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Authors: Mohamed Soula, Richard Newton, Carlos Ruiz, Leticia Regueiro, Diego Mendez, Martiña Ferreira, David Little, Johan Johansen

WP 3 – Policy and markets

Task 3.1 Review of regulatory and legislative issues for the circular economy in aquaculture

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GLOSSARY OF ACRONYMS

Acronym	Definition
ABP	Animal by-product
BSE	Bovine spongiform encephalopathy
CE	Circular Economy
CCoP	Code of Practices
EEA	European Economic Area
EC	European Commission
EQSD	Environmental Quality Standards Directive
EU	European Union
FAO	Food and Agriculture Organisation
FF	Former Foodstuffs
GES	Good Environmental Status
IFFO	The Marine Ingredients Organisation
MS	Member State
MSFD	Marine Strategy Framework Directive
PAPs	Processed Animal Proteins
TSE	Transmissible spongiform encephalopathy
WFD	Waste Framework Directive

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Table of contents

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Highlights

- First systematic revision on circular economy legislation of aquaculture, with a focus on EU.
- Circular economy legislation in some non EU countries.
- SWOT analysis of the full implementation of circular economy in aquaculture, within the EU/EEA.
- GAIN partners' perception concerning the implementation of circular economy processes in the aquaculture sector in different EU countries.

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1. Executive summary

GAIN is a collaborative project funded by the European Union (EU) designed to support the ecological intensification of aquaculture in the EU and the European Economic Area (EEA), with the dual objectives of increasing production and competitiveness of the industry, while ensuring sustainability and compliance with EU regulations on food safety and environment. GAIN, as a whole, aims to contribute to transform EU aquaculture, still a largely lineal economic sector, through the implementation of circular economy principles and concepts. This involves the following main lines of action: (i) creation of value from finfish and shellfish by-products and side streams to other productive sectors and vice versa, strengthening the use of by-products from other sectors into EU aquaculture; (ii) demonstration of the performance and contribution of the project technical advances to the eco-intensification of EU aquaculture; (iii) dissemination and exploitation of project outcomes, providing guidelines and recommendations to farmers, managers and policy-makers for sustainable ecological and economic intensification, and (iv) addressing current regulatory barriers to the circular economy applied to aquatic production, through integrated policy formulation.

This last aspect is crucial. Whereas the EU regulatory framework guarantees highest standards of food safety and traceability worldwide, at the same time some regulations may pose constraints inhibiting the full implementation of circular economy in the aquaculture sector. GAIN envisages the analysis of the EU legislation body to identify opportunities of adapting specific policies, in order to enable the integration of aquaculture eco-intensification into circular economy.

This document aims to provide an overall picture of the status of the implementation of processes related to circular economy in EU aquaculture, under current regulatory framework regarding aspects of health and safety, commercialisation and environmental protection. Opportunities for the valorisation of inputs from other processes to aquaculture and vice versa are described, both within and out of the scope of extant regulations. In order to support these proposals, UE legislation is compared to that of third countries where aquaculture is an important contributor to fish products availability.

Full structure of EU legislation regarding GAIN eco-intensification topics and its linkages to other guidelines on health issues, such as: i) Codex Alimentarius; ii) best practice such as FAO Code of Practices (CoP) for fisheries and aquaculture; iii)other important standards, e.g. IFFO RS for responsible marine ingredient supplies; have been examined and recommendations made for policy changes that may better allow for eco-intensification to progress. Finally, proposals are made for the revision of legislation in order to implement circular economy in aquatic production sectors based on gaps and opportunities detected on the state of art.

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2. Introduction

EU28 aquaculture is divided into three main sectors: marine fish, freshwater fish and shellfish production, being the first of them the most profitable generating 2,731 M € in 2016 (STECF, 2018). Main species produced in marine sector in EU28 in terms of economic value are Atlantic salmon, oysters, seabream, seabass and trout, whereas according to weight production the Mediterranean mussels dominate the market. Regarding shellfish, France is the main producer of oysters, meaning 89% of total EU28 production, whereas Spain contributes to the 43% of the Mediterranean mussel production. Looking at freshwater production the market is clearly dominated by rainbow trout with 48% of the volume and 43% of the value, being Italy, France and Denmark the main producers (EUROSTAT, 2018).

In 2016, the global aquaculture production reached 110.2 million tonnes including plant production (FAO, 2018), providing 46.8% of the global supply of marine and aquatic food products. 590 aquatic species are cultivated throughout the world with diverse systems and facilities, with different degrees of inputs and technological complexity, using fresh, brackish and marine water. Aquaculture is still one of the faster growing food production sectors, and the average annual growth was 5.8% during the period 2000–2016. Nevertheless, this rise is very heterogenic and Europe is the region with the lowest growth rate, 2.2 % per year (FAO, 2018). Given the steady growth of fish consumption in developing regions and low-income food-deficit countries, together with the stagnation of wild captures since mid 1990s, it is expected that aquaculture will be the prime source of seafood by 2030. This need for growth also urges the reinforcement of the sustainability of aquaculture processes worldwide, particularly concerning the consumption of raw materials and the impact over water bodies due to the use of chemicals and the discharge of N and P. Aquaculture, like other economic activities, uses and transforms resources into products with economic and social value. Therefore, it is essential to continue making aquaculture production more sustainable, efficient and profitable.

EU aquaculture is a transversal subject which is tackled by many policies and bodies of regulation regarding water, environmental protection, residues, marine and coastal management, fisheries, animal health or trade, but which is devoid of specific regulations and harmonisation among MS.

The importance of the sustainable development of the EU aquaculture was recognised by the European Commission (EC) in the early 2000s, when the communication COM/2002/0511 final, "Strategy for the Sustainable Development of European Aquaculture" (European Commission, 2002) was released. This document provided a vision to maintain the competitiveness, productivity and durability of the aquaculture sector, at the same time guaranteeing coherence with the strategies for environmental protection. Some of the issues identified as barriers by this analysis were the demand of fishmeal and fish oil and competence with land farming, animal health and welfare, competition for space, potential risk of eutrophication and the lack of specific EU legislation for aquaculture. Technology, rational use of natural resources, governance and socio-economics would be integrated to achieve that goal.

This strategy set out policy directions which contributed to the environmental sustainability, safety and quality of EU aquaculture. Nevertheless, production stagnated over the following years, in

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contrast with the high growth rate in the rest of the world. Communication COM/2009/0162 final ("A new impetus for the Strategy for the Sustainable Development of European Aquaculture", European Commission, 2009) reported that challenges for EU aquaculture continued to be those previously identified in 2002, plus commercial and financial pressures and the stringent EU rules governing aquaculture, particularly regarding environmental protection. Whereas environmental protection should be the bedrock of the development of EU aquaculture, this document highlighted the importance of strengthening the governance to create a level-playing field at EU level and facilitate the integration of regulations relevant to aquaculture. Cooperation among public authorities and stakeholders at European, national and local level was likewise considered crucial in order to lead the development potential of aquaculture in the EU.

Looking for a more active implementation of measures to boost the aquaculture sector, the Commission presented the common priorities and general objectives at EU level (COM 2013(0229) final, European Commission, 2013), identifying four priority areas: administrative burdens, access to space and water, competitiveness and competitive advantages due to high quality, health and environmental standards. This document aimed to assist MSs in defining their own national targets taking account of their relative starting positions, national circumstances and institutional arrangements, through the setup of multiannual plans to promote aquaculture.

It is remarkable that, despite the time lapse since the first strategy document was released, the main issues hampering the sustainable development and competitiveness of EU aquaculture still remain unresolved. In order to grow sustainably, EU aquaculture must be able to simultaneously intensify its productivity and its environmental performance, and mitigate the competition for resources such as fish meal and fish oil or suitable locations. This is a transdisciplinary challenge that involves research and technical innovation, mitigation of social constraints and, specially, the development of *ad hoc* policies removing regulatory barriers to the eco-intensification of EU aquaculture.

GAIN (Green Aquaculture Intensification in Europe) aims to tackle these aspects by implementing principles of circular economy into aquaculture processes. Circular economy is expected to contribute to the long-term sustainability and competitiveness by reducing waste and use of resources, saving costs and developing innovative and cost-efficient business. In December 2015, the EC launched the Circular Economy Action Plan (COM(2015) 614 final), and its complete execution was reported in March 2019 (COM(2019) 190 final). No specific actions on aquaculture have been included in these plans, likely because of its low environmental impact compared to priority sectors such as electronics, plastics, textiles or mobility. Still, some of the envisaged measures in the Circular Economy Action Plan are clearly relevant to aquaculture, particularly those related to water reuse or secondary raw materials.

For a proper and comprehensive development of the circular economy, a detailed analysis of the legal, technical and practical implications for the reintegration of recycled materials into the productive economy is required. Legal aspects are of particular importance since they are at the interface of regulations dealing with different subjects: products, chemicals, waste, or water. Hence, new pieces of legislation must be created to deal with the creation of circular economy processes involving waste and by-products in sectors such as food, feed, agriculture or livestock production. In this document, extant regulations on these and other relevant topics are revised on the scope of GAIN objectives and activities, and turned into analysis and recommendations for the aquaculture sector to address challenges to CE implementation and to support policy development in this area.

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3. Circular economy and connection to GAIN concept

3.1. Concept and origin

The rapid growth of the world population and the limitations of the traditional economic linear model to ensure all necessary resources for the next generations, determined the interest for a design of a new model of economic organization that would provide the necessary goods and services for maintaining and improving living standards for more people without the increasing of raw materials consumption and the quantity of waste generated. CE seems to be the adequate alternative model to remediate the negative effects caused by the linear model and enhance the stability of the economies and the integrity of natural ecosystems that are essential for humanity's survival (Ghisellini et al., 2016).

Circular economy as defined by Ellen MacArthur Foundation (2012) is “an industrial system that is restorative or regenerative by intention and design. It replaces the end-of-life concept with restoration, shifts towards the use of renewable energy, eliminates the use of toxic chemicals, which impair reuse, and aims for the elimination of waste through the superior design of materials, products, systems, and, within this, business models”.

CE is not only an approach to more appropriate waste management as often misinterpreted (Ghisellini et al., 2016), but is a solid concept to optimise process and product to reduce waste generation. This concept is mainly related to “closing the loop” of product lifecycles throughout the 3R concept: Reduce, Recycle, and Reuse of material and by-products in the aim to reach a sustainable development and to bring benefits for both the economic and environmental aspects (Kirchherr et al., 2017). Recently a new model evolving from 3R to 9R was defined. In this 9R model the lowest level is “recovery” and describes the linear economy, i.e. the waste is burned and energy is recovered from it. The highest level in this 9R model is ‘refuse’ and describes the “perfect” circular economy where the products become redundant or are replaced by a completely different and sustainable product. However, this is not always possible and the use of non-renewable sources should be lower than the creation rate of renewable substitutes in the transitional stage of CE implementation.

The strategies included in the 9R model are shown in Figure 1 (Kirchherr et al., 2017).

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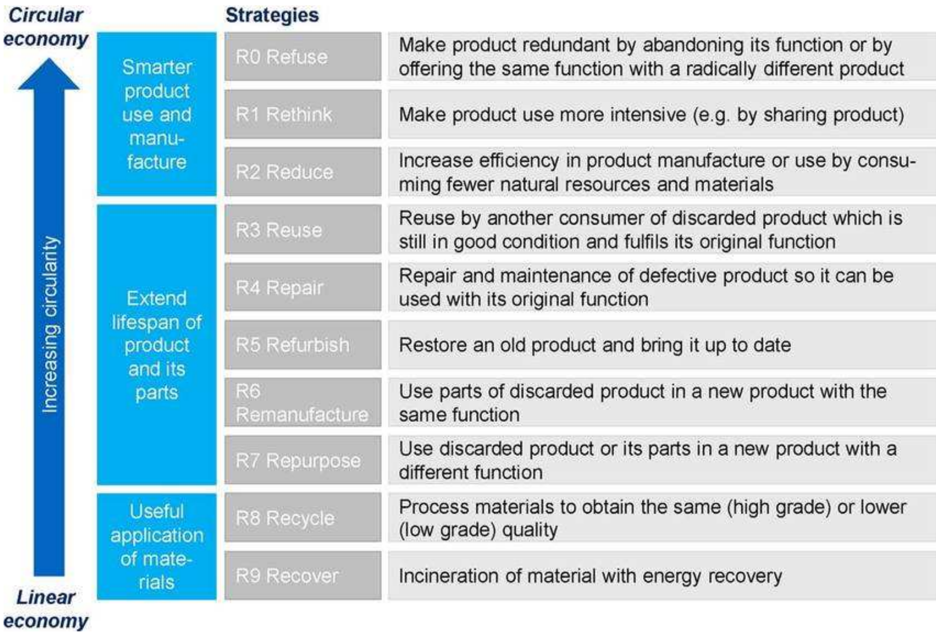

Figure 1. Comparative scheme between linear and circular economy (Kirchherr et al., 2017).

There is no clear evidence of a single origin, originator or date of the CE concept (Winans et al., 2017; Wautelet, 2018). However, many researchers could be mentioned as a precursor of this concept such as Pearce and Turner (Wautelet, 2018; Geisendorf and Pietrulla, 2018), John Lyle, William McDonough, the German chemist Michael Braungart, and the architect and economist, Walter Stahel (Winans et al., 2017). Since 1970 and led by this small number of academics, practical applications to modern economic systems and industrial processes have gained momentum. Also, according to Ellen MacArthur Foundation (2012), recent theories such as performance economy, cradle to cradle, biomimicry and blue economy have contributed to refine and develop the concept of CE giving continuity to several works based in ecological and environmental economics and in industrial ecology.

Therefore, the main strategies to take into account the 9R-principles can be summarized as follows as: trying to minimize inputs from raw materials (mainly non-renewable ones) and to maximize outputs from waste or by-products; maintaining the resource value of a product as long as possible during its life cycle; rethinking the process and reintegrating the discard materials (when they reach their end-of-life) for other applications in the same or new systems. Obviously, the CE principles must be applied at all levels in the society, i.e. not only manufacturers, but also consumers, to have success in their application.

Respect to the application of CE concept, China was the first country popularizing this concept in the 1990s in response to economic growth and natural resource limitations. Also, China was the first country to integrate the CE concept in its national strategy in 2005. In Europe, the implementation of CE primarily emerged through waste policies, particularly the Waste Disposal Act in Germany in the early 1976 and EU Waste Directive 2008/98/EC, which have been promoting mainly the recycling principle of a CE. In December 2015, the European Commission launched the Circular Economy Action Plan, which establishes a concrete and ambitious programme of action with measures that

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will help stimulate EU’s transition towards a circular economy, boost global competitiveness, foster sustainable economic growth and generate new jobs.

The European Commission has taken the lead role in the EU regarding CE strategy since 2014. Some MSs picked up EU recommendations and they started to implement them through roadmaps, as is the case of Finland, France, Slovenia, and the Netherlands. Other countries, such as Italy set the stage for implementing a roadmap and in Spain some regions, such as Galicia and País Vasco, recently presented their own strategies. ,. Germany has adopted a CE definition close to resource efficiency, not taking into account other principles of CE definition. This overview indicates that, each country is trying to promote its own strategy, depending on its particular interests. For instance, Germany strategy is focused on raw materials availability and material flows, which are very relevant for its heavy industrialized economy. On the other hand, the the Netherlands promote new business models based on CE.. The same happens with other MSs, such as France and Italy.

Therefore, the EU and MS policies respect to CE should be implemented in a coordinated way, taking into account each particular case, but always considering the global context. To this respect, such coordination will be challenging in the current political context, and policymakers should play this vital role. They have the obligation to promote the transition to CE considering Europe as an overall system and focusing the measures at environmental, economic and social level from the better approach for all MSs. It is necessary to consider the CE application as a new possibility to kickstart new business models away from extraction and consumption since the future must be circular or it will not be any future

3.2. Opportunities for the development and implementation of circular processes in aquaculture

The sustainability of an aquaculture process is determined by how its inputs and outputs are managed. Fish aquaculture, the most important sector in the EU, demands high quantities of feed and hence of valuable feed ingredients both of marine and terrestrial origin, thus having similar footprints as farming of terrestrial animals. Meanwhile, aquaculture activities generate a diversity of waste that depends on the cultured species, the productive system used, the degree of intensity of the activity and the production capacity.

Despite the Circular Economy Action Plan encourages the reuse of industrial by-products and side-streams, the full implementation of the principles of CE in the EU is limited by the current legislation and, to some extent, by the social acceptance of processes in which side-streams are re-used, particularly in the agri-food sector. One of the keys is developing the analysis of the legal, technical and practical issues in order to pave the way for the transformation of waste into secondary raw materials and their fed back into the productive economy. GAIN provides scientific and technical support in this area, as well as a revision of the applicable regulation and recommendations to address the challenges to the valorisation of by-products and side-streams.

Many residues from aquaculture activities can be injected back in productive processes as secondary raw materials. These outputs can be classified as side-streams, i.e. managed as waste with no further use, and by-products which can be subsequently and legally used after a processing within normal

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industrial practice. Mortalities, sludge and wastewater are the most important side-streams, and GAIN designs innovative approaches for their recovery and value addition. On the other side, "by-product" refers mainly to residues from fish processing –viscera, heads, spines, trimmimgs, etc., and shells from shellfish culture and processing. Generally, aquaculture residues can be classified in the following categories:

- **Solid waste.** The two major sources of solid wastes in aquaculture are faeces and uneaten feed. Solid wastes may be discharged to the water column as particulate organic matter (POM) or dissolved organic matter (DOM), being incorporated to aquatic food webs and eventually transformed into inorganic compounds. In offshore systems, they also may deposit directly on the seabed or water basin, contributing to the BOD of sediments due to their high C content; in land-based tanks solid wastes may deposit as sludge, being managed through effluent treatment systems. The amount of solid wastes varies with culture systems and densities, quantities of feed supplied, and effectiveness of feeding technique.
- **Wastewater.** Wastewater is another output from aquaculture which must also be considered. Wastewater contains both particulate and dissolved organic and inorganic matter. Nitrogen and phosphorous released by aquaculture animals are a concerning waste due to their potential eutrophication effect, particularly if they are discharged to contained water bodies such as lagoons, rivers or estuaries.
- **Residues of animal origin.** Mortalities, i.e. dead animals because of diseases or other events, and residues from the processing of fish or bivalves –viscera, heads, spines, skin, trimmings, shells- are outputs of high interest, since they show a range of valorisation options, particularly fish residues being a source of valuable proteins and oils.
- **Other.** Finally, other types of waste may be assimilated to urban or domestic waste: plastic sacks and bags, cardboard, etc.

GAIN has identified the most interesting possibilities to reintroduce these different types of waste into productive economy: the innovative processes being investigated are summarized in D2.1, D2.2, D2,3, D2.4.Whereas reinjection into aquaculture production schemes is priority, the valorisation of aquaculture waste and by-products in other productive sectors have also been considered. Accordingly, part of the objectives of GAIN is directly related to the development of technically feasible solutions for the implementation of CE processes, but also to the analysis and the overcoming of regulatory barriers to CE through the revision and the improvement of current legislation. The impact of these outcomes will be further assessed both in ecological and economic terms, and these performance assessments will be properly communicated to citizens, policy-makers and markets. Finally, these outputs will be translated into exploitable information (i.e. guidelines) towards the socially and economically effective eco-intensification of EU aquaculture.

Whereas aquaculture is not explicitly considered a priority area in the CE Action Plan as other productive sectors such as plastics, food or construction, aquaculture seems to be an adequate activity to implement the 9R concept previously described and demonstrate its feasibility. Some examples are:

- **Rethink** the processes. Switching from open to close cages and from raceway to RAS would allow the concentration and recovery of wastes from large aquaculture industries, i.e. salmon, trout, seabass/seabream farming; furthermore small-scale aquaculture could switch towards

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Integrated Multi-Trophic Aquaculture (IMTA)/Aquaponics approaches, including the farming of low trophic level products.

– **Recover** energy. By-products coming from aquaculture and identified as category 2 (as will be explained in next sections) could be used together with the aquaculture sludge to produce biogas, a renewable energy that in the circular economy concept would be use in the own plant.
– **Recycling** aquaculture by-products into feed ingredients such as fishmeal and fish oil whenever possible is a higher-value application than the production of biogas.
– **Repurpose** is a concept that would be applied in the case of protein hydrolysates, that is using the traditional inputs for fishmeal and increasing their added value throughout enzymatic hydrolysis making them bioactive products or additives.
– The final example is related with the **Reduce** concept: in GAIN we are developing new modelling tools, based on real time detection of environmental and animal variables for the implementation of precision aquaculture: intelligent systems for feeding and the new feed with higher digestibility will allow reduce the feed waste and at the same time decrease the environmental impact of the farms.

Considering the main resource inputs and side stream or waste outputs of aquaculture production, the priority aspects to consider when designing and assessing circular processes (considering both reintroduction into aquaculture production and transference to other productive processes) are related to:

- the design and manufacturing of fish feed,
- the valorisation of aquaculture by-products and
- the uses of water and sludge.

3.2.1. Fish feed design and manufacturing

The manufacturing of aquaculture feeds requires large quantities of fish oil, fishmeal and soy, which puts pressure on marine and forest ecosystems. In fact, nearly 20 million tons of raw materials are used annually for the production of fishmeal and fish oil, of which around 14 million tons come from whole fish (Jackson and Newton, 2016) (Table 1). The FAO forecast on aquaculture growth by 2030 implies an increase in the need for fishmeal and fish oil (FAO, 2018) which could contribute to overfishing, even though advances on fish nutrition and feed development have reduced dietary fishmeal and fish oil to a minimum in shrimp and fish feed, and both ingredients are being used more strategically and efficiently, thus reducing the "fish in: fish out" ratio. On the other hand, terrestrial ingredients, particularly soy, pose a pressure over terrestrial ecosystems due to the need of croplands (WWF, 2012; Ytrestøyl et al., 2015).

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Table 1. Fishmeal production and raw material sources used (000 t) (Jackson and Newton, 2016).

Region	**Whole fish**	**By-product from wild capture**	**By-product from aquaculture**	**Total raw material used**
Europe	1,502	1,165	331	2,998
Asia (exc China)	2,577	827	851	4,255
China	1,251	168	367	1,787
Middle East	188	32	19	240
CIS	260	103	-	364
Africa	650	222	6	877
S. America	6,810	768	331	7,909
N. America	730	427	31	1,188
Oceania	11	42	13	66
Total	**13,980**	**3,754**	**1,949**	**19,683**

The availability of fish meal and fish oil for the manufacturing of aquaculture feeds not only depends on the sustainable exploitation of wild captures which constitute the main source of these raw materials, but also on environmental and meteorological phenomena such as El Niño which cause dramatic fluctuations of fish stocks. Moreover, the amount of these captures addressed to human consumption is increasing; since the volume of wild catches has stabilized since the 1990s, it is expected that fishmeal and fish oil from fisheries will decrease in the next years.

Exploring alternative sources of fishmeal and fish oil is therefore crucial for an aquaculture sector which grows every year. An increasing proportion of fish for human consumption reaches the final consumer processed, which renders more by-products available for the production of fishmeal and fish oil. The downsides are the current limitations in the logistics and valorisation chains to use this resource, as well as the large amount of fish by-products still generated in households and restaurants which cannot be used. Industry must implement valorisation schemes to take advantage of this potential.

Therefore, by-products from by catch and aquaculture processing begin to be a viable option to reduce the pressure on wild source. The use of this raw material reached 5.7 million tons in 2014 representing 28% of whole raw material used for fish meal production. FAO predicts that this quantity will increase to 49% by 2022, and that 95 % of this increase will be due to the use of by-products (FAO, 2018). Currently, aquaculture by-products represent 34% of total fish by-products used to produce fishmeal and it is expected to represent an even higher percentage if some barrier respect to logistic, economic efficiency and legislation could be optimized. Finally, the increase of their use as future aquaculture feed fits with circular economy principles.

Regarding alternative feed ingredients and feed design, GAIN pays particular attention to the valorisation of by-products of aquaculture activities, exploring technical (e.g. fish hydrolysed proteins as described in D2.2) and legal possibilities and assessing those regulatory aspects currently limiting the use of these resources, e.g. the authorised uses of Category 2 by-products. Also, the production of emerging aquafeed ingredients such as microalgae and macroalgae biomass in aquaculture wastewater is foreseen.

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3.2.2. Aquaculture finfish by-products

From the legal point of view, the term aquaculture fish by-product refers, *sensu lato*, to remnants of fish processing, after the edible parts have been removed, and fish that have died because of a disease or any other reason different from slaughtering for human consumption. The classification and legal uses of both types of by-products are different. Whereas the former are classified as Category 3 by-products and can be used as feed ingredients (among a range of less added-value applications), the latter are considered Category 2, and their use as animal feed is restricted to fur animals. Regulation (EC) No. 1069/2009 (European Union, 2009) details the categories of by-products and their respective allowed treatment and uses (see below).

Category 3 aquaculture fish by-products are already considered a highly valuable resource and, as mentioned above, they are currently exploited as a source of fishmeal and fish oil. Following the principle of the food recovery hierarchy for fish by-products (Figure 2), as proposed by Iñarra et al. (2018) and Stevens et al. (2018), the most valuable and thus desirable uses of these by-products are those maintaining food grade, either maximising the edible yield of fish or processing by-products into food supplements, nutraceuticals, etc. The immediately lower level of valorisation, and the best fitted to the implementation of CE in aquaculture, is fish feed. The by-product valorisation scheme is well consolidated in Norway, where 90% of farmed salmon by-products is used, but for salmon from other countries and Mediterranean aquaculture species it may still be underdeveloped. It has been estimated that a proper valorisation of Scottish farmed salmon by-products could increase the revenues of this secondary raw material, in 803%, and the food production of salmon industry in 61% (Stevens et al., 2018).

GAIN explores processing methods to obtain different products (protein hydrolysates, oils, collagen, gelatine, mineral-rich fractions) from fish by-products, aiming at designing a valorisation scheme which provides high environmental and economic benefits.

Another great challenge is the valorisation of Category 2 by-products to high-value applications. Regulation EC No. 1069/2009 only allows some technical uses such as the manufacturing of cosmetics, medical devices, veterinary and medicine products, in vitro diagnostic products or feed for zoo, circus, pets or fur animals, provided these by-products do not pose unacceptable risks for human or animal health; furthermore, collection and manufacturing of these by-products are subjected to legislation. Otherwise, Category 2 by-products must be disposed of as waste after incineration or co-incineration, disposed of in a landfill, or used for the manufacturing of organic fertilisers, to produce biogas or as fuel.

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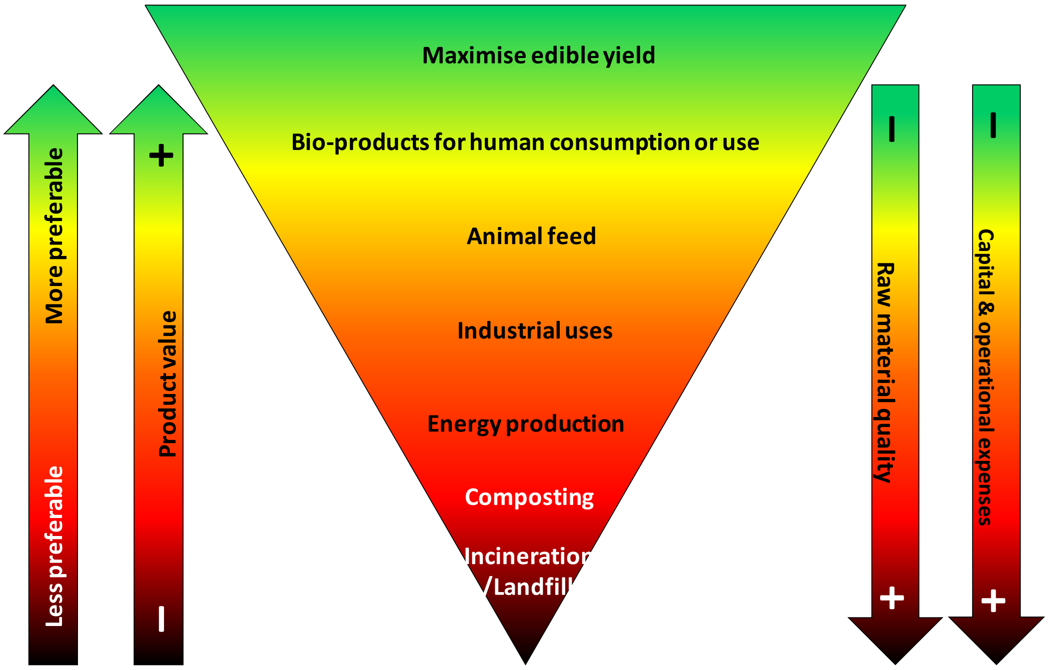

Figure 2. Prioritisation of valorisation process for fish by-products according to the food recovery hierarchy. Adapted from Iñarra et al. (2018) and Stevens et al. (2018).

3.2.3. Reuse of water

The implementation of valorisation processes for used aquaculture water is obviously only possible where water is confined, i.e. in land-based aquaculture in tanks or ponds. In these conditions, culture water may contain POM, DOM and inorganic nitrogen and phosphorous from the excretions and faeces of reared animals and from uneaten feed. Opportunities for reuse may focus on the water itself, once treated to remove the aforementioned contaminants, or in the organic and inorganic matter which can be regarded as a source of nutrients for further uses.

Probably, recirculating aquaculture systems (RAS) are the best example to valorise used water in aquaculture facilities. In RAS, rearing water undergoes treatment processes to remove solid and dissolved nutrients and is reintroduced back into culture tanks. Only a small fraction –ca. 10%- of water is exchanged daily, to avoid the build up of nitrate as the final product of the ammonium nitrification process. Another residue from RAS is sludge from the removed particulate matter, which may be disposed of as waste or valorised elsewhere, e.g. as biogas, co-incineration, or fertiliser. RAS may operate both in marine water and in freshwater.

Apart from RAS, the reuse of aquaculture effluents is probably insignificant in the EU and discharge previous treatment, if needed, is the predominant fate. Nevertheless, technological development and legislation may enable a range of solutions for valorisation. Scarcity of freshwater is a growing concern in some parts of the EU and the CE Action Plan identifies the reuse of treated wastewater in safe and cost-effective conditions as a means of increasing water supply with no pressure over water resources. Moreover, the use of freshwater aquaculture effluents in irrigation would also contribute to the recycling of nutrients, thus alleviating the need for solid fertilisers. The EC is expected to promote the use of treated wastewater, as part of the implementation of the Water Framework

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Directive (Directive 2000/60/EC, European Community, 2000) and the development of legislation on minimum quality requirements for reused water.

Other options for the valorisation of aquaculture effluents rely on the recycling of nutrients and the restoration of water quality in the culture setup itself, with the objective of increasing the productivity of the system or decreasing exploitation costs related e.g. with water treatment or feed. IMTA consists on the simultaneous rearing of organisms of different trophic levels, where some species uptake nutrients from the residues of others. The efficiency of IMTA in terms of nutrient recycling and their effective contribution to intensify productivity is only realistic in land-based aquaculture, where there are no nutrient losses due to dispersion or solution. Nevertheless, EU regulations on animal feeding may pose strong constraints to the full implementation of this scheme. Likewise, aquaponics consists on the hydroponic culture of plants sourcing nutrients from fish culture. Aquaponic culture has been validated both in freshwater and in marine water aquaculture, using halophiles such as *Salicornia* spp. GAIN develops IMTA- and aquaponics-based processes to exploit dissolved nutrients in effluents through the culture of macroalgae, microalgae and terrestrial plants, and proposes different applications for the produced biomass according to the regulatory framework in force.

Finally, bioflocs is a methodology broadly used in some countries for the culture of omnivorous fish and crustacean species which tolerate high concentrations of particulate matter, such as tilapia and shrimp. Wastewater is enriched with a source of organic carbon to promote the growth of heterotrophic bacteria, which together with microalgae also uptake dissolved nitrogen and phosphorous. Zooplankton thrives on this microbial community, and the whole planktonic assemblage is introduced in the rearing tanks as a supplementary feed. Although bioflocs is common in developing countries, typically used in warm water species, and no strict control is done neither on the process, nor in the quality control of water, this approach could be implemented in EU aquaculture, e.g. for carps. Since bioflocs involves an effective recycling of fish waste not to animals intended for human consumption but for live feed for fish, this approach could be lawful according to regulations on feed hygiene (see Section 4.4).

3.2.4. Valorisation of sludge

Solid waste from fish and other organisms is rich in organic matter and it may build up to high amounts. In land-based aquaculture, sludge is removed from tanks, separated from wastewater by filtration or decantation and mostly disposed of. Different valorisation methods may be applied: in situ co-incineration to generate heat, biogas production or as raw material for the manufacturing of fertilisers, the latter being the approach selected for evaluation within GAIN. The use of sludge for the direct feeding of filter- or deposit-feeders in IMTA setups is currently banned, but this material could be used in biofloc setups or as a source of nutrients for the production of microalgae or macroalgae, as an intermediate step between fish and invertebrate (bivalves, sea urchins, polychaetes, rotifers) culture.

3.2.5. Bivalve shells

Shells are a type of aquaculture ABPs, but their composition and physical properties make them very

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different from finfish by-products. Shells are a locally abundant residue in EU, e.g. from mussel or oyster farming in Galicia (Spain) and France respectively, up to thousand tons per year. Legislation classifies bivalve shells either as animal by-products (ABPs) if soft tissue remnants are attached, or as waste if shells are cleaned from meat. EU Regulation No. 1069/2009 on ABPs foresees the use of shells as fertilisers after adequate treatment. Furthermore, their content of calcium carbonate and their crystalline structure has raised interest on their potential applications shells as construction material, feed supplement, agricultural agent, etc.; a detailed review can be found in Morris et al. (2018).

In contrast, valorisation options of bivalve shells in circular processes in aquaculture may be more restricted, and they could deal with their buffering capacity and the maintenance of pH and alkalinity levels in aquaculture facilities, being used e.g. as packaging material in biofilters. This approach is part of a specific technical task of GAIN and described in (Soula M. et al., 2019).

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4. Legal aspects of the valorisation of aquaculture outputs

4.1. Waste vs. by-product

The Directive 2008/98/EC (Waste Framework Directive, hereinafter WFD, European Union, 2008) is the key legislative document on waste at the EU level. It is the revision of the former Directive 2006/12/EC (European Community, 2006), which codified previous legal texts on waste, and it has been amended in several occasions, being Directive (EU) 2018/851 (European Union, 2018) the current in force version. Being a directive, the WFD is transposed into the national legislation of the MSs by means of separate legal acts. The scope of the directive is determined by the definition of 'waste' in Article 3 as: 'any substance or object which the holder discards or intends or is required to discard'.

EU approach to waste management seeks turning waste into a resource. It is based on the "waste hierarchy", which sets priorities to shape waste policies and operational management: prevention, (preparing for) reuse, recycling, recovery and, as the least preferred option, disposal (which includes landfilling and incineration without energy recovery). Thus, wastes generated by the aquaculture sector and classified as mentioned above could be considered as a new source in a circular economy process.

The main purpose of WFD is setting down the definitions and the basic principles that may rule waste management in the EU, i.e. waste hierarchy, the protection of human health and the environment, as well as establishing responsibilities, management plans or inspections. It must be kept in mind that WFD coexists with previous and further regulations regarding different types of industrial and household origin.

In order to provide "a common terminology throughout the Community with the purpose to improve the efficiency of waste management activities", the Commission published the European Waste Catalogue (Commission Decision 94/3/EC; European Community, 1994). It was further developed into the European List of Waste (LoW) by Commission Decision 2000/532/EC (European Community, 2000). The LoW is the key document for classification of waste. A consolidated version of the LoW has existed since 2000 and has been revised by Commission Decision 2014/955/EU (European Union, 2014), in order to adapt it to scientific progress and align it with developments in chemicals legislation. In this list, aquaculture waste is classified within wastes from agriculture, horticulture, forestry, hunting and fishing, food preparation and processing (code 02). Aquaculture waste could be classified as type 02.01 (waste from aquaculture) and 02.02 (waste from preparation and processing) and identified as sludges from washing and cleaning and from on-site effluent treatment, animal-tissue waste, waste plastics (except packaging), animal faeces, urine and manure (including spoiled straw), or effluents. All these types of wastes are mainly absolute non-hazardous entries (ANH), which means that they cannot be allocated to hazardous entries and are non-hazardous without any further assessment.

Following the waste hierarchy principle that pursues the decrease of waste production and establishing management principles aimed at maximizing reuse and recycling, it was clear that the

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definition of waste set down in the Directive 2006/12/EC was too broad and thus could refer to materials that are not the main objective of a productive process, but which should not be necessary treated as waste. In 2007, a Communication (COM 2007/59; European Commission, 2007) was published to explain the definition of waste set down in the Directive 2006/12/EC, as interpreted by the European Court of Justice, and definitions of the concepts “product”, “production residue” and “by-product”. WFD incorporated the concept "by-product" into the legal order of the European Union in such a way that an object or substance can only be considered as a by-product when certain conditions are met, according to the article 5 of the Directive 2008/98/EC:

- Further use of the substance or object is certain
- The substance or object can be used directly without any further processing other than normal industrial practice
- The substance or object is produced as an integral part of a production process
- Further use is lawful, i.e. the substance or object fulfils all relevant product, environmental and health protection requirements for the specific use and will not lead to overall adverse environmental or human health impacts.

Is important to highlight that (1) waste waters and (2) animal by-products, except those which are destined for incineration, landfilling or use in a biogas or composting plant, shall be excluded from the scope of the WFD. These residues are regulated (1) by the Water Framework Directive and (2) by Regulation (EC) No. 1069/2009.

4.2. Aquaculture animal by-products

Regulation (EC) No 1069/2009 is the legislative document in force laying down health rules as regards animal by-products and derived products not intended for human consumption, establishing measures to ensure safety, traceability and biosecurity. As defined by this regulation in the article 3 (1) ‘animal by-products’ (ABPs) means “entire bodies or parts of animals, products of animal origin or other products obtained from animals, which are not intended for human consumption, including oocytes, embryos and semen”. These by-products are classified in 3 categories based on their risk to human and animal health (article 7 (1)). Food consisting of, containing or being contaminated with products of animal origin may not be directly used in the manufacturing of feed. It must be firstly always subject to the provisions of the animal by-product Regulation. Due to the absence of a defined minimum content of materials of animal origin, all such food consisting of, containing any quantity of or being contaminated with products of animal origin is subject to the animal by-product legislation.

Regulation (EC) No 1069/2009 stresses the importance of traceability through adequate labelling, health certification and record keeping at each point of transfer, and includes by-products and their derivatives imported from outside the EEA. For these purposes, by-products are classified in 3 categories based on their risk to human and animal health (Figure 3).

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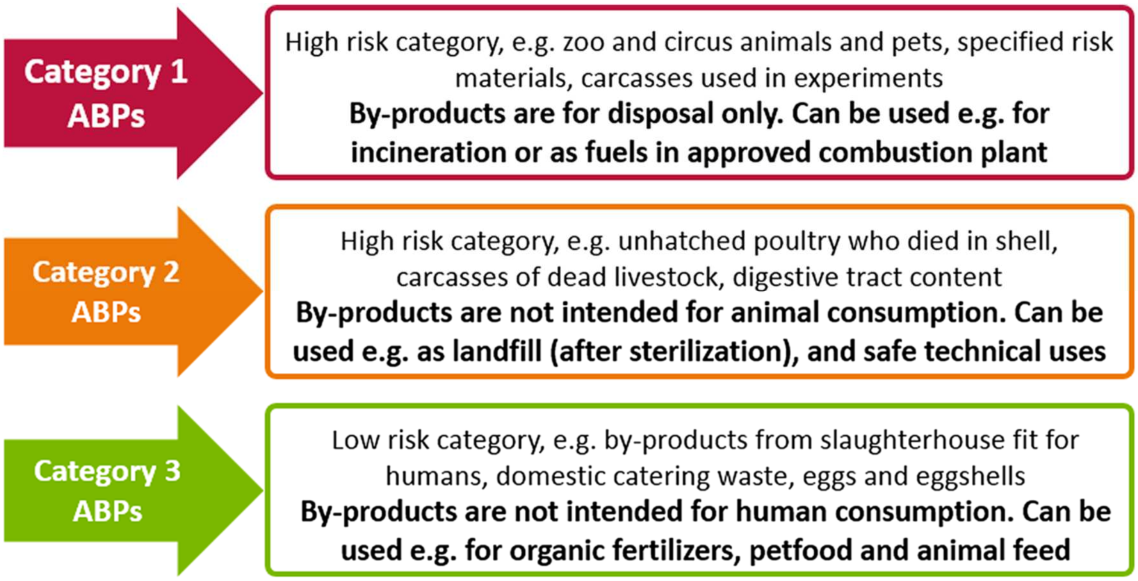

Figure 3. ABP categories as established by Regulation EC No. 1069/2009.

Category 1 is very high-risk material (animals suspected or confirmed as being infected by a TSE, animals killed in the context of TSE controls, Specified Risk Material). This category also includes animals other than farmed and wild animals (e.g. pets, zoo animals and circus animals) and experimental animals. This category has different allowable options concerning their utilisation or disposal. The specific details of these operations are now given in detail in the annexes of Commission Regulation (EU) No. 142/2011, which establishes the processing methods authorised for each category

Category 2 is also high-risk material. It includes farm mortalities, diseased and contaminated processing by-products. Generally, category 2 materials may not be fed to animals which will enter into the human food chain but may be fed to other animals such as pets or zoo animals. Where category 2 products are used for feed, there must be adequate biosecurity measures to prevent the possible spread of pathogens, otherwise they may be used for industrial purposes or must be disposed of in an appropriate manner such as incineration at an approved plant.

Aquaculture mortalities classified as category 2 must be disposed as waste by incineration, recovered or disposed of by co-incineration directly without prior processing; or following pressure sterilisation if the competent authority so requires, and permanent marking of the resulting material. Also, they can be disposed of in an authorised landfill, following pressure sterilisation and permanent marking of the resulting material, or used for the manufacturing of organic fertilisers or soil improvers to be placed on the market in accordance with Article 32 following pressure sterilisation, when applicable, and permanent marking of the resulting material. Also, they can be ensiled, composted or transformed into biogas.

Otherwise, mortality that are not result of the presence or suspected presence of a disease communicable to humans or animals could be fed to zoo animals, circus animals, reptiles and birds of prey other than zoo or circus animals, fur animals, wild animals, dogs from recognised kennels or packs of hounds, dogs and cats in shelters and used as maggots and worms for fishing bait

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Category 3 are considered low risk materials including by-products from slaughterhouses, eggs and eggs shell which are fit for human consumption. They may be used in the same way as category 2 materials but can also be used in livestock and aquaculture feeds as long as there is no risk of intra-species feeding and appropriate biosecurity measures have been followed. As stated by Regulation (EU) No. 142/2011, Category 3 material shall be processed, based on methods 1–5 and 7 for material originating from domestic animals and methods 1–7 for aquatic animals. The different heat treatment operation conditions are based on the following critical control parameters: (1) raw material particle size, (2) achieved core particle temperature level, (3) pressure, (4) duration of heat treatment and (5) in case of chemical treatment, the achieved pH level.

In general, aquatic ABPs, including those from aquaculture, may fall within Categories 2 and 3. Although cases of transmission of TSE to fish through contaminated feed have been demonstrated experimentally (Matthews and Cooke, 2003), regulations on the use of ABPs (see below) in aquaculture feed preclude this from happening in production systems.

Shells from shellfish are classified as Category 3 by product when organic material is still attached. This by-product with organic material could be used under conditions determined by the competent authority which prevent risks arising to public and animal health. If shells are stripped of soft tissue and meat are considered as a residue, and they can be reused as inert material in cement plants or to produce buttons. Before processing, shells must be previously screened and washed in order to eliminate the non-inert parts.

Despite the valorisation options available for ABPs, the most valuable uses are those related to keeping the food grade of Category 3 ABPs, so that human consumption is allowed, either maximising edible yield or after processing to produce nutritional supplements (collagen, oil, protein). High added value upgrade is also possible to pharmaceutical, veterinary or medical devices and products. In all cases, the manufacturing of these products must comply with relevant regulations.

The next level of valorisation recommends using aquaculture category 3 ABPs to produce feed (fishmeal, fish oil and other marine ingredients) for non-ruminants (poultry and pigs), fish (excluding intra-species feeding) and shrimp, in comply with EC No. 1096/2009. Ruminants are excluded from this possibility following the transmissible spongiform encephalopathies (TSE) regulation (EC) No. 999/2001 (European Community, 2001) with the exception of fishmeal as milk replacer for weaning animals.

Another important issue is the restriction on the use of ABPs from the same species in feed. Following the adoption of Regulation (EC) No 1774/2002, other implementing acts were adopted, namely Regulation (EC) No 811/2003 on the prohibition of recycling within the same species (intra-species feeding). Regarding aquaculture feeds, these regulations stated that only fishmeal from wild fish and their by-products could be used. Later on, regulations (EC) No. 1069/2009 and (EU) No. 142/2011 removed this limitation, establishing traceability measures to avoid intra-species feeding. For fish meal derived from farmed fish, packaging, containers or vehicles must bear the words 'contains fishmeal from farmed fish of the […] species only – may only be used for the feeding of farmed fish of other fish species'. The sentence in this case should mention the taxonomic name of

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the fish. For fishmeal derived from mixture of wild fish and farmed fish, packaging, containers or vehicles must bear the words ‘contains fishmeal from wild fish and farmed fish of the […] species – may only be used for the feeding of farmed fish of other fish species’. The ban on intra-species feeding of by-products originating from wild fish does not apply to dedicated reduction fisheries or by-products from wild fish as the species may be mixed, and although there are sometimes identification problems, the risk to human and animal health is thought to be low. However, aquaculture products have a clear advantage in this respect in that their species is easily determined and uniform.

Table 2[1]. Authorised treatments of disposal and/or valorisation for ABPs as established by Regulation (EU) No. 142/2011.

Category 1 ABPs	**Minimum Treatment for Category 1**
• BSE associated animals and their by-product. • The carcasses of pet animals. • Catering waste from international transport • Any mixture containing cat. 1	• Incineration or co-incineration • Rendering followed by landfill, incineration or co-incineration; • Burial - pets only.

[1] Despite the valorisation options available for ABPs, the most valuable uses are those related to keeping the food grade of Category 3 ABPs, so that human consumption is allowed, either maximising edible yield or after processing to produce nutritional supplements (collagen, oil, protein). High added value upgrade is also possible to pharmaceutical, veterinary or medical devices and products. In all cases, the manufacturing of these products must comply with relevant regulations.
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Category 2 ABPs	Minimum Treatment for Category 2
• Manure/Digestive tract content • Products containing drug residues • Products of animal origin, imported from outside the EU • Fallen and Culled animals. • Animal by-products not falling into categories 1 or 3. • Any mixture containing Category 2 including wastewater treatment Materials from Category 2 slaughterhouses	• Manure and gut contents may be used directly in a biogas or compost plant or land spread. • Rendering followed by incineration or landfill • In restricted circumstances, burial (but not burning) • Rendering to the pressure cooking standard, then use as fertiliser or treated in biogas / compost plant or AD in approved sites
Category 3 ABPs	**Minimum Treatment for Category 3**
• These are generally former foodstuffs of animal origin, once for human consumption. • Catering waste not of international origin if destined for composting. • It is NOT specified if mixtures containing cat 3 are so classified	• Biogas or compost treatment; • Petfood or technical production. • Rendering followed by – landfill, incineration or co-incineration; production of feedstuffs for livestock (mammalian material, must be rendered to the pressure cooking standard); fertiliser production; • Incineration or co-incineration

As was previously stated, according to Regulation (CE) No 1069/2009, fish residues at slaughtering are considered Category 3 ABPs. These products can be transformed to be used as feed ingredients. Regulation (UE) No 142/2011 provides 7 standard processing methods. Category 3 aquatic ABPs shall be processed in accordance with any of the processing methods 1 to 7 or processing method 7:

- Method 1 of pressure sterilization, involves the application of 133 °C to at least 3 bars of pressure and for at least 20 minutes in particles not exceeding 50 mm in particle size. The transformation can be done through a continuous or discontinuous system.
- Method 2, the particles cannot be greater than 150 mm and the heating will be 100 °C at least 125 minutes, 110 °C at least 120 minutes and 120 °C at least 50 minutes. The internal heating will be achieved consecutively or through the coincident combination of the indicated periods, always with a discontinuous system.
- Method 3, the particles may not be greater than 30 mm and the heating shall be at least 100 °C for 95 minutes, 110°C for 55 minutes and 120 °C for at least 13 minutes. The internal heating will be achieved consecutively or through the coincident combination of the periods indicated and the system may be continuous or discontinuous.
- Method 4, the particles cannot be greater than 30 mm and the heating will be applied to the

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by-products in a container with added grease. The temperature and time combinations are 100 °C 16 minutes, 110 °C 13 minutes, 120 °C for 8 minutes and 130 °C for at least 3 minutes. The internal heating will be achieved consecutively or through the coincident combination of the periods indicated and the system may be continuous or discontinuous.

- Method 5, the particles may not be greater than 20 mm. This method involves heating until coagulation and subsequent pressing to separate fat and water from the protein material. The protein in turn will be heated at 80 °C for 120 minutes and 100 °C for 60 minutes. The internal heating will be achieved consecutively or through the coincident combination of the periods indicated and the system may be continuous or discontinuous.
- Method 6 is exclusively applicable to Category 3 material from aquatic animals and aquatic invertebrates. Material must be grinded to a particle size of 50 mm if they are heated at 90 °C for 60 minutes or 30 mm if the temperature applied is 70 °C for 60 minutes. After grinding, pH is reduced to 4 or below by mixing with formic acid and material is stored for at least 24 h before heat treatment. The transformation may be carried out through a continuous or discontinuous system.
- Method 7, any method authorized by the competent authority based on compliance with a series of requirements: (1) Identification of hazards and risks and capacity of the method o reduce them. (2) Daily sampling for 30 days for compliance of certain microbiological criteria relating to *Clostridium perfringens*, *Salmonella* and *Enterobacteriaceae*.

Also, there are several alternative processes as:

- Alkaline hydrolysis process, which can be applied to by-products of all categories. By-products should be placed in a closed steel alloy container with an alkaline solution based on sodium or potassium hydroxide and heated to 150 °C and 4 bar pressure for 3 uninterrupted hours or 6 hours in case of bodies or parts of animals TSE suspects or officially confirmed disease and those killed as a result of eradication measures.
- Hydrolysis process at high pressure and high temperature, only for materials of categories 2 and 3. The by-products will be heated to 180 ° C for at least 40 minutes at a pressure of at least 12 bars by applying steam to the biolytic reactor.

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Figure **4** gives an overall picture of the options for treatment and/or valorisation of ABPs, depending on the category.

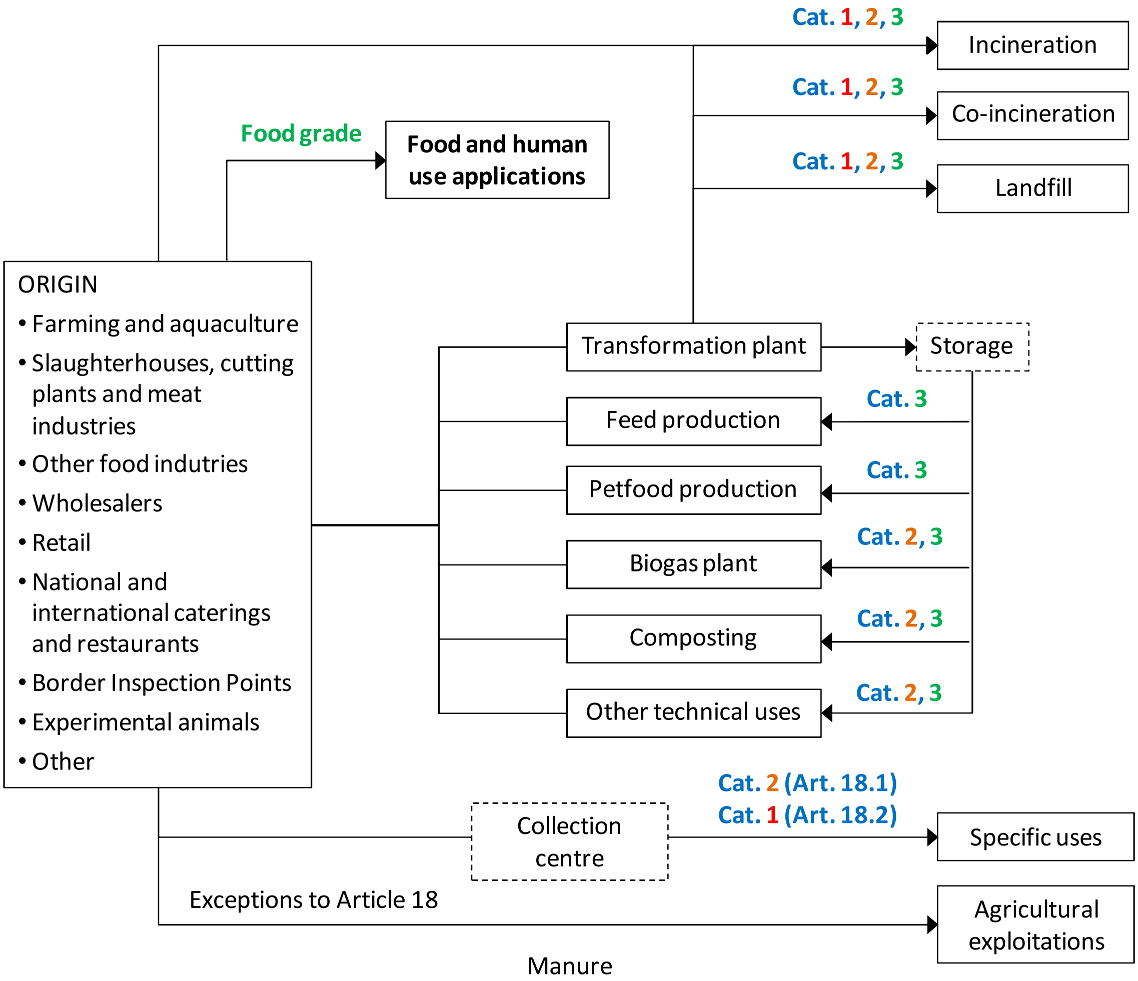

Figure 4. Flowchart of ABPs treatment and/or valorisation, according to Regulations (EC) No 852/2004 on the hygiene of foodstuffs (European Community, 2004), (EC) No 853/2004 laying down specific hygiene rules for food of animal origin (European Community, 2004), (EC) No 1069/2009 and (EC) No 142/2011.

The final product derived from the ensilaging of Category 2 ABPs may be incinerated, used for organic fertiliser, a compost, industrial fuel as a biogas without any further treatment or as feed for animals referred to in Article 18 or Article 36(a)(ii) of Regulation (EC) No 1069/2009. Silage produced from Category 3 materials, could be used for all the purpose detailed previously and defined in article 14 of Regulation (EC) No 1069/2009. Also, by products classified as category 3 could be transformed as fertilisers produced in accordance with the conditions for pressure sterilisation or with other conditions to prevent risks arising to public and animal health, in accordance with the requirements laid down pursuant to Article 15 and any measures which have been laid down in accordance with paragraph 3 of this Article. In the same grade level Regulation (EU) No 142/2011 sets out standards

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for the transformation of animal by-products into industrial energy (biogas, biofuel, biodiesel) and compost. Specific procedure and requirement are detailed in annex V of the above cited regulation.

Regulations for ABPs not intended for human consumption do not apply to mollusc shells stripped of soft tissue and meat (Regulation (EC) No 1069/2009, Article 2, point 2 f). Shells deriving from the aquaculture industry can be reused as inert material in cement plants or to produce buttons. Before processing, shells must be previously screened and washed in order to eliminate the non-inert parts. If organic material is still attached, shells are classified as Category 3 ABPs, otherwise they are classified as a waste. This by-product with organic material could be used under conditions determined by the competent authority which prevent risks arising to public and animal health.

4.3. Non-aquaculture ABPs and other feedstuffs

4.3.1. Fishmeal and fish oil

The expanding aquaculture sector is by far the largest user of these products and thus one of the main responsible for their sustainable exploitation. Commission Regulation (EU) 2017/786 (European Union, 2017) defines fishmeal as processed animal protein derived from aquatic animals except sea mammals, including farmed aquatic invertebrates, including those covered by Article 3(1)(e) of Council Directive 2006/88/EC (European Community, 2006), and starfish of the species *Asterias rubens* which are harvested in a mollusc production area. With this new definition aquatic invertebrates which are not covered by the definition, such as starfish and farmed aquatic invertebrates other than molluscs and crustaceans, and which pose no risk of disease transmission may be used under the same conditions as the aquatic animals that fall under the definition, for instance for the production of fishmeal.

Fishmeal produced based on by-products material should comply with extant regulations of food and feed safety and the Regulation EC No. 999/2001. Fishmeal from wild fish intended as ingredient for aquaculture feed must be labelled as “contains fishmeal from wild fish only” and “may be used for the feeding of farmed fish of all species”. Thus, regulations (EC) No. 1069/2009 and (EU) No. 142/2011 establishing measures to avoid intra-species feeding regarding aquaculture ABPs are not applied to fishmeal of wild origin.

4.3.2. ABPs of terrestrial origin

The permitted uses of the different ABPs as feed ingredients are summarized in Table 3.

Table 3. Authorised uses of ABPs according to their nature and origin (modified from Jędrejek et al., 2016).

ABP material	Ruminants (cattle, sheep and goats)	Non-ruminants (pigs and poultry)	Aquaculture (fish and shellfish)
Former foodstuffs	permitted – under requirements of Feed	permitted – under requirements of Feed	permitted – under requirements of Feed

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	Regulation	Regulation	Regulation
Fats from ruminants and non-ruminants and fish oils	permitted	permitted	permitted
Hydrolysed protein from ruminants and non-ruminants	permitted	permitted	permitted
Collagen and gelatine from non-ruminants	permitted	permitted	permitted
Milk products	permitted	permitted	permitted
Egg products	permitted	permitted	permitted
Fishmeal	banned (with the exception of use as milk replacer for young animals)	permitted	permitted
PAPs from non-ruminants	banned – under TSE Regulation	banned – under TSE Regulation	permitted
PAPs from ruminants	banned – under TSE Regulation	banned – under TSE Regulation	banned – under TSE Regulation
Blood products and blood meal from non-ruminants	banned – under TSE Regulation	permitted (only blood products)	permitted
Di- and tri-calcium phosphate from non-ruminants	banned – under TSE Regulation	permitted	permitted
Catering and kitchen waste	banned – under ABP Regulation	banned – under ABP Regulation	banned – under ABP Regulation

Besides the authorised uses above, ABPs as feed ingredients are subjected to the following regulations:

- Regulation (EU) No. 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives in animal nutrition (European Union, 2013);
- Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005, laying down requirements for feed hygiene (European Community, 2005);
- Regulation (EC) No. 767/2009 of the European Parliament and of the Council of 13 July of 2009 on the marketing and use of feed (European Union, 2009);
- Commission Regulation (EU) No. 68/2013 of 16 January 2013 on the Catalogue of feed materials (European Union, 2013).

Raw feed materials that are not listed in the catalogue may be marketed and used in the EU, provided they are notified in the Community register of raw materials for animal feed (http://www.feedmaterialsregister.eu/).

ABPs of terrestrial origin were common ingredients of animal feeds until Regulation (EC) No 999/2001, laying down provisions for the prevention, control and eradication of certain TSE, banned the use of materials of animal origin in feeds for ruminants in the context of the bovine spongiform encephalopathy (BSE) crisis, with a few exceptions including milk and egg products. This regulation also strongly limited the range of these products in feeds for non-ruminant and aquatic farm animals, i.e. milk and milk products, eggs and egg products, blood products and di-calcium/tri-calcium phos-

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phate of animal origin. Nevertheless, on the view of research findings and scientific advice, this banning was partially lifted by Commission Regulation (EU) No. 56/2013 (European Union, 2013) which modified the annexes I and IV of Regulation (EC) No. 999/2001 by authorising the use of processed animal proteins (PAPs) from non-ruminants in aquaculture feeds. The different controls and studies developed in recent years allow ensuring that there is no risk if the requirements of the regulations are met in relation to the use of PAPs of non-ruminants in terms of handling and processing of the proteins required by the EU in the Regulation (EC) 1069/2009. Regulation (EU) 56/2013 clearly recognizes that there is a chronic protein deficit in the EU, estimated in 70 % by Häusling (2011), and it does not make sense to maintain indefinitely a ban that is unfounded, thus improving the availability of proteins for aquaculture from alternative sources to wild catches or terrestrial crops.

Animal fats and oils from slaughtered ruminants and non-ruminants rendered from category 3 by-products are permitted to be used in aquaculture feed under the regulation 1069/2009 as listed in Article 6(1) points (a) to (j) and its implementing regulation 142/2011. However, they cannot be contaminated with animal protein, such as tissue, muscle fibre and bone, to avoid the risk of TSE.

Hydrolysed proteins as defined in the ABPs regulation, are products from animal protein hydrolysis which comprises polypeptides, peptides and amino acids, and mixtures thereof. It can be obtained after hydrolysis of either ruminant or non-ruminant ABP material, and can be used in feeds for ruminants, non-ruminants and aquaculture. Hydrolysed protein must be produced through a process involving the preparation of raw category 3 ABP material by brining, liming and intensive washing, followed by exposure of the material to a highly acidic (≤ 2) or alkaline (≥ 11) pH and heat treatment (140 °C) under pressurized condition (≥ 3 bar) to minimize the risk of contamination. Hydrolysed protein derived from ruminants shall have a molecular weight below 10,000 Dalton as specified in Regulation (EC) No 767/2009. Feed business operators wanting to process ABPs into hydrolysed protein for animal feed need to comply with the requirements of the TSE Regulation and ensure that product being used for farm animal feed does not contain animal tissues (Regulation (EU) No 142/2011). As for collagen and gelatin, aquaculture feeds may contain both ingredients provided they are manufactured from non-ruminants, including fish.

Blood products from non-ruminants are allowed for the manufacturing of aquaculture feeds. These materials must have been produced in accordance with Section 2 of Chapter II of Annex X to Commission Regulation (EU) No 142/2011. With reference to point B of that Section, blood products have to be submitted to any of the processing methods 1 to 5 or processing method 7 as set out in Chapter III of Annex IV to that Regulation (see Section 4.2), or another method which ensures that the blood products comply with the microbiological standards as set out in Chapter I of Annex X to Commission Regulation (EU) No 142/2011.

4.3.3. Former foodstuffs

Former foodstuffs (FF) comprise expired products or products no longer intended for food use due to practical or logistical reasons, such as surplus, problems with manufacturing, or other defects, which do not present any health risk for further use as feed (Jensen, 2012). Only certain FF can be used for feeding farm animals: products from bakeries, supermarkets, retail stores, crisp manufacturers and confectioners. Catering, kitchen and restaurant waste cannot be used for feeding farm animals.

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Moreover, FF containing any ingredient of animal origin falls under ABP regulation, being classified as low risk category 3 materials.

Although regulations (EC) No. 1069/2009 and (EU) No. 142/2011 allow the use of FF in aquaculture feeds, in practise most of these products do not fit the nutritional requirements of fish, so this valorisation rout is unlikely.

4.3.4. Insects

Although not ABPs, insects for feed purposes are included in this section.

Insects are a promising sustainable source of proteins not only for animal feed, but potentially also for human consumption. Aspects related to insect production sustainability are their low requirements of land and water and the capacity to feed in waste streams. However, insects are farm animals and assimilated to non-ruminants, from the perspective of the EU legislation (Regulation (EC) No. 1069/2009), and thus the same regulations related to feed, health and safety or use of ABPs apply. Hence, the use of insect protein for aquaculture feeds was approved recently, via Regulation (EU) No. 2017/893 (European Commission, 2017), as an exception to other PAPs that must be derived from slaughterhouses or cutting plants, which are not used in insect production.

Regarding insect feeding, current legislation limits the animal origin materials that can be fed to insects for aquafeeds as for other terrestrial animals: only fishmeal, blood products from non-ruminants, egg and eggs products, milk and milk based products, honey and rendered fats are allowed.

4.4. Sludge

Faeces and uneaten feed may accumulate at the bottom of aquaculture tanks and on the seabed underneath off-shore facilities such as fish cages and mussel rafts or longlines, occasionally building up to tons over time in locations with a high density of cultures. These residues rich in organic matter constitute part of the natural diet of filter feeders –when particles are still suspended in the water column- and deposit feeders. Nevertheless, Regulation (EC) No. 767/2009 on the placing on the market and use of feed, prohibits the use of animal waste to feed any other animal, both for food producing and non-food producing animals (Article 6, Annex III). This prohibition invalidates de facto IMTA schemes in which bivalves, sea anemones or detritivores such as sea cucumbers, sea urchins or polychaetes are co-cultivated with fish or fed on fish tank waste, thus posing and insurmountable barrier.

Presently, only waste treatment options such as landfill, incineration or biogas production would be allowed for this type of waste. A new approach will be possible from 2022, when the new Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products will enter into force (European Union, 2019). This regulation will introduce harmonised rules for organic fertilisers manufactured from secondary raw materials such as agricultural by-products and

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recovered bio-waste, replacing current Regulation (EC) 2003/2003 (European Community, 2003) which only allows the free trade across the EU of conventional, non-organic fertilisers.

4.5. Waste water

Building on a tradition of water protection legislation, the EU has now in force four main pillars addressing discharges to aquatic ecosystems. The first two are the directives from 1991 on urban waste water treatment (Council Directive 91/271/EEC; European Community, 1991) and on nitrates pollution from agricultural sources (Council Directive 91/767/EEC, or the Nitrates Directive; European Community, 1991). Furthermore, the Water Framework Directive (Directive 2000/60/EC) is the 'flagship' of EU water policy and legislation, which has expanded the scope of EU water policies to all inland and coastal water bodies and addresses all sources of impacts, not only related to waste water from municipal and industrial sources. Finally, the Environmental Quality Standards Directive (Directive 2008/105/EC, EQSD; European Union, 2008) is the legislative framework regulating the release of chemicals into the aquatic environment across the EU. The EQSD applies to surface waters, i.e. inland waters, transitional waters (estuaries and inlets) and coastal waters out to 12 nautical miles.

The Water Framework Directive aims to improve and protect the chemical and ecological status of surface waters in order to protect human health, water supply, natural ecosystems and biodiversity, considering all types of water bodies: river basin catchments, rivers, lakes, ground-waters and coastal waters. The Waste Framework Directive presents a breakthrough in EU water policy, not only with regard to the scope of water protection, but also with regard to its development and its implementation. Moreover, other EU directives have modified the previous Water Framework Directive such as the Directive 2008/105/EC (European Union, 2008).

Besides Water Framework Directive, aquaculture activities in the EU regarding water use and management lie within the scope of the Marine Strategy Framework Directive (Directive 2008/56/EC, MSFD; European Union, 2008). MSFD is a legislative framework aiming to managing human activities having an impact on the marine environment through the integration of environmental protection and sustainable use. Both Water Framework Directive and MSFD aim to achieve and maintain the good ecological/environmental status (GES) and the good chemical status of inland, coastal and marine waters. Besides the aforementioned directives 91/271/EEC and 91/767/EEC, this objective is supported by other EU legislation: the Industrial Emissions Directive (Directive 2010/75/EU; European Union, 2010), the REACH legislation (Regulation (EC) No 1907/2006; European Union, 2006, and Directive 2006/121/EC; European Union, 2006), the Biocidal Products Regulation (Regulation (EU) No 528/2012; European Union, 2012), the Veterinary Medicines Directive (Directive 2001/82/EC), the Plant Protection Products Regulation (Regulation (EC) No 1107/2009 (European Union, 2009); European Union, 2009) and the Sustainable Use of Pesticides Directive (Directive 2009/128/EC; European Union, 2009).

Moreover, Directive 91/271/EEC may also affect aquaculture plants as long as it concerns the collection, treatment and discharge of biodegradable waste water from certain food industry sectors, including fish processing plants.

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It must be taken into account that neither the Water Framework Directive nor the MSFD contain explicit obligations for aquaculture. Nevertheless, freshwater aquaculture is subjected to the requirements comprised in the Water Framework Directive, and it has to comply with implementing transpositions to MS national legislations. In Annex II, section 1.4 the Water Framework Directive requires to MS to collect and maintain the information on the type and magnitude of significant anthropogenic pressures on surface waters in each River Basin District to compile this information. MS should identify significant point source and diffuse source pollution, in particular substances listed in Annex VIII, from urban, industrial, agricultural and other installations and activities for the purposes of each River Basin Management Plan, the key tool implementing Water Framework Directive. Discharges from aquaculture can be regarded as point-source inputs and thus monitoring information is likely to be required as a precursor to effective management (SWD (2016) 178 final).

The MSFD is relevant to marine aquaculture. Regarding water protection, marine aquaculture may pose impacts related to nutrient and organic matter discharge and use of pesticides and drugs. The magnitude of aquaculture impact in marine waters, in contrast with impacts from other sources, has not been fully assessed, as it is difficult to gauge in relation to the overall impacts of anthropogenic activities. However, the effects are dependent on factors such as the hydrological conditions at each aquaculture facility, the type of species being cultured, the production method and the management practices.

The MSFD aims to achieve GES in marine waters by 2020. GES is based in eleven descriptors, among which eutrophication, hydrographical conditions and contaminants are related to water quality and discharges. Whereas GES assessment is expected for large sea areas, impacts of aquaculture facilities are likely to happen at a local scale, thus contributing only to a small part of anthropogenic impacts. However, the existence of multiple facilities could mean a threat to achieve GES, particularly in contained environments such as land-based facilities discharging at a specific point, shallow waters or closed areas such estuaries. Hence, despite the current scale of aquaculture operations and the local impacts, it is possible that aquaculture, alongside all other sectors, will need to reduce impacts in order to reach GES under MSFD.

Aquaculture is strongly dependent on a healthy environment and thus must respect sustainability principles in order to contribute to achieve GES. It is expected that GES will be positive for aquaculture production, due to the benefits of the better water quality resulting from the reduction in contaminants, nutrient enrichment, eutrophication and the presence of litter.

In view of mitigating the impacts of aquaculture activities regarding the preservation of inland and marine water quality, national, regional or local licensing regulations may set limitations to the discharges from aquaculture facilities through direct or indirect measures. In order to control the release of nutrients, direct measures set maximum discharge levels, whereas indirect measures may consist of limiting biomass and production levels, since emissions are related to the stocked and the feeding rate. It is obvious that some of these rules are applicable to land-based aquaculture plants whereas others refer to off-shore facilities.

The release of chemicals into the aquatic environment is regulated by a range of EU and national regulations, besides the EQSD. Currently, Environmental Quality Standards (EQS), i.e. limiting concentrations on water, have been established for 45 priority substances and 8 other chemical pollutants of high concern across the EU. Hence, MS must take measures to progressively reduce pollution from priority substances and suppress discharges. Among priority substances, only the

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antiparasiticide cypermethrin and the antifoulant cybutryne are of direct relevance to aquaculture operations. In addition to this, certain Member States have identified as river basin specific pollutants substances that are relevant for aquaculture:

- Copper and zinc: present in compounds used as antifoulants
- Diflubenzuron and azamethiphos: parasiticides against sealice
- Formaldehyde: still widely used to control a range of diseases in aquaculture
- EDTA: ethylenediaminetetraacetic acid, used to improve water quality by reducing heavy metal concentrations or remove organic substances in the water

These substances are likely to enter the list of priority substances if their negative environmental effects are confirmed, and then subjected to measures to progressively suppress their discharges to water bodies.

The revision of the EU legislation that links aquaculture and water management and protection shows that the only matter of interest that is considered is the interaction between aquaculture facilities, as potential sources of pollution, and the water environment where effluents are discharged. These regulations do not deal with other aspects related to the use of water inside aquaculture facilities, such as the recycling of water into following aquaculture operations or the reutilisation of effluents. Nevertheless, the Water Framework Directive and some national regulations, foresee the reutilisation of treated waste water for certain applications such as irrigation or street cleaning. For this purpose national regulations set different microbiological and physico-chemical quality criteria depending on the use. The reuse of aquaculture waste water is thus more likely in the case of freshwater.

Following with the possibilities to use effluents from aquaculture or even for their reutilisation in aquaculture, the Circular Economy package presented by the EC at the end of 2015 reflects the commitment to develop actions to promote the reuse of water at the EU level. The Action Plan was implemented in the years 2016-2017, and it is summarized in the following key points:

- Reuse in integrated water planning and management. The reuse of water should be considered systematically by MS as an option when implementing water legislation at the community level.
- Minimum quality requirements for the reuse of water in irrigation and aquifer recharge.

To this end, the Commission is still evaluating the most appropriate instrument at EU level to promote the reuse of water, while ensuring environmental protection and human health and the free trade of food products. One of the main barriers to achieving greater water reuse is the lack of a coherent and harmonized legislative framework within the EU. MS develop their own standards, which often differ from one another, creating difficulties in the trade of agricultural products, for example. At the moment, only six MS have a standard of minimum requirement of water reuse. In five of these countries (Cyprus, Greece, France, Italy and Spain) the standards are compulsory and included in the relevant water reuse legislation. In Portugal, the standards are enforced through the permitting requirement rules (European Committee of the Regions, 2018). Belgium, Denmark and Malta are beginning to prepare a guideline for water reuse. The rest of MS do not have a legislation or guideline on water reuse so far.

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In February 2019, the European Commission endorsed a proposal to stimulate and facilitate the reuse of treated wastewater for agricultural irrigation (COM(2018) 337 final) to counteract the shortage in times of drought. This document proposes minimum quality requirements for the reuse of treated wastewater and also establishes obligations for production, distribution and storage, as well as risk management measures. The reclaimed water (i.e treated wastewater in specialized facilities) can be used for all types of agricultural irrigation (food and non-food crops). The CE must evaluate within a period of five years whether regenerated water can have other uses. Again, this proposal is only valid for freshwater aquaculture.

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5. Comparison between EU and third countries legislation

The EU has one of the most stringent legislation in the world in terms of food and feed quality and hygiene, which ensures the highest safety of the food and feed produced and traded in Europe and the protection of consumers and livestock. Regulation (EC) No. 178/2002 (or General Food Law), which lays down the basic principles of food law, establishes that regulations must be based on precautionary principles with the best and most up to date scientific opinion. In order to separate responsibilities for risk assessment and for risk management by policy-maker bodies, the General Food Law created the European Food Safety Authority (EFSA), whit the duty of producing scientific opinions and advice that form the basis for European policies and legislation on food and feed safety. For years, the EU legislative and executive institutions and EFSA have worked together with the objective to contribute to the hygienic and sanitary quality of all the links in the food chain. Another principle that has operated in some of the resolutions, such as specific measures on the eradication of the risk of spongiform encephalopathy transmission, is the precautionary principle according to which the lack of scientific certainty does not prevent taking exceptional measures in order to protect public health.

Under these principles, progress has been made in the harmonization via community regulations in several aspects. In this same line, Regulation No. 183/2005 was drawn up, laying down the requirements for the hygiene of feed. This regulation has meant a very profound change of mentality in the primary sector at European level, requiring all animal feed operators, either directly or indirectly, to assume their participation in this sector, registering or authorizing their activity, depending on the case, thus contributing to the excellence and improvement of livestock production, both in its good hygienic and sanitary quality.

In spite of many regulations, guidelines and standards which aim to govern best practice for food safety, traceability and efficiency of resources in the EU aquaculture industry are far to a fully harmonisation. The scope of the various regulations and their detail on required practices is diverse, from specific technological requirements in some of the EU regulations to vague references to best practices in some of the private certification standards. The strictness of national regulations varies between countries and regions leading to confusion and difficulty for producers in terms of adhering to the laws of international markets which they wish to target. This complexity may be added to as regulations are constantly up-dated, especially in the EU, and the various standards which need to adhere to them are slow to react.

5.1. Codex Alimentarius

Overarching international and regional guidelines are provided by the Codex Alimentarius (www.codexalimentarius.org), published jointly by the Food and Agriculture Organisation of the United Nations (FAO) and World Health Organisation (WHO). The Codex Alimentarius, established in

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1965, provides standards on the production of food raw materials and commodities for trade and further processing in value chains for human consumption, directly and indirectly. It covers topics such as drug residues, contamination, labelling and traceability as well as sampling protocols. In many cases, especially in regard to food processing, it incorporates a Hazard Analysis Critical Control Point (HACCP) approach, developed by the US Food and Drug Administration (FDA). HACCP offers a scientific framework for identifying and acting upon specific points within a production facility which may pose health risks and does not form a standard in its own right. A summary of how it can be implemented for seafood production and processing is given by the Codes of Practice (COP) for fish and fishery products (WHO, FAO 2003). While the Codex Alimentarius does not provide actual law with regards to permissible production and utilisation practices, it provides COPs which act as unifying standards in consultation with the FAO and WHO, to which many legislators can turn. The HACCP framework is also widely adopted by processors at all stages of food and feed processing. Feed safety is covered by the Codex Alimentarius COP on Good Animal Feeding (WHO/FAO, 2004) and COP for Fish and Fishery Products (WHO/FAO, 2003), which include traceability of feed ingredients and correct labelling. There is also a standard related to contaminants in animal feeds (WHO/FAO, 2010b). However, within these guidelines there is little reference to the use of by-products. Instead, feed safety issues focus on contamination from microbes, pesticides and toxins, although the COP for Fishery Products points to proper heat treatment of fish silage and offal. There are no references to intra-species feeding although avoidance of the use of ingredients that could be a source of BSE agents is advocated.

The World Organisation for Animal Health (OIE) also works in collaboration with Codex Alimentarius, WHO and FAO for maintaining the health and welfare of animals, worldwide. OIE issues standards related to aquaculture feeds (OIE, 2013). While in general it advocates the use of fishery and aquaculture by-products, it warns against the use of by-products for species which are closely related, e.g. between salmonids. This is not because of the risk of transferring Transferable Spongiform Encephalopathies (TSEs), of which BSE is one, but because of the risk of spreading other pathogens between susceptible species. It actually acknowledges that cannibalism is prevalent in the aquatic environment but there has been no evidence of prion transfer in aquatic species to date. It also advocates the need for more research on the risk of terrestrial animal proteins in aquafeeds, so that the pressure on marine feed ingredients may be relaxed. In general, however, it points to HACCP measures for feed processing as laid out by Codex Alimentarius (OIE 2013).

In the case of fish oils, the Codex standard for Fish Oil was finally adopted at the 40th Session of the Codex Alimentarius Committee (CAC40) held in Geneva 17 – 21 July 2017. The Codex Alimentarius Commission approved the development of a Codex Standard for Fish Oils as new work as proposed by the 22nd session of the Codex Committee for Fats and Oils (CCFO) in 2011. It was a long process involving many discussions on the finer details which was important to clarify as the purpose of this Standard is to protect consumer health and promote fair practices in the trade of fish oil.

Fish oils means oils intended for human consumption derived from the raw material as defined in Section 2 of the Code of Practice for Fish and Fishery Products. Processes to obtain fish oil for human consumption may involve, but are not limited to, extraction of crude oil from raw material and refining of that crude oil.

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5.2. FAO Code of Conduct for Sustainable Fisheries

The FAO Code of Conduct for Sustainable Fisheries (FAO 1995) was developed mainly for capture fisheries although it does also refer to the development of aquaculture, regarded as a sub-set of fisheries by the FAO. It particularly encourages the maximisation of fisheries resources for human consumption and reduction of waste through better use of by-catch and by-products for value addition. It also refers to the Codex Alimentarius for ensuring good food safety standards throughout production and processing, and to appropriate disposal of wastes such as dead fish in order to avoid human health risks and the spread of disease. However, no detail is given on these practices.

5.3. International legislation

In terms of aquaculture production there are some differences between European and non-European countries. These differences can be also appreciated at other levels, such as the legislation in terms of by-products use for fish feed or the regulations for aquaculture by-products treatment. Many countries do not assume the EU ban on the use of fishmeal in feed for ruminants, nor the intraspecific feeding ban. Based on the Terrestrial Animal Health Code (Terrestrial Code) of the OIE, EU approach is to assess whether the country products are in the list of countries in which the risk of bovine spongiform encephalopathy is insignificant. Therefore, it is possible to say that there is a lack of harmonization of the standards in matter of feed safety and quality. In part this gap is partially covered by the Codex Alimentarius. Notwithstanding the guidelines, standards and recommendations produced by Codex are not legally binding; however, they do provide a template for laws and are used by the World Trade Organization (WTO) as an agreed benchmark in global trade disputes.

5.3.1. China

China is a country with a long history of aquaculture and the largest producer with more than 60% the world’s total aquaculture output by quantity. Chinese aquaculture, including a wide variety of freshwater and marine fishes, shellfish, crustaceans, and aquatic plants, has become one of the most vital primary industries and a centre of economic activity within the local and global economies. With the development of the sector, the Chinese government has established the basic policy of “managing and developing fisheries by law” in order to ensure food quality and safety in the country.

Respect to feed legislation, regulations on feed and feed additives were issued by the State Council of the People's Republic of China on May 29, 1995. The document aims to strengthen the administration of feed and feed additives, improve their quality, increase the development of the feed industry and animal production and enhance public health safety. The regulation was updated and re-issued on Nov 29, 2001, Dec 7, 2013 and finally in Mar 1, 2017. Also, a Regulation on the Administration of Feed and Feed Additives Decree No.609 was adopted on the 3rd of 2011. The

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Chinese ministry of agriculture issued in 2014 the feed catalogue "MOA Announcement No. 1773" which includes a list of allowed ingredients to be used in feed production. The list contains feed materials (including carriers and diluents) derived from animals, plants, microorganisms or minerals for processing feeds but not for feed additives. All ingredients shall comply with the requirements of mandatory standards such as Feed Hygiene Standard and Feed Label. In these laws fish and seafood by-products are allowed as a raw material for feed production. Few conditions are observed and are limited to the prohibition of infected and contaminated fish. However, in the case of terrestrial animal by-products several restrictions were observed. Article 12 of the feed catalogue establishes the prohibition of use of ruminant ABPs without previous treatment and the obligation to indicate the process used in the label product. The use of by-products from animal with epidemic diseases and prohibited substances is also banned, and the raw materials must be mono-specific. The use of internal organs of fresh edible animals is limited to pet food final product.

Regarding the use of insects, there are no mentions to feeding restrictions for insects in the Chinese legal document, only a specification on the health safety of human and animal and denomination of specie origin on labelling process.

According to China regulations, water quality and discharge of wastewater are tackled in various environmental laws, but without specific mentions to aquaculture. The Law on the Prevention and Control of Water Pollution provides for the establishment of national standards for water environment quality and for discharge of water pollutants. This law designates protected zones with regard to major fishery water bodies, which are defined as those parts of water bodies designated for the spawning, feeding, wintering or migratory passage of fish or shrimp, and for breeding fish, shrimp or shellfish or growing algae. The Law is implemented by the Rules for Implementation of the Law on the Prevention and Control of Water Pollution (2000).

5.3.2. Canada

Canada aquaculture legislation is overseen by a combination of federal, provincial and local authorities. The federal government has jurisdiction over the regulation of fish products marketed in export and inter-provincial trade, the conservation and protection of wild fish stocks and fish habitat and research and development. Federal authority to regulate the aquaculture industry is shared between 17 departments and agencies, with the Department of Fisheries and Oceans Canada (DFO) as the lead.

Respect to animal feed, the manufacture, sale and import are regulated in Canada under the *Feeds Act* "R.S.C., 1985, c. F-9" and Regulations SOR/83-593 adopted in 1983 and amended on July 30, 2009 administered by the Canadian Food Inspection Agency (CFIA). Canada legislation is generally more permissive than EU legislation respect to animal by-product use in aquaculture. In fact, the feed Act allow the use of ruminant protein to non-ruminant and to aquaculture species. Proteins derived from ruminant species are only prohibited material to ruminant animals, such as cattle, sheep, goats and deer (Part XIV of the Health of Animals Regulations). Also, Canadian regulation don't mention the banning of interspecific use of fishmeal protein, fishmeal could be used regardless the origin species. No specifications were detected on the use aquaculture or wild fish for meal manufacturing.

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5.3.3. Other countries

In other countries, such is the case of South Korea, the recycling food waste use is regulated under the Control of Livestock and Fish Feed Act Article 8, indicating that food waste can only be included in animal feed if it has been treated at registered feed production (MOE, 2008). Moreover, in the United States of America (USA), food waste–derived feeds must meet the regulations set by the Department of Agriculture. In this case the meat present in waste must be submitted to heat at 75 °C for 30 min to inactivate pathogens (USDA, 2009). However, despite these regulations, more information related to the use of food waste as an ingredient in fish feed is necessary to have a better control related with the animal welfare in terms of animal feed.

Also in India, wastewater reuse through aquaculture is still practised, notably in the EKW (East Kolkata Wetlands).

5.4. Conclusions

There is a clear lack of harmonisation inside and outside the EU. This may be related to the different formulation of basic principles on which EU regulations are based on those of other countries, obeying, perhaps to a different approach to risk analysis and the precautionary principle, evoked at the beginning of this chapter.

On the prohibition of the use of fishmeal in the feed of ruminants many countries do not assume the EU ban. Based on the Terrestrial Animal Health Code (Terrestrial Code) of the OIE, its approximation is to assess whether the country products are in the list of countries in which the risk of BSE is insignificant. Therefore, it is possible to say that there is a lack of harmonization of the standards in matter of Feed Safety and Quality. This gap is partially covered by the Codex Alimentarius. Notwithstanding the guidelines, standards and recommendations produced by Codex are not legally binding; however, they do provide a template for laws and are used by the World Trade Organization (WTO) as an agreed benchmark in global trade disputes. Linked to this question are the criteria of practical application of the identification of DNA traces of ruminants in fishmeal, linked with the sensitivity of the method by laboratories involved in official control, based on sampling plans, that are far from being harmonized. The consequence is discretion in the rigor of the application of the regulation.

It must be emphasised that the principle of avoiding feeding farmed fish with PAPs derived from farmed fish of the same species, is not clearly stated outside EU. Moreover, requirements for a specific labelling of fishmeal and marine ingredients indicating the species are not clearly stated. Therefore, no specifications were detected on the use of aquaculture or wild fish for meal manufacturing outside EU.

On the other hand, the regulations relating to the control of undesirable substances, contribute to normalize the content of undesirable substances of all products related to animal feed are lacking of harmonisation to. A good example at UE level is the upcoming deadlines for marketing and use of ethoxyquin in certain feed materials.

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Finally, regarding wastewater treatment or reuse the laws to indicate permitted levels of nutrients and contaminants in wastewater discharge are specific for each country, but it is necessary to clarify and also to regulate the use of new recirculation (as RAS) and reuse (IMTA) systems to promote circular economy innovations.

6. Regulatory gaps, barriers and opportunities related to the implementation of circular economy in EU aquaculture

As said in the previous section, EU legislation on food and feed is designed to guarantee the highest safety standards, and precautionary principles based on scientific opinions or in their absence are envisaged. In the end, all regulations dealing with any process involved in food or feed production must be in agreement with this legislation. Given this prerequisite, it is expected that some of the techno-economic solutions developed by GAIN towards the eco-intensification of EU aquaculture do not fully meet current regulations, not due to the existence of potential risks for food and feed safety or animal health or welfare, but because of legislative gaps, or even barriers related to the lack of scientific data or opinion supporting the implementation of the project outcomes into aquaculture processes. This does not only refer to food and feed legislation, but to other areas such as water protection and use, waste management, etc. This situation may be exacerbated due to the lack of harmonisation of national and regional regulations following transposition of EU directives.

This section aims to give a glimpse of those regulatory aspects which might affect the objectives of GAIN, and provide recommendations to address current legislative barriers to the development of CE approaches in aquaculture, also those beyond the scope of GAIN, at the same time guaranteeing the safety and quality of aquaculture products.

6.1. Closing the loop of aquaculture feed ingredients: barriers to the enhancement of the use of fish by-products

Current major protein and oil sources for fish feed are one of the main constraints for the sustainable development of aquaculture. The use of traditional fishmeal from wild catches is no longer viable due to the growing demand of aquaculture and the stagnation of fish stocks which cannot endure a higher exploitation, whereas the use of plant-based ingredients poses similar environmental footprints as the farming of any terrestrial animal (EFARO). Another option is the use of krill; however, removal of large quantities of krill will have adverse effects at long-term in marine ecosystems on dependent species, such as marine mammals and birds (Nicol and Endo, 1999; Plagányi and Butterworth, 2012). Nevertheless, there is still a great scope to maximise the use of by-products from both fisheries and aquaculture. The landing obligation of all fishing catches in the EU to gradually eliminate the practice of discarding unwanted catches that cannot be used as food opens an opportunity to increase the availability of raw materials for the production of fishmeal and fish oil. MS and producer organisations have the duty to assist fishermen to find adequate outlets for

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these catches, and therefore to help to develop profitable schemes for the valorisation of these by-catches, based on the correct management of the material and appropriate logistics in order to decrease operational costs of preservation, transport and processing and to obtain valuable products.

The use of emerging feed ingredients, such as insect meal, microalgae or macroalgae can also serve to diminish the gap between protein supply and protein demand in EU. The recent Regulation (EU) 2017/893 allowing the use of insects for this purpose will indicate the way forward in this line. In all cases, traditional and new ingredients must comply with legislation dealing with feed hygiene (Regulation (EC) No. 183/2005) and marketing and use of feed (Regulation (EC) No. 767/2009).

Following with the available options to increase the availability of fishmeal and fish oil for aquaculture feeds, GAIN has identified a substantial lack of valorisation of finfish and shellfish farming secondary outputs, but particularly APBs, including here processing side streams and mortalities. Whereas by-products from processing will be generally Category 3 ABPs, authorised to be used as feed raw materials, mortalities are Category 2 ABPs and their legal uses are currently restricted to some technical applications, besides low-value composting or biogas and fuel production.

Category 2 ABPs may be locally and temporarily abundant and thus are a resource potentially easy to manage and exploit. Regulation (EC) No. 1069/2009 recognises that “progress in science and technology may lead to the development of processes which eliminate or minimise the risks to public and animal health. Amendments to the lists of animal by-products set out in this Regulation should be possible, in order to take account of such progress. Prior to any such amendments, and in accordance with the general principles of Community legislation aimed at ensuring a high level of protection of public and animal health, a risk assessment should be carried out by the appropriate scientific institution, such as EFSA, the European Medicines Agency or the Scientific Committee for Consumer Products, depending on the type of animal by-products for which risks are to be assessed”. Following this principle, this regulation amended previous Regulation (EC) No. 1774/2002 which disproportionately classified certain ABPs as Category 2 according to the risks involved, and reclassified these ABPs as Category 3. Hence, it is possible to re-evaluate and modify rules comprised in extant regulations regarding risks derived from the management and use of ABPs, provided that scientific evidence supports those changes in terms of guaranteeing the protection of public and animal health.

In this context, new methods for the treatment and valorisation of aquatic ABPs are regularly proposed and submitted to EFSA for assessment, as a previous step for their legal authorisation. As an example, the Norwegian Food Safety Authority requested an opinion in 2011 about a new method for the treatment of Category 2 fish ABPs similar to the method 6 for Category 3 ABPs described in the Regulation (EC) No. 142/2011, Annex IV, Chapter III (EFSA, 2011). More recently, the Dutch Competent Authority applied for the evaluation of an alternative method for the treatment of Category 3 ABPs consisting of the hydrolysis of the material to short carbon chains, resulting in medium-chain fatty acids (EFSA, 2015). After EFSA provides the risk assessment of the proposed new methods, the EC provides with the risk management and decides whether or not to authorise it.

Both examples illustrate the opportunities to update EU legislation in view of scientific and technical findings to make a better use of ABPs, and particularly aquatic ABPs, provided safety and quality criteria are respected. Among the technical assessment GAIN will provide on innovative valorisation

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processes for different side streams, the use of mechanical fluidization and superheated steam (Nygaard and Høstmark, 2008) for the drying, sanitisation and stabilisation of mortalities is proposed, in order to eliminating the use of chemicals and associated costs and hazards. In a more ambitious way, scientific data should be generated in order to review the current limitations to the use of large quantities of aquaculture ABPs: the ban of intra-specific feeding and the limited options for the valorisation of Category 2 ABPs.

Regarding intra-specific feeding, cannibalism is a phenomenon widely distributed among fish species, occurring both in nature and in aquaculture, particularly during juvenile stages. Therefore, it is relatively likely that marketed farmed fish have fed on their siblings at some point in their lifecycles; to the best of current knowledge, this does not compromise the safety of derived products. Additionally, since the presence of fish from the same species is not taken into account when fishmeal is manufactured from wild catches –although the probabilities are low-, the potential risks due to using by-products from a fish species to feed conspecific individuals would require further assessment, in order to confirm the current prohibition or in the contrary, to consider a partial or total lift.

Likewise, currently authorised uses of Category 2 ABPs strongly limit their potential for high value applications. It must be considered that Category 2 includes such a wide variety of by-products that distinctions should be made regarding their hypothetical risks for animal health. For instance, the potential risks of Category 3 ABPs that have been mixed with Category 2 APBs regardless the proportion, or animals killed for disease control purposes but which may not be clinically ill or infected may be much lower than those of diseased animals or products containing drugs or other contaminants. Therefore, it can be questioned whether a valuable resource is being underused due to the limitations on the generally allowed applications for Category 2 ABPs.

The use of Category 2 ABPs from diseased fish for the manufacture of fish feed would pose the hypothetical risk of disease transmission. Nevertheless, fish pathogens are not regarded by the microbiological standards in current legislation, while this should be an essential criterion to demonstrate the safety of a fish feed ingredient. Microbiological quality criteria for treated Category 2 ABPs only apply to *Salmonella*, Enterobacteriaceae and *Clostridium perfringens*. A study by the Norwegian Scientific Committee for Food Safety performed a risk assessment regarding the inactivation of fish pathogens in Category 3 fish by-products by a combination of acidic silage followed by heat treatment, and concluded that the process would inactivate all pathogens, including the most heat-resistant infectious pancreatic necrosis virus (IPNV). It can be followed that methods for the treatment of ABPs foreseen in Regulation (EC) No 142/2011, much more intense in terms of heat treatment, would equally inactivate fish pathogens thus eliminating that risk on the view of using Category 2 by-products for the manufacturing of fish feed.

6.2. The regulatory barriers to the implementation of IMTA in the EU

Among IMTA schemes, GAIN only considers land-based, close-contained aquaculture, where nutrient outputs are kept within the facility and no dilution, which would strongly decrease the efficiency of

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nutrient recycling, occurs. In a typical modern IMTA system fish or shrimp receive feed as an external nutrient input, and two side streams are generated: POM and dissolved nutrients such as ammonia and phosphate. Thus, two additional trophic levels can be added to the system: a filter-feeder (bivalves, anemones) or a detritivore (sea urchins, sea cucumbers) to feed on particulate matter and seaweeds to uptake dissolved nitrogen and phosphorous.

6.2.1. Restrictions to the rearing of animals

Land-based IMTA systems are strongly affected by Regulation (EC) No. 767/2009 on the placing on the market and use of feed, according to which animal waste cannot be fed to other animal, neither food producing or non-food producing (Article 6, Annex III). This rule eliminates the option of introducing filter-feeders or detritivores in the facility which feed directly on fish waste, and thus limits the potential of IMTA to contribute to the implementation of CE in aquaculture in the EU. Considering that in recent years a number of research projects on IMTA have been developed thanks to EU funding (IDREEM, OOMU,etc.), this is a clear example of how technology always develops faster than regulations.

The precautionary principle behind the ban on the use of animal waste as feed is related to the preservation of animal health and eventually, the potential risk of disease transmission to humans. Nevertheless, the risk of transmission of diseases typical of aquatic animals to humans is negligible. There are, indeed, potential risks to human health associated to the consumption of bivalves, particularly raw, derived from their filtering activity and the potential accumulation of biotoxins from toxic phytoplankton species or human pathogens present in water. Regulations setting requirements about water quality in bivalve producing areas, depuration and presence of marine biotoxins in bivalves guarantee the safety of bivalves that are placed on the market. But in no case these risks could be directly linked to the feeding of bivalves in fish waste since the possibilities of the presence of human pathogens or biotoxins are remote.

Crossed infections between e.g. fish and bivalves also seem an unlikely event, given that pathogens affecting both groups are different, even those taxonomically closed (e.g. *Vibrio*). Further research should be required in order to propose exceptions to this regulation in situations where risks are low, and where the potential to increase food production with positive environmental implications is hampered due to excessively stringent limitations. In the case of bivalves or detritivores such as sea cucumbers or sea urchins, an intermediate solution would be allowing their rearing in IMTA systems during juvenile stages, far before commercial size. In fact, the high cost of feed production for the rearing of spat is one of the more critical limitations to the expansion of bivalve aquaculture in hatcheries, and the implementation of IMTA systems would help to overcome this situation.

A possible alternative to solve this situation in the current regulatory framework is the use of aquaculture waste water for the culture of microalgae that in turns serve as food for filter-feeders. The valorisation of different types of waste water –urban, industrial, aquaculture- through the production of microalgal biomass has been thoroughly assessed in a wide number of scientific studies (Cai et al., 2013; Gonçalves et al., 2017; Acién Fernández et al., 2018) and projects which

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demonstrate a reliable recovery of nutrients, although some technical critical points have to be solved. Potential applications of the produced biomass range are diverse, but animal feeding seems to be one of the most interesting due to the content of proteins, polyunsaturated fatty acids and micronutrients. Whereas valid concerns due to the potential presence of contaminants in waste water may arise, currently there is a lack of legislation regulating the use of microalgae to treat waste water and the applications of biomass. In this context, it seems that the use of microalgae grown in waste water, and particularly aquaculture waste water, as animal feed is governed by Regulations (EC) No 183/2005 and (EC) No. 767/2009. Moreover, microalgae are not included in the latest version of the Catalogue of feed materials, but at the same time are widely used in bivalve and live feed culture, both fresh and as commercial products.

An ultimate conclusion may be drawn on that the current regulatory framework allows the production and use of microalgal biomass in the feeding of aquaculture animals provided the ingredient complies with rules determining criteria for safety, marketing and use of feed.

6.2.2. Cultivation of macroalgae

The valorisation of dissolved nutrients in aquaculture waste water through the culture of seaweeds is another activity which is out of the scope of extant regulations. Currently there is no framework to guide or direct seaweed aquaculture in the EU, apart from regulations dealing with the authorisation of activities or the deployment of structures on the sea or on the coast. Hence, clarification of the current legal status of seaweed culture is needed in order to boost this activity to its real potential for the sustainable intensification of EU aquaculture.

Recently, the PHYCOMORPH network, composed by research teams expert in seaweeds, released the report PEGASUS: Phycomorph European Guidelines for a Sustainable Seaweed Aquaculture (Barbier et al. 2019). This report provides guidelines on best practices, legislation and regulations that currently apply to seaweed production as food and food supplement, and concludes that a regulatory framework must be developed to guide seaweed aquaculture in the EU in terms of law harmonisation and simplification of procedures, the adaptation of food safety monitoring programmes, or a risk assessment for the cultivation of exotic species.

Regarding the safety of seaweeds as food, in 2018 a recommendation was published on the monitoring of metals and iodine in seaweeds, halophytes and marine algae-based products (Recommendation (EU) 2018/464). Seaweed naturally accumulate arsenic, cadmium, lead, mercury and iodine in significant amounts, and in view of their increasing consumption in the EU, it is necessary to assess the exposure of consumers to these substance in order to decide about the establishment of maximum levels.

6.2.3. Aquaponics

Aquaponics can be considered a particular variation of IMTA in freshwater systems. Whereas no specific regulations for aquaponic production exist in the EU, relevant policies are those related to agriculture and animal production, food safety and hygiene and environment. Given the potential contribution of aquaponics to the sustainable use and reutilisation of water and the prevention of waste through nutrient recycling, besides the intensification of aquaculture production, policies

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should promote the development of this activity by means of creating specific and harmonised regulations and promoting the creation of businesses.

6.3. Other uses of waste water

The need to treat and reuse waste water from different origins and for diverse applications is being increasingly recognized for reasons including prevention of ecosystem degradation from pollution and intentional reuse, particularly in regions with water scarcity. However, the implementation of processes to reuse waste water in aquaculture systems is still low, mainly due to the lack of incentives towards a circular economy models, the prioritization of short-term results, the lack of enforcement of the “polluter pays” principle, among other possible reasons.

One of the main barriers to achieving greater water reuse is the lack of a coherent and harmonized legislative framework within the EU. MS develop their own standards, which often differ from one another, creating hurdles e.g. in the trade of agricultural products. The publication of the proposal COM(2018) 337 final in February 2019 aims to facilitate the reuse of treated wastewater for agricultural irrigation and increase the availability of water in drought periods. If turned into law, this proposal would boost the use of freshwater aquaculture effluents for food and non-food crops, at the same time establishing directions for the treatment and use of this wastewater and minimum quality requirements.

6.4. Opportunities for the valorisation of sludge

Since the use of sludge as a source of food for detritivores has to be currently discarded in view of Regulation (EC) No 767/2009, permitted treatments only allowed for low value valorisations such as biogas until very recently.

The 2015 Circular Economy Action Plan identified the need to find new valorisation routes for organic waste material, whose nutrient content makes them appropriate to be used as fertilisers. This application would reduce the need for mineral-based fertilisers, which requires the import of phosphate rock and has negative environmental impacts. Nevertheless, differences in rules as well as quality and environmental standards among MS hamper the circulation of fertilisers based on recycled nutrients in the EU, and only conventional non-organic fertilisers can be freely trade across the EU according to Regulation (EC) 2003/2003. As part of the implementation of the CE Action Plan, this regulation was revised and recently replaced by Regulation (EU) 2019/1009 which includes all kinds of fertilisers. This is expected to stimulate the manufacturing and marketing of alternative fertilisers and create more value for organic-rich waste such as aquaculture sludges.

Connecting wastewater treatment and valorisation of sludge, GAIN aims to demonstrate the feasibility of magnetic particle separation and sono-electro-flocculation techniques to recover

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particulate and dissolved matter from aquaculture effluents, and novel technologies for the drying and heat sanitisation of the resulting sludge in compliance with the new regulation for its use as fertiliser.

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7. Conclusions and recommendations

The implementation of CE concepts can be a practical solution for aquaculture processes. Many of the barriers identified with CE are regulatory, but also economic burdens exist, related to business models, economies of scale, remoteness of the supplies, logistics and also the market due to consumer product acceptance. These economic issues could be solved in the long term through technological improvements and promotion of low carbon footprint products, making them competitive in terms of price; however, the regulatory barriers are more complex, since they cannot be simply removed and the mechanisms for the amendment of EU regulations may require long and comprehensive procedures.

In order to promote a full implementation of the Circular Economy Action Plan, the priority of the Commission is to encourage the reuse of by-products from the industrial sector. However, some legal issues still interfere to the application and the re-integration of some products on the economy. One of the key initiatives of the Commission in 2017 was to put forward a detailed analysis of the legal, technical or practical problems at the interface of chemical, product and waste legislation that may hinder the transition of recycled materials into the productive economy. In this sense the Commission is working on legislation trying to clarify the rules on by-products to facilitate industrial symbiosis between sectors. Looking at it, the Commission will include the guidance, throughout the Best Available Techniques reference documents (BREFs), to promote best waste management and resource efficiency practices. Although the lack of legislation supporting the circular economy in aquaculture industry can be an impediment, at the same time this could constitute an advantage or opportunity to give court to promote legislative and regulatory measures for the sector setting out the basis for developing specific “circular economy” practices and guidance on aquaculture regulation at the EU level.

Moreover, also environmental aspects related to circular economy concepts in aquaculture should be considered for the development of the regulatory framework. The main objective of the sustainable development must be promoting the economy of the future at the same time guaranteeing environmental protection. In particular the centralization of production and extensive global transport should be replaced by local schemes able to close the loops in more limited geographical areas in order to redistribute economic activities, facilitate logistics and reduce environmental footprint. This trend will show positive effects not only in the local economy growth, but also in the food security and it will serve to increase the UE independence in terms of food production systems. Some examples of this concept are the use of CO_2 from nearby industries for microalgal culture, in-situ biomethanisation of biodegradable wastes in aquaculture plants, to be used as power source or for heating, or increasing maximum recovery yields of fish products, at the same time applying the best available practises to manage the animal by-products, but also the effluents.

Aquaculture industry and related stakeholders should consider the implementation of CE a clear necessity, as well as its promotion throughout regulations to progress in terms of giving added value to own and other by-products, promoting product diversification, contributing to alternative energy generation, and guarantee sustainability, traceability and biosecurity of their products, always

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considering information and transparency towards consumers and market acceptance. Figure 5 provides a brief SWOT analysis of the current framework for the implementation of CE concepts in EU aquaculture.

Strengths

- Possibilities of circular economy promotion of legislation for approving "Recycling and Reutilization" based on the current laws absence.
- Important market development in aquaculture systems based on environmental sustainable techniques.
- Use of conventional wastewater resource recycling knowledge assuring powerful competitiveness using nutrient rich waters.
- Experienced operators with proven track record
- Global recognition as a leading producer of organic specie and also people's well-educated environmental concept.
- Technically advanced systems.

Weaknesses

- Lack of a unified and integrated regulatory framework at EU and international level, implying water reuse, by-products for fishmeal, etc. Laws should be unified in order to contribute to food security in the UE through competitive and sustainable aquaculture and market.
- Insufficient source of sustainable raw materials at economical prices due legislation hurdles and traditional fishmeal source depletion.
- Insufficient investment in R&D projects to promote circular economy in aquaculture field joined to the lack of private investment.
- Lack of a coordinated route to market approach at EU level.
- Aquaculture companies work as ancillary industries where even minimal changes are seen like a huge jump.

Opportunities

- Implementation of cloud technology and 4.0 industries to reduce the consumption of electrical energy, water resources and fuel going to a sustainable production.
- Promotion of win-win thinking in the aquaculture involving all actors: aquaculture industry, other local companies and consumers from a bioeconomy point of view.
- Improve EU competitiveness throughout new markets taking advantage of the global demand based on eco-certified products.
- Employment potential in coastal populations.
- Encouraging and subsidizing industry in using by-products and also recycled products.
- New fishmeal possibilities based on mortalities and discards coming from landing obligation.
- Promote off-shore aquaculture sites.
- Increasing demand and also possibilities of important export potential.
- Possible biomethanation of aquaculture sludges.
- Development of shellfish hatcheries.
- Use both land and sea based nursery sites.
- Use of funding instruments to promote new sustainable economy.
- Looking for profit-seeking investment in sectors with high demand (i.e, health) could create a solid background for R&I.
- Integration of reuse systems to reduce consumption in water scarcity areas.

Threats

- Fish diseases and parasites due to new fishmeal sources, i.e. by-products.
- Public opposition to circular economy concept regarding feed of future food.
- Natural occurring events such as diseases and algal blooms that hampers normal activity.
- Lower exploitation costs in Asian and American countries that implied higher competition for export trading.
- Spatial restrictions due to development of aquaculture activities in Natura 2000 habitats
- Lack of access to funding.
- Impact of foreign species in biodiversity.
- Climate change regulations.
- Impact of aquaculture in water eutrophication.

Figure 5. Summary of SWOT analysis of the implementation of circular economy in the EU aquaculture.

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The revision of the status quo of the aspects of EU aquaculture with highest potential for the introduction of CE principles, both those explicitly tackled by GAIN and those beyond the scope of the project, has identified the areas where legislation barriers must be revised, or new regulations must be created in order to fill gaps current hampering the development of circular processes in EU aquaculture.

General legislation and policies

- General legislation. The main issue in current circular economy implementation in aquaculture is legislation. Firstly, there is an almost complete lack of specific legislation on aquaculture in the EU at all levels: water quality, feed and by-products, wastewater reuse, nutrient recycling, etc., which hampers the development of harmonised processes. Also, the homogenization of the criteria for the application of risk analysis and the precautionary principle that underlies the lack of homogeneity of criteria in areas where there is no precise legal development should be considered.
- Policy framework. It is necessary to put in place a comprehensive and concerted policy framework for the development of CE in the EU which facilitates, amplifies and complements primary action and control at national and sub-national levels.
- Role of the Aquaculture Advisor Council. The AAC must promote a comprehensive EU study to identify gaps and opportunities for the circular economy and support a debate on its implementation in aquaculture.
- Acknowledgement of the potential of aquaculture to contribute to food and nutrition security for EU citizens and the circularity and resource efficiency of food systems, encouraging innovation and the empowerment of communities.
- Information to the consumer. A general framework of minimum requirements for the application of the carbon footprint or ecolabel in general should be set. It would be in the recognition of the operators that align with the objectives of the circular economy.

Fish feed, feed ingredients and aquaculture or fishery by-products

- Intraspecific feeding. The majority of aquatic species cultured in EU are carnivore or omnivore species with tendency of cannibalism in most of them. The ban of the use of meal from the same species in fish feed may affect the efficient valorisation of aquaculture ABPs, e.g. when more than one species is processed at the same facility and by-products are mixed. In view of the absence of this restriction on fishmeal from wild catches, it should be revised under the light of scientific evidence to confirm or discard issues for food and feed safety.
- Category 2 fish by-products. Some Category 2 by-products may be of as low or no risk as Category 3; besides foreseen treatment methods ensure the microbiological safety of these materials. Regulation should be revised to allow the use of certain types of Category 2 fish by-products as fish feed ingredients, provided their safety (e.g. microbiological) is demonstrated. Although scientific evidence should be constructed to support this possibility,

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if feasible its economic benefits for the EU fish farms and feed manufacturers would be remarkable.

- Insect meal. With the EU authorisation to the use of insects in aquaculture feed and the growing interest in this raw material, it is expected that imports would help cover the internal demand. Based on EU regulations on animal feed, restrictions to the import of insect meal should be considered if producing countries cannot guarantee the same standards in force in the EU.
- Equality in the application of specific derogations. It is fundamental to remove the restrictions that are currently conditioning the viability of initiatives for the use of by-products, especially when at small-scale farms.

Other side streams: water, dissolved nutrients and sludge

- Reuse of water through IMTA or aquaponics. EU countries should move the mind from preventive/precautionary principles to the permissive/promotional also keeping the food safety standards. This will require changes in policy and legislation related to moving the focus from the single species approach to incorporate bi-culture and poly-culture through mechanisms such as the EU Aquaculture Advisory Council and also to develop health and food legislation that directly acknowledges the safety of IMTA products maintaining close contact with regulators and giving inputs to promote the reforms for establishing legislation regarding this field.
- Use of sludge as feed source for detritivores. In line with the revisions to allow the implementation of IMTA systems for the reuse of water, the same approach should be done for the valorisation of tank aquaculture sludge for the feeding of sea cucumbers, sea urchins or polychaetes.
- Reuse of aquaculture wastewater. Applying to freshwater aquaculture, this would be of special interest in regions with water scarcity, for instance for irrigation of crops or parks. Forthcoming legislation on wastewater reuse should encourage the valorisation of this type of effluent and restrict their direct discharge.

8. GAIN Partner Expert opinion on EU legislation

One of the main purposes of GAIN is to investigate the most efficient use of by-products and side-streams, environmentally and economically. This includes challenging the existing legislation to ensure that it is fit for purpose, up-to-date and referring to the most recent and robust scientific evidence, while maintaining optimum safety for both consumers and cultured species. In order to do this, GAIN partners were invited to comment on the legislation, particularly affecting their own area of research and expertise from their own perspective as shown in Table 4. The individual answers are included in Annex1. Generally, participants were of the opinion that the legislation is robust and keeps consumers safe, but many were of the opinion that either the legislation was out of date compared to current scientific evidence or could be relaxed in some areas to allow for new treatment methods. There was opinion that in some circumstances, science was poorly

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communicated to legislators. In a few cases, the feeling was that more science was needed to align safety concerns with scientific observations on efficiency (See Annex 1).

Table 4. GAIN partner questionnaire to gauge opinion on current EU legislation related to GAIN innovations

Name		Institution/company	
Task and innovation			
1) What are the key pieces of legislation that control the activity/ innovation?			
2) Does the legislation actively protect consumers from food safety concerns?			
3) Does the legislation adequately protect the environment?			
4) Does the legislation act as a barrier to value addition?			
5) Does the legislation provide for the most environmentally efficient use of the resource (assuming consumer safety is ensured)?			
6) Does the legislation reflect the most up-to-date science on a) consumer safety b) environmental protection?			
7) Can the legislation be improved referring to current science? How?			
8) What science needs to be done to better inform the legislation?			
9) Is the legislation making the EU uncompetitive?			
10) Any further comments/recommendations?			

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Annex 1. GAIN partner responses to survey on EU legislation.

Name	Christian Bruckner	Institution/company	Salten Havbrukspark
Task and innovation	1) Algae as multifunctional feed components (T1.1)		
1) What are the key pieces of legislation that control the activity/ innovation? Selenium content in animal feed is regulated by the European Union (EU) towards a maximum content of 0.5 mg per kg feed (EC 1831/2003 and amendments). Only 0.2 mg selenium per kg feed may be added as a supplement.			
2) Does the legislation actively protect consumers from food safety concerns? Yes			
3) Does the legislation adequately protect the environment? Not applicable			
4) Does the legislation act as a barrier to value addition? Not applicable			

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5) Does the legislation provide for the most environmentally efficient use of the resource (assuming consumer safety is ensured)? Not applicable
6) Does the legislation reflect the most up-to-date science on a) consumer safety b) environmental protection? Requires expert opinion
7) Can the legislation be improved referring to current science? How? Requires expert opinion
8) What science needs to be done to better inform the legislation? Requires expert opinion
9) Is the legislation making the EU uncompetitive? Requires expert opinion

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10) Any further comments/recommendations?

Name	Christian Bruckner	Institution/company	Salten Havbrukspark
Task and innovation	3) Valorisation of aquaculture side streams (T2.1)		
1) What are the key pieces of legislation that control the activity/ innovation? Seaweed farming requires application for a license based on the Norwegian law for aquaculture: LOV-2005-06-17-79-§1, LOV-2005-06-17-79-§2, LOV-2005-06-17-79-§4, LOV-2005-06-17-79-§5, LOV-2005-06-17-79-§6, LOV-2005-06-17-79-§8, LOV-2005-06-17-79-§9, LOV-2005-06-17-79-§10, LOV-2005-06-17-79-§11, LOV-2005-06-17-79-§16, LOV-2005-06-17-79-§19, LOV-2005-06-17-79-§26			
2) Does the legislation actively protect consumers from food safety concerns? Not applicable			
3) Does the legislation adequately protect the environment? No, the legislation has been rather developed for fish			

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4) Does the legislation act as a barrier to value addition? Yes, it slows down and complicates development of seaweed farming
5) Does the legislation provide for the most environmentally efficient use of the resource (assuming consumer safety is ensured)? No
6) Does the legislation reflect the most up-to-date science on a) consumer safety b) environmental protection? No
7) Can the legislation be improved referring to current science? How? Yes, by taking into account actual and also classical scientific literature about seaweed cultivation
8) What science needs to be done to better inform the legislation? None, the legislation should simply use and refer to existing literature

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9) Is the legislation making the EU uncompetitive? No, it is eventually specific for Norway.
10) Any further comments/recommendations?

Name	**Hallstein Baarset,**	Institution/company	**Waister AS** (previously Multivector AS)
Task and innovation **2.1 Valorisation of aquaculture side streams**			
1) What are the key pieces of legislation that control the activity/ innovation? **Norwegian legislation is compliant with EC Regulation No 1774/2002 on animal by-products not intended for human consumption: https://lovdata.no/dokument/SF/forskrift/2016-09-14-1064. Norwegian legislation on organic fertiliser: https://lovdata.no/dokument/SF/forskrift/2003-07-04-951 regulates the use of fish sludge as fertiliser product. Dried fish sludge is currentlu being used as fertiliser by Grønn Gjødsel (gronngjodsel.no) as a blend with other organic compounds in their product range "Hybrid". Høst (høst.no) collects dried fish sludge, including it in a mix with other bio-residues as fertiliser exported to Vietnam.**			
2) Does the legislation actively protect consumers from food safety concerns? **This far the legislation is allowing dried fish sludge to be used as a bio-fertiliser product, but there is no clear reference to this in the legislation. Food safety seems to be good for consumers.**			

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3) Does the legislation adequately protect the environment? **Environment is improved by utilising the dried fish sludge as a bio-fertiliser, rather than disposing it to land fills, incineration or composting.**
4) Does the legislation act as a barrier to value addition? **It does not act as a barrier, but it should be much clearer on approval of dried fish sludge as a safe bio-fertiliser product.**
5) Does the legislation provide for the most environmentally efficient use of the resource (assuming consumer safety is ensured)? **Legislation should be much clearer on approval of dried fish sludge as a safe bio-fertiliser product, and thereby indicating this as the most environmentally efficient use of the resource.**
6) Does the legislation reflect the most up-to-date science on a) consumer safety b) environmental protection? **It should be updated and more clearly state the use of dried fish sludge as a bio-fertiliser.**
7) Can the legislation be improved referring to current science? How? **Yes. The documented results from research on dried fish sludge as high grade bio-fertiliser in growth of plants, the analysis of elements mentioned in the regulation on bio-fertiliser in dried fish feed.**
8) What science needs to be done to better inform the legislation? **Allow mixing dried fish sludge with other substrates rich in K for making a full value NPK product is important for best application of future dried fish sludge.**

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9) Is the legislation making the EU uncompetitive? **Difficult to say, but I do not see this as the case today.**
10) Any further comments/recommendations? **See above answers. Especially allowing mixing of dried fish sludge with other substrates rich in K for making a full value NPK product is important for best application of future dried fish sludge.**

Name	**Hallstein Baarset,**	Institution/company	**Waister AS** (previously Multivector AS)
Task and innovation **2.1 Valorisation of aquaculture side streams**			
1) What are the key pieces of legislation that control the activity/ innovation? **Norwegian legislation is compliant with EC Regulation No 1774/2002 on animal by-products not intended for human consumption: https://lovdata.no/dokument/SF/forskrift/2016-09-14-1064. Norwegian legislation on organic fertiliser: https://lovdata.no/dokument/SF/forskrift/2003-07-04-951 regulates the use of fish sludge as fertiliser product.** **Mortalities can be in category 2 or 3 depending on the circumstances for the fish being discarded (but still alive) or dead. Different regulations on each of these categories according to EC Regulation No 1774/2002.**			
2) Does the legislation actively protect consumers from food safety concerns? **Current regulation is strict and food safety seems to be good for consumers.**			

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3) Does the legislation adequately protect the environment? **The use of formic acid producing ensilage is posing a risk to the environment as well as workers health and safety. The innovative method of drying of mortalities eliminates the need for formic acid and will be better for health, safety and environment.**
4) Does the legislation act as a barrier to value addition? **The process of drying mortalities as site needs to be documented as safe for this method to be used by fish farmers. There will be a need to further analyse the bacteria content of dried mortalities.**
5) Does the legislation provide for the most environmentally efficient use of the resource (assuming consumer safety is ensured)? **The allowing of ensilage may not be the most environmentally efficient use of the resource, as it includes transporting substantial amounts of liquid state mixture of formic acid, water and fish. A reduction of approx. 85 % of weight and volume is obtained by drying compared to ensilage.**
6) Does the legislation reflect the most up-to-date science on a) consumer safety b) environmental protection? **Drying of mortalities will be demonstrated as a safe and e**
7) Can the legislation be improved referring to current science? How? **Yes. The documented results from research on dried fish sludge as high grade bio-fertiliser in growth of plants, the analysis of elements mentioned in the regulation on bio-fertiliser in dried fish feed.**
8) What science needs to be done to better inform the legislation? **Allow mixing dried fish sludge with other substrates rich in K for making a full value NPK product is important for best application of future dried fish sludge.**

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9) Is the legislation making the EU uncompetitive? **Difficult to say, but I do not see this as the case today.**
10) Any further comments/recommendations? **See above answers. Especially allowing mixing of dried fish sludge with other substrates rich in K for making a full value NPK product is important for best application of future dried fish sludge.**

Name	Mohamed Soula, Diego Méndez, Martiña Ferreira	Institution/company	ANFACO-CECOPESCA
Task and innovation Valorisation of aquaculture side streams (T2.1): channelling the dissolved nutrient flow through a pilot scale aquaponics system (macro- and microalgae in seawater, microalgae and plants in fresh water)			
1) What are the key pieces of legislation that control the activity/ innovation? Regarding microalgae and macroalgae biomass and aquaponics-grown plants for human consumption: ▪ Regulation (EC) No 178/2002 on food safety ▪ Regulation (EU) No 2015/2283 on novel foods (when appropriate) Regarding microalgae and macroalgae biomass and aquaponics-grown plants for aqua feeds: ▪ Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene ▪ Commission Regulation (EU) No 2017/1017 of 15 June 2017 amending Regulation (EU) No 68/2013 on the Catalogue of feed materials Regarding the reuse of water: To our understanding, currently there is a regulatory gap at EU level dealing with the reuse of water, particularly freshwater. Whereas the publication of the			

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proposal COM(2018) 337 final in February 2019 aims to facilitate the reuse of treated wastewater for agricultural irrigation and to increase the availability of water in drought periods, its conversion into law is still pending. Nevertheless, MS may have their own regulations and standards on the reuse of water, such as the case of Spain where a Royal Decree (Real Decreto 1620/2007) lays down the regulatory scheme on the reuse of treated water. In this piece of legislation, minimum quality standards are set for the reutilisation of treated water in different applications, included agricultural irrigation. To our knowledge, there are no regulations at EU level on the reuse of marine water from aquaculture or other applications either.
2) Does the legislation actively protect consumers from food safety concerns? To our understanding, legislation related to this topic actively protects consumers from food safety concerns.
3) Does the legislation adequately protect the environment? We consider there is a regulatory gap at EU level regarding the use and valorisation of aquaculture wastewater. Moreover, regulations on the quality criteria for discharges from different sources, including aquaculture, are set at national level. In many occasions, quality criteria establish the acceptable levels of nutrient concentration in recipient water bodies, but they do not consider the absolute quantities of discharged nutrients. A higher level of environmental protection should pose more stringent conditions for wastewater discharge, and stimulate the removal of dissolved nutrients, e.g. through IMTA approaches, denitrification, phosphorous uptake, etc.
4) Does the legislation act as a barrier to value addition? The lack of legislation, rather than legislation itself, may contribute to discourage the setup of tools to create added value from dissolved nutrients in aquaculture effluents. But these also may be hampered by the necessary investments in facilities, equipment and labour. The profitability of these measures must be effectively demonstrated so that their implementation becomes a reality, in a context in which legislation favours the disposal of aquaculture effluents instead of their valorisation.
5) Does the legislation provide for the most environmentally efficient use of the resource (assuming consumer safety is ensured)? As previously said, our impression is that current legislation does not favour the efficient use of the resource since wastewater discharge is the most usual option for the management of this residue. Whereas the European Commission Staff Working Document SWD(2016) 178 final on the application of the Water Framework Directive (WFD) and the Marine Strategy Framework Directive (MSFD) in relation to aquaculture considers IMTA as a good industry practice for mitigation against the impacts of organic enrichment and nutrient input, but this document is in no way binding in terms of regulation.

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6) Does the legislation reflect the most up-to-date science on a) consumer safety b) environmental protection? Regulation related to food and feed safety are continuously complemented and subjected to revision by EFSA. Regarding environmental protection, it must be considered that the impact of aquaculture on the quality of water bodies is minimum compared to other industries, because of its size and also to the type of discharged substances, mostly dissolved nutrients; hence regulations for aquaculture discharges are not particularly stringent. Certainly, other compounds such as drugs may also be released, but they are not the object of this document.
7) Can the legislation be improved referring to current science? How? State-of-the-art scientific information provides solid assessment on the effects of the discharge of dissolved nutrients from aquaculture facilities into the environment, as well as on water treatment and bioremediation.
8) What science needs to be done to better inform the legislation? In our opinion, efforts must focus on the development and promotion of technically and economically viable strategies for the valorisation of aquaculture dissolved nutrient outputs, rather than on the generation of new scientific information.
9) Is the legislation making the EU uncompetitive? Rather than on legislation, probably the focus should be placed on the assessment and promotion of IMTA approaches regarding the valorisation of dissolved nutrients through the production of macroalgae, microalgae and terrestrial plants. Nevertheless, current legislation poses clear constraints regarding other IMTA processes such as the recycling of solid waste, i.e. faeces, as feed for filter feeders or detritivores (Regulation (EC) No 767/2009 on the placing on the market and use of feed).
10) Any further comments/recommendations?

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Name	Mohamed Soula, Diego Méndez, Martiña Ferreira	Institution/company	ANFACO-CECOPESCA

Task and innovation

Valorisation of secondary products of the aquaculture supply chain (T2.2): production of marine peptones, protein hydrolisates and oils for aqua feeds. **NOTE:** we include here considerations about the management of aquaculture mortalities (which are tackled in T2.1), since they are secondary products as much as residues from fish processing are, although they fall into a different category of animal by-product.

1) What are the key pieces of legislation that control the activity/ innovation?

Regulation (EC) No 811/2003, on the intra-species recycling ban for fish, the burial and burning of animal by-products and certain transitional measures.

Regulation (EC) No 1069/2009, laying down health rules as regards animal by-products and derived products not intended for human consumption.

Regulation (EU) No 142/2011, implementing Regulation (EC) No 1069/2009.

Regulation (EU) No 56/2013 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

2) Does the legislation actively protect consumers from food safety concerns?

To our knowledge, consumers are effectively protected by relevant legislation regarding this topic.

3) Does the legislation adequately protect the environment?

Current legislation only allows the use of Category 3 ABPs to be transformed into feed ingredients. This strongly limits the amount of available raw materials to produce fishmeal and fish oil, so the contribution of aquaculture ABPs to the global supply of fishmeal and fish oil is thus beyond their potential. Therefore, the bulk of the demand of both ingredients must be fulfilled with wild catches. A higher permissiveness on the use of aquaculture ABPs as source of fishmeal and fish oil would contribute to reduce the pressure on wild fish stocks, provided human health and feed safety are guaranteed.

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4) Does the legislation act as a barrier to value addition? The same regulatory restrictions affecting environmental protection hamper the full exploitation of aquaculture ABPs and the creation of added value, since Category 2 ABPs are processed in to low-value applications, if not sent to landfill or incineration. Other aspect in which legislation limits the exploitation of aquaculture ABPs is the prohibition of intra-specific feeding.
5) Does the legislation provide for the most environmentally efficient use of the resource (assuming consumer safety is ensured)? Current legislation certainly ensures consumer safety, but our view is that there is scope for a more efficient use of the resource not only regarding environmental protection, but also economic efficiency. Nevertheless, this hypothesis that must be supported for scientific evidence to demonstrate the safety of certain ABPs of Category 2 for their valorisation as aqua feed ingredients.
6) Does the legislation reflect the most up-to-date science on a) consumer safety b) environmental protection? Legislation is likely updated to the most recent knowledge on consumer safety and environmental protection.
7) Can the legislation be improved referring to current science? How? Regarding the ban of intra-specific feeding in aquaculture feeds, it must be considered that many aquacultured fish species are naturally cannibalistic, and this behaviour is displayed in culturing facilities. Therefore, intra-specific feeding is expected regardless the species composition of the feed. This fact should be considered in view of the revision of the intra-specific feeding ban. In other cases, our opinion ins that current science is insufficient to suggest regulatory changes that allow for an environmentally more efficient use of aquaculture ABPs; see below.
8) What science needs to be done to better inform the legislation? There is a clear need for a better assessment on the potential risks of Category 2 aquaculture ABPs, since the actual threats to feed, animal or human health and safety may be overrated in some cases. Category 2 is a heterogenic group which comprises all types of dead livestock, digestive tract content and mixture of Category 3 + Category 2 ABPs, whatever the proportions. Regulation (EC) No. 1069/2009 recognises that “progress in science and technology may lead to the development of processes which eliminate

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or minimise the risks to public and animal health. Amendments to the lists of animal by-products set out in this Regulation should be possible, in order to take account of such progress. Prior to any such amendments, and in accordance with the general principles of Community legislation aimed at ensuring a high level of protection of public and animal health, a risk assessment should be carried out by the appropriate scientific institution, such as EFSA, the European Medicines Agency or the Scientific Committee for Consumer Products, depending on the type of animal by-products for which risks are to be assessed". Following this principle, this regulation amended previous Regulation (EC) No. 1774/2002 which disproportionately classified certain ABPs as Category 2 according to the risks involved, and reclassified these ABPs as Category 3. Hence, it is possible to re-evaluate and modify rules comprised in extant regulations regarding risks derived from the management and use of ABPs, provided that scientific evidence supports those changes in terms of guaranteeing the protection of public and animal health.

Category 3 ABPs must be processed according to 7 processing methods described in Regulation (UE) No 142/2011 in order to be used as feed ingredients. Some of these methods comprise the use of high temperature, high pressure, or both. It is likely that some of these methods could be applied to certain types of Category 2 ABPs, and that the resulting product would be free from human and animal pathogens, hence complying with this and other requirements on feed hygiene. Scientific research should be done in order to assess the possibilities of processing Category 2 products to obtain safe materials for feed, establishing criteria to select those Category 2 ABPs which would be fit for this type of valorisation.

9) Is the legislation making the EU uncompetitive?

Many of the regulations banning the use of Category 2 ABPs in aqua feeds or intra-species feeding do not exist in other countries, so legal restrictions in the EU, although fully justifiable from the point of view of food safety and animal health, may cause a disadvantage for European aquaculture producers who must compete with imported products that do not necessarily comply with the strict EU regulations. Hence, more stringent conditions to the imports of certain aquaculture products should be set.

10) Any further comments/recommendations?

Name	Mohamed Soula, Diego Méndez, Martiña Ferreira	Institution/company	ANFACO-CECOPESCA

Task and innovation

Valorisation of shellfish industry by-products (T2.3). Two aspects are considered: 1) use of shells as filling material for biofilters, and 2) as a partial substitute

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for limestone in cement production.
1) What are the key pieces of legislation that control the activity/ innovation? Regulation (EC) No 1069/2009, laying down health rules as regards animal by-products and derived products not intended for human consumption. Regulation (EU) No 305/2011, laying down harmonised conditions for the marketing of construction products.
2) Does the legislation actively protect consumers from food safety concerns? The proposed valorisation route for this secondary product is not directly linked to food and consumers safety.
3) Does the legislation adequately protect the environment? Classification of shell waste depends on the presence of flesh of soft tissue remnants. If this is the case, shells are considered animal by-products (ABPs) according to Regulation (EC) No. 1069/2009, whereas clean shells are considered a residue subjected to Directive 2008/98/EC on waste. Since EU policies and strategies on waste encourage the prevention and the recycling of residues, even though shells can be landfilled or incinerated, valorisation processes should be proposed.
4) Does the legislation act as a barrier to value addition? No. Shell residues can be used in different applications, e.g. liming agent in agricultural soils, calcium supplement in feed, etc. Limited valorisation of this resource is mostly related to the lack of demand.
5) Does the legislation provide for the most environmentally efficient use of the resource (assuming consumer safety is ensured)? Current legislation does not pose any restriction to the disposal of shell waste, and given the limited options for valorisation, landfill is the most usual destination.

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6) Does the legislation reflect the most up-to-date science on a) consumer safety b) environmental protection? a) valorisation of shell waste does not pose any significant implication to consumer safety. b) state of the art provides a range of technically and legally viable options for shell valorisation, but the use of this material is not explicitly considered in any EU strategy to reduce waste production and promote recycling or other ways of valorisation.
7) Can the legislation be improved referring to current science? How? In our opinion it is difficult that legislation becomes stricter to ensure the valorisation of shellfish residues since these cannot be recycled, but must be used as raw material for other applications, and these are subjected to demand.
8) What science needs to be done to better inform the legislation? The development of new materials from shell waste, or process improvement to reduce the cost of the transformation of the shell, could contribute to provide basis for a more strict regulation on shell disposal, once feasible alternatives are available. Although not directly related to the valorisation of aquaculture by-products, it is agreed that healthy, dense bivalve populations play an important role on calcium and alkalinity dynamics in coastal and estuarine ecosystems. Considering that tons of bivalves are yearly harvested from very specific areas, e.g. Galician rías that produce thousand tons of mussel, research should be done to assess whether the removal of these high amounts of calcium carbonate as shells plays any effect on alkalinity dynamics and biogeochemistry of calcium in these areas. Scientific evidence would help to decision making in the management of shell waste, e.g. to decide whether shells must be returned to the sea in particular locations or situations.
9) Is the legislation making the EU uncompetitive? No.

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10) Any further comments/recommendations?

Name	Andrea Alberto Forchino	Institution/company	Ca’ Foscari University of Venice (UNIVE)
Task and innovation			
1) What are the key pieces of legislation that control the activity/ innovation? The key pieces of legislation that control the innovation concern the food safety for human consumption and for fish health. In particular, for the Italian legislation, the by-product Regulation states that Foodstuffs containing fish may not be used directly as feed but may be further treated into fishmeal, and the fishmeal may not be fed to ruminant animals other than un-weaned ruminants. A number of products of animal origin may be safe for human consumption, but not safe for animal health, e.g. because it may contain pathogens causing foot-and-mouth disease, classical swine fever or African swine fever. Thus, a number of animal products which are eligible for human consumption are not eligible without further processing for feed use or must be partly excluded from the feed chain. According to **REG (CE) n. 1069/2009**, fish wastes at slaughtering (fish waste, skin, blood, heads…) are considered CATEGORY III products. These products must be transformed to be used as feed ingredients.			
2) Does the legislation actively protect consumers from food safety concerns? Yes, I think so. By the way, legislation should be updated according to the latest scientific researches and social needs.			
3) Does the legislation adequately protect the environment? Yes, I think so. By the way, legislation should be updated according to the latest scientific researches and social needs.			

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4) Does the legislation act as a barrier to value addition? Not properly as a barrier, but in some case, legislation it is not so updated to take into consideration new ways of utilization of new feed ingredients or by-products/secondary products.
5) Does the legislation provide for the most environmentally efficient use of the resource (assuming consumer safety is ensured)? Probably not. There is still a gap between the new scientific researches and the legislation. The filling of this gap will ensure the most environmentally use of the resources.
6) Does the legislation reflect the most up-to-date science on a) consumer safety b) environmental protection? No, I don’t think so. For example, the legislation regarding the processes allowed to transform Category III materials to be used as feed ingredients (**REG.(UE) N. 142/2011)** is dated 2011.
7) Can the legislation be improved referring to current science? How? In order to improve the legislation, a constructive dialogue must be set up between legislators and scientists. The current scientific researches could mark the path following which the legislation could be improved.
8) What science needs to be done to better inform the legislation? The point is not what science needs to be done, but how scientist communicates their research to the legislators. Working on the maximization of the exploitation of scientific outputs of a project could be the best way to better inform the legislation.

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9) Is the legislation making the EU uncompetitive? Probably yes. However, I think that a more competitive development of EU should be promoted, only in the respect of the strictest food safety principles.
10) Any further comments/recommendations? No

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