hurdles that must be clarified to support the implementation of circular economy policies. Aquaculture effluents share similarities with manure from other farmed animals in terms of composition and potential risks. However, despite not posing a greater threat of disease transmission to humans, they are explicitly excluded from the definition of manure under the ABP legislation. As a result, some EU member states categorize these effluents as sludge, a classification that significantly limits their possible applications. This designation imposes stringent safety and monitoring requirements, which are justified for urban wastewater sludge but may be unnecessarily restrictive for RAS, where effluent composition and management differ.

Furthermore, treating aquaculture effluents as waste introduces different regulatory obstacles. The process for determining their end-of-waste status remains unclear, creating uncertainty about their potential reuse. A fundamental question is whether aquaculture effluents—traditionally regarded as waste—should still be treated as such when they become an integral component of systems like RAS or IMTA.

Clarifying regulatory pathways and aligning classifications with their actual environmental impact could enhance the sustainable management of aquaculture effluents while supporting circular economy principles. Addressing these regulatory ambiguities is required to facilitate their responsible use, unlocking their potential as a resource rather than a disposal challenge.

Fish processing waste falls under Category 3 ABP, meaning it is considered lower risk but still subject to strict regulatory controls before it can be repurposed for human food applications. However, there is uncertainty regarding how the process of reclassification will occur, as the specific pathways for approval and assessment are still evolving. Before any processing takes place, the waste must meet specific conditions, ensuring it is safe and suitable for further use.

Additionally, placing such products on the EU market requires formal authorization. This involves securing approval for inclusion in the Novel Food List, a classification intended for foods that were not widely consumed in the EU before May 1997. Inclusion in this list ensures that novel food products undergo rigorous safety assessments before reaching consumers.

Once fish processing waste is officially classified as a novel food, both its production process and final product must adhere to the specific requirements outlined in EU Regulations. These requirements encompass food safety protocols, hygiene standards, and any additional directives aimed at ensuring the product maintains its intended quality while meeting public health criteria.

Part 3. Algae grown in aquaculture effluents

Algae as Food

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

For the use of algae in human foods, the Novel Food Regulation is applicable. Specifically, Article 3 includes among its provisions: “Food consisting of, isolated from, or produced from microorganisms, fungi, or algae.” According to the available information on the EFSA´s database, the following algae used in the INNOAQUA project have been used for human consumption to a significant degree within the Union before 15 May 1997: *Gracilaria gracilis*, *Gracilaria verrucosa*, *Porphyra dioica*, *Porphyra umbilicalis*, *Chlorella sorokiriana* and *Ulva lactuca Linnaeus*. The microalgae *Nannochloropsis oculata* and *Phaeodactylum tricornutum* are not established as being used in the EU and therefore would require an authorization.

For food products, the EU has established maximum residue levels (MRLs) for pesticides (EC Regulation 396/2005) and heavy metals (EC Regulation 1881/2006). **It is essential to ensure that seaweed extracts do not contain pesticides or heavy**

metals above the levels set by the EU. The Rapid Alert System for Food and Feed (RASFF) often flags high levels of iodine in dried seaweed or seaweed salads, cadmium (typically found in seaweed used as feed materials), or unauthorized substances such as ethylene oxide or oils.

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. This recommendation does not specify regulatory thresholds for seaweed that Member States should adopt. It notes 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. The EU's regulatory framework currently lacks a clear differentiation between harmless organic arsenic and toxic inorganic arsenic levels in seaweed. This oversight poses a substantial challenge for producers of seaweed-based products and 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 and poses severe health concerns. The EFSA provides guidance on maximum allowable levels of inorganic arsenic in various food items, which indirectly influences the regulation of arsenic in seaweed-based products. This ambiguity poses a significant challenge for producers, making it difficult for them to guarantee that their products meet safety requirements.

Algae for food contact material (packaging)

Regulation 195/2004 is applicable for placing on the market materials and articles intended to come into contact directly or indirectly with food. Hence, in the case of the development of algae-based plastic resin for food contact packaging, the packaging material must comply with the general requirements of the aforementioned Regulation. According to the regulation, materials and articles must be manufactured according to good manufacturing practices to ensure they do not transfer their constituents to food in quantities that could:

- Endanger human health;
- Cause an unacceptable change in the food's composition; or
- Lead to a deterioration in the food's taste, smell, or texture.

Commission Regulation (EU) No 10/2011 establishes specific requirements for the manufacture and marketing of plastic materials and articles: (a) intended to come into contact with food; or (b) already in contact with food; or (c) which can reasonably be expected to come into contact with food. In addition to these regulations, all food contact materials must be manufactured in accordance with good manufacturing practices and national legislation.

In conclusion, the EU has established a comprehensive regulatory framework to ensure the safety, quality, and traceability of seaweed and algae-based products intended for human consumption and food contact applications. These regulations encompass food safety standards under the General Food Law and Novel Food Regulation, hygiene and manufacturing practices, and specific limits for contaminants such as pesticides, heavy metals, and arsenic.

While several algae species used in the INNOAQUA project are recognized as traditional foods within the EU, others require novel food authorization due to their limited history of consumption. Additionally, the regulatory landscape for food contact materials, including algae-based packaging, mandates strict compliance with safety and manufacturing standards to prevent contamination and preserve food integrity.

However, challenges remain—particularly in the differentiation between organic and inorganic arsenic—highlighting the need for clearer guidelines to support both producers and consumer safety.

Nagoya Protocol – EU Regulation 511/2014

All genetic resources, such as fish and algae, used in the development of new products must comply with EU Regulation 511/2014, which governs the use of genetic resources and traditional knowledge associated with them. This regulation serves as the European Union's implementation of the Nagoya Protocol, establishing a legal framework to ensure that such resources are accessed lawfully and used fairly, with equitable benefit-sharing. It imposes a due diligence obligation on users, including researchers, academic institutions, and companies, to verify that access complies with the laws of the

provider country and that necessary permits are in place.

The regulation applies specifically when genetic resources are used for research and development, and it includes responsibilities such as maintaining documentation, submitting due diligence declarations, and cooperating with national authorities during compliance checks. For EU-funded research projects, Regulation 511/2014 identifies two key checkpoints where due diligence must be demonstrated:

- Upon Receiving Research Funding:
  When a user receives financial support from the EU or a Member State for research involving genetic resources or associated traditional knowledge, they must submit a due diligence declaration through the DECLARE platform, confirming lawful access and the existence of appropriate benefit-sharing arrangements.
- At the Final Stage of Product Development:
  A second declaration is required once product development is complete and commercialization is imminent. This ensures compliance has been maintained throughout the R&D process.

These due diligence checkpoints are crucial for ensuring legal certainty, transparency, and adherence to international ABS obligations. Non-compliance can lead to sanctions, withdrawal of funding, or barriers to market access for the resulting products.

Part 4. Conclusion and outlook

This legal analysis has highlighted the significant potential of RAS and IMTA to transform aquaculture waste streams into valuable resources, including food ingredients, nutraceuticals, and food contact materials. However, the realization of this potential is currently hindered by several regulatory bottlenecks and uncertainties and two critical legal challenges have emerged from this analysis

Uncertainty within a complex regulatory framework

The regulatory landscape governing aquaculture, waste, food safety, and novel foods in the EU is fragmented and primarily designed for traditional, linear production models. The innovative nature of INNOAQUA's circular systems—particularly the reuse of aquaculture effluents and fish by-products—does not align neatly with existing classifications and procedures. This misalignment creates uncertainty for operators and regulators alike, particularly regarding the classification of aquaculture effluents as waste (by-products, or end-of-waste materials) and animal by-products and the eligibility of fish processing waste for transformation into food ingredients under the Animal By-Products and Novel Food Regulations.

Ambiguity in applying EU "End-of-Waste" criteria

The application of the EU's "end-of-waste" criteria remains inconsistent across Member States, with varying interpretations and decision-making authorities. This lack of harmonization complicates the legal status of materials reused within RAS and IMTA systems, potentially impeding their marketability and cross-border movement. Furthermore, the absence of clear guidance on the lawful use of such materials under environmental and food safety legislation adds to the regulatory burden.

These challenges pose a risk to the scalability and commercial viability of INNOAQUA's innovations. Without regulatory clarity, producers may face delays, increased compliance costs, or even legal barriers to market entry.

To address these risks, a mitigation plan will be developed by INNOAQUA that will:

- Propose legal interpretations and strategies to navigate current regulatory ambiguities.
- Identify opportunities for regulatory engagement and harmonization at the EU and Member State levels.
- Recommend best practices for compliance and risk management tailored to INNOAQUA's value chains.
- Explore pathways for recognition of end-of-waste status and novel food authorization for key ingredients.

The mitigation plan will be informed by ongoing stakeholder consultations, technical developments within the project, and evolving EU policy initiatives related to sustainable aquaculture and the circular bioeconomy.

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Annex II: Other references

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