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DRAFT GUIDELINES FOR THE CONTROL OF AQUATIC ANIMAL HEALTH HAZARDS IN AQUATIC ANIMAL FEEDS

1. INTRODUCTION

One of the key objectives of the OIE *Aquatic Animal Health Code* (hereafter referred to as the *Aquatic Code*) is to help Member Countries trade safely in *aquatic animals* and their products by developing relevant aquatic animal health measures. These Guidelines address aquatic animal health *hazards* in aquatic animal *feeds*. It does not address food safety issues as this is not within the mandate of the OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission). These Guidelines should be read in conjunction with relevant recommendations of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) (Appendix containing recommendations on animal *feed*). The Food and Agriculture Organization of the United Nations (FAO) has also published recommendations¹ relevant to terrestrial and aquatic animal *feed*.

Key considerations relevant to aquatic animal *feeds* are as follows:

- Intensive rearing in *aquaculture establishments* causes a concentration of fish, *feed* and faecal matter in time and space and this heightens the risk of *disease* transmission, whether the pathogen enters the culture system via *feed* or other means.
- For many aquatic species, predation (including cannibalism) is their natural way of feeding in their natural habitat.
- Historically, animal proteins used in *feeds* were mainly sourced from the marine environment, due to the nutritional needs of *aquatic animals* and for reasons of economy. This practice increases the *disease* risks, especially when animals are fed with live or whole fish of the same or related species. There are many examples of this type of practice, e.g. early stage crustaceans fed on *Artemia* species and aquaculture tuna fed on whole wild caught fish.
- The usage of *feed* in moist, semi-moist and dry form implies different levels of risk due to the processing applied to the *feed*.
- With the increasing number of species being farmed (especially marine finfish), the use of live and *moist feed* has increased. It is likely that these industries will shift in future to formulate *feeds* as appropriate formulations are developed.
- *Hazards* may be transmitted from *feed* to *aquatic animals* via direct or indirect means. Direct transmission occurs when the cultured species consumes *feed* containing a pathogenic agent (e.g. shrimp larvae consuming rotifer infected with white spot syndrome virus) while indirect transmission refers to pathogens in *feed* entering the aquatic environment or infecting non target species, and thereby establishing a mechanism for indirect infection of the species of commercial interest. Pathogens that are less host-specific (e.g. white spot syndrome virus, *Vibrio* species) present a greater risk of indirect transmission as they can establish reservoirs of infection in multiple species.

¹ Technical guidelines for responsible fisheries – aquaculture development: 1. Good aquaculture feed manufacturing practice. FAO 2001.
Draft good practices for the animal feed industry – implementing the Codex Alimentarius' Code of practice on good animal feeding, IFIF/FAO (*In preparation*).

As new species become the subject of *aquaculture*, new pathogens emerge in association with these hosts. The expression of *disease* may be facilitated by culturing species under intensive and novel conditions. Also, it is necessary to conduct research and develop new *feeds* (and *feed ingredients*) that are appropriate to the species and its culture system. As more and more aquatic species are being cultured, it is difficult to make recommendations for all significant *disease agent*/host species combinations.

2. PURPOSE AND SCOPE

To document risk mitigation measures, including traceability and certification, to deal with aquatic animal health risks through trade in aquatic animal *feeds* and *feed ingredients*. *Hazards* include *diseases* of interest i.e. *OIE-listed diseases* and any others considered to be important to aquatic animal health.

This guideline recommends the control of aquatic animal health *hazards* through adherence to recommended practices during the production (procurement, handling, storage, processing and distribution) and use of both commercial and on-farm produced *feed* (and *feed ingredients*) for *aquatic animals*. While *aquatic animals* grown for food are the main focus, the same principles apply to *feed* for aquarium species.

3. DEFINITIONS

Cross contamination

Means contamination of a material or product with another material or product containing a *hazard*.

Dry feed

Means *feed* that has a dry matter content = or > than 90%.

Feed

Means any material (single or multiple), whether processed, semi-processed or raw that is intended to be fed directly to food-producing animals.

Feed additives

Means any ingredient intentionally added in micro-amounts not normally consumed as *feed* by itself, whether or not it has nutritional value, which affects the characteristics of *feed* or animal products. Micro-organisms, enzymes, acidity regulators, trace elements, vitamins, attractants, pigments, synthetic binders, synthetic amino acids, antioxidants and other products fall within the scope of this definition, depending on the purpose of use and method of administration. This excludes veterinary drugs.

Feed ingredient

Means a component, part or constituent of any combination or mixture making up a *feed*, including *feed additives*, whether or not it has a nutritional value in the animal's diet. Ingredients may be of plant, animal or aquatic origin and may be organic or inorganic substances.

Hazard

Means a biological, chemical or physical agent in, or a condition of, *feed* or a *feed ingredient* with the potential to cause an adverse effect on animal or public health.

Intra/inter species feeding

Means feeding *aquatic animals* on products made from animals of the same species, or products made from species that are susceptible to the same pathogens as the animals receiving the *feed*.

Live feed

Means live farmed or wild caught animals used as *feed* for *aquatic animals*. *Live feed* is often fed to aquatic species at an early life-stage (e.g. Artemia cysts, rotifers, copepods) and to aquatic species that have been cultured for a relatively short time.

Medicated feed

Means any *feed* which contains a veterinary drug administered to food producing animals, for therapeutic or prophylactic purposes or for modification of physiological functions.

Moist (or wet) feed

Means *feed* that has a dry matter content = or < than 30% (e.g. frozen adult Artemia, whole fish or fish *offal*, molluscs, crustaceans, polychaetes for feed purposes).

Semi-moist feed

Means *feed* that has a dry matter content between 30 and 90%.

Fish solubles

Means a by-product of the fish oil production system, comprising the product remaining when water is drawn off (evaporated) from the residual aqueous phase.

Undesirable substance

Means a contaminant or other substance that is present in and/or on *feed* or *feed ingredients* and that constitutes a risk to animal or public health.

4. GENERAL PRINCIPLES**a) Roles and responsibilities**

The *Competent Authority* has the legal power to set and enforce regulatory requirements related to animal *feeds*, and has final responsibility for verifying that these requirements are met. The *Competent Authority* may establish regulatory requirements for relevant parties, including requirements to provide information and assistance.

It is a particular responsibility of the *Competent Authority* to set and enforce the regulatory requirements pertaining to the use of veterinary drugs, animal disease control and the food safety aspects that relate to the management of live animals on farm.

Those involved in the production and use of animal *feed* and *feed ingredients* have the responsibility to ensure that these products meet regulatory requirements². All personnel involved in the procurement, manufacture, storage and handling of *feed* and *feed ingredients* should be adequately trained and aware of their role and responsibility in preventing the spread of *hazards* of animal health and public health significance. Appropriate contingency plans should be developed in case of a *feed-borne disease* outbreak. Equipment for producing, storing and transporting *feed* should be kept clean and maintained in good working order.

² If at the national level, there are specific food-safety or animal health regulations related to genetically modified organisms, these should be taken into account in relation to feed and feed ingredients as these products form an important part of the food chain.

Private *veterinarians* and others (e.g. laboratories) providing specialist services to producers and to the feed industry may be required to meet specific regulatory requirements pertaining to the services they provide (e.g. disease reporting, quality standards, transparency).

b) Regulatory standards for feed safety

All *feed* and *feed ingredients* should meet regulatory standards for feed safety. In defining limits and tolerances for *hazards*, scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be taken into account.

c) Risk analysis

Internationally accepted principles and practices on risk analysis (see Section 1.4. of the *Aquatic Code* and relevant Codex texts) should be used in developing and applying the regulatory framework.

A generic *risk analysis* framework should be applied to provide a systematic and consistent process for managing disease risks and the risk of contamination with *undesirable substances*.

d) Good practices

Where national guidelines exist, good *aquaculture* practices and good manufacturing practices (including good hygienic practices) should be followed. Countries without such guidelines are encouraged to develop them.

Where appropriate, Hazard Analysis and Critical Control Point³ (HACCP) principles should be followed to control *hazards* that may occur in *feed*.

e) Relationship between terrestrial animal disease agents and aquatic species

Scientific knowledge is lacking on the relationship between certain terrestrial animal *disease agents*, notably prions, and aquatic species. There is no evidence to suggest that the use of terrestrial animal by-products as ingredients in aquatic animal *feeds* gives rise to risks in respect of prion *diseases*. More scientific information is desirable to enable *aquaculture* industries to utilise more terrestrial animal by-products and plant matter as a means of reducing dependency on aquatic protein and lipid sources.

f) Bioaccumulation

Heavy metals and polychlorinated biphenyls (PCB) persist in fatty tissues and therefore tend to accumulate through the food chain.

g) Geographic and environmental considerations

Aquatic and terrestrial harvest areas for *feed ingredients* should not be located in proximity to

³ Hazard Analysis and Critical Control Point, as defined in the Annex to the Recommended International Code of Practice on General Principles of Food Hygiene (CAC/RCP 1-1969).

sources of animal health or food safety *hazards*. Where this cannot be avoided, preventive measures should be applied to control risk. The same recommendations apply for the processing of *feed ingredients*, the manufacture of *feed* and the location of *aquaculture* operations.

Aquatic animal health considerations include factors such as *disease* status, location of quarantined premises, existence of processing plants without proper biosecurity measures and the existence of *zones/compartments* of specified health status.

Public health considerations include factors such as industrial operations and waste treatment plants that generate pollutants and other hazardous products. The potential accumulation of pollutants in the food chain through *feed ingredients* needs to be considered.

h) Zoning and compartmentalisation

Feed and *feed ingredients* are important components of biosecurity and need to be considered when defining a *compartment* or *zone* in accordance with Chapter 1.4.4. of the *Aquatic Code*.

i) Sampling and analysis

Sampling and analytical protocols should be based on scientifically recognized principles and procedures and OIE standards, where applicable.

j) Labelling

Labelling should be clear and informative on how the *feed* and *feed ingredients* should be handled, stored and used and should comply with regulatory requirements. Labelling should provide for trace-back.

See Section 4.2. of Codex Code of practice on good animal feeding (CAC/RCP 54-2004).

k) Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislation or required by *importing countries*, *Competent Authorities* contribute through the direct performance of some tasks or through the auditing of animal and public health activities conducted by other agencies or the private sector.

Operators in the *feed* and *feed ingredients* business and other relevant industries should implement procedures to ensure compliance with regulatory standards for procurement, handling, storage, processing, distribution and use of *feed* and *feed ingredients*. Operators have the primary responsibility for implementing systems for process control. Where such systems are applied, the *Competent Authority* should verify that they achieve all regulatory requirements.

l) Assurance and certification

Competent Authorities are responsible for providing assurances domestically and to trading partners that regulatory requirements have been met.

m) Hazards associated with animal feed

Biological hazards

Biological hazards that may occur in *feed* and *feed ingredients* include agents such as bacteria, viruses, prions, fungi and parasites.

Chemical hazards

Chemical hazards that may occur in *feed* and *feed ingredients* include naturally occurring chemicals (such as mycotoxins, gossypol and free radicals), industrial and environmental contaminants (such as heavy metals, dioxins and PCBs), residues of veterinary drugs and pesticides and radionuclides.

Physical hazards

Physical hazards that may occur in *feed* and *feed ingredients* include foreign objects (such as pieces of glass, metal, plastic or wood).

n) Cross contamination

It is important to avoid cross-contamination during the manufacture, storage, distribution (including transport) and use of *feed* and *feed ingredients*. Appropriate provisions should be included in the regulatory framework. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be drawn upon in developing this framework.

Procedures such as flushing, sequencing and physical clean-out should be used to avoid cross-contamination between batches of *feed* or *feed ingredients*. National regulations should be followed in order to avoid the use of unauthorised *feed ingredients* with a risk of cross-contamination.

o) Antimicrobial resistance

Concerning the use of antimicrobials in animal *feed* refer to Section X.X.X. of the *Aquatic Code*.

p) Management of information

The *Competent Authority* should establish requirements for the provision of information by the private sector on regulatory requirements.

Records should be maintained in a readily accessible form on the production, distribution and use of *feed* and *feed ingredients*. These records are required to facilitate the prompt trace-back of *feed* and *feed ingredients* to the immediate previous source, and trace-forward to the next/subsequent recipients, to address animal health or public health concerns.

Animal identification (in the case of *aquatic animals* this will normally be on a group basis) and traceability are tools for addressing animal health and food safety risks arising from animal *feed* (see Section 3.5. of the *Terrestrial Code*; Section 4.3 of CAC/RCP 54-2004).

5. HAZARDS

Biological

This document addresses the following biological hazards:

- a) bacteria, virus, parasites, fungi affecting *aquatic animals*. These hazards include the *OIE-listed diseases* (Chapter 1.2.3. of the *Aquatic Code*) and other important *diseases* (including IPN and IMNV);
- b) prions.

Chemical

[under study]

Physical

[under study]

6. PATHOGENS IN FEED

- a) Pathogens in *feed* can be introduced at two points:
 - i) at source: via the harvest of infected *aquatic animals*;
 - ii) during storage, processing and transport.

Contamination may occur at the manufacturing facility via poor hygienic practices and/or the presence of pests.

Feed and *feed ingredients* may be exposed to contamination during storage, manufacturing or transport, due to residues of previous batches of *feed* remaining in processing lines, containers or transport vehicles.

- b) Exposure pathways include:
 - i) Direct exposure

The use of raw unprocessed *feed* or *feed ingredients* derived from *aquatic animals* to feed aquatic species presents a risk of exposure to *hazards* of infectious nature. There are risks associated with feeding whole *aquatic animals* and unprocessed products of *aquatic animals* to species that are susceptible to the same *diseases* as the 'fed animal' e.g. feeding salmonid *offal* to salmonids or feeding rotifers or *Artemia* species to crustaceans.

- ii) Indirect exposure

Feed and *feed ingredients* containing pathogenic agents may be transmitted to *aquatic animals* in *aquaculture* and wild fish via contamination of the environment, including infection/contamination on non-target species.

7. RECOMMENDED APPROACHES TO RISK MITIGATION

The following measures are relevant to *exporting countries*:

- a) Source of raw materials

Raw materials/ingredients should not be sourced from areas/*populations* known to be infected with significant pathogens. It may be appropriate to adopt routine testing procedures to verify that pathogens are not present at unacceptable levels; or

When using *feed* and *feed ingredients* originating from areas known to be affected by a significant pathogen:

- i) *feed* and *feed ingredients* should be delivered directly to feed manufacturing plants for processing under conditions approved by the *Competent Authority*; and
- ii) effluent and other wastes from the feed manufacturing plants should be treated under conditions approved by the *Competent Authority* before discharge into the aquatic environment; or
- iii) *feed* and *feed ingredients* known or suspected to be infected with significant pathogens should only be used and/or processed in a *zone* or *compartment* that does not contain species susceptible to the pathogen in question.

b) Feed production

To prevent contamination by pathogens during production, storage and transport of *feed* and *feed ingredients*:

- i) flushing, sequencing or physical clean-out of manufacturing lines and storage facilities should be performed between as appropriate;
- ii) buildings and equipment for processing and transporting *feed* and *feed ingredients* should be constructed in a manner that facilitates operation, maintenance and cleaning and prevents *feed* contamination;
- iii) in particular, *feed* manufacturing plants should be designed to avoid cross-contamination between batches;
- iv) processed *feed* and *feed ingredients* should be stored separately from unprocessed *feed ingredients*, under appropriate packaging conditions;
- v) *feed* and *feed ingredients*, manufacturing equipment, storage facilities and their immediate surroundings should be kept clean and pest control programmes should be implemented;
- vi) measures to inactivate pathogens, such as heat treatment or the addition of authorised chemicals, should be used where appropriate. Where such measures are used, the efficacy of treatments should be monitored at appropriate stages in the manufacturing process;
- vii) labelling should provide for the identification of *feed* and *feed ingredients* as to the batch/lot and place/date of production. To assist in tracing *feed* and *feed ingredients* as may be required to deal with animal disease incidents, labelling should provide for identification by batch/lot and date/place of production.

c) The following measures are relevant to *importing countries*:

- i) imported *feed* and *feed ingredients* should be delivered directly to feed manufacturing plants or *aquaculture* facilities for processing/use under conditions approved by the *Competent Authority*;
- ii) effluent and waste material from feed manufacturing plants and *aquaculture* facilities

should be managed under conditions approved by the *Competent Authority*, including, where appropriate, treatment before discharge into the aquatic environment;

- iii) *feed* that is known to contain significant pathogens should only be used in a *zone* or *compartment* that does not contain species susceptible to the *disease* in question;
- iv) the importation of raw unprocessed *feed* or *feed ingredients* derived from *aquatic animals* to feed aquatic species should be avoided where possible.

8. CERTIFICATION PROCEDURES FOR AQUATIC FEEDS

- a) The following products represent a negligible risk because of the extensive processing used to produce them:
 - i) fish oil;
 - ii) crustacean oil;
 - iii) *fish solubles*;
 - iv) fish meal;
 - v) crustacean meal;
 - vi) squid meal and squid liver-meal;
 - vii) bivalve meal;
 - viii) finished *feed* (e.g. flake, pelleted and extruded *feeds*).

For these products, *Competent Authorities* should not require conditions in relation to aquatic animal *diseases*, regardless of the aquatic health status of the *exporting country, zone* or *compartment*⁴.

- b) Other products

The following risk mitigation measures should be considered:

- i) sourcing *feed* and *feed ingredients* from a *disease* free area; or
- ii) confirmation (e.g. by testing) that pathogens are not present in the product; or
- iii) treatment (e.g. by heat or acidification) of product to inactivate pathogens.

- c) Importing country measures

When importing *feed* and *feed ingredients* of aquatic origin, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* (or a *certifying official* approved by the *importing country*).

⁴ In relation to the risk associated with contamination after harvest/processing, point 4 (below) applies.

This certificate should certify:

- i) that *feed* and *feed ingredients* of aquatic origin were imported from a country, *zone* or *compartment* that is free from relevant aquatic animal *diseases*⁵; or
- ii) that *feed* and *feed ingredients* of aquatic origin were tested for relevant aquatic animal *diseases*⁶ and shown to be free of these *diseases*; or
- iii) that *feed* and *feed ingredients* of aquatic origin have been processed to ensure that they are free of relevant aquatic animal *diseases*.

9. **RISK CHART OF PATHOGEN TRANSMISSION AND CONTAMINATION THROUGH HARVEST OF FEED INGREDIENTS AND MANUFACTURE OF AQUATIC FEEDS**

Some ingredients used in *aquaculture*, in particular of aquatic origin (e.g., krill, shrimp, fish, crab, *Artemia*) can be a source of pathogen contamination to cultured aquatic species. These ingredients can carry live pathogens (virus, bacteria, and parasites) and reach the aquaculture operation through different types of *feeds* (live, moist, semi-moist or dry feeds).

In aquaculture farms, there are two routes of pathogen contamination through aquatic animal feeding: transmission of pathogens and contamination. **Transmission of pathogens** can take place when the *feed* itself is already infected with a pathogen. This type of contamination is more common with *live feeds* and *moist feeds*. Ingredients that constitute their composition are either kept in a raw state in the final product (e.g., feeding tuna with wild caught fish) or at times require little treatment(s) prior to feeding aquatic organisms.

Harvest of aquatic ingredient sources from infected areas has a high *risk* of pathogen contamination, especially if these are transported to an *aquaculture* operation without any prior treatment. Processing of these ingredients places a moderate risk of contamination, and it should actually be taken as a possibility to reduce the risk of pathogen transmission (e.g., through heat, chemical treatments). Storage and transportation of these ingredients has a low risk of contamination, but should also be considered as a direct route of pathogen contamination. For example, when two or more batches of ingredients of different sanitary status are handled, stored and/or transported together without any biosecurity measure there is a risk of direct contamination to the farmed animal.

Contamination occurs when the pathogen is introduced in a feed manufacturing facility, both through infected ingredients or finished feeds and later to the aquaculture facility. Contamination occurs with the use of *semi-moist feeds* and *dry feeds*. With these feed types, contamination can take place in the manufacturing plant during:

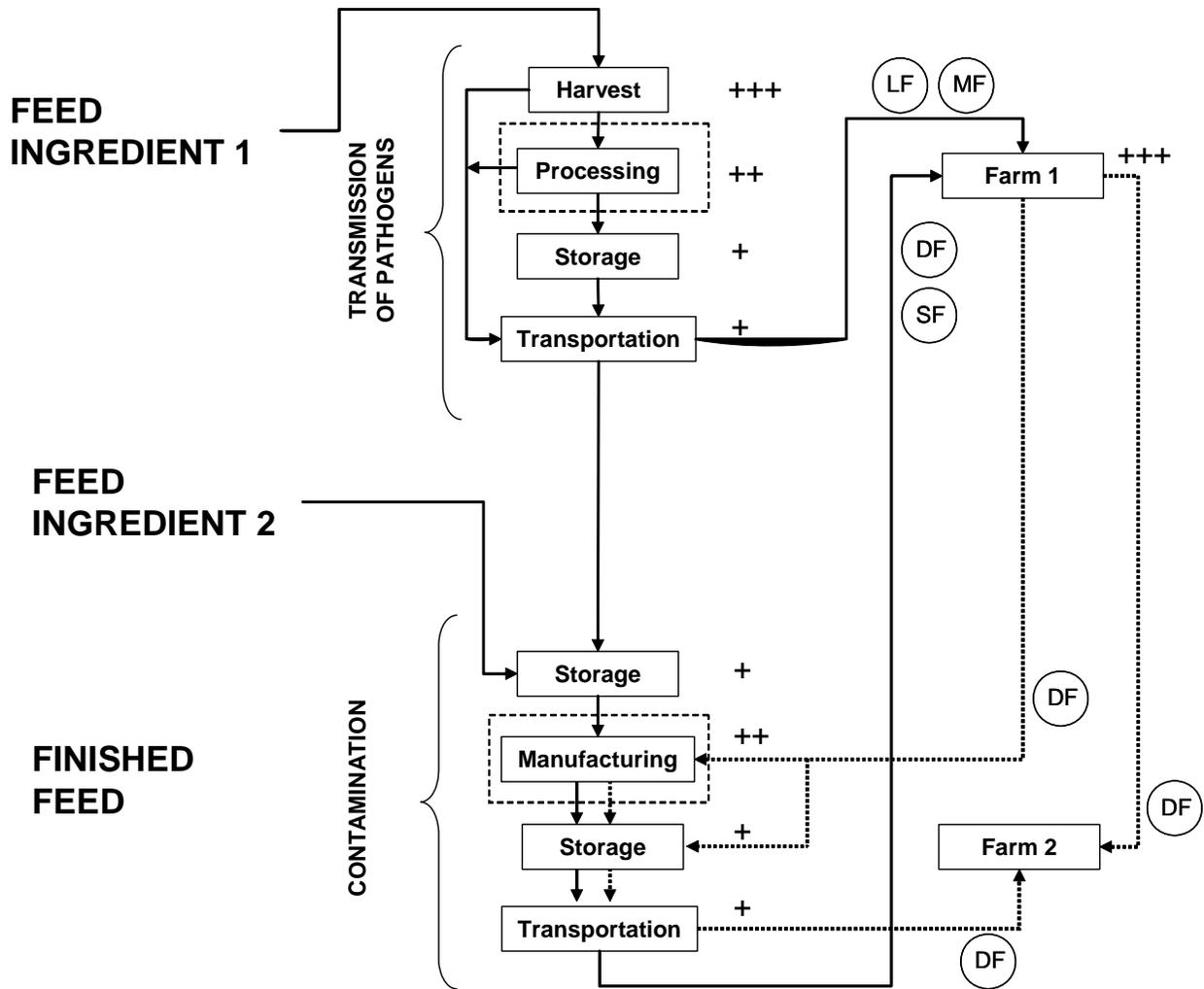
- a) Storage of ingredients: it has a low risk of contamination, but it can take place when ingredients of different sanitary status are handled or placed together.
- b) Feed manufacturing: during feed processing, ingredients are commonly subjected to heat treatment which can eliminate certain pathogens. However, use of manufacturing lines with remains of contaminated ingredients from a previous batch of feed can result in cross contamination of feeds.
- c) Storage and transportation of finished feeds: it has a low risk of contamination, but when

⁵ Conditions agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations of the OIE *Aquatic Animal Health Code*.

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finished feeds are stored or transported together with unprocessed ingredients or with feeds of different sanitary status it can result in pathogen contamination.

An aquaculture facility can also be a source of pathogen contamination in aquatic feeds. At this level, contamination can take place when a finished feed is delivered to a farm located in an infected area. Transmission of pathogens can occur when feed is withdrawn from the aquaculture and is returned to the manufacturing facility for reprocessing or transferred to another farm.



LF: Live feed MF: Moist feed SF: Semi-moist feed DF: Dry feed	Possibility for risk reduction
+++: High risk of pathogen contamination ++: Moderate risk of p. c. +: Low risk of p. c.	Redistribution or recycling of finished feed