

Export of Fishery Products (Aquaculture Feed) Regulations, 2010

[6th December 2010]

1. (1) These Regulations may be cited as the Export of Fishery Products (Aquaculture Feed) Regulations, 2010.

(2) These Regulations shall be in addition to and not in derogation of any other written law for the time being in force relating food safety and public health.

2. In these Regulations —

“Competent Authority” means the Fish Inspection and Quality Control Unit referred to in the Export of Fishery Products Act;

“feed” or “feedstuff” means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding of animals or fish;

“feed business” means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed and includes any persons producing, processing or storing feed for feeding of animals on that person's own holding;

“feed business operator” means the person responsible for ensuring that the requirements of law are met within the feed business under their control;

“fishmeal” means any substance or product originating from seafood products and including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding of animals;

“by-product” means any material or product that is not the primary product of a specific processing operation, yet may be used in the production of secondary products for either for human consumption or as an ingredient in the manufacture of other products intended for consumption by humans or in the manufacture of animal feed;

“fishery waste” means material originating from fishery products, whole fish or parts thereof, that have been identified as either being potentially harmful to the consumer or of no commercial value *and* are permanently and irreversibly removed from the human and animal supply chain;

“processing” means any action that substantially alters the initial product, including but not limited to heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes.

3. (1) Feed shall not be placed on the market or fed to any food producing animal if it is unsafe for consumption.

(2) Feed shall be declared to be unsafe for its intended use if it is considered to —

(a) have an adverse effect on human or animal health;

(b) make the food derived from food-producing animals unsafe for human consumption.

(3) Where a feed that has been identified as being unsafe is part of a batch, lot or consignment from the same processing conditions, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless the establishment can demonstrate to the Competent Authority the product safety of the rest of the batch, or consignment and so satisfy the feed safety requirement.

4. (1) Feed business operators at all stages of production, processing and distribution within businesses under their control shall ensure that, feeds satisfy the requirements of the Export of Fishery Products Act which are relevant to their activities and verify that such requirements are satisfied.

(2) The Competent Authority shall enforce this regulation, and monitor and verify that the relevant requirements are fulfilled by the feed business operators at all stages of production, processing and distribution.

5. (1) The Competent Authority shall —

- (a) perform its functions in a non-discriminatory manner;
- (b) assess the food safety risks on the available scientific evidence in an independent, objective and transparent manner; and
- (c) where there are reasonable grounds to suspect that a fishery product or feed may present a risk to human health, take steps to identify the fishery product in question and to implement appropriate measures to prevent, reduce or eliminate that risk.

6. (1) The Competent Authority shall undertake official control and monitoring of food safety conditions in establishments and vessels to which section 3 of the Act applies, and of imports of fishery products for re-export to ensure compliance with these Regulations.

(2) The official controls shall include the checks set out in Schedule 2.

(3) Official control of fishery products and feed shall be carried out —

- (a) regularly and according to priorities determined by risk assessment;
- (b) where non-compliance is suspected; and (c) for the purpose of issue of permits and certificates.

(4) Official control shall be carried out using means proportionate to the end to be attained.

(5) Official control shall cover all stages of production, manufacture, processing, storage, transport, distribution and production of aquaculture feeds.

7. (1) Feed business operators shall conduct their manufacturing operations according to the requirements set out in Schedule 1.

(2) Feed business operators shall put in place, implement and maintain permanent written procedures based on the HACCP principles, as set out in Schedule 12 of the Export of Fishery Products (Sanitary) Regulations, 2010.

(3) If a feed business operator has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the relevant public authorities thereof. In these circumstances or, where the batch, lot or consignment does

not satisfy the feed safety requirements, that feed shall be destroyed, unless the Competent Authority determines otherwise.

(4) The feed business operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

8. (1) The traceability of raw materials, ingredients and additives, and any other substance intended to be incorporated in the feed shall be established at all stages of production, processing and distribution by the feed business operator.

(2) Feed business operators shall know the identity of persons who have supplied them with raw materials, and any ingredients or additives used or to be used in the production of aquaculture feeds.

(3) The feed business operators shall have in place systems and procedures which allow for such information to be made available to the Competent Authority on request.

(4) Feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the Competent Authority on demand.

(5) Feed which is placed on the market or is likely to be placed on the market shall be adequately labelled or identified to facilitate its traceability.

9. (1) Aquaculture feeds shall not be placed on the market unless the following particulars are indicated by labelling —

- (a) type of feed: e.g. “shrimp feed”, “complete feed” or “complementary feed”, as appropriate;
- (b) name or business name and address of the feed business operator responsible for labeling particulars;
- (c) establishment approval number;
- (d) batch or lot reference number;
- (e) net quantity expressed in units of mass in the case of solid products, and in units of mass or volume in the case of liquid products;
- (f) list of feed additives preceded by the name and the content expressed as 'additives per kg';
- (g) moisture content if greater than 8%;
- (h) fat/oil content if greater than 5%;

(2) In addition the product labelling may include the following details —

- (a) the country of production or manufacture;
- (b) the description or trade name of the product;
- (c) an indication of the physical condition of the feed or the specific processing it has undergone;

- (d) the moisture content;
- (e) the date of manufacture;
- (f) special storage conditions;
- (g) the price of the product.

(3) Feed may be placed on the market only in sealed packages or containers. Packages or containers shall be sealed in such a way that when the package or container is opened the seal is damaged and cannot be reused.

SCHEDULE 1

Regulation 7

Conditions of Manufacturing of Aquaculture Feeds

1. (1) Feed processing and storage facilities, equipment, containers, crates, vehicles and their immediate surroundings shall be kept clean, and effective pest control programmes shall be implemented.

(2) The lay-out, design, construction and size of the facilities and equipment shall —

- (a) permit adequate cleaning;
- (b) be such as to minimise the risk of error and to avoid contamination, cross-contamination and any adverse effects generally on the safety and quality of the products and machinery coming into contact with feed shall be dried following any wet cleaning process.

(3) Facilities and equipment to be used for mixing and manufacturing operations shall undergo appropriate and regular checks, in accordance with written procedures preestablished by the manufacturer.

(4) All scales and metering devices used in the manufacture of feeds shall be appropriate for the range of weights or volumes to be measured and shall be tested for accuracy regularly.

(5) All mixers used in the manufacture of feeds shall be appropriate for the range of weights or volumes being mixed, and shall be capable of manufacturing suitable homogeneous mixtures and homogeneous dilutions and operators shall demonstrate the effectiveness of mixers with regard to homogeneity.

(6) Facilities must have adequate natural artificial lighting.

(7) Drainage facilities must be adequate for the purpose intended and must be so designed and constructed as to avoid the risk of contamination of feeding stuff.

(8) Water used in feed manufacture shall be of suitable quality for animals and the conduits for water shall be of an inert nature.

(9) Sewage, waste and rainwater shall be disposed of in a manner which ensures that equipment and the safety and quality of feed are not affected. Spoilage and dust shall be controlled to prevent pest invasion.

(10) Windows and other openings must, where necessary, be proofed against pests. Doors must be closefitting and proofed against pests when closed.

(11) Where necessary, ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles that can affect the safety and quality of feed.

2. Feed businesses must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the products concerned. An organisation chart setting out the qualifications (e.g. diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the Competent Authority.

(2) All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, so as to obtain the desired product quality.

3. (1) A qualified person responsible for production must be designated.

(2) Feed business operators must ensure that the different stages of production are carried out according to preestablished written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process.

(3) Technical or organisational measures must be taken to avoid or minimise, as necessary, any cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.

(4) The presence of prohibited feed, undesirable substances and other contaminants in relation to human or animal health shall be monitored, and appropriate control strategies to minimise the risk shall be put in place.

(5) Waste and materials not suitable as feed should be isolated and identified. Any such materials containing hazardous levels of veterinary drugs, contaminants or other hazards shall be disposed of in an appropriate way and not used as feed.

(6) Feed business operators shall take adequate measures to ensure effective tracing of the products.

(7) Where appropriate, a qualified person responsible for quality control must be designated.

(8) Feed businesses must, as part of a quality control system, have access to a laboratory with adequate staff and equipment.

(9) A quality control plan must be drawn up in writing and implemented, including in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications and the destination in the event of non-compliance from processed materials to final products.

(10) Documentation relating to the raw materials used in final products must be kept by the manufacturer in order to ensure traceability. Such documentation must be available to the Competent Authority for a period appropriate for the use to which the products are placed on the market. In addition, samples of ingredients and of each batch of products manufactured and placed on the market or of each specific portion of production (in the case of continuous production) must be taken in sufficient quantity using a procedure preestablished by the manufacturer and be retained, in order to ensure traceability (on a regular basis in the case of manufacture solely for the manufacturer's own needs). The samples must be sealed and labelled for easy identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any adulteration.

They must be kept at the disposal of the Competent Authority for a period appropriate to the use for which the feed is placed on the market. In the case of feeding stuff for animals not kept for food production, the manufacturer of the feeding stuff must only keep samples of the finished product.

4. (1) Processed feeds shall be separated from unprocessed feed materials and additives, in order to avoid any cross contamination of the processed feed and proper packaging materials shall be used.

(2) Feeds shall be stored and transported in suitable containers. They shall be stored in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorised by the feed business operator have access.

(3) Feeds shall be stored and transported in such a way as to be easily identifiable, in order to avoid any confusion or cross contamination and to prevent deterioration.

(4) Containers and equipment used for the transport, storage, conveying, handling and weighing of feed shall be kept clean. Cleaning programmes shall be introduced, and traces of detergents and disinfectants shall be minimised.

(5) Any spillage shall be minimised and kept under control to reduce pest invasion.

(6) Where appropriate, temperatures shall be kept as low as possible to avoid condensation and spoilage.

5. All feed business operators, including those who act solely as traders without ever holding the product in their facilities, shall keep in a register relevant data, comprising details of purchase, production and sales for effective tracing from receipt to delivery, including export to the final destination.

6. Feed businesses must have a system of documentation designed to define and ensure mastery of the critical points in the manufacturing process and to establish and implement a quality control plan. They must keep the results of the relevant controls. This set of documents must be kept so that it is possible to trace the manufacturing history of each batch of products put into circulation and to establish responsibility, if complaints arise.

7. (1) Feed business operators shall implement a system for registering and processing complaints.

(2) They shall put in place, where this proves necessary, a system for the prompt recall of products in the distribution network. They shall define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality control reassessment.

SCHEDULE 2

Reg. 6

General principles of inspection

1. Official control of the food safety conditions shall comprise one or more of the following checks and where necessary any consequential actions —

- (a) periodic inspection of aquaculture feed manufacturing establishments and monitoring of compliance with permit conditions;

- (b) examination of any control systems that aquaculture feed manufacturing establishments have put in place and the results obtained;
- (c) inspection of —
 - (i) raw materials, ingredients, processing aids and other products used for the preparation and production of fishery products, their sources (including fishing vessels and landing sites) and the conditions under which they are produced;
 - (ii) semi-finished and finished products;
 - (iii) cleaning and maintenance of facilities, equipment products and processes;
- (d) labelling, presentation and advertising;
- (e) assessment of procedures on good manufacturing practices (GMP), good hygiene practices (GHP)

SCHEDULE 3

Sch.2, Para 3

Maximal levels of contaminants in aquaculture feeds

1. These levels are maximal levels designated beyond which the product is declared unsafe for use as aquaculture feed.
2. Analysis shall only be required for the purposes of verifying product safety where contamination is thought to have occurred, where it is the responsibility of the processor to demonstrate product safety.

	Mg/kg	Notes
Arsenic	15 mg/kg	Feeding stuffs obtained from the processing of fish or other marine animals
Lead	5.0 mg/kg	Complete feeding stuffs
Flourine	0.5 mg/kg	Complete feeding stuffs for fish
Mercury	0.5 mg/kg	Feeding stuffs produced by the processing of fish or other marine animals
Cadmium	2.0 mg/kg	Feed materials of animal origin
Aflatoxin B1	0.01 mg/kg	Other complete feeding stuffs

Aldrin	0.02 mg/kg	Fish feed
Dieldrin Camphechlor	0.05 mg/kg	Feeding stuffs for fish (1)
Dioxins	2.25 ng WHO- PCDD/F- TEQ/kg	Feed for fish
Sum of dioxins and dioxins and dioxin- like PCBs	7.0 ng. WHO- PCDD/F- PCB/kg	Feed for fish (sum of polychlorinated dibenzoparadioxins (PCDDs), polychlorinated dibenzofurans (PCDF's) and polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO – TEFs (toxic equivalency factors, 1997 (3)
