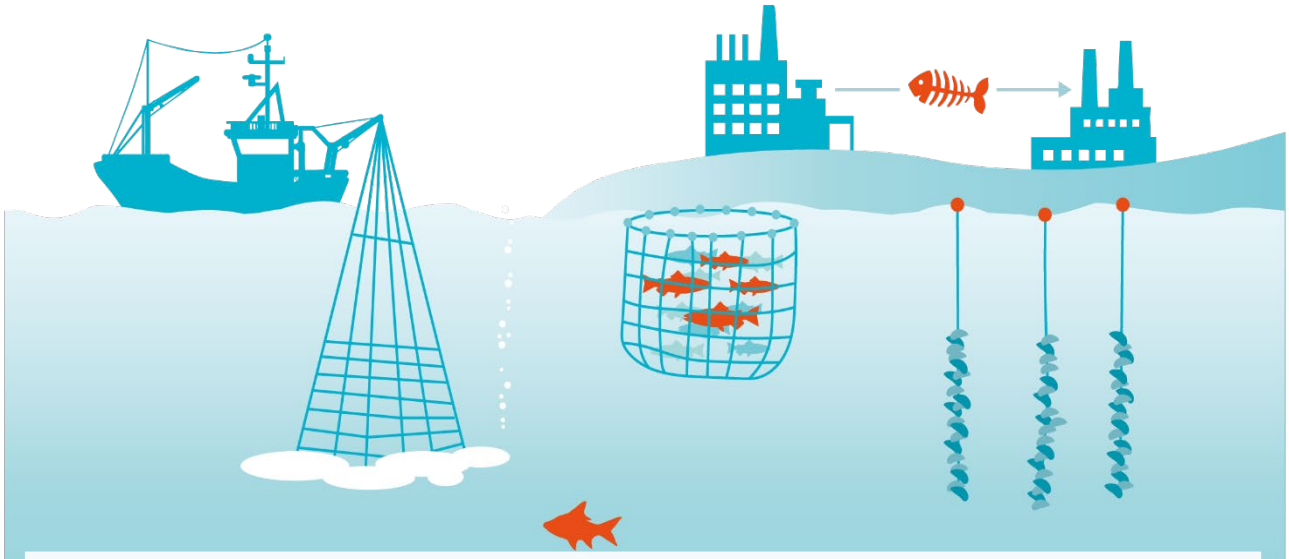
waseabi

Optimal utilization of seafood side-streams through the design of new holistic process lines

D5.4

Legal and Regulatory Barriers Hindering WASEABI Concept Adoption



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Executive Summary

This report has been prepared within the scope of WaSeaBi, an EU-funded Horizon 2020 project. The report aims to help stakeholders involved in the project to navigate the regulatory landscape and promote successful implementation of innovative solutions. Thus, it provides an overview of the applicable legal requirements and possible barriers to innovations linked to the project objectives. Based on the regulations evaluated in this report, it is anticipated that the main regulatory barrier for the project products would be some products being classified as novel foods.

Deliverable Description

This report outlines the regulatory assessment carried out to ensure the compliance of proposed innovative solutions with EU policies and regulations. The assessment was conducted to guarantee that the proposed techniques align with EU regulations, as well as to identify any legislative barriers to their market uptake. The goal of this regulatory assessment is to provide valuable information to industrial partners on how to adapt their processes to comply with EU regulations. By addressing the regulatory requirements, companies can improve their ability to successfully implement innovative solutions while also meeting the necessary compliance standards. The regulation assessment shows that the project products are not expected to face any significant legal barriers, except for potential classification as novel foods. This report provides a comprehensive overview of relevant regulations with regard to the production, processing, and marketing of the project products.

How does the deliverable relate to the objectives of WP5?

This report has been prepared within the scope of Work Package 5, which aims to quantify specific environmental and economic impacts of the proposed solutions and evaluate the logistic chains. Additionally, the legal and regulatory framework in Europe is also examined within this WP. This report, which was prepared as part of Task 5.4, aims to ensure that the innovations to be developed comply with the relevant regulations, to identify the obstacles to their introduction to the market, and to propose measures to prevent these obstacles.

Compliance with the policies and regulations is a crucial aspect to consider when proposing innovative solutions. To endure this aspect, it is essential to conduct a regulatory assessment that evaluates the proposed techniques. Through this evaluation process, stakeholders can understand the legal and regulatory framework surrounding the proposed solutions and take appropriate measured to address any compliance issues before implementation.

1 Introduction

WaSeaBi aims to bring a sustainable approach to the use of aquatic resources by developing efficient and sustainable storage solutions, classification technologies, and decision tools for side streams from the aquaculture, fisheries, and aquatic processing industries. The project paves the way to increase the market value of side-stream products by bringing an innovative approach to the entire supply chain of raw materials. Thus, it aims to achieve more sustainable and commercially attractive exploitation of aquatic products.

In this context, the applicable legal regulations in Europe regarding the project products have been reviewed. Among these reviewed legal regulations, the applicable ones within the scope of the project were selected and summarized from a broad perspective. Relevant legal regulations are listed according to their content and presented in this report. In addition, the requirements of applicable regulations are explained under **food preparation, feed preparation and labelling categories** to facilitate the follow-up of relevant compliance steps.

The European Union has established food regulations that govern the production, processing, labelling, and marketing of food products in order to ensure that they are safe for consumers. These regulations cover a wide range of topics, including hygiene standards, additives, contaminants, and marketing. Compliance with these regulations is mandatory for all food businesses operating within the European Union. Therefore, it is important for companies that are involved in the food industry to have a clear understanding of the EU food law and its requirements. This report includes regulations that operators working on food and feed processing in the European market should follow. The report is on applicable regulations regarding fish side-stream products in connection with the objectives of the WaSeaBi project.

During the regulatory assessment, the EUR-Lex database was primarily used to examine the legal regulations that apply to the solutions, techniques, and products within the scope of the project. In addition to this database, resources from institutions such as the European Food Safety Authority (EFSA) and the European Fisheries Control Agency (EFCA) were also considered. To further refine the assessment, feedback was gathered from experts in relevant legal regulations, as well as industrial partners and advisory board members involved in the project. Based on this feedback, the applicable regulations were selected, and the report was prepared. By taking into account a variety of sources and perspectives, the regulatory assessment provides a comprehensive understanding of the legal and regulatory framework surrounding the proposed innovative solutions.

Operators engaged in side-stream production are subject to the rules applicable to the entire food industry. Besides the general rules to be followed, there are also regulations that the operator should consider according to the field of activity. Thus, while the second part of this report includes the fundamental regulations to be followed, the third part includes process-based regulations. A decision tree of relevant regulations for legal compliance is depicted in Figure 1.

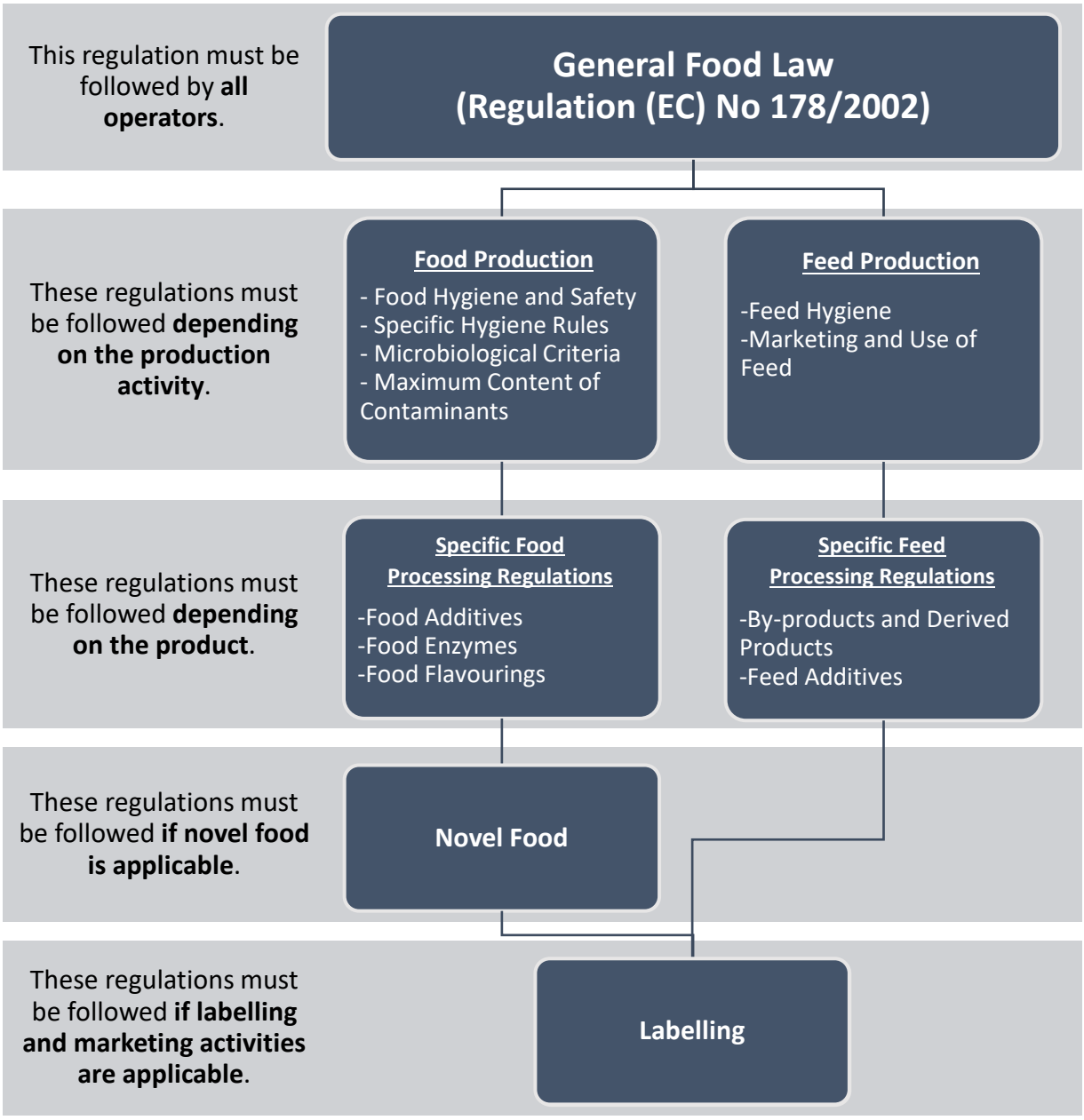

***Figure 1**. A decision tree of relevant regulations for legal compliance.*

Table 1 presents the regulations reviewed in this report under the relevant categories.

Table 1. Key legal regulations reviewed in this report.

<table>
<tr><td colspan="2"><u>General Food Law</u>
Regulation (EC) No 178/2002 lays down the general principles and requirements of food law and strengthens the rules on the safety of food and feed.</td></tr>
<tr><td><u>Food Production</u>
Food Hygiene and Safety
Regulation (EC) No 852/2004 defines the requirements that food business operators must meet.
Specific Hygiene Rules
Regulation (EC) No 853/2004 establishes the specific standards on the hygiene of the food of animal origin.
Microbiological Criteria
Regulation (EC) No 2073/2005 lays down microbiological criteria.
Maximum Content of Contaminants
Regulation (EC) No 1881/2006 establishes the maximum content of certain contaminant limits for food products.</td><td><u>Feed Production</u>
Feed Hygiene
Regulation (EC) No 183/2005 lays down requirements for feed hygiene.
Directive 2002/32/EC on undesirable substances in animal feed.
Marketing and Use of Feed
Regulation (EC) No. 767/2009 on the placing on the market and use of feed.
Regulation (EU) 2017/1017 on the catalogue of feed materials.</td></tr>
<tr><td><u>Specific Food Processing Regulations</u>
Regulation (EC) No 1331/2008 lays down common authorisation procedure for food additives, food enzymes and food flavourings.
Regulation (EC) No 1332/2008 on the food enzymes.
Regulation (EC) No 1333/2008 on the food additives.
Regulation (EC) No 1334/2008 on the flavourings and certain food ingredients with flavouring properties for use in and on foods.</td><td><u>Specific Feed Processing Regulations</u>
Regulation (EC) No 1069/2009 lays down health rules as regards animal by-products and derived products not intended for human consumption.
Regulation (EU) No 142/2011 lays down health rules as regards animal by-products and derived products not intended for human consumption.
Regulation (EC) No 1831/2003 lays down regulations on additives for use in animal nutrition.</td></tr>
<tr><td><u>Novel Foods</u>
Regulation (EC) No 258/97 establishes novel foods and novel food ingredients.
Regulation (EU) No 2015/2283 lays down general rules on placing a product as a novel food in the European market.</td><td></td></tr>
<tr><td colspan="2"><u>Labelling</u>
Regulation (EU) No 1169/2011 on the provision of food information to consumers.
Regulation (EU) No 1379/2013 on the common organisation of the markets in fishery and aquaculture products.</td></tr>
</table>

2 Regulations

As indicated above, this section will present the different applicable regulations included in the decision tree (Figure 1), starting with the **General Food Law** and then showing the corresponding regulations for **Food** and **Feed** production and, finally, presenting the regulations linked to product **Labelling**, all from a European context.

2.1 General Food Law

Regulation (EC) No 178/2002 specifies the general safety principles and requirements of the General Food Law, covering all processes involved in the production of food and feed. This regulation refers to the common principles and responsibilities, providing a framework for determining whether a product can be placed on the market. Additionally, this regulation serves as a foundation for other food and feed-related regulations within the European Union. Its primary objective is to ensure that no foodstuff hazardous to health can be sold on the market.

➢ Some of the key points in **Regulation (EC) No 178/2002** are as follows:

- Food businesses must ensure that the foodstuff they place on the market is safe and complies with relevant regulations;
- This regulation establishes the European Food Safety Authority (EFSA). EFSA, referred to as "the Authority" in the regulations, provides scientific information and technical support for testing and evaluating food and feed. It is an independent scientific body responsible for providing scientific advice on food safety;
- A rapid alert system for food and feed, which facilitates rapid sharing of information in case of risk, was established within the scope of this regulation;
- Article 6 states that for this regulation to achieve its objectives, food law is based on risk analysis. According to the regulation, risk analysis must be based on scientific evidence, objective, and transparent;
- General food law also states the traceability rules. Food businesses must trace and keep records of the food. They are obliged to present this information to the relevant authorities when necessary.

2.2 Food Production

2.2.1 Food Hygiene and Safety

Regulation (EC) No 852/2004 presents the legal regulations containing the basic health principles of food hygiene. This regulation sets the general rules for food business operators. It applies to all food businesses and covers all stages from primary production to the final consumer. The regulation is based on good hygiene practices and Hazard Analysis and Critical Control Points (HACCP) principles.

According to this the regulation, the specific hygiene measures that food businesses should adopt are listed as follows:

- Compliance with microbiological criteria for foodstuffs;
- Procedures necessary to meet targets set to achieve the objectives of this regulation;
- Compliance with temperature control requirements for foodstuffs;
- Maintenance of the cold chain;
- Sampling and analysis.

Also, the HACCP principles that need to be adapted are mentioned in the regulation as follows:

- Identifying any hazards that must be controlled;
- Identifying the critical control points to control a hazard;
- Establishing critical limits which separate acceptability from unacceptability of hazards;
- Establishing and implementing effective monitoring procedures;
- Establishing corrective actions when a critical control point is not under control;
- Establishing procedures to verify that the measures are working effectively;
- Establishing documents and records of the food business to demonstrate the effective application of the measures.

Annex I of the regulation mentions general hygiene provisions to be followed throughout primary production. In this section, transport operations to deliver primary products from the place of production to an establishment are also within the scope.

In Annex II, general health measures that food products companies should follow in the processes following primary production are listed. The scopes in this annex are as follows:

- Keeping food premises and facilities clean and in good condition;
- Ensuring the quality of transport processes;
- Cleaning and disinfecting of fittings and equipment;
- Providing food waste management;
- Providing adequate water supply;
- Ensuring personal hygiene;
- Ensuring hygiene in wrapping and packaging of foodstuffs;
- Ensuring hygiene in equipment and processes used for heat treatment;
- Providing training on food hygiene as a work activity.

➸ With the publication of **Regulation (EC) No 1019/2008**, the water supply title in Annex II has been updated. This update states that clean water is usable with whole fishery products and that adequate facilities and procedures should be in place to ensure that such use is not a source of contamination for the foodstuff.

2.2.2 Specific Hygiene Rules for Food of Animal Origin

Specific hygiene rules for foods of animal origin in Europe have been determined within the framework of **Regulation (EC) No 853/2004**. This regulation contains specific hygiene rules that must be met in the production of animal origin foods, such as meat, fishery products and dairy

products. It applies unprocessed and processed products of animal-origin. These rules are laid down by Regulation (EC) No 852/2004. The general rules to be applied in this context are as follows:

- Only clean water should be used in processes;
- Products must be processed in approved or registered organizations;
- Products must have an approved health mark;
- Products outside the EU must be proven to meet the requirements with the relevant certificates.

This document lists specific rules for various food industries in Annex III. Fishery products are included in section VIII. This section does not apply to bivalve molluscs, echinoderms, tunicates, and marine gastropods when placed on the market live. With this section, the following specific hygiene categories regarding fishery products are listed:

- Requirements for vessels;
- Requirements during and after landing;
- Requirements for establishments, including vessels, handling fishery products;
- Requirements for processed fishery products;
- Health standards for fishery products;
- Wrapping and packaging of fishery products;
- Storage of fishery products;
- Transport of fishery products.

Following this regulation, additional amending regulations were published. These amending regulations include changes in fish products and the requirements that fish producers must meet. With **Regulation (EC) No 1662/2006**, new requirements for fish oil have been added with the title requirements for fish oil for human consumption. Then, with **Regulation (EC) No 1020/2008**, changes were made to the cooking of crustaceans and molluscs and fish oil intended for human consumption. With **Regulation (EU) No 558/2010**, some changes have been made in Annex III, where the regulation provides specific requirements. This regulation also includes changes regarding the requirements of fresh and frozen fishery products.

2.2.3 Microbiological Criteria Applicable to Food Products

Regulation (EC) No 2073/2005 sets microbiological criteria applicable to food products. The regulation aims to provide food safety and facilitate fair trade in the market. In this regulation, general responsibilities are specified. Accordingly, food businesses **should ensure HACCP principles and good hygiene practices** in all processes. All production, processing and transportation processes must be carried out by meeting hygiene criteria. With **Regulation (EC) No 1441/2007**, specific microbiological criteria values have been amended.

Regulation (EC) No 2073/2005 includes two different microbiological criteria: as food safety criteria and process hygiene criteria. While food safety criteria assess the safety of the products for relevant foodborne bacteria, their toxins and metabolites, such as salmonella, listeria monocytogenes, enterobacter sakazakii, staphylococcal enterotoxins and histamine, the process hygiene criteria

assess the hygienic conditions during the production processes. The criteria related to the fishing industry are presented in Table 2 and Table 3. In the tables, the value "n" refers to the number of units comprising the sample. Additionally, "c" is the number of sample units giving values between m and M.

The food safety criteria for fishery products are presented in Table 2.

Table 2. Food safety criteria for fishery products.

Food category	Micro-organisms/ their toxins, metabolites	Sampling-plan		Limits		Analytical reference method	Stage where the criterion applies
		n	c	m	M		
Fishery products from fish species associated with a high amount of histidine	Histamine	9 (18)	2	100 mg/kg	200 mg/k	HPLC	Products placed on the market during their shelf-life
Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine	Histamine	9	2	200 mg/kg	400 mg/kg	HPLC	Products placed on the market during their shelf-life

"n" refers to the number of units comprising the sample; "c" is the number of sample units giving values between m and M.

The particularly defined fish species listed in Table 2 are as follows:

- Scombridae;
- Clupeidae;
- Engraulidae;
- Coryfenidae;
- Pomatomidae;
- Scombresosidae.

Single samples may be taken at the retail level for the sampling plan of the fishery products associated with a high amount of histidine category. In such a case, the directive in Regulation (EC) No 178/2002 stating that the whole batch is to be deemed unsafe shall not be applied. According to this regulation, regarding the interpretation of test results, histamine in fishery products from fish species associated with a high amount of histidine:

- Satisfactory, if the following requirements are fulfilled:
  - the mean value observed is ≤ m;
  - a maximum of c/n values observed are between m and M;
  - no values observed exceed the limit of M.
- Unsatisfactory, if the mean value observed exceeds m or more than c/n values are between m and M or if one or more of the values observed are > M.

Process safety criteria for fish products are presented in Table 3.

Table 3. Process safety criteria for fishery products.

Food category	Micro-organisms/ their toxins, metabolites	Sampling-plan		Limits		Analytical reference method	Stage where the criterion applies
		n	c	m	M		
Shelled and shucked products of cooked crustaceans and molluscan shellfish	E. coli	5	2	1 /g	10 /g	ISO TS 16649-3	End of the manufacturing process
	Coagulase-positive staphylococci	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process

"n" refers to the number of units comprising the sample; "c" is the number of sample units giving values between m and M.

At the values given in Table 3, in case of unsatisfactory results, improvements in production should be made.

When interpreting the results of the relevant micro-organisms and their toxins, metabolites, e. coli in shelled and shuttered products of cooked crustaceans and molluscan shellfish:

- Satisfactory, if all the values observed are ≤ m;
- Acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m;
- Unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M.

On the other hand, coagulase-positive staphylococci in shelled and cooked crustaceans and molluscan shellfish:

- Satisfactory, if all the values observed are ≤ m;
- Acceptable, if a maximum of c/n values are between m and M, and the rest of the values observed are ≤ m;
- Unsatisfactory, if one or more of the values observed are > M or more than c/n values are between m and M.

2.2.4 Maximum Content of Certain Contaminants in the Foodstuff

Regulation (EC) No 1881/2006 sets the maximum content of certain contaminants in foodstuffs. The regulation aims to protect public health in the union. Food with includes higher contaminants than the specific limits which are defined in the annex cannot be sold in the market. These limits also apply to dried, diluted, processed and compound foodstuffs.

The regulation covers the following contaminants:

- Mycotoxins (aflatoxins, ochratoxin A, Fusarium toxins, patulin and citrinin, ergot alkaloids);
- Metals (lead, cadmium, mercury, inorganic tin and arsenic);

- 3-monochloropropane-1,2-diol (3-MCPD) and its fatty acid esters and glycidyl fatty acid esters;
- Dioxins and polychlorinated biphenyls (PCBs);
- Polycyclic aromatic hydrocarbons (PAHs);
- Melamine;
- Erucic acid, hydrocyanic acid, tropane alkaloids, pyrrolizidine alkaloids;
- Nitrates;
- Perchlorate.

According to this regulation, foods containing contaminants higher than the specific values stated in the annex cannot be sold. Maximum values of metal, dioxins and PCBs, and polycyclic aromatic hydrocarbons determined for fish products are presented in Table 4.

Table 4. Maximum values of metal, dioxins and PCBs, and polycyclic aromatic hydrocarbons.

Section		Fish Species	Maximum levels (mg/kg wet weight)
Metals	Lead	Muscle meat of fish	0.30
	Cadmium	Muscle meat of fish	0.050
		Muscle meat of the fish species defined in Section 3 of the Annex	0.10
		Muscle meat of swordfish	0.30
	Mercury	Fishery products and muscle meat of fish	0.50
		Muscle meat of the fish species defined in Section 3 of the Annex	1.0
Dioxins and PCBs		Muscle meat of fish and fishery products and products thereof, excluding eel	4.0 pg/g wet weight (Sum of dioxins) 8.0 pg/g wet weight (Sum of dioxins and dioxin-like PCBs)
		Marine oils (fish body oil, fish liver oil and oils of other marine organisms intended for human consumption)	2.0 pg/g fat (Sum of dioxins) 10.0 pg/g fat (Sum of dioxins and dioxin-like PCBs)
Polycyclic aromatic hydrocarbons	Benzo(a)pyrene	Muscle meat of smoked fish and smoked fishery products	5.0
		Muscle meat of fish other than smoked fish	2.0

➨ With **Regulation (EC) No 565/2008**, fish liver and derived products type were also added under the dioxins and PCB section and the maximum sum of dioxins and dioxin-like PCB value was determined as 25.0 pg/g wet weight. Also, **Regulation (EU) No 1259/2011** has been published as an amendment to establish maximum levels for dioxins, dioxin-like PCBs, and non-dioxin-like PCBs in foodstuffs.

2.2.5 Specific Food Processing Regulations

In this section, the legal regulations applicable to food processing will be examined. When producing food intended for human consumption, it is essential to follow legal regulations on food safety, specific hygiene rules, microbiological criteria, and the maximum content of certain contaminants. These regulations determine the criteria and rules that must be met in all processes applied by food production operators. Thus, it is necessary to follow the criteria and requirements in Regulation (EC) No 852/2004, Regulation (EC) No 853/2004, Regulation (EC) No 2073/2005 and Regulation (EC) No 1881/2006.

Regulation (EC) No 1331/2008, which is one of the main regulations to be considered regarding food processing, establishes a common authorisation procedure for food additives, food enzymes and food flavourings in the EU.

This regulation is based on the risk assessment determined by Regulation (EC) No 178/2002. This risk assessment process is carried out by the European Food Safety Authority (EFSA). After the application is made regarding the harmonization process, the commission requests an opinion from EFSA. After the application, EFSA shall give its opinion within nine months. Additional information may be requested during this process if deemed necessary. This regulation also provides information on implementation, transparency, and confidentiality-related processes.

The Regulation (EU) 2019/1381 is published as an amendment and provides updates on transparency and sustainability of risk assessment.

Regulation (EC) No 1331/2008 has also been adopted together with the companion legislations. These companion legislations refer to more detailed rules on the relevant food products. These regulations and their categories are as follows:

- Regulation (EC) No 1332/2008 presents legal regulations on food enzymes;
- Regulation (EC) No 1333/2008 presents legal regulations on food additives;
- Regulation (EC) No 1334/2008 presents legal regulations on flavourings.

Regulation (EC) No 1332/2008 describes the approved enzymes, the requirements for their use in foods, and the conditions for labelling. This includes only the enzymes added to the food for a technological purpose in the manufacture, preparation, treatment, packaging, transport, and storage processes. Therefore, an enzyme that is not present in the final product (or present in an inactive form) would not meet this definition. The scope of this regulation does not cover the enzymes that are not added to food to perform a technological purpose but are intended for human consumption. According to this regulation, only enzymes on the approved list can be added to foods. This list, published by the EU, contains the names of approved enzymes and detailed information about them. This regulation also provides information on the procedure for the

application and approval processes of new and existing enzymes. Chapter IV provides detailed information about the procedure and its application. The following general conditions must be met for the enzyme expected to be included in the list:

- It does not pose a safety concern to the health;
- There is a reasonable technological need;
- It does not mislead the consumer.

A safety assessment is carried out by the EFSA for the enzymes applied for inclusion in the list. Procedures for this risk assessment are also described in guidelines published by EFSA.

Another aspect involved in this regulation is the labelling of enzymes. Articles 10 and 11 provide detailed information on this subject. Accordingly, enzymes to be sold in the market only be marketed with the labelling procedures provided in Article 11. This article details all the requirements that the label must contain.

Regulation (EC) No 1333/2008 includes the approved list of food additives, terms of use and the rules for labelling these additives. This regulation prohibits the use and sale of additives containing a health concern. According to this regulation, only additives on the EU-approved list can be used and sold. The list of approved food additives is provided in Annexes II and III.

The general requirements for the approval of a food additive are that it does not pose a risk to health and does not mislead the consumer. There are specific conditions for sweeteners and colourants. In order for a food additive to be on the list, it must serve the following purposes:

- Preserving the nutritional quality of the food;
- Providing necessary ingredients;
- Enhancing the keeping quality or stability of the food;
- Aiding in the manufacture, processing, preparation, treatment packing, transport or storage of food.

Besides approved additives, this regulation also contains information on their use and labelling. Article 22 provides general labelling requirements. According to this article, labelling should be easily visible, clearly legible, and indelible.

Regulation (EC) No 1334/2008 has been prepared specifically for the use of flavourings in food products and presents the general requirements. This regulation, which basically aims for the safe use of flavourings, includes general conditions, labelling procedures and a list of approved flavourings.

This regulation lists substances that should not be added to food in Annex III. If these substances are naturally present in flavourings and food ingredients, maximum values have been determined for these amounts. These maximum values are also given in this annex.

Similarly, this regulation requires only the use and sale of flavouring substances on the approved list. This list is periodically updated.

Another procedural issue included in this regulation is the reporting obligation. According to Article 19, the producer or user must report the amount of the substance added to food in the Community

over a 12-month period. In addition, any scientific or technical information that may threaten security should be reported immediately.

Regarding to the labelling of the flavourings, Chapter IV contains explanations on labelling and presents general requirements. These labelling requirements are specific conditions, flavourings are also subject to the labelling requirements laid down in Regulation (EU) No1169/2011.

➽ **Regulation (EC) No 1334/2008** also contains a list of source materials for which restrictions apply in the manufacture of food ingredients with flavouring properties and specific values on heat treatment and flavouring production conditions.

2.3 Feed Production

2.3.1 Feed Hygiene

Regulation (EC) No 183/2005 applies to all production processes, including primary production, and ensures that animal feed is safe and of good quality. It includes subjects such as mandatory requirements, requirements to be met by feed businesses, hygiene requirements for all businesses, and the introduction of HACCP principles in the sector.

Regulation (EC) No 183/2005 also includes guides to good practice. These practices can be applied at every stage of agricultural production and feed use. Good hygiene practices, which are based on the application of HACCP principles, are also important in meeting the national legal regulations of both the commission and the countries within the union.

Another regulation that should be taken into consideration regarding ensuring safe animal feed is **Directive 2002/32/EC**. This regulation sets the rules for limiting undesirable ingredients in animal feed. Directive 2002/32/EC applies to all products for animal feed purposes. This includes additives and complementary feeding stuff. **Commission Regulation (EU) No 277/2012** amends the annexes of this directive and determines the maximum levels and action thresholds for dioxins and polychlorinated biphenyls.

2.3.2 Marketing and Use of Feed

Regulation (EC) No. 767/2009 aims to ensure the safety of feed and its components, and it lays down requirements for the marketing and use of feed on the European market. This regulation covers labelling, packaging, and presentation requirements. The fields covered in this regulation are marketing and use, traceability, labelling and presentation, and packaging. Some key takeaways are as follows:

- Animal feed must be safe, not pose a threat to the environment and animal health; labelled, packaged, and presented in accordance with appropriate regulations;
- It should be possible to trace the feed throughout the entire supply chain;

- Labelling should be in accordance with the relevant regulations and should not mislead the consumer.

In addition, **Regulation (EU) 2017/1017**, amended to Regulation (EU) No 68/2013, provides a catalogue of applicable feed materials. The use of the catalogue is voluntary.

2.3.3 Specific Feed Processing Regulations

For by-products and derived products, **Regulation (EC) No 1069/2009** must be followed. It aims to protect public health by ensuring that food and feed supply chains are healthy. This regulation replaces Regulation (EC) No 1774/2002.

According to this regulation, food operators producing by-products and derived products of animal origin must meet the following aspects:

- They must ensure that they comply with the legislation in the entire supply chain;
- They must keep records of the products;
- They must inform the national authorities about their facilities.

Regulation (EU) No 142/2011 has been published as the implementation of this regulation. Similarly, it focuses on the health rules that animal by-products and derived products are not intended for human consumption.

Regulation (EC) No 1831/2003 is related to feed additives and provides information on the standardized procedure. It also includes regulations on the use, labelling, and release of feed additives. This regulation applies to all feed additives and premixtures. According to this regulation, only authorized additives should be available and used on the European market. The authorization process is explained in the regulation. This process is carried out in coordination with the risk assessment provided by the EFSA. The regulation also provides the labelling process for additives and the essential information that the label should contain.

Regulation (EU) 2019/1009 has been published specifically regarding fertilising products and is an amendment of Regulation (EC) No 1069/2009. This regulation sets the limits of contaminants, as well as determines the safety and labelling rules for fertilizing products. This regulation does not apply to animal by-products or derived products evaluated in Regulation (EC) No 1069/2009.

2.4 Novel Food

Novel food is defined as food not used for human consumption to a significant degree before 15 May 1997 in this regulation. **Regulation (EC) No 258/97** includes rules regarding the placing of novel foods on the market. The main purpose of this regulation is to ensure the protection of public health and to meet consumer demands. This regulation has been amended with **Regulation (EU) 2015/2283**. General rules and regulations are established by Regulation (EU) 2015/2283 and Regulation (EC) No 1852/2001. With the publication of (EU) 2015/2283, these regulations were repealed and replaced. Regulation (EU) 2015/2283 on novel foods does not apply to foods used as enzymes, additives and flavourings covered by Regulations (EC) No 1332/2008, (EC) No 1333/2008, (EC) No 1334/2008.

According to the regulation, the commission is obliged to publish a list of authorised novel foods. This list is updated regularly. To be included in the list, a product must meet certain conditions. These conditions are as follows:

- The food does not pose a safety risk to human health;
- The food's intended use does not mislead the consumer;
- If the food is intended to replace another food, it does not differ from that food in a way that is nutritionally disadvantageous.

➨ The commission publishes a list of products and substances that are the subject of the Novel Food Regulation. This list, called "**Novel Food Catalogue**", is intended to assist in determining whether a product needs authorisation as a novel food.

There is an application procedure for the product that is intended to be added to the list as a novel food. This process is described in detail in Chapter III of the regulation. The information that the application should contain is as follows:

- The name and address of the applicant;
- The name and description of the novel food;
- The description of the production processes;
- The detailed composition of the novel food;
- The evidence demonstrating that the novel food does not pose a safety risk to health;
- The analysis methods;
- A proposal for the conditions of intended use and specific labelling requirements.

During the application process, the commission may ask the EFSA for an opinion related to the safety of the novel food. EFSA provides its opinion within nine months. At this stage, EFSA has the right to request additional information from the operator.

In addition, Article 4 provides detailed information on the procedure for the determination of novel food status. According to this article, food business operators verify whether the food they intend to place on the market within the Union is this novel food. If the operator is unsure about this, they consult the competent authority in the member country where they intend to launch novel food for the first time.

These regulations present the definitions related to novel food, the actions required by companies that want to register their products as novel food, and the criteria novel food must meet. Accordingly, **novel foods should not pose a risk to human health, should not mislead the consumer when they replace another food, and in this case, should not be disadvantageous in terms of nutrition.**

Regulation (EU) 2018/456 has been published as implemented. It provides information on the procedural steps of the consultation process for the determination of novel food status under Regulation (EU) 2015/2283. Regulation (EU) 2018/456 contains the template cover letter

accompanying a consultation request for the determination in Annex I, and the technical dossier template in Annex II.

➽ The following key points can be considered regarding the classification as a novel food:

- In case of uncertainty, the situation can be discussed with local authorities, as well as with the EFSA.
- For the hydrolysates, the regulations are well-established. For the products considered as a novel food, it is advised to have the certification number which approves the use in the targeted market (food, feed, nutraceuticals) at the time of application.
- The initial raw material ratio of hydrolysates purified by ultrafiltration is important for classification as a novel food.
- For the purified peptides, novel food regulations are usually applicable. Nonetheless, the degree of purification plays a significant role in the evaluation.
- The change during the production process is also an important criterion. For instance, if the final product's composition differs from its raw material by 35-40% or more, it should generally be considered a novel food. It should be noted that this percentage is based on expert opinions and does not present a certain value. For products that differ in a lower percentage and are therefore uncertain if they fall under the novel food category, it is recommended to consult the local authorities.

2.5 Labelling

The requirements to be met regarding the labelling process are included in a harmonized manner within the regulations explained in the previous sections. Labelling processes related to food processing and feed processing are covered by Regulation (EC) No 1331/2008 and Regulation (EC) No 1831/2003. However, there are also some specific regulations regarding marketing and labelling.

➽ It should be noted that specific labelling rules according to the activity are also specified in the relevant regulations. For example, regulations on enzymes, additives and flavourings presented under Regulation (EC) No 1331/2008 provide labelling conditions for these products. The regulations in this section provide general requirements for food and feed labelling and marketing.

The general rules on labelling are determined by **Regulation (EU) No 1169/2011**. This regulation ensures food information for consumers. It includes general principles, requirements, and responsibilities. It applies to all businesses within the food supply chain. According to this regulation, the list of mandatory particulars can be sorted as follows:

- The name of the food;
- The list of ingredients;
- The quantity of certain ingredients;
- The net quantity of the food;
- The date of minimum durability or the 'use by' date;

- Any special storage conditions and/or conditions of use;
- The name or business name and address of the food business operator;
- The country of origin;
- Instructions for use;
- A nutrition declaration.

Detailed information on all these requirements is also provided by this regulation.

Regulation (EU) No 1379/2013 has been prepared specifically for the fishing and aquaculture industries regarding the labelling and marketing processes. It includes the regulations on the common organization of the market. In this sense, it provides the information that the labels should specify in order to inform the consumer.

Regarding labelling, the information that the label should contain according to this regulation is as follows:

- The commercial designation of the species and its scientific name;
- The production method, in particular by the following words "... caught ..." or "... caught in freshwater ..." or "... farmed ...";
- The area where the product was caught or farmed;
- Whether the product has been defrosted;
- The date of minimum durability.

In addition, this regulation contains information on competition rules, market intelligence and marketing standards.

Regarding the labelling of feeds, **Regulation (EC) No. 767/2009** lays down rules on the placing on the market and use of feed and labelling, packaging, and presentation requirements. Thus, this regulation also presents the requirements for marketing, use and traceability. According to this regulation, general mandatory labelling requirements are as follows:

- The type of feed;
- The name and the address of the feed business operator;
- The batch or lot reference number;
- The net quantity;
- The list of feed additives;
- The moisture content.

Besides these general requirements, specific mandatory labelling requirements for feed materials are given in Article 16 of Regulation (EC) No. 767/2009. These specific requirements also include information that the feed material should contain when additives are incorporated.

The relevant rules on labelling are also expressed in the regulations related to the Common Market Organization (CMO). CMO is the policy aiming to ensure the sustainable production of fishery and aquaculture products. In 2014, several changes were implemented regarding the labelling of fishery and aquaculture products (European Commission, 2015). These changes are included in the CMO Regulation. An example label is shown in Figure 2.

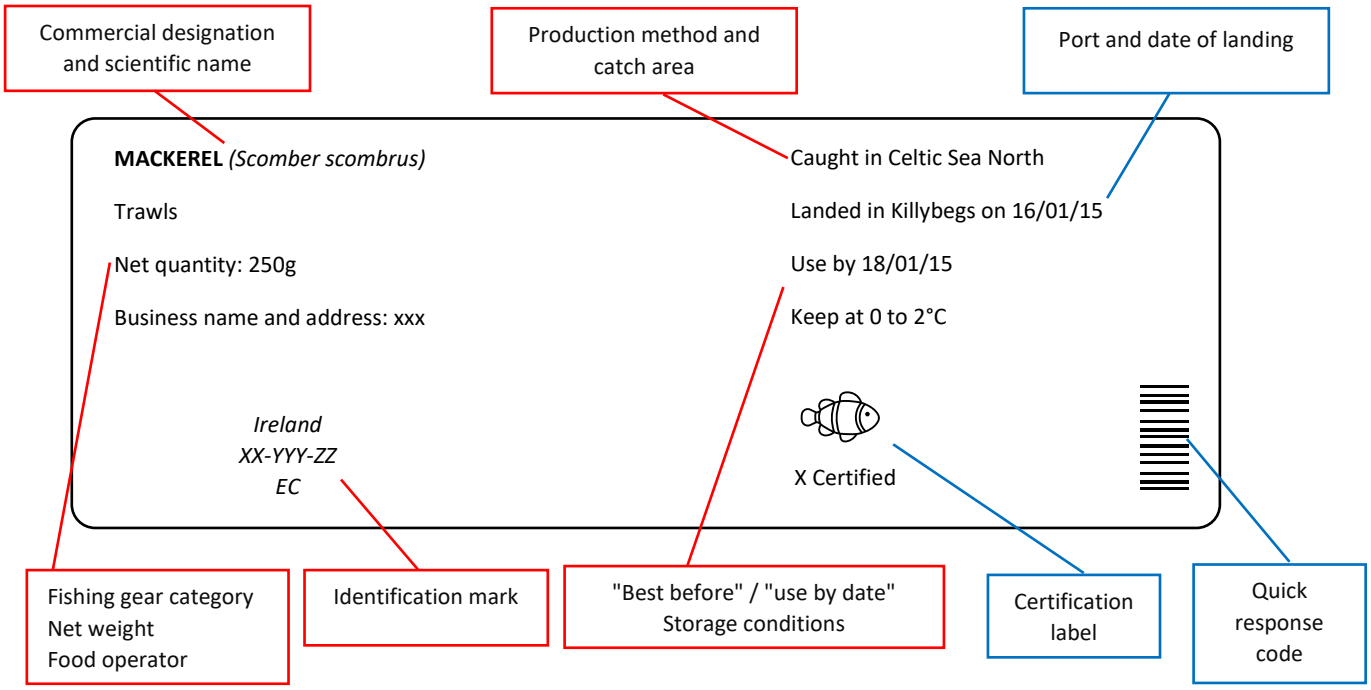

Figure 2. A sample label prepared for an unprocessed fishing sample. Red boxes indicate mandatory information and blue boxes indicate voluntary information. Adapted from "A pocket guide to the EU's new fish and aquaculture consumer labels" (European Commission, 2015).

3 Conclusion

This report has been prepared to identify the regulations that may apply to the fish side-stream sourced products planned to be produced within the scope of the WaSeaBi project (at European level). The report examines the rules that may apply to food, feed, and labelling, as well as the regulations in general for food and feed operators. The products within the scope of the project are not anticipated to be subject to any unique regulations beyond the standard rules applied to all food and feed products on the market. It is anticipated that the main legal barrier for the project products would be related to the classification of certain products as novel foods.

Based on the legal regulations reviewed, it is foreseen that the project products are not likely to encounter any legal barriers concerning hygiene and safety. The studies conducted as part of the project also support this conclusion. For example, during the evaluation of the savoury ingredients produced from cod, salmon, and hake, microbiological counts were within acceptable limits. Based on these results, it can be concluded that if the same process is upscaled, there should not be any concerns regarding microbiological safety. Similarly, regarding the herring side-streams, it has been demonstrated that antioxidant dipping is effective for controlling microbial growth and the maximum levels below the limits recommended by EFSA (Wu et al., 2023).

According to the regulations reviewed in this report, Regulation (EC) No 178/2002 establishes the basis for all food and feed production operations. This regulation, which contains fundamental procedures and principles, also serves as a basis for other regulations. In addition, other regulations may apply depending on the field of activity. For products intended for human consumption, regulations on food hygiene and safety, microbiological and maximum content values should be taken into consideration. These regulations set the fundamental requirements that food products must meet to be placed on the market. Additionally, specific regulations must be followed for food additives, food enzymes, and food flavourings under Regulation (EC) No 1331/2008.

If the product is to be evaluated in the novel food category, the procedures set by Regulation (EU) 2015/2283 must be followed. In order to determine whether a product is subject to novel food authorization, the Novel Food Catalog can be considered as a resource. In case of uncertainty in the determination, the situation can be discussed with the local authorities and the EFSA. There are specific criteria to be taken into account in the determination, such as the percentage of raw materials in the product. These criteria may vary depending on the product or production process. The percentage of raw material change during the production process is also a criterion for determining whether a product is subject to novel food regulations. However, the regulation does not specify any specific value for determining this change. Therefore, in cases of uncertainty, it is recommended to consult with local authorities.

It is important to note that this report provides only an overview of the relevant regulations to guide the potential producers and operators, and the official documents should be consulted for comprehensive information. Additionally, approved ingredient or contaminant lists are updated with newly amended regulations. It is relevant to keep in mind that regulations on food and feed products may change over time. Thus, it is crucial to stay up to date with any new or updated regulations that may impact production or marketing. Furthermore, as the use of side streams in

the fisheries and aquaculture industry increases, new regulations are expected to be implemented or added to existing ones. Therefore, it is advisable to check official regulations for the most up-to-date values in the near future.

4 References

European Commission, Directorate-General for Maritime Affairs and Fisheries, (2015). A pocket guide to the EU's new fish and aquaculture consumer labels, Publications Office. https://data.europa.eu/doi/10.2771/86800

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

Regulation (EC) No 1019/2008 of 17 October 2008 amending Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin

Regulation (EC) No 1662/2006 of 6 November 2006 amending Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin

Regulation (EC) No 1020/2008 of 17 October 2008 amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and Regulation (EC) No 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products

Regulation (EU) No 558/2010 of 24 June 2010 amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin

Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Regulation (EC) No 1441/2007 of 5 December 2007 amending Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs

Regulation (EC) No 565/2008 of 18 June 2008 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards the establishment of a maximum level for dioxins and PCBs in fish liver

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients

Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001

Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings

Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97

Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives

Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC

Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive Text with EEA relevance

Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition

Regulation (EU) 2017/1017 of 15 June 2017 amending Regulation (EU) No 68/2013 on the Catalogue of feed materials

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council

Regulation (EU) No 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009

Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003

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