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# Regulations on the use of rest raw materials from seafood processing in EU and India

## **ReValue Project Deliverable 4.2**

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## Report

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#### ABSTRACT

Surimi processing generates rest raw materials (RRM) including viscera, skin, filleting frame, bone and wash water, which potentially could be used in preparation of valuable ingredients like marine proteins and oil, protein hydrolysate, and gelatine for food or feed application. The report gives and overview over regulations for the rest raw materials, and handling and processing to the final products such as protein powders, fish meals, oils etc. The review focuses on the legislations adopted by the EEA, national legislation in Norway and India. Concluding, if the raw material (in this case rest raw material after fish processing) produced in human grade factories are processed under food hygiene legislation, the final product can be used for food application. The requirements for the raw material, handling and processing and final product for human consumption are very similar both in EEA and India and discussed in report. By-product definition is regulated only in EU, for India no specific definitions of by-product categories exit. By-products or RRM can be used for feed application under specific regulations discussed in the report. In India Bureau of Indian Standards issues regulations for quality of animal feed ingredients such as fish meal.

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#### **1** Introduction

The consumption of marine foods, and especially fish, has seen a significant increase in demand worldwide during the recent decades. This increase can be mainly attributed to the recognition of fish as important in human health (Lopes et al., 2015). The continuously growing world population expecting to exceed 9 billion by 2050, will result in a high demand for increased food production by 60%, thus creating an urgent need to explore alternative sustainable food sources. Various co-streams are generated in seafood processing industry which are abundant and contain valuable protein and lipid compounds, which all together make them an excellent alternative source of valuable ingredients for the food or feed industry. In this report, the term rest raw materials (RRM) are used to describe all co-streams and by-products from the fish processing industry which are not used directly for human consumption. Globally, fish losses account for 160.000.000 tonnes/year (FAO), out of which the surimi industry is responsible for more than 3.5%. Surimi processing generates RRM including viscera, skin, filleting frame, bone and wash water with potential to be used in preparation of valuable ingredients like marine proteins and oil, protein hydrolysate, and gelatine. Valorisation of surimi processing RRM into high added value protein and lipid ingredients is the objective of the ReValue project.

This report is a deliverable for Task 4.2 and provides an overview on the regulatory landscape regarding the main ReValue project objectives: the use of the rest raw materials from seafood/surimi processing industry for the food and feed applications. The requirements for raw material, handling, processing and final products are reviewed. The review focuses on the legislations adopted by the EU, national legislation in Norway and India. The regulations are provided for three different stages in a seafood processing chain: 1) raw material handling and 2) processing, and 3) requirements for final products in EU. The ReValue project focuses on the use/processing of RRM after processing of fish for food and feed applications; therefore, the requirements of other possible applications are not included.

#### 2 Regulations

Regulations related to the handling of animal RRM are harmonized within the European Union (EU) and should be the same in all countries within EU. The EU achieves a uniform regulatory framework by creating so-called regulations, rules that apply directly in the individual EU countries as they are written. As an example, Annex I provides an overview of Spanish laws that are derived from mandatory EU laws. Since Norway is not a member of the EU, the rules must be transposed into Norwegian law before they become applicable in Norway. The following sections provide the EU regulations for food, feed and waste products.

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#### 2.1 EU legislation for Food Hygiene Regulations, Animal hygiene Regulations, Quality Regulations for Fish and Fishery Products

- **Regulation (EC) No 852/2004** It establishes general rules for food business operators in the field of hygiene of food products, applying to all stages of food production, processing and distribution and exports, without prejudice to other more specific hygiene requirements.
- **Regulation (EC) No 853/2004** It complements the measures established by the former, through the establishment of specific standards for food business operators in the field of hygiene of food of animal origin. This Regulation does not apply to foods that contain both products of plant origin and processed products of animal origin. However, processed products of animal origin used in the preparation of such products must be obtained and handled in accordance with the provisions established.
- **Regulation (EC) No 854/2004** lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption.
- **Regulation (EC) No 931/2011** 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 (EU) No 579/2014 list the rules with regard the transport of liquid oils and fats by sea
- Regulation (EC) No 2073/2005 establishes the microbiological criteria for certain microorganisms and the application standards that must be met by food business operators when applying the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004. It also establishes that food business operators will ensure that food products meet the relevant microbiological criteria set out in Annex I to that Regulation.
- **Regulation (EC) No 2074/2005** laying down implementing measures for certain products under Regulation (EC) No 853/2004
- **Regulation (EC) No 234/2011** of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings
- Regulation (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16
   December 2008 on food additives
- **Regulation (EC) No 1881/2006** Maximum content of certain contaminants in food. This regulation lists the contaminants that should be controlled in foodstuffs, example contaminants in fish oil.

#### 2.2 EU regulations for animal by-products and feed

• **Regulation (EC) No 1069/2009** establishes public health and animal health regulations applicable to animal by-products and derived products, in order to prevent and minimize the risks to public



health and animal health that they entail such products, and, in particular, preserve the safety of the human and animal food chain.

- Regulation (EC) No. 142/2011 establishes the measures of application: of public health and animal health standards applicable to animal by-products and derived products provided in Regulation (EC) No. 1069/2009, as well as those relating to certain samples and articles exempt from veterinary controls at border inspection posts as defined in Article 16, paragraph 1, letters e) and f), of Directive 97/78 / EC.
- Regulation (EC) No 183/2005 laying down requirements for feed hygiene
- **Regulation (EC) No 1774/2002** laying down health rules concerning animal by-products not intended for human consumption
- **Regulation (EU) No 51/2013** amending Regulation (EC) No 152/2009 as regards the methods of analysis for the determination of constituents of animal origin for the official control of feed

#### 2.3 EU regulations for waste

• **Directive 2008/98/EC** of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives.

#### 3 Raw material

Regarding terminology, although there is no agreed definition, the term RRM usually includes raw material, which can be edible and obtained during the preparation of the food grade main product (Penven et al., 2013). For example, for fish such as cod, the main product is considered to be the fillet, and the head, backbones, trimmings, skin can constitute as the **RRM**. The RRM that is food grade can be used further for food applications. The term "by-product" is also used in the literature with the same meaning, but it implicitly considers those raw materials as less valuable than the main product. **By-products** can be differentiated from **waste**, which refers to components or products that cannot be used for feed or value-added products (Rustad et al., 2011). **By-products** also should be differentiated from **RRM** as by-products cannot be used for food, they can be used for feed, fertilisers or other purposes described shortly in chapter 3.2. Figure 1 illustrate the possible scenario in fish processing industry. If the RRM after processing is considered as food grade material, it can be further processed into food chain ingredient or product. If the raw materials is considered as by-product, it can be used only for animal feed application that can be used for food later, when farmed animal/plants become food.

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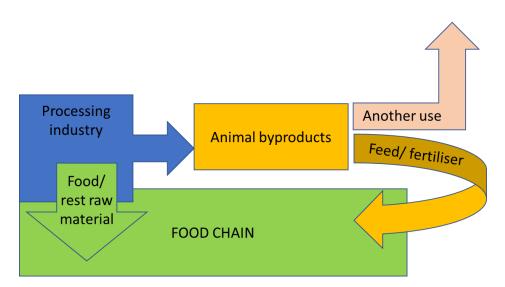


Figure 1. The raw material classification and use ("Veiledning av animalske biprodukter", 2014).

#### 3.1 Rest raw materials (RRM) for food application

The EU's food hygiene legislation regulates the use of marine RRM for human consumption, and thus controls the greatest potential for value creation (FHL, 2013). RRM that are going to be used for food application, must follow the requirements listed in the regulations on quality of fish and fishery products (see Chapter 2. Regulations). The regulations mentioned above describe the requirement for the handling equipment, processing and transportation of the fish raw materials for food application. In terms of quality requirements for RMM, no requirements have been set beyond what is stated in the regulations. This means that the producers of food products (in the case of ReValue project, producers of food ingredients from the RRM) themselves must consider which criteria in terms of raw materials will be necessary to be applied to RRM so that the end-product (e.g. protein hydrolysate) will be food grade quality. RRM do not fall under special category, therefore the regulations for unprocessed fishery products must be followed. Some of the relevant requirements are given below.

Unprocessed fishery products must not be placed on the market if chemical tests reveal that the limits with regard to value volatile basic nitrogen (TVBN) 25-35 mg of nitrogen/100g flesh. Fishery products from fish species associated with large quantities of histidine should not exceed histamine levels 100 mg/kg - 200 mg/kg.

Regulation (EC) No 2073/2005 on microbiological criteria for foods, lays down food safety criteria for relevant foodborne bacteria, their toxins and metabolites, such as Salmonella, Listeria monocytogenes, Enterobacter sakazakii, staphylococcal enterotoxins and histamine in specific foods.



For final products, where L. monocytogenes can be obtained, there is a limit of 100 cfu/g or absence in 25 g. Recommended microbiological limits for fresh and frozen fish (Fernandes, 2009 adopted from ICMSF 1986):

Test	limit per gram	limit per cm <sup>2</sup>
Aerobic plate count	5x10 <sup>5</sup>	10 <sup>7</sup>
E.coli	11	500
Add	itional tests can be carried out v	when appropriated
Salmonella	0	-
V. parahaemolyticus	10 <sup>2</sup>	10 <sup>3</sup>
Staph. Aureus	10 <sup>3</sup>	10 <sup>4</sup>

According the above discussed microbiological recommendations, measurements of Listeria, total aerobic plane count and E.coli could be used as a quality parameter for raw materials that are going to be processed into ingredients.

Raw materials used in the production of fish oil intended for human consumption shall:

- a) come from establishments, including vessels, registered or approved according to Regulation (EC) No 852/2004 or No 853/2004;
- b) come from fishery products which are fit for human consumption and which comply with the provisions of this section;
- c) transported and stored under hygienic conditions;
- d) chilled as soon as possible and maintain the temperature specified in Chapter VII Regulation (EC) No 852/2004.

The raw material should be processed within 36 hours after unloading to the processing plant, provided that the freshness criteria are met and the total value volatile basic nitrogen (TVBN) in unprocessed fishery products does not exceed the limit values (TVBN, histidine) laid down in Chapter II, Section I, point 1 of Annex II to Commission Regulation (EC) No 2074/2005.

Norwegian regulation on quality of fish and fish products (Regulation on quality of fish and fish products (<u>https://lovdata.no/forskrift/2013-06-28-844</u>) says that for the production of fishmeal, fish protein hydrolyzate, fish oil and other marine ingredients for human consumption, all fish and all fishery products can be used. This also includes whole fish and raw materials that arise during processing of fishery products, if they are still suitable for human consumption. Raw materials covered paragraph § 14 (see below under § 14) may nevertheless be used as raw material for the production of fishmeal, fish protein hydrolyzate, fish oil and other marine ingredients for human consumption. For raw materials contaminated as described in section § 14, it must be documented that these substances will not be



present in the final product. **§ 14** Fish and fishery products that cannot be marketed for human consumption (see paragraph above), exceptions which can be used as raw material for eg fish protein hydrolysate:

- fish and fishery products which have irreparable marks after freezing or drying;
- is abdominal or has significant liver and / or bile spots;
- are farmed and where errors mentioned in § 17 first paragraph cannot be corrected
- is farmed and has a distinctive sex suit
- is bloodshot or dissolved in the fish flesh or has a different odor
- detectable reddish, blackdish or browndish or is significantly grounded
- is contaminated by substances in concentrations that give fish and fishery products abnormal sensory properties
- have higher values of trimethylamine nitrogen than on average, 100 g of fish meat shall contain no more than 10 mg of trimethylamine nitrogen and no single sample above 15 mg.

#### 3.2 Procedures for by-product regulation in EU

Animal (including aquatic animals (as live animals, fish, molluscs and crustaceans) as defined in Article 3(1)(e) of Directive 2006/88/EC) by-product is part of an animal or animal products that are not intended for human consumption. Animal by-products have a special regulation regarding their management, reflecting especially several food crises. Under **Regulation (EC) 1069/2009** animal by-products are divided into three categories regarding their potential risk towards human health, animal health and the environment, and each category implies different treatments.

**Category 3 materials** (Article 10 of Regulation (EC) 1069/2009) are materials with no risk for health, including parts not intended for human consumption but whose hygienic quality could allow use them for human consumption. Examples of category 3 are bones and skin. Category 3 material is considered low risk material and may be used in the food chain as feed for food producing animals. The material comprises animals or parts of animals suitable for human consumption, but which, for commercial reasons, should not be used for human consumption.

**Category 2** covers material is high risk; it includes fallen stock, manure and digestive tract content. Category 2 is also the default status of any animal by-product not defined in Regulation (EC) 1069/2009 as either category 1 or category 3 material.

**Category 1** material is the highest risk material and consists principally of material that is considered a Transmissible Spongiform Encephalopathies (TSE) risk, such as Specified Risk Material (SRM) - those parts of an animal considered most likely to harbour a disease such as Bovine spongiform encephalopathy (BSE), for example bovine spinal cord. Pet animals, zoo and circus animals and experimental animals are also classified as category 1 material due to the level of veterinary drugs and residues they may contain. Wild



animals may also be classified as category 1 material when they are suspected of carrying a disease communicable to humans or animals. Catering waste from means of international transport (catering waste which has come from outside the EU) is also category 1.

Regulation (EC) 1069/2009 describes disposal and use of the category 3 material. It stands that if establishment generated animal by-products is approved in accordance with Regulation No 852/2004 and 853/2004 no notification with a view to registration shall be required. Further processing of by-products should be approved by article 24 Regulation (EC) 1069/2009. Regulation No 183/2005 lay down requirements for feed hygiene. The primary responsibility for feed safety rests with the feed business operator, they need to ensure feed safety throughout the food chain, starting with primary production of feed, up to and including, the feeding of food-producing animals.

#### 3.3 Waste

In addition, the disposal of waste, particularly food waste, is highly regulated and the legislation is constantly evolving (Archer et al., 2001). The directive 2008/98/EC of the European Parliament relating to waste management states that the states should ensure that any waste producer or holder carries out the treatment of waste himself or has it handled by another party. These principles are the basis for waste management and thus rest raw materials management. As the ReValue project focuses on the utilisation of RRM for food and feed application, further extensive discussion of the regulation for waste management and processing is not of focus in this review.

#### 4 Handling/processing

The rest raw materials and by-products usually are/can be processed to different products such as protein hydrolysates, gelatine, fish meal and oils. Different production technologies can be applied to gain the products for market with principal scheme given in Figure 2.



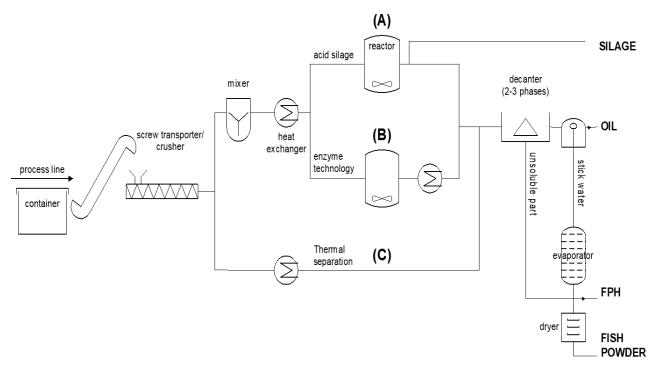


Figure 2. Bulk processes for utilisation of marine raw materials (Falch et al., 2007)

The ReValue project focuses on optimisation the hydrolysis process and gelatine extraction from fish rest raw materials, therefore the regulations in chapter 4.1 will focus on those processing technologies.

#### 4.1 Regulation for handling and processing

#### 4.1.1 Processing for food

Regarding fish processing, the most known safety control system is the Hazard Analysis Critical Control Point (HACCP) programme, which identifies and controls the critical steps in the production. Many countries, including Norway, have decided to implement preventive procedures based on HACCP principles, in order to ensure to a large extent food safety in seafood processing (Jouvenot, 2015). Several agencies or institutes are responsible for different roles in seafood safety in Norway. For example, the Norwegian Food Safety Authority (NFSA) is responsible for the development of legislation, inspections and monitoring. The Norwegian Environmental Agency is responsible for the development of legislations, inspections and monitoring related to environment pollution. Due to EEA-agreement, the Norwegian legislation is harmonized with the EU. The NFSA is responsible for the evaluation and implementation of EU food regulations in Norway (Jouvenot, 2015).

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If the rest raw materials are processed to ingredients the processing lines should follow the hygiene regulation (EC) No 852/2004 and No 853/2004. When processing RRM to *fish protein hydrolysate*, usually some enzymes (e.g. proteases) are added to hydrolyse the proteins and they must be approved as food

grade (Regulation (EC) No 234/2011). Regulations for hygiene of the products to ascertain hygienic secure products often include a heating process, hence the heat inactivation of the enzymes and hygiene are often combined.

In the *fish oil production* process, it must be ensured that all raw materials intended for the production of crude fish oil undergo necessary treatment, including heating, pressing, separating, centrifuging, preprocessing, refining and purifying to gain food grade quality for the final consumer. If the raw materials and production processes meet the requirements for fish oil intended for human consumption, a commercial operator can produce and store both fish oil for human consumption and fish oil and fish meal not intended for human consumption in the same factory/facilities.

#### 4.1.2 Processing for feed

Animal by-products are processed into derived products in approved plants. Processing plants are coded PROCP (processing plants) and HYDP (hydrolyzed protein plants) in the Food Safety Authority's systems. Norwegian Food Safety Authority's official list of by-products handling operators with its own list for type of processing plants.

The amount of infectious substances of category 3 materials is difficult to predict, because clinically healthy fish may also carry high levels of infectious substances. Therefore, according Regulation (EC) 1069/2009 and Regulation No 183/2005 the processing methods must be sufficient for inactivating all types of infectious agents.

The freshness of raw material is important as it affects the quality of protein in the end product. Spoilage of fish and its products occur mainly due to enzyme and bacterial actions and begins as soon as the fish perishes. Therefore, it is important to minimise the time spent between catching and processing. Fish by-product, especially when it contains viscera, deteriorate very rapidly and it is therefore important that it is preserved as soon as possible after being produced/generated. The raw material should be kept at a low as possible temperature during the various processes to minimise spoilage.

In addition to fish oil/meal and hydrolysate production fish silage is an alternative option o utilise byproducts The by-products are liquefied by the action of enzymes in the fish in the presence of added acid such as formic acid which reduces the pH to less than 4. The liquid silage product can be stored at ambient conditions for long periods. The quality of the raw material is often measured by the total volatile base nitrogen content which should be in the region of 50mgN/100g raw material (Pike, 1999).



Regulation (EC) 1774/2002 specifies different methods for handling by-products. The processing plants for production of hydrolysates should be approved by national authorities and should be able to prove that proteins are enough hydrolysed and cannot spread infection. In order hinder the spread infection, the Norwegian Food Safety Authority therefore assumes processing methods for hydrolysed proteins and fishmeal:

- The fishmeal processing any method that ensures the absence of Salmonella and Enterobacteriaceae
- Fish silage:
  - **< pH4**
  - < 50mm particle size, 90 ° C for another 60 minutes
  - < 30mm particle size, 70 ° C over 60 minutes
- Any other method approved by the Food Safety Authority with heat treatment, which ensures the absence of Clostridium perfringens, Salmonella and Enterobacteriaceae
- Heat fish silage method:
  - fish silage, particle size < 10 mm,
  - < pH4 for at least 24 hours,</li>
  - then 85 ° C for at least 25 minutes

#### **5** Final products

#### 5.1 Food grade protein hydrolysates

Food application ingredients like protein hydrolysates should follow food hygiene and quality regulations given in Chapter 1.1 Regulations. There are no special regulations for fish protein hydrolysates (personal communication with Norwegian Food Safety authorities), they should follow hygiene regulation 853/2004. Some requirements by industry can be used as a guideline for fish protein powder microbiological quality criteria:

- To lay down freshness criteria and limits with regard to histamine and total volatile nitrogen for fisheries products.
- Powder supplementary mixtures Salmonella absent in a 25 gram sample
- Milk and whey powder Enterobacteriaceae less than 10 per gram

Figure 3 shows examples of fish protein powder microbiological quality given in the commercial protein products data sheet.

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Microbiological profile		<b>Specification</b>	<b>Typical Range</b>	Test Method
Aerobic Plate Count	[CFU/g]	< 10 000	1 000 - 2 500	NMKL** #86
Coliform	[CFU/g]	< 10	< 10	NMKL** #44
Yeast	[CFU/g]	< 100	< 100	NMKL** #91
Mold	[CFU/g]	< 100	< 100	NMKL** #91
Clostridium perfringens	[CFU/g]	not detected	not detected	NMKL** #95
Yeast Mold	[CFU/g] [CFU/g]	< 100 < 100	< 100 < 100	NMKL** #9 NMKL** #9

Micro organism ( pr g of product )	Target	Max	Method of analysis
Total number of bacteria (aerobic)	< 5000	< 50 000	NCFA 146
Coliform bacteria (37 °C)	< 10	< 100	NCFA 147
Escherichia coli (44 °C)	neg. in 10g	< 10	NCFA 147
Salmonella	A Dramerousias	absent in 25g	AOAC 99138 + NCFA 71
Mould and yeast	< 100	< 1000	AOAC ref

Figure 3. Microbiological profile of some commercial fish protein powders

#### 5.2 Food grade gelatine

In the Food Chemicals Codex (Pharmacopoeia 34) gelatine is defined as the product obtained from the acidic, alkaline, or enzymatic hydrolysis of collagen, the chief protein component of the of the skin, bones, and connective tissue of animals, including fish and poultry.

Edible gelatine must meet the requirements laid down by the Food Hygiene Regulation (EC) No 853. Regulation (EC) No. 853/2004 lays down the general conditions for the production of edible gelatine and collagen peptide. It addresses all aspects, beginning with the raw materials right up to the delivery of the final product: origin, transport and storage of raw materials, manufacturing conditions, chemical requirements for gelatine and collagen peptide as well as packaging, storage and transport.

Only raw materials from animals that fit for human consumption and that have been approved by the respective veterinary authorities may be used. Full documentation of their origin must also be available. Raw materials that have not undergone any preservation treatment other than chilling, freezing or quick-freezing must come from establishments registered or approved pursuant to Regulation (EC) No 853/2004, on the hygiene of foodstuffs or in accordance with this Regulation.

**Contaminants and microbiology**. The important safety parameters, such as levels of heavy metals, toxic contaminants and microbiological safety are covered by the Regulation (EC) No. 2073/2005. Gelatine is an excellent growth medium for bacteria. Therefore, strict sanitary practices must be followed during manufacture in order to assure a clean, wholesome product.

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Food grade gelatins typically contain less than 3,000 bacteria per gram, with no pathogens present. Pharmaceutical gelatins are limited to aerobic plate counts of 1000 per gram. The National Formulary and the Food Chemical Codex monograph on gelatine both require that Salmonella species and Escherichia coli be absent.

As a dry powder, gelatine is very stable, and can be stored in air-tight containers for years with no loss in quality. Gelatin in solution, or soaked in water, should be left in this state only if kept very cold, or hot enough to destroy or inhibit bacterial growth. The nature of the organisms which grow in gelatine solutions and gels depends upon a number of factors. The pH has a most important influence. At pH values less than 4, bacterial growth is suppressed, while yeasts and molds grow abundantly. Above pH 5, proteolytic bacteria can become active. Degradation of gelatine solutions and gels by bacteria, yeasts, and molds may be inhibited by the use of preservatives. The selection of the preservative depends upon whether the product application is edible or technical. Gelatine gels generally require a greater concentration of preservative than dilute gelatin solutions. The addition of other nutrients to the gelatine may also increase the amount of preservative required.

#### **5.3 Feed grade protein hydrolysates**

Fish processing by-products are increasingly used as raw material to produce fishmeal and fish oil. It must be kept in mind though that some countries have restrictions on using animal by-products in animal feed. For instance, EU regulation, EC 1069/2009, stipulates that animal by-products may not be used to feed animals or farmed fish of the same species. Processed proteins like fish meal from salmon cannot be used for salmon feed, but for cod, trout, sea bass and other fish species. Pure fish oil (protein free) has no species restriction related to the application. When the protein is sufficiently hydrolyzed, the species barrier in the by-product regulatory framework does not apply. Thus, for example, hydrolyzed protein of salmon can be fed to salmon or hydrolyzed protein of fish can be used in feed for ruminants. Particle size requirements for hydrolysed proteins <10,000 Daltons. Regulation (EU) 51/2013 describes light microscopy as the method for the detection of animal constituents. The provisions are implemented in Norwegian law in Regulation No. 1621 of December 22, 2008.

#### 6 Regulations in India

#### 6.1 Food regulations/seafood regulations

Regulation regarding different food product safety and security are given by **FSSAI - Food Safety and Standards Authority of India**. More detailed description of food regulations in India is given in Annex II. FSSAI is an autonomous body established under Food Safety and Standards Act, 2006 by Ministry of Health & Family Welfare, Government of India. In India no regulations or guidelines are available for by-products



or RRM produced during processing. However, producing food products like protein hydrolysates, gelatins both the raw material, handling/ processing and the final product should, in theory, follow the food regulations described below.

**FSSAI regulation for Fish and Fish Products:** Section 92 (1) of Food Safety and Standards Act, 2006 empowers the Food Authority to make regulations/standards in consistent with this Act and Rules. The regulations, 2011, in regulation 2.6 relating to "Fish and Fish Products", in sub-regulation 2.6.1, have been notified in the gazette of India on 1<sup>st</sup> August, 2011 and came into force on 5<sup>th</sup> August, 2011. In this section regulations for selection of raw materials for product development, its transportation conditions, storage, and packaging conditions are provided.

#### Selected general regulation for processed fish and fish products:

- Product shall be prepared from sound fish which are of a good quality to be sold fresh for human consumption and for further processing.
- The product after preparation shall be subject to a freezing process. The freezing process shall be carried out in appropriate equipment in such a way that the range of temperature of maximum crystallization is passed quickly. The freezing process shall not be regarded as complete unless and until the product temperatures has reached -18°C or lower at the thermal centre after thermal stabilization.
- The product shall be kept deep frozen to maintain the quality during transportation, storage and distribution.
- The product shall be processed and packaged to minimize dehydration and oxidation. The practice of repacking frozen products under controlled conditions which shall maintain the quality of the product, followed by the reapplication of the freezing process as defined, is permitted.
- If glazed, the water used for glazing or preparing glazing solutions shall be of potable quality (IS 10500:2012) or shall be clean seawater, which meets the same microbiological standards as potable water and is free from potential contaminants.
- Hygiene during products preparation shall be in accordance with the guideline specified in Part-II of Schedule 4 of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011. The guidelines for hygiene are provided time to time in Food Safety and Standard Act, 2006.
- Contaminants, Toxins and Residues of the products covered under Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011 regulations.
- The products packaging and labelling requirements are specified in the Food Safety and Standards (Packaging and Labelling), Regulations, 2011 and shall also apply to the pre-packaged products. The product shall be stored at -18°C or lower and shall be displayed on the label.
- The raw material shall **not contain more than 100 mg/Kg of histamine**. This shall only apply to fish species including Carangidae, Chanidae, Clupeidae, Coryphaenidae, Engraulidae, Istiophoridae, Mugilidae, Pristigasteridae, Scombridae and Xiphiidae.

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- The final product shall be free from foreign materials, filth and from grittiness.
- The total volatile base nitrogen (TVBN) level of raw material (fin fish or shellfish) should not exceed 35mg/100g.

Guideline for hygiene and quality of water (IS 10500:2012) during processing is explained in **FSSAI regulation for microbiological limits in fish Product Standards and fish Additives:** Food Safety and Standards Authority of India has notified the Final Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulation, 2017 in the official gazette of India w.r.t microbiological requirements for fish and fishery products. This regulation prescribes revised microbiological requirements for sea foods and covers new varieties of fish and fisheries products, maximum permissible limits of hygiene indicator organisms and safety indicator organisms in vide range of fish and fishery products. In addition, the regulation also prescribes the sampling plan and reference test methods for microbiological parameters. Table 1 provides the microbiological requirements for various fish and fishery products.

	Limits (CFU	/g						
Products category	Aerobic plate count	Staphylo coccus count	Yeast & mold count	E. coli count	Salmonella count	Vibrio cholerae	Listeria monocyt ogenes	Clostridium botulinum
Dried/ Salted and dried fishery products	1 X 10 <sup>5</sup>	-	100-500	20	-	-	-	-
Thermally processed fishery products		-	-	-	-	-	-	-
Accelerated Freeze Dried Fishery Products	1 X 10 <sup>4</sup>	100	-	20	-	-	-	-
Fish Mince/Surimi and Analogues	1 X 10 <sup>5</sup> -1 X 10 <sup>6</sup>	1 X 10 <sup>2</sup> -1 X 10 <sup>3</sup>	-	20	-	-	-	-
Convenience Fishery Products	1 X 10 <sup>3</sup> -1 X 10 <sup>4</sup>	1 X 10 <sup>2</sup> -1 X 10 <sup>3</sup>	-	1-10	-	-	-	-

#### Table 1 Microbiological requirements for selected fish and fishery products in India

**FSSAI regulation for contaminants, toxins and residues in fish Product Standards and fish Additives**: Section 92 (2) of Food Safety and Standards Act, 2006 empowers the Food Authority to develop regulations/standards regarding contaminants, toxins and residues. The Food Safety and Standards Authority of India number F. No. 1-10(6)/Standards/SP(Fish and Fisheries Products)/FSSAI-2013 dated the

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12<sup>th</sup> June, 2015 in the Gazette of India, Extraordinary, Part III, Section 20 and 21. Fish and fish product can contain Polychlorinated biphenyls (0.5-2.0 ppm) and Benzo(a)pyrene (5.0 ppb). The limits of biotoxins in fish and fishery products such as Paralytic Shellfish Poison (80  $\mu$ g/100g); Amnesic Shellfish Poison (20  $\mu$ g/g); Diarrhetic shellfish poison (160  $\mu$ g of Okadaic acid equivalent/Kg); Azaspiracid poison (160  $\mu$ g of azaspiracid equivalent/Kg) and Brevetoxin (200 mouse units or equivalent/Kg) are st in the document.

In the FSSAI final Food Safety and Standards Eleventh Amendment Regulations, 2017, described the requirements among other also for sardine oils and edible Fish Powder. Some examples of the requirements: Edible fish powder means the product prepared from non-oily white fish like sprats, either from a single species or their mixture. Fresh fish of edible quality which is normally consumed whole should be used for the preparation. Poisonous fish like marine snakes, elasmobranch fish with a high quantity of urea, oily fish and fish with black viscera are not considered suitable for preparation of edible fish powder. Relevant requirements for edible fish powder are given in Table 2.

Sr.No	Characteristic	Requirement
1.	Moisture % by weight, Max	10
2.	Crude protein content (N X 6.25) on dry basis percent by weight, Min	65
3.	Total available lysine g/100g of Protein, Min	6
4.	Fat content on dry basis % by Weight, Max	6
5.	Ash on dry basis % by weight, Max	18
6.	Acid insoluble as on dry basis % by weight, Max	0.5

#### Table 2. Requirements for edible fish powder

#### 6.2 Feed regulations

In India, the Bureau of Indian Standards (BIS) is a statuary body to control quality of animal feeds called animal feeds sectional committee who check the quality of animal feeds and feeds ingredients. BIS is responsible for standardization, certification, testing, traceability and tangible benefit to provide safe and reliable quality product to consumer. More detailed discussion of feed regulations in India is given in Annex III.

Most of Indian feed industry applies HACCP measures to ensures safety of feeds. BIS formed subcommittee checks the quality of animal feeds and feed ingredients. According to FAO, the feed must have required proximate composition (moisture content, protein, lipid, fibre and ash content), vitamin, mineral, available phosphorus, amino acid and polyunsaturated fatty acids. Fish meal is excellent source of good quality protein, mineral (Phosphorus), vitamins B and essential fatty acids (Table 3). Different fish meal composition is also given in appendix III.



Nutrients	Grade1	Grade 2	Grade 3
Moisture (%, maximum)	10	10	10
Crude protein (%, minimum)	60	50	40
Crude lipid (%, maximum)	8	10	11
Salinity (%, maximum)	2	3	5
Ash (% maximum)	2	3	4
Hard and sharp solid materials	Not permitted		
Total volatile nitrogen (mg/100g, maximum)	150	250	350

#### Table 3 Nutrient of feeds produced from Fishmeal (TCVN 1644:2001) \$\$\$

Source: http://www.fao.org/fishery/affris/feed-and-feed-ingredient-standards/en/

According BIS standard IS 4307 (1983): Fish Meal as Livestock Feed Ingredient, fish meal shall be obtained from fresh fish and/or fish wastes or from unsalted dried fish or all of them, eliminating poisonous fishes. Preparation: The fish meal shall be prepared by cooking the raw material or by heat-treating the dried fish, pressing the cooked mass, drying and pulverizing the treated material to the required mesh size. Fish meal shall be in the form of powder ground to such fineness that 99 percent of material shall pass through 2-80-mm IS Sieve. Microbiological Requirements: The material shall be free from Salmonella.

No commercial activities with respect to animal feed can be undertaken except under BIS certification. FSSAI had made it mandatory in December 2019 for commercial feeds/ feed materials intended for food producing animals to comply with the relevant BIS standards. FSSAI had issued these directions after it had been noted that foods of animal origin were sometimes found to be non-compliant with the relevant food quality and safety standards as has been laid down in the Food Safety and Standards Act, 2006 with respect to pesticides, heavy metals and Aflatoxin M1. Since the major source of contaminants comes from feed and fodder hence FSSAI had felt the need for regulatory control of animal feeds.

Specifications are not available for aqua feeds regarding the acceptable levels of microbiological parameters. According Ebeneezar et al., (2018) the microbiological indices of feed quality may include Total plate count (TPC), Escherichia coli count, coliforms, Enterobacteriaceae count, yeast and mould count. Ideally E. coli should not be detected and as such a level of <3 per gram (the limit of the Most Probable Number test) has been given as the satisfactory criteria for this organism. Levels exceeding 100 per gram are unacceptable and indicate a level of contamination which may have introduced pathogens or that pathogens, if present in the food prior to processing, may have survived (ICMSF, 1996).

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#### 7 Conclusions

The RRM obtained after processing of fish is an attractive food or feed resource. The regulations related to the handling of animal RRM are harmonized within the EEA and should be the same in all countries. Since Norway is not a member of the EU, the rules are transposed into Norwegian law before they become applicable in Norway. But generally, Norway follows EU regulations.

If product is intended for human consumption, the RRM, handling, processing and the final product must follow the food hygiene (e.g. No 852/2004, No 853/2004 No 854/2004), No 2073/2005 - microbiological criteria and safety requirements (e.g. No 1881/2006). If the RRM are going to be processed into some food ingredients, theoretically there are no special requirement for the raw material except that it should be food grade. The producer must consider which criteria in terms of raw material quality, handling and processing will be necessary to provide that the end-product (e.g. protein hydrolysate) will be food grade quality. The similar requirement for food product production also exist in India, where FSSAI - Food Safety and Standards Authority of India is an autonomous body that sets food safety rules and regulations in the country. Very similar quality regulations are both in EU and India: for unprocessed fishery products must not exceed: TVB-N 25-35 mg of nitrogen/100g flesh, histamine levels 100 mg/kg - 200 mg/kg, L. monocytogenes < 100 cfu/g or absence in 25 g. There are no special regulations for fish protein hydrolysates or powders they should follow hygiene regulation 853/2004. Therefore, taking into consideration requirements for fish products, and dry powders, microbiological quality for the final dry fish protein powder products (per gr) must be: Total count  $<10^5$ , E. Coli<10, Salmonella absent in 25 g, Moulds and Yeast  $< 10^3$ . Very similar microbilogical quality requirements for dry fish products are also given by FSSAI in India.

In EEA, if the RRM or by-products are going to be used for **feed application**, the raw material should follow description of category 3 after Regulation (EC) 1069/2009. Handling and processing of by-products should follow the regulation 1774/2002 and hygiene for feed described No 183/2005. In India there are no special regulations for the by-products not intended for human consumption. However, the requirements for processing for fish meal are regulated by BIS standards and detailed described the requirements. In EU the processing plants should be also approved. It must be kept in mind that EU regulation, EC 1069/2009, stipulates that animal by-products may not be used to feed animals or farmed fish of the same species. Pure fish oil (protein free) has no species restriction related to the application. When the protein is sufficiently hydrolyzed, the species barrier in the by-product regulatory framework does not apply.

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#### Appendix I Regulations for fishery by-products in Spain

THE LEGISLATION APPLICABLE TO FISHERY BY-PRODUCTS DIFFERS DEPENDING ON WHETHER OR NOT THEY ARE INTENDED FOR HUMAN CONSUMPTION IN SPANISH CALLED SANDACH: subproductos alimentarios no destinados a consumo humano

These by-products are those materials that are generated in primary livestock production and in the food processing industries of animal origin and that, for commercial or sanitary reasons, do not fall within the human food chain.

#### EUROPEAN LEGISLATION

Directive (EU) 2018/851 of the European Parliament and of the Council of May 30, 2018 amending Directive 2008/98 / EC on waste. This directive regulates waste in general within the European Union

Since March 4, 2011, when Regulation (EC) 1774/2002 was repealed, the Community legal framework applicable to SANDACH is constituted by Regulation (EC) No 1069/2009, of the European Parliament and of the Council and the Regulation (EU) No. 142/2011 of the Commission.

Regulation (EC) No 1069/2009 establishes public health and animal health regulations applicable to animal by-products and derived products, in order to prevent and minimize the risks to public health and animal health that they entail such products, and, in particular, preserve the safety of the human and animal food chain.

Regulation (EU) No. 142/2011 establishes the measures of application: of public health and animal health standards applicable to animal by-products and derived products provided in Regulation (EC) No. 1069/2009, as well as those relating to certain samples and articles exempt from veterinary controls at border inspection posts as defined in Article 16, paragraph 1, letters e) and f), of Directive 97/78 / EC.

#### EUROPEAN LEGISLATION

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

Application provisions:

• Regulation of the management of animal by-products from the moment they are generated until their final use, recovery or destruction.

• Minimize risks to public and animal health, the safety of the human and animal food chain, and the confidence of consumers, which may cause the misuse of certain animal by-products.

#### SPANISH NATIONAL LEGISLATION



The transposition of the directive 2008/98 / CE of the European Parliament of November 19, 2008 on waste, modified by Directive (EU) 2018/851 of the European Parliament and of the Council of May 30, 2018 in our internal legal system takes carried out through Law 22/2011, of July 28, on contaminated waste and soil that replaces the previously valid Law 10/1998, of April 21, on Waste.

This Law 22/2011 aims to regulate the management of waste by promoting measures that prevent its generation and mitigate the adverse impacts on human health and the environment associated with its generation and management, improving efficiency in the use of resources. Its purpose is also to regulate the legal regime of contaminated soils.

Royal Decree 1429/2003. Establishment of the conditions for the application of the Community regulations on by-products:

• Definition of the distribution of competences between different departments of the General State Administration and the Autonomous Communities.

• Creation of the National Commission of By-Products not intended for human consumption, as an interministerial and disciplinary collegiate body.

Order PRE / 468/2008: Management tool that defines the strategic lines of action to achieve an effective application of the regulations on by-products. Its basis stems from the recommendations and conclusions of the comprehensive study on the by-product management chain, the result of which is contained in the White Paper on SANDACH.

This legislation is based on Regulation (EC) No. 1774/2002 (repealed by Regulation (EC) No. 1069/2009) and is currently being modified to adapt to current European legislation.

#### FISHING SANDACH Animal feed

Parts of fish that are considered fit for human consumption, in accordance with Community regulations, but not intended for this purpose for commercial reasons.

Parts of fish that have been rejected because they are not suitable for human consumption, but that do not show any sign of disease that can be transmitted to humans or animals and that come from channels that are suitable for human consumption in accordance with Community regulations

SANDACH derived from the elaboration of products intended for human consumption.

Old foods of fishery origin or containing products of fishery origin, other than kitchen waste, which are no longer intended for human consumption for commercial reasons or for manufacturing problems or packaging or other defects that do not pose any risk to the human being or for the animals.



Fish or other marine animals, with the exception of mammals, caught offshore for the production of fishmeal.

Fresh fish SANDACH from industrial facilities that manufacture fish-based products intended for human consumption.

PROCEDURE FOR THE DECLARATION OF SUBPRODUCT

The Waste Framework Directive and its transposition to the Spanish state through Law 22/2011, of July 28, on contaminated waste and soil, define the conditions for a substance or object, resulting from a production process, and whose purpose is not the production of that substance or object, it can be considered as a by-product and not as a waste, when the following conditions are met:

a) That there is certainty that the substance or object will be used later,

b) that the substance or object can be used directly without having to undergo further transformation other than usual industrial practice,

c) that the substance or object is produced as an integral part of a production process, and

d) that subsequent use complies with all relevant product requirements, as well as the protection of human health and the environment, without causing adverse general impacts to human health or the environment.

In order to consider a substance or object as a by-product, these four conditions must be met simultaneously; that is, only if they satisfy each and every one of them, will we be facing a by-product; otherwise, the applicable legal regime will necessarily be that of waste.

Consequently, those substances or objects that are declared as by-products will be applicable to the specific regulations for products or substances, in particular, Regulation (EC) 1907/2006 of the European Parliament and of the Council on registration, evaluation, authorization and the restriction of chemical substances and preparations (REACH) and Regulation (EC) 1272/2008 of the European Parliament and of the Council of December 16, 2008 on classification, labelling and packaging of substances and mixtures (CLP) and other specific regulations that may affect the substance or object (fertilizer, pharmaceutical, etc.)

In most of the Autonomous Communities (hereinafter CCAA) the term by-product had been used prior to the approval of Law 22/2011, of July 28, and in many cases, it does not exactly conform to the new concept of by-product that it introduces Community legislation.

The First Transitory Provision of Law 22/2011, of July, provided that the administrative procedures in force in the matter would continue to be applied until the mechanisms provided for in article 4.2 of the

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aforementioned Law, that is, the evaluation, were implemented. within the Coordination Commission on waste, of the consideration as a by-product of certain production waste and if applicable, the corresponding Ministerial Order is issued.

The Coordination Commission on waste will evaluate the consideration of these substances or objects as by-products, taking into account what is established in this regard in the field of the European Union, and will propose their approval to the Ministry of Agriculture and Fisheries, Food and Environment which will prepare the corresponding Ministerial Order.

The concept of by-product is only applicable to waste from production processes, as specified in the Communication to the Council and the interpretive European Parliament on waste and by-products, developed by the Commission of the European Communities, and will therefore be excluded the materials / substances obtained in the waste treatment.

Those residues of production that can be used in another process, either in facilities of the same company or in different companies, are within the scope of this procedure.

The by-product consideration declared by Ministerial Order shall be valid in the national territory and such clarification shall be included in the corresponding Ministerial Orders.

Only such material will be exported as a by-product, in case the country of destination accepts it as such. For this, that company that wants to export a by-product must contact the competent authority on the matter of transfer of waste, which will consult the member state of destination if it accepts such material as a by-product. If not, the export of the material will take place within the scope of Regulation 1013/2006 on the transfer of waste (Article 28). The procedure for the declaration as a by-product has been based on the *Draft Guidelines on the interpretation of key provisions of Directive 2008/98 / EC on waste and on the Communication from the Commission to the Council and the European Parliament (COM).* Interpretive communication on waste and by-products, developed by the European Commission.

The procedures existing in some Autonomous Communities regarding the practical application of the "byproduct" concept before Law 22/2011 of July 28, the procedures developed by four Member States for the declaration of a production waste as by-product and in the contributions made by the technical staff of the Autonomous Communities belonging to the Working Group of the Coordination Commission on waste.

In addition to the definitions included in article 3 of Law 22/2011, of July 28, the following definitions are included to facilitate the understanding of the procedure:

- Production process: activity whose main objective is to obtain a certain product with certain characteristics, such as in industrial production and agricultural and livestock production.



- Product: all material deliberately obtained in a production process. In many cases it is possible to identify a "primary" product (or several), which is the main material produced.

- Waste of production processes: material or object that is produced in a production process in an unintentional way.

- By-product: substance or object, resulting from a production process, whose purpose is not the production of that substance or object, which meets the four conditions established in section 4 of article 4 of Law 22/2011, of July 28, and that is declared as such through the corresponding Ministerial Order.

- By-product producer: any natural or legal person that generates a by-product in a production process.

- Receiver of the by-product: any natural or legal person whose production process uses a by-product in substitution of a raw material.

#### PRODUCTION WASTE AS SUBPRODUCTS

In the event that the production waste obtained meets the criteria to be declared as a by-product, specified in the corresponding Ministerial Order for a specific use, it may be declared as such and will no longer be considered waste. On the contrary, if the production waste does not meet the criteria of the Ministerial Order for the specific intended use, a waste will continue to be considered and, therefore, the legal regime of waste will apply.

#### PROCESS

The procedure to regulate the declaration of a production waste as a by-product is sequenced in two phases:

- the first, corresponding to the general request for by-product declaration and

- the second, regarding the notification of the intention to benefit from the provisions of the corresponding Ministerial Order.

In relation to the first phase, it will be the Working Group of the Coordination Commission on waste, responsible for assessing compliance with the conditions of article 4 for the specific use of the production waste in question. As a result of this analysis, the corresponding Ministerial Order will be approved, if applicable, which will be open to all those companies that want to manage a by-product under the conditions established in said Order.

In relation to the second phase and for those production residues that meet the requirements and conditions for the specific use established in the Ministerial Order, the intention to use the corresponding production waste as a by-product will be notified in a particular way. Autonomous Community where this



production waste is generated, as well as the Autonomous Community of destination. The provisions regarding the notification procedure will be determined in the Ministerial Order itself.

The request for a by-product declaration shall be submitted jointly by the producing industry or grouping of industries producing a certain production waste and by the receiving companies or grouping of receiving companies interested in using it.

The request to declare a certain production waste as a by-product, together with the attached documentation, will be submitted to the Ministry of Agriculture and Fisheries, Food and Environment, and will be addressed to the Coordination Commission on waste.

The Ministry will establish the shipping address, as well as the conditions and the format to be used for sending the request for the by-product declaration.

Those responsible for the application must submit the model established for this purpose available on the website of the Ministry of Agriculture and Fisheries, Food and Environment.

Along with the request, a Justification Report will be attached that includes all the information necessary to verify that the requirements of article 4 of Law 22/2011, of July 28, are met.

At this stage, only the minimum information necessary to ensure verification of compliance with the legislation dictates will be requested. If deemed necessary, the reports of producers and recipients will be allowed separately in order to preserve the confidentiality of both parties. In addition, documents that include confidential information may be identified as such and attached independently.

#### IMPLICATIONS

The term "by-product" will be applicable only to those production residues that are declared as byproducts through the corresponding Ministerial Order. The waste that is currently called by-products in the Autonomous Communities or the materials included in the Bags of by-products of the Chambers of Commerce, cannot be considered as by-products. However, materials that had been declared as byproducts before the publication of this procedure may be managed according to the legal regime that was declared as such until their status as a by-product has been accepted or rejected according to the new procedure or the completion of the authorization granted by the Autonomous Community In relation to other product regulations applicable to by-products (REACH: Regulation (EC) 1907/2006 of the European Parliament and of the Council regarding the registration, evaluation, authorization and restriction of chemical substances and preparations (REACH) and CLP : Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures) it should be noted that:

- According to the Draft Guidelines on the interpretation of key provisions of Directive 2008/98 / EC on waste, by-products under the Waste Framework Directive are subject to the REACH Regulation, in its

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entirety. However, in the event that by-products are not imported or marketed as such, they may qualify for the registration exemption as set out in entry 5 of REACH Annex V.

- In accordance with the CLP regulation, which harmonizes the criteria for the classification of substances and mixtures and the labelling and packaging standards for hazardous substances and mixtures marketed, those by-products that are marketed, will be subject to the conditions established in this regulation, in the same terms as the substances or mixtures regulated by it.

ANIMAL SUBPRODUCTS FOR THE DEVELOPMENT OF PRODUCTS OR COMPONENTS FOR HUMAN CONSUMPTION

In this case they must be treated as materials suitable for human consumption and, therefore, must be handled and processed as such, guaranteeing the safety conditions established by the applicable legislation.

• Regulation (EC) No 852/2004

It establishes general rules for food business operators in the field of hygiene of food products, applying to all stages of food production, processing and distribution and exports, without prejudice to other more specific hygiene requirements. food

• Regulation (EC) No 853/2004

It complements the measures established by the former, through the establishment of specific standards for food business operators in the field of hygiene of food of animal origin. This Regulation does not apply to foods that contain both products of plant origin and processed products of animal origin. However, processed products of animal origin used in the preparation of such products must be obtained and handled in accordance with the provisions established.

• Regulation (EC) No. 2073/2005

It establishes the microbiological criteria for certain microorganisms and the application standards that must be met by food business operators when applying the general and specific hygiene measures referred to in Article 4 of Regulation (EC) No 852/2004. It also establishes that food business operators will ensure that food products meet the relevant microbiological criteria set out in Annex I to that Regulation.

• Regulation (EC) No. 1881/2006

Sets the maximum content of certain contaminants in food products.

## **()** SINTEF

#### Appendix II Food product safety and security in India

#### Introduction

Regulation regarding different food product safety and security are given by FSSAI (Food Safety and Standards Authority of India. FSSAI is an autonomous body established under <u>Food Safety and Standards</u> <u>Act, 2006</u> by <u>Ministry of Health & Family Welfare, Government of India</u>. The FSSAI has its headquarters at <u>New Delhi</u> and 6 regional offices located in <u>Delhi</u>, <u>Guwahati</u>, <u>Mumbai</u>, <u>Kolkata</u>, <u>Cochin</u>, and <u>Chennai</u>.14 referral laboratories notified by FSSAI, 72 State/UT laboratories located throughout India and 112 laboratories are <u>NABL</u> accredited private laboratories notified by FSSAI. In india no regulation /guideline are available for by-product produced during processing

#### **Product Definitions:**

- (1) Chilled/Frozen Finfish includes clean and wholesome finfish, which are either in raw, chilled or frozen condition. Chilling is the process of cooling fish or fish products to a temperature approaching that of melting ice. The quick freezing process shall not be regarded as complete unless and until the product temperature reached -18° C.
- (2) **Chilled/Frozen Crustaceans** includes clean, whole or peeled crustaceans (shrimp/prawn, crabs and lobster) which are either in raw, chilled or frozen condition and handled in accordance with good manufacturing practices.
- (3) **Chilled/Frozen Cephalopods** includes cleaned, whole or de-skinned cephalopods (squid, cuttlefish and octopus) which are either in raw, chilled or frozen condition and handled in accordance with good manufacturing practices.
- (4) **Live Bivalve Molluscs** includes Oyster, Clam, Mussel, Scallop, Abalone which are alive immediately prior to consumption. Live bivalve molluscs are harvested alive from a harvesting area either approved for direct human consumption or classified to permit harvesting for an approved method of purification like relaying or depuration, prior to human consumption.
- (5) **Chilled/Frozen Bivalves** includes clean, whole or shucked bivalves, which are live either in chilled or frozen condition and handled in accordance with good manufacturing practices such as oysters, mussels, clams, cockles and scallops.
- (6) Frozen cooked Crustaceans or Frozen heat shucked Mollusca means clean, whole or peeled crustaceans, which are cooked at a defined temperature and time and subsequently frozen. Cooking of crustaceans must be designed to eliminate six log reduction of most heat resistant vegetative bacteria i.e. *Listeria monocytogenes*. Frozen heat shucked mollusca includes bivalves where meat is removed from the shell by subjecting the animals to mild heat before shucking to relax the adductor muscle and subsequently frozen.
- (7) **Dried or Salted and Dried fishery Products** means the product prepared from fresh or wholesome finfish or shellfish after drying with or without addition of salt. The fish shall be bled, gutted, beheaded, split or filleted and washed prior to salting and drying. Salt used to produce salted fish shall be clean, free from foreign matter, and has no visible signs of contamination with dirt, oil, bilge or other extraneous materials.



- (8) **Thermally Processed Fishery Products** means the product obtained by application of heat or temperature for sufficient time to achieve commercial sterility in hermetically sealed containers.
- (9) Fermented Fishery Products includes any fish product that has undergone degradative changes through enzymatic or microbiological activity either in presence or absence of salt. Nontraditional products manufactured by accelerated fermentation, acid ensilage and chemical hydrolysis also belong to this category.
- (10) **Fish Mince/Surimi and analogues** means comminuted, mechanically removed meat which has been separated from and are essentially free from bones, viscera and skin. Surimi is the stabilized myofibrillar proteins obtained from mechanically deboned fish flesh that is washed with water and blended with cryoprotectants. Surimi analogues are variety of imitation products produced from surimi with addition of ingredients and flavor.
- (11) **Fish Pickle** means an oily, semi-solid product with spices and acidic taste obtained from maturation of partially fried fish with vinegar. It is produced by frying edible portions of fish, shrimp or mollusc, followed by partial cooking with spices, salt and oil and maturing for 1-3 days with added organic acids. The product is intended for direct human consumption as a seasoning, or condiment for food.
- (12) **Battered and Breaded Fishery Products** include fish portions, fillets or mince coated with batter and/or breading. Batter means liquid preparation from ground cereals, spices, salt, sugar and other ingredients and/or additives for coating. Breading means dry breadcrumbs or other dry preparations mainly from cereals with colourants and other ingredients used for the final coating of fishery products.
- (13) **Convenience Fishery Products** are tertiary food products made of fish, which are in ready to eat form and also includes snack based items prepared from fish and fishery products meant for direct human consumption such as extruded fishery products, fried items namely fish wafers, crackers, fish cutlets, fish burgers and other such products. These products can be consumed directly after minimal handling and processing.
- (14) **Powdered Fish based Products** include the products which are prepared from finfish/shellfish or parts thereof, with or without other edible ingredients in powdered form suitable for human consumption. These may be consumed directly or as supplements and also after hydration and this category includes powdered and dried fish products generally used as ingredients in food preparations such as fish soup powder, fish chutney powder, ready to use fish-mix, and such other food.
- (15) Smoked Fishery Products means fish or fishery product subjected to a process of treatment with smoke generated from smouldering wood or plant materials. Here the product category refers to hot smoked fish where fish is smoked at an appropriate combination of temperature and time sufficient to cause the complete coagulation of the proteins in the fish flesh. Fermented Fishery Products includes any fish product that has undergone degradative changes through enzymatic or microbiological activity either in presence or absence of salt. Non-traditional products manufactured by accelerated fermentation, acid ensilage and chemical hydrolysis also belong to this category.



- (16) **Fermented Fishery Products** includes any fish product that has undergone degradative changes through enzymatic or microbiological activity either in presence or absence of salt. Non-traditional products manufactured by accelerated fermentation, acid ensilage and chemical hydrolysis also belong to this category.
- (17) Accelerated Freeze dried Fishery Products means fish, shrimp or any fishery product subjected to rapid freezing, followed by drying under high vacuum so as to remove the water by sublimation to a final moisture content of less than two percent.

#### A. FSSAI regulation for Fish and Fish Products

Section 92 (1) of Food Safety and Standards Act, 2006 empowers the Food Authority to make regulations/standards in consistent with this Act and Rules. The regulations, 2011, in regulation 2.6 relating to "Fish and Fish Products", in **sub-regulation 2.6.1**, have been notified in the gazette of India on 1st August, 2011 and came into force on 5th August, 2011. In this section regulation for selection of raw materials for product development, its transportation conditions, storage, and packaging condition is given. Guideline for hygiene and quality of water (IS 10500:2012) during processing is explain.

The principal FSSAI regulations (F. No. 2-15015/30/2010, dated the 1st August, 2011) for fish and fisheries products are

- 1. F.No. 4/15015/30/2011, dated 7th June, 2013
- 2. F.No. P. 15014/1/2011-PFA/FSSAI, dated 27th June, 2013
- 3. F. No. 5/15015/30/2012, dated 12th July, 2013
- 4. F.No. P. 15025/262/2013-PA/FSSAI, dated 5th December, 2014
- 5. F.No. 1-83F/Sci. Pan- Noti/FSSAI-2012, dated 17th February, 2015
- 6. F.No. 4/15015/30/2011, dated 4th August, 2015
- 7. F.No. P.15025/264/13-PA/FSSAI, dated 4th November, 2015
- 8. F.No. P. 15025/263/13-PA/FSSAI, dated 4th November, 2015
- 9. F.No. P. 15025/261-PA/FSSAI, dated 13th November, 2015
- 10. F.No. P. 15025/208/2013-PA/FSSAI, Dated 13th November, 2015
- 11. F.No. 7/15015/30/2012, dated 13th November, 2015
- 12. F.No. 1-10(1)/Standards/SP9Fish and Fisheries Products)/FSSAI-2013, dated 11th January, 2016
- 13. No. 3-16/Specified Foods/Notiifcation(Food Additives)/FSSAI-2014, dated 3rd May, 2016
- 14. F.No. 15-03/Enf/FSSAI/2014, Dated 14th June, 2016
- 15. No. 3-14F/Notification (Nutraceuticals)/FSSAI-2013, dated 13th July, 2016
- 16. F.No. 1-12/Stnadards/SP (Sweets, Confectionery)/FSSAI-2015, dated 15th July, 2016
- 17. F.No. 1-120(1)/Standards/Irradiation/FSSAI-2015, dated 23rd August, 2016
- 18. F. No. 11/09/Reg/Harmoniztn/2014, dated 5th September, 2016
- 19. F.No. Stds/CPLQ.CP/EM/FSSAI-2015, dated 14th September, 2016
- 20. F.No. 11/12 Reg/Prop/FSSAI-2016, dated 10th October, 2016
- 21. F.No. 1-110(2)/SP (Biological Hazards)/FSSAI/2010, dated 10th October, 2016



- 22. F.No. Stds/SP (Water & Beverages)/Notif (2)/FSSAI-2016, dated 25th October, 2016
- 23. F.No. 1-11(1)/Standards/SP (Water & Beverages)/FSSAI-2015, Dated 15th November, 2016
- 24. F.No. P.15025/93/2011-PFA/FSSAI, Dated 2nd December, 2016
- 25. F.No. P. 15025/6/2004-PFS/FSSAI, dated 29th December, 2016
- 26. F.No. Stds/O&F/Notification(1)/FSSAI-2016, dated 31st January, 2017
- 27. F.No. 1-12/Standards/2012-FSSAI, dated 13th February, 2017
- 28. F.No. 1-10(7)/Standards/SP (Fish & Fisheries Products)/FSSAI-2013, dated 13th February, 2017
- 29. F. No. Stds /SCSS&H/ Notification (02)/FSSAI-2016, dated 15th May, 2017
- 30. F. No. Stds/03/Notification (LS)/ FSSAI-2017, dated 19th June, 2017
- 31. F.No. 1/Additives/Stds/14.2Notification/FSSAI/2016, dated 31st July, 2017
- 32. F.No. Stds/F&VP/Notification(01)/FSSAI-2016, dated 2nd August, 2017
- 33. F.No. 1-94(1)/FSSAI/SP(Labelling)/2014, dated 11th September, 2017
- 34. F.No. Stds/M&MPIP(1)/SP/FSSAI-2015, dated 15th September, 2017

#### B. FSSAI regulation for salted fish/dried salted fish and fishery products

Regulations on salted fish/dried salted fish and fishery products are given in sub-regulation 2.6.1 in clause (7) of regulation food safety and standards (food products standards and food additives) of section 2. In this section guidelines for fish filleting before salting and drying, quality of salt used for salting, microbiological and chemical requirement are given. The salted and dried salted fish products should have Water activity (aw<0.78% at 25 °C); Histamine (200mg/kg) and acid insoluble ash on dry basis (not more than 1%).

The principal FSSAI regulations (F. No. 2-15015/30/2010, dated the 1st August, 2011 part III, section 4) for salted and dried salted fish products

- 1. F. No. 4/15015/30/2011, dated the 7th June, 2013
- 2. F. No. P.15014/1/2011-PFA/FSSAI, dated the 27th June, 2013
- 3. F. No. 5/15015/30/2012, dated the 12th July, 2013
- 4. F. No. P.15025/262/13-PA/FSSAI dated the 5th December, 2014
- 5. F. No.1-83L/Sci.Pan-Noti/FSSAI-2012 dated the 17th February, 2015
- 6. F. No. 4/15015/30/2011, dated the 4th August, 2015;
- 7. F. No. P. 15025/263/13-PA/FSSAI, dated the 4th November, 2015
- 8. F. No. P. 15025/264/13-PA/FSSAI, dated the 4th November, 2015
- 9. F. No. 7/15015/30/2012, dated the 13th November, 2015
- 10. F. No. P. 15025/208/2013-PA/FSSAI, dated the 13th November, 2015
- 11. F. No. P. 15025/261/2013-PA/FSSAI, dated the 13th November, 2015.

#### C. FSSAI regulation for microbiological limits in fish Product Standards and fish Additives

Food Safety and Standards Authority of India has notified the Final Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulation, 2017 in the official gazette of India w.r.t

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microbiological requirements for fish and fishery products. This regulation prescribes revised microbiological requirements for sea foods and covers new varieties of fish and fisheries products, maximum permissible limits of hygiene indicator organisms and safety indicator organisms in vide range of fish and fishery products. In addition, the regulation also prescribes the sampling plan and reference test methods for microbiological parameters.

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### Table 1 Microbiological Requirements for Fish and Fishery products

		Limits (CFU/g)										
S.No	Products category	Aerobic plate count	Staphylococcus count	Yeast & mold count	E. coli count	Salmonella count	Vibrio cholerae	Listeria monocytogene s	Clostridium botulinum			
1	Chilled/ frozen finfish	5 X 10 <sup>5</sup> -1 X 10 <sup>7</sup>	-	-	11-500	-	-	-	-			
2	Chilled/ frozen crustaceans	1 X 10 <sup>6</sup> -1 X 10 <sup>7</sup>	-	-	11-500	-	-	-	-			
3	Chilled/frozen Cephalopods	1 X 10 <sup>5</sup> -1 X 10 <sup>6</sup>	-	-	20	-	-	-	-			
4	Live Bivalve Molluscs	1 X 10 <sup>5</sup> -1 X 10 <sup>6</sup>	-	-	230- 700/100g	-	-	-	-			
5	Chilled/Frozen Bivalves	1 X 10 <sup>5</sup> -1 X 10 <sup>6</sup>	-	-	46	-	-	-	-			
6	Frozen cooked crustaceans/Frozen heat shucked mollusca	1 X 10 <sup>5</sup> -1 X 10 <sup>6</sup>	1 X 10 <sup>2</sup> -1 X 10 <sup>3</sup>	-	1-10	-	-	-	-			
7	Dried/ Salted and dried fishery Products	1 X 10 <sup>5</sup>	-	100-500	20	-	-	-	-			
8	Thermally processed fishery Products		-	-	-	-	-	-	-			
9	Fermented fishery products	-	1 X 10 <sup>2</sup> -1 X 10 <sup>3</sup>	100	4-40	-	-	-	-			
10	Smoked Fishery Products	1 X 10 <sup>5</sup>	1 X 10 <sup>2</sup> -1 X 10 <sup>3</sup>	-	11-500	-	-	-	-			
11	Accelerated Freeze Dried Fishery Products	1 X 10 <sup>4</sup>	100	-	20	-	-	-	-			
12	Fish Mince/Surimi and Analogues	1 X 10 <sup>5</sup> -1 X 10 <sup>6</sup>	1 X 10 <sup>2</sup> -1 X 10 <sup>3</sup>	-	20	-	-	-	-			
13	Fish Pickle	1 X 10 <sup>3</sup>	1 X 10 <sup>2</sup> -1 X 10 <sup>3</sup>	100	20	-	-	-	-			
14	Battered and Breaded Fishery Products	1 X 10 <sup>5</sup> -1 X 10 <sup>7</sup>	1 X 10 <sup>2</sup> -1 X 10 <sup>3</sup>	100	11-500	-	-	-	-			
15	Convenience Fishery Products	1 X 10 <sup>3</sup> -1 X 10 <sup>4</sup>	1 X 10 <sup>2</sup> -1 X 10 <sup>3</sup>	-	1-10	-	-	-	-			
16	Powdered Fish Based Products	1 X 10 <sup>4</sup> -1 X 10 <sup>5</sup>	1 X 10-1 X 10 <sup>2</sup>	100	-	-	-	-	-			

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The principal FSSAI regulations (F. No. 2-15015/30/2010, dated the 1st August, 2011 part III, section 4) for fish Products Standards and Additives.

- 1. F.No.4/15015/30/2011, dated the 7th June, 2013
- 2. F.No.P.15014/1/2011-PFA, dated the 27th June, 2013
- 3. F.No.5/15015/30/2012, dated the 12th July, 2013
- 4. F.No.P.15025/262/13-PA/FSSAI, dated the 5th December, 2014
- 5. F.No.1-83F/Sci.Pan-Noti/FSSAI-2012, dated the 17th February, 2015
- 6. F.No.4/15015/30/2011, dated the 4th August, 2015
- 7. F.No.P.15025/263/13-PA/FSSAI, dated the 4th November, 2015
- 8. F.No.P.15025/264/13-PA/FSSAI, dated the 4th November, 2015
- 9. F.No.7/15015/30/2012, dated the 13th November, 2015
- 10. F.No.P.15025/208/2013-PA/FSSAI, dated the 13th November, 2015
- 11. F.No.P.15025/261/2013-PA/FSSAI, dated the 13th November, 2015
- 12. F.No.1-10(1)/Standards/SP (Fish and Fisheries Products)/FSSAI-2013, dated the 11th January, 2016
- 13. No. 3-16/ Specified Foods/Notification(Food Additive)/FSSAI-2014, dated the 3rd May, 2016

# D. FSSAI regulation for contaminants, toxins and residues in fish Product Standards and fish Additives

**Section 92 (2)** of **Food Safety and Standards Act, 2006** empowers the Food Authority to make regulations/standards regarding contaminants, toxins and residues. The Food Safety and Standards Authority of India number F. No. 1-10(6)/Standards/SP(Fish and Fisheries Products)/FSSAI-2013 dated the 12th June, 2015 in the Gazette of India, Extraordinary, Part III, Section 20 and 21. Fish and fish product should contain Polychlorinated biphenyls (0.5-2.0 ppm) and Benzo(a)pyrene (5.0 ppb). The limits of biotoxins in fish and fishery products such as Paralytic Shellfish Poison (80 μg/100g); Amnesic Shellfish Poison (20 μg/g); Diarrhetic shellfish poison (160 μg of Okadaic acid equivalent/Kg); Azaspiracid poison (160 μg of azaspiracid equivalent/Kg) and Brevetoxin (200 mouse units or equivalent/Kg)

The principal FSSAI regulations (F. No. 2-15015/30/2010, dated the 1st August, 2011 part III, section 4) for fish Products Standards and Additives.

- 1. F. No. 1-12/Sci.panel/(Notification)/FSSAI/2012, dated 3rd December, 2014
- 2. F. No. P. 15025/264/13-PA/FSSAI, dated 4th November, 2015
- 3. F. No. 1-99/1/SP(contaminants)/FSSAI/2009, dated 4th November, 2015
- 4. F. No. 1-99/4/SP(Contaminants)/FSSAI/2014, dated 4th November, 2015.

# E. FSSAI regulation for Non-Specified Food and Food Ingredients in fish Product Standards and fish Additives

Section 92 (2) of Food Safety and Standards Act, 2006 empowers the Food Authority to make regulations/standards regarding Non-Specified Food and Food Ingredients. The Food Safety and

Standards Authority of India number **F.No. 12/PA Regulation/Dir (PA)/FSSAI-2016** dated the 31st January, 2017 in the Gazette of India, Extraordinary, Part III, Section 4. **Non-specified food** means any food other than proprietary food or food ingredients, including additives, processing aids and enzymes for which standards have not been specified in any regulation made under the Act. In this section guidelines for prior approval for manufacture, storage, sale, distribution and import of non-specified food and food ingredients.

#### General regulation for processed fish and fish products

- Product shall be prepared from sound fish which are of a good quality to be sold fresh for human consumption and for further processing.
- The product after preparation shall be subject to a freezing process. The freezing process shall be carried out in appropriate equipment in such a way that the range of temperature of maximum crystallization is passed quickly. The freezing process shall not be regarded as complete unless and until the product temperatures has reached -18°C or lower at the thermal centre after thermal stabilization.
- The product shall be kept deep frozen to maintain the quality during transportation, storage and distribution.
- The product shall be processed and packaged to minimize dehydration and oxidation. The practice of repacking frozen products under controlled conditions which shall maintain the quality of the product, followed by the reapplication of the freezing process as defined, is permitted.
- If glazed, the water used for glazing or preparing glazing solutions shall be of potable quality (IS 10500:2012) or shall be clean sea-water, which meets the same microbiological standards as potable water and is free from potential contaminants.
- Hygiene during products preparation shall be in accordance with the guideline specified in Part-II of Schedule 4 of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011. The guidelines for hygiene are provided time to time in Food Safety and Standard Act, 2006.
- Contaminants, Toxins and Residues of the products covered under Food Safety and Standards (Contaminants, toxins and Residues) Regulations, 2011 regulations.
- The products packaging and labeling requirements are specified in the Food Safety and Standards (**Packaging and Labeling**), Regulations, 2011 and shall also apply to the pre-packaged products. The product shall be stored at -18°C or lower and shall be displayed on the label.
- The raw material shall not contain more than **100 mg/Kg of histamine**. This shall only apply to species of Carangidae, Chanidae, Clupeidae, Coryphaenidae, Engraulidae, Istiophoridae, Mugilidae, Pristigasteridae, Scombridae and Xiphiidae.
- Canned fishery products are packed in hermetically sealed containers and shall have received a processing treatment sufficient to ensure commercial sterility.
  - The product shall be prepared in one of the following packing media: own juice, brine or water, edible oil, tomato sauce or curry.

- The can shall not show any visible external defects like denting, paneling, swelling or rusting.
- The contents of the can, on opening shall not display any disintegration. Pieces from which portions have separated out would be treated as disintegrated units.
- 4 The product shall have the odor, flavor and color characteristic of the species.
- The final product shall be free from foreign materials, filth and from grittiness.
- Smoked Fish is prepared by exposing it to smoke from smouldering wood or plant materials. This process is usually characterised by an integrated combination of salting, drying, heating and smoking steps in a smoking chamber:
  - wood or other plant material for generation of smoke or smoke- condensates shall not contain toxic substances either naturally or through contamination(such as chemicals, paint or impregnating materials)
  - Smoking of fish shall be done in a manner that the formation of polycyclic aromatic hydrocarbons (PAH) is minimum.
- Ready-to-Eat fish curry should be prepared in **Retortable Pouches** from species of sound quality without any visible sign of decomposition.
  - The product is prepared from the edible portions of sound fish, packed in gravy of spices, vegetable fat and other ingredients appropriate to the product and heat processed by an appropriate manner after being sealed in a container so as to prevent spoilage.
  - The total volatile base nitrogen (TVBN) level of raw material (fin fish or shell fish) should not exceed 35mg/100g.
  - the product shall be free from foreign materials such as sand, dirt and insects, objectionable odour, or flavour;
  - The residual air in the pouch after processing shall be less than 2 % of the volume of the pouch contents;
  - 4 the average proportion of fish to curry in retort pouch shall be in the ratio of 60: 40.
  - **4** The percentage of salt in the product shall be 1% to 2 %.
  - Processing (Retorting) shall be done in over pressure autoclave till the product reaches a F0 value of 8-10 minutes at the slowest heating point. The water used for cooling of retort pouches shall be as per IS 10500:2012 standards and chlorinated to maintain free residual chlorine of less than 2 mg/l.

#### Reference

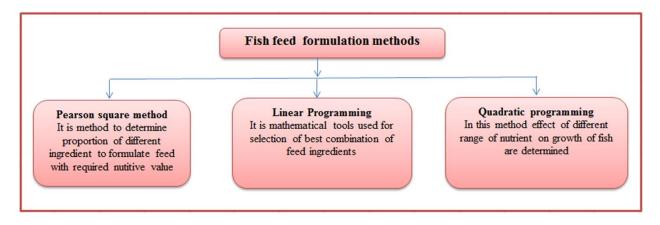
https://www.fssai.gov.in/cms/right-to-information-act-rti.php

## Appendix III Animal Feeds Regulations in India

#### 1. Feed formulation

Any ingredient added intentionally which affect the characteristic of feeds with without having nutritive values (**IS 1374:2007, Bureau of Indian Standards).** 

The quality of feeds play very crucial role in economic production of healthy and high quality fish products. Fish feed technologies are least developed in developing countries because commercially available fish feed are used mainly nutritional and diet development of temperate fish species in developed countries whose ingredient are expensive.



#### Figure 1 Method for formulation of fish feeds

(Source: http://ecoursesonline.iasri.res.in/mod/page/view.php?id=40381)

#### 2. Different type of feeds

#### • Dry feeds

Dry feeds are generally made from dry ingredients or from mixtures of dry and moist ingredients. Generally dry feeds carry 10-12 % moisture depending on the environmental conditions. The dry feed is classified in to two groups (1) Mashes/ Meals and (2) Pellets. The mashes/ meals refer to simple mixtures of dry ingredients. While the pellets refers to ingredients being compacted to give defined shape by a mechanical means.

#### • Non-dry feeds

The non-dry feeds are composed of two types (1) wet feeds and (2) moist feeds. The wet feeds are generally made from trash fish, slaughter house wastes etc. which contain 45-70% moisture. The moist feeds on the other hand are made from mixtures of wet and dry raw materials or from dry ingredients to which water is added. The moisture content ranges from 18-40.

In India Bureau of Indian Standards (BIS) is a statuary body to control quality of animal feeds called animal feeds sectional committee who check the quality of animal feeds and feeds ingredients. BIS is responsible for standardization, certification, testing, traceability and tangible benefit to provide safe and reliable quality product to consumer. The head quarter of BIS is in New Delhi and has five regional offices (Kolkata, Chennai, Mumbai, Chandigarh and Delhi); 33 branches offices (Ahmedabad, Bengaluru, Bhubaneswar, Bhopal, Chandigarh, Chennai, Coimbatore, Dehradun, Delhi, Durgapur, Faridabad, Ghaziabad, Guwahati, Hyderabad, Jaipur, Jammu, Jamshedpur, Kochi, Kolkata, Lucknow, Mumbai, Nagpur, Parwanoo, Patna, Pune, Raipur, Rajkot and Visakhapatnam) and eight laboratories (central laboratory, Sahibabad; western regional office laboratory, Mumbai; Northern Regional office laboratory, Mohali; Eastern Regional office laboratory, Bengaluru; Patna branch office laboratory, Patna and Guwahati branch office Laboratory, Guwahati) **Figure** 3. The feeds used for poultry nutrition is given in livestock feeds and equipment systems sectional committee and approved by the Food and Agriculture Division Council and Bureau of Indian standards. In India first regulation related to feed was issued in 1959 in fields of poultry. The composition of poultry feeds made from fishmeal is given Figure 2.

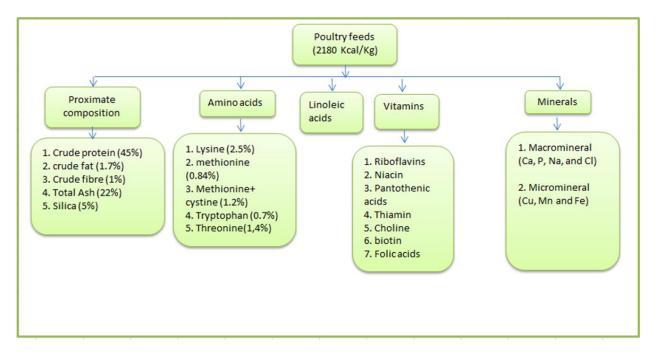


Figure 2 Composition of Poultry feeds made from Fish meal (BIS: IS 1374:2007)

Most of Indian feed industry applies HACCP-hazard analysis critical control point measures to ensures safety of feeds. BIS formed sub-committee especially to check the quality of animal feeds and feed ingredients. This subcommittee is nutritionist from ICAR institutes, state agricultural universities, feed industry, government department having specialization in animal nutrition and feed technologist. Grading and marketing of agricultural products with AGMARK" are empowered by Indian government. International Feed Safety Alliance (IFSA) is a joint program initiated in order to combine the existing feed

ingredients quality programs into one program that can operate across the world with one set of standards.

#### Regulation to ensure quality standards in animals feeds in India are:

- 1. The Prevention of Black Marketing and Maintenance of Supplies of Essential Commodities Act, 1980
- 2. The Standards of Weights and Measures (Packaged Commodities) Rules, 1977
- 3. The Consumer Protection Act, 1986
- 4. Schedule of Tariff Values of the Articles Liable to Cess for 2006-07 Agricultural Produce Cess Act,1940
- 5. Edible Oils Packaging (Regulation) Order, 1998
- 6. The Prevention of Food Adulteration Rules, 1955
- 7. Regulation of Manufacture and Sale Order, 2009.

#### Codex guidelines on feed safety are:

- 1. Classification of foods & animal feeds (CAC/Misc 4 93)
- 2. Codex General standard for contaminants in foods & feeds (Codex stan193-1995)
- 3. MRLs for pesticides (CAC/MRL 1-2009); veterinary drug (2-2009), extraneous MRLs (CAC/MRL 3-2001)
- 4. Code of Practice on reduction of dioxin & dioxin-like PCB contamination in foods & feeds (CAC/RCP 62-2006)
- 5. Code of practice for reduction of aflatoxin B1 in raw material & supplemental feeding stuffs for milk producing animals (CAC/RCP 45-1997)
- 6. Code of practice on good animal feeding (CAC/RCP 54-2004)
- 7. Principles for traceability/ product tracing as a tool within a food inspection & certification system (CAC/GL 60 2006)

Quality Standard followed by Indian feed industry needs to compare with the international standards to have more credibility. The possible and cheaper source for raw material for feed production is needed to find to attain self-sustenance in animal feed production.



Figure 3 Bureau of Indian Standards headquarter and its branches

(Source: BIS Annual report 2017-18)

According food Safety and Standards Authority of India (FSSAI, 2019) commercial feeds given to animal producing foods should be manufacture according to BIS standards. Animal feeds should not be imported, distributed and sold without BIS certification mark. According to National Milk and Quality Survey (2018) the traces of aflatoxin MI was found in raw milk supplied by both organized and unorganized supplier. Therefore main focus of FSSAI is to frame guideline for contaminants, pesticides and heavy metals in animal's feeds. FSSAI has directed that cattle feed must be manufacture according to BIS standards till FSSAI regulation are finalized

According to FAO, the feed must have required proximate composition (moisture content, protein, lipid, fiber and ash content), vitamin, mineral, available phosphorus, amino acid and polyunsaturated fatty acids. Protein from some plant source lack some essential amino acids such as methionine is found in fish meal but absent in wheat bran. Fish meal is excellent source of good quality protein, mineral (Phosphorus), vitamins B and essential fatty acids.

Table 1 Nutrient of feeds produced from Fishmeal (TCVN 1644:2001)
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Nutrients	Grade1	Grade 2	Grade 3
Moisture (%, maximum)	10	10	10
Crude protein (%, minimum)	60	50	40
Crude lipid (%, maximum)	8	10	11
Salinity (%, maximum)	2	3	5
Ash (% maximum)	2	3	4
Hard and sharp solid materials	Not permitted		
Total volatile nitrogen (mg/100g, maximum)	150	250	350

Source: http://www.fao.org/fishery/affris/feed-and-feed-ingredient-standards/en/

 Table 2 Proximate composition of natural feeds

S.No.	Feed Ingredient source	Moisture content (%)	Crude protein (%)	Crude Lipid (%)	Crude Fibre (%)	Crude Ash (%)	Cholesterol (%)	Astaxanthin (mg/Kg)	Calcium (%)
1	Crustacean meal (Langostene)	5	40.9	7.4	10	32	0.28	15	7
2	Fish meal (50% tuna)	6.8	52	7.6	3.1	25.2	0.08	0	5.4
3	Fish meal (65% anchovy)	9.6	68	8.95	1	15.7	0.05	0	4.4
4	Krill meal	7.1	58	18	6	13	0.55	120	1.91
5	Shrimp (fresh)	75.9	20.3	1.7	1.5	1.2	0.15	5	0.05
6	Shrimp head meal	6	58.6	7.2	14	25.8	0.7	15	7.3
7	Shrimp shell meal	7.4	36.3	7	20	30.4	0.6	10	8
8	Squid meal	7.3	60	11.9	2	8.5	1.2	0	0.36
9	Trash fish (anchovy)	73.4	20.4	4.8	0.2	1.4	0.06	0	0.15
10	Trash fish (mixed)	79.2	19.4	1	0.2	1.2	0.04	0	0.03
11	Trash fish (white fish – mixed)	72.8	19.1	5.9	0.2	1.1	0.06	0	0.03

Source: http://www.fao.org/fileadmin/user\_upload/affris/docs/Indian\_White\_Prawn/English/table\_13a.htm

#### Table 3 Fatty acids composition of natural feeds

Feed Ingredient source	18:2n-6 (%)	18:3n-3 (%)	20:4n-6 (%)	20:5n-3 (%)	22:6n-3 (%)	Total n-3 (%)	Total n-6 (%)
Crustacean meal (Langostene)	0.01	0	0.12	0.5	0.3	0.9	0.2
Fish meal (50% tuna)	0.076	0.03	0.12	0.34	1.18	1.9	0.21
Fish meal (65% anchovy)	0.09	0.04	0.14	0.4	1.4	2.2	0.25
Krill meal	0.14	0.06	0.03	1.6	0.66	2.3	0.06
Shrimp (fresh)	0.02	0.01	0.04	0.26	0.22	0.53	0.03
Shrimp head meal	0.04	0	0.05	0.94	0.89	2	0.36
Shrimp shell meal	0.08	0.1	0.05	1.63	0.58	2.25	0.09
Squid meal	0.47	0.11	1.11	1.24	1.56	2.9	0.6
Trash fish (anchovy)	0.05	0	0.01	0.54	0.91	1.48	0.1
Trash fish (mixed)	0.01	0.01	0.01	0.03	0.22	0.27	0.02
Trash fish (white fish –mixed)	0.27	0.18	0.2	0.32	0.94	1.6	0.5
	Crustacean meal (Langostene) Fish meal (50% tuna) Fish meal (65% anchovy) Krill meal Shrimp (fresh) Shrimp head meal Shrimp shell meal Squid meal Trash fish (anchovy) Trash fish (mixed)	Crustacean meal (Langostene)0.01Fish meal (50% tuna)0.076Fish meal (65% anchovy)0.09Krill meal0.14Shrimp (fresh)0.02Shrimp head meal0.04Shrimp shell meal0.08Squid meal0.47Trash fish (anchovy)0.01	Crustacean meal (Langostene)       0.01       0         Fish meal (50% tuna)       0.076       0.03         Fish meal (65% anchovy)       0.09       0.04         Krill meal       0.14       0.06         Shrimp (fresh)       0.02       0.01         Shrimp head meal       0.04       0         Shrimp shell meal       0.04       0         Squid meal       0.47       0.11         Trash fish (anchovy)       0.05       0         Trash fish (mixed)       0.01       0.01	Crustacean meal (Langostene)       0.01       0       0.12         Fish meal (50% tuna)       0.076       0.03       0.12         Fish meal (65% anchovy)       0.09       0.04       0.14         Krill meal       0.14       0.06       0.03         Shrimp (fresh)       0.02       0.01       0.04         Shrimp head meal       0.04       0       0.05         Shrimp shell meal       0.08       0.1       0.05         Squid meal       0.47       0.11       1.11         Trash fish (anchovy)       0.05       0       0.01	Crustacean meal (Langostene)0.0100.120.5Fish meal (50% tuna)0.0760.030.120.34Fish meal (65% anchovy)0.090.040.140.4Krill meal0.140.060.031.6Shrimp (fresh)0.020.010.040.26Shrimp head meal0.0400.050.94Shrimp shell meal0.080.10.051.63Squid meal0.470.111.111.24Trash fish (anchovy)0.0500.010.03	Crustacean meal (Langostene)0.0100.120.50.3Fish meal (50% tuna)0.0760.030.120.341.18Fish meal (65% anchovy)0.090.040.140.41.4Krill meal0.140.060.031.60.66Shrimp (fresh)0.020.010.040.260.22Shrimp head meal0.080.10.050.940.89Shrimp shell meal0.470.111.111.241.56Trash fish (anchovy)0.0500.010.030.22	Crustacean meal (Langostene)0.0100.120.50.30.9Fish meal (50% tuna)0.0760.030.120.341.181.9Fish meal (65% anchovy)0.090.040.140.41.42.2Krill meal0.140.060.031.60.662.3Shrimp (fresh)0.020.010.040.260.220.53Shrimp head meal0.0400.050.940.892Shrimp shell meal0.080.10.051.630.582.25Squid meal0.470.111.111.241.562.9Trash fish (anchovy)0.010.010.030.220.27

**Note:** Octadecadienoic acid (18:2n-6), Octadecatrienoic acid (18:3n-3), Eicosatetraenoic acid (20:4n-6), Eicosapentaenoic acid (20:5n-3), Docasahexaenoic acid (22:6n-3), Omega 3 fatty acid (n-3) and Omega 6 fatty acid (n-6) Source: <u>http://www.fao.org/fileadmin/user\_upload/affris/docs/Indian\_White\_Prawn/English/table\_13a.htm</u>

#### Table 4 Amino acid composition natural feeds

S.No.	Feed Ingredient source	Arg (%)	His (%)	IIL (%)	Leu (%)	Lys (%)	Met (%)	Met +Cys	Phe (%)	Phe+ Tyr (%)	The (%)	Trp (%)	Val (%)
1	Crustacean meal (Langostene)	3.14	0.76	1.44	2.15	1.67	0.32	2.73	1.36	2.55	1.39	0.46	1,58
2	Fish meal (50% tuna)	4.04	1.29	2.45	4.37	4.13	1.37	1.95	2.39	4.29	2.55	0.85	2.92
3	Fish meal (65% anchovy)	4.03	1.68	3.33	5.29	5.28	2.09	2.71	2.91	5.26	2.95	0.79	3.67
4	Krill meal	3.25	0.99	2.47	3.85	3.82	1.59	2.02	2.07	3.94	1.96	0.68	2.43
5	Shrimp (fresh)	1.78	0.41	0.99	1.61	1.77	0.57	0.8	0.86	1.53	0.82	0.28	0.97
6	Shrimp head meal	2.14	0.68	1.37	2.36	2.32	0.83	1.3	1.69	3.1	1.45	0.45	1.74
7	Shrimp shell meal	2.1	0.6	1.3	2.2	2.1	0.75	1.2	1.5	2.8	1.4	0.4	1.65
8	Squid meal	6.87	1.5	2.54	4.82	6.36	1.4	1.76	2.6	4.43	2.99	0.4	0.4
9	Trash fish (anchovy)	1.22	0.6	0.94	1.65	1.87	0.6	0.82	0.79	1.48	0.89	0.23	0.23
10	Trash fish (mixed)	1.16	0.57	0.89	1.58	1.78	0.57	0.78	0.76	1.4	0.85	0.22	0.22
11	Trash fish (white fish –mixed)	1.14	0.56	0.88	1.55	1.75	0.57	0.77	0.75	1.4	0.84	0.21	0.21

Note: Arginine (Arg), Histidine (His), Isoleucine (IIL), Leucine (leu), Lysine(Lys), Methionine (Met), Methionine+ cysteine (Met+Cys), Phenylalanine (Phe), Phenylalanine + tyrosine (Phe+Tyr), Theonine (The), Tryptophan (Trp)and Valine (Val) Source: <u>http://www.fao.org/fileadmin/user\_upload/affris/docs/Indian\_White\_Prawn/English/table\_13a.htm</u>

### Table 5 Quality standard for Tilapia (Oreochromis sp.) feeds formulation

Standards	Feed type									
	1	2	3	4	5	6				
Diameter of pellet (mm, maximum)	1.0	1.5	2.0	4.0	4.0	6.0				
Length/diameter ratio	1.0-1.5									
Broken rate (%, maximum)	2									
Durability (hours, minimum)	30									
Crude energy (kcal/kg feed, minimum)	3200	3000	2860	2800	2750	2700				
Moisture (%, maximum)	11			·	·					
Crude protein (%, maximum)	40	35	30	27	25	20				
Crude lipid (%)	6	6	5	5	4	4				
Crude fiber (%, maximum)	5	5	6	6	7	7				
Ash (%, maximum)	19									
Sand (%, maximum)	1	1	2	2	2	2				
Calcium (%, maximum)	2.5									
Calcium/phosphorus ratio	1.0-1.5									
NaCl (%, maximum)	2.5									
Lysine (%, minimum)	1.7	1.6	1.4	1.3	1.1	0.9				
Methionine (%, minimum)	1.0	0.9	0.8	0.7	0.6	0.5				
Alive insects	Not permit	ted								
Pathogenic bacterium (salmonella)	Not permit	ted								
Aspergillus	Not permit	ted								
Aflatoxin	< 10ppb									

Source: http://www.fao.org/fishery/affris/feed-and-feed-ingredient-standards/en/

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