### **Philippines**

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#### 1. Introduction

Successful national food control systems are necessary to protect the health and safety of domestic consumers. They are also essential for ensuring the quality and safety of aquacultured products entering the international trade and making sure that the product conforms to the international requirements.

Trading partners are taking much interest in the way food is produced, processed and marketed and these partners are relying heavily on the governments to take greater responsibility in food quality and safety assurance. They require supplementary efforts and proactive behavior from the authorities and private sector in an increasingly competitive environment in establishing food safety control structures or its equivalent.

The Philippines has to keep up with the dynamic trade requirements, notably with the technical requirements and SPS measures to gain a better access to foreign markets. Trade partners have become more demanding and the corresponding technical requirements tend to become more complex and stringent.

Participation in the Philippines on this Japanese Trust Fund (JTF) II Project, specifically on Regional survey of pesticide residues in fish and fish products and Regional survey of chloramphenicol and nitrofuran in fish and fish products and in Japanese Trust Fund II Project "Food Safety Program: Research and Analysis of Chemical Residues and Contamination: Chemical and Drug Residues in Marine and migratory species and straddling stocks is one of the positive responses of the country to the aforementioned stringent requirements on fish trade.

#### Food Safety Management

At the Central Office, the food safety management for Fish Inspection and Quality Assurance Services is directly under the Office of the Director and is composed of five units: the Fish Product Testing Laboratory (FPTL), the Marine Biotoxin Laboratory (MBL), the Administrative Support and Product Certification Unit (ASPCU), the HACCP-based Fish Inspection Unit (HFIU) and the Fish Health Management and Quality Assurance Section (FHMQAS).

The FPTL and MBL are in charge of providing services to other units in their respective fields. The HFIU is responsible for the inspection of accredited fish processing plants based on 94/356/EEC, 91/493/ EEC and to ensure consistent compliance with EU requirements as per 91/493/EEC, the new European Food Law, and other relevant national rules and regulations on the export of fishery and aquaculture products. The APSCU is responsible for the issuance of product health certificates for fishery and aquaculture products for export to the EU and other markets. To ensure the safety and quality of fishery and aquaculture products for export, the FIQAS implements a HACCPbased inspection program. It coordinates with the FHMQAS, FPTL and the BFAR Regional Offices on the effective implementation of the Quality Assurance Program. The FIQAS supervises the overall inspection of fish processing plants and certification of fishery and aquaculture products for export in coordination with the BFAR Regional Offices. The FHMQAS spearheads the registration of aquaculture farms, residues and health monitoring, as well as provision of diagnostic services, technical and advisory assistance to the aquaculture industry. Its monitoring program includes residues and disease surveillance and the reporting system, aquatic animal health certification, implementation of quarantine procedures, assessment of the health status of stocks of selected fish and the management of other aquatic resource farms in the Philippines.

At the Regional Offices, food safety management is under the responsibility of BFAR regional directors located in 15 regional offices. Each has a Fish Health Unit, linked to the central FHMQAS, and a Fishery Inspection unit, linked to the HFIU and central laboratories.

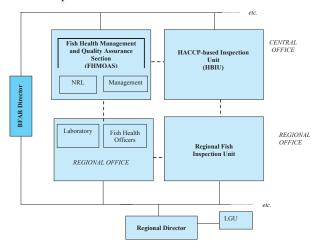
## <u>Central Fish Health Management and Quality Assurance Laboratory</u>

The residues monitoring is implemented by the FHMQAS in coordination with the 15 BFAR Regional Offices. The regional directors have full responsibility over their area of jurisdiction. However, matters of policy-determining nature still lie under the jurisdiction of the Bureau Director. The organizational structure and coordination between regional and central offices are presented in Figure 1.

Role of National and Regional Fish Health Officers are as follows:

- Register aquaculture farms.
- Monitor the hygiene of production.
- Disseminate information and educate the aquaculture chain operators on the need of aquatic animal feeds, veterinary drugs and products registration prior to marketing and usage.
- Conduct surveillance and monitoring of aquatic animal feeds, veterinary drugs and products in their areas of responsibility.
- Recommend regulatory actions for any violations on policies and guidelines on registration, manufacturing, distribution and usage of aquatic animal feeds.
- Assist in planning, directing and supervising national programs on aquatic feeds, veterinary drugs and products control.
- Assist in the registration, evaluation and inspection of establishments engaged in manufacturing, distribution and sale of aquatic animal feeds, drugs, products premixes and water solubles, whenever necessary

Figure 1. Organizational structure for residues monitoring and coordination between regional and central departments.



## Coordination of the Activities of Central and Regional Departments

The FHMQAS develops and updates standardized routine procedures and guidelines for the operation of the regional fish health laboratories. It also supervises the activities and sets directions for the operation of such laboratories. The FHMQAS also provides technical guidance and instructions to the 44 BFAR-designated Regional Fish Health Officers on the execution of diagnostic activities and provide technical assistance on fish health-related and residues monitoring problems. It also provides specialized training on sanitary and phyto-sanitary programs of the government to fishery biologists, extension workers and fish farmers. The section sets national programs for the surveillance and monitoring of aquatic animal feeds, veterinary drugs, products and their control as well as formulates standardized monitoring procedures on field inspections and reporting, to ensure high feed quality and compliance to the regulations of the government. The FHMQAS also supervises the implementation and monitoring activities of the Fish Health Officers deputized as Aquatic Animal Feeds, Veterinary Drugs and Products Control Officers (AAFVDAPCO) nationwide. To harmonize activities, the FHMQAS coordinates with the other sector on the results of monitoring aquaculture farms supplying raw materials to the fish processing plants. Regional Fish Health Officers regularly coordinate with the officers of the Central FHMQAS in the implementation of the official program, including residues monitoring. Reports are also submitted to the Central FHMQAS for consolidation and analysis.

#### 2. Objectives And Goals

#### Objectives:

- To increase export of aquacultured products like shrimp and milkfish, and marine products like lobster, crab and grouper.
- To develop monitoring and surveillance mechanism for chemical contaminants, for example antibiotic residues, for food safety and quality assurance of aquacultured and marine fish products.
- To develop sampling method and establish baseline information on the level pesticides in fish and fish products.

#### Goals:

- To ensure food safety and quality of fish and fish product for export.
- To obtain baseline information of the usage and extent of antibiotic contamination for Chloramphenicol and Nitrofurans.
- To develop capability on the analysis of harmful substances, for example in the use of LC/MS/MS, through attending trainings held by SEAFDEC-MFRD, in collaboration with a country in the region with the capability.
- To be able to establish a good network and increase communication with the laboratories in the region.
- To adopt methods used by recognized laboratories, for example, SEAFDEC-MFRD.

#### 3. Survey Methodologies

## a. Sampling Method, Location, Species, Number of Samples and Sampling Size

### Sampling

The sampling for official samples took place at random timings, unknown to the farms, markets and processing plants. Sampling was carried out at variable intervals over the year at farms, markets and receiving areas of processing plants. The processing plants, farms and markets sampling were defined using as much targeting criteria as possible, making sampling homogeneous.

All accredited establishments and registered farms that export products to the EU and other countries were under the scope of the monitoring plan. The number of sampling was defined using the regional production statistics as a minimal level, as well as taking into account the risks and results of past monitoring plans.

All available information of targeted samples were taken into consideration, for example, the use of presently unknown substances, sudden appearance of diseases in particular regions and indications of fraudulent activities.

<u>Collection of samples from farms, auction areas/markets and processing</u> establishments

Samples were taken from farms, processing plants or purchased from the markets in a random manner. Identification and traceability of the samples back to the source was ensured. Important information like the source was taken. Information of the source was only available up to the provincial level for samples taken from the markets. Measures to prevent contamination of samples were taken during transportation of the samples to the laboratory. Suitable sampling tools, plastic bags and transportation boxes were provided for the collection of samples.

Each sample was equivalent to 1 kg of raw material. Every sample was packed separately into a disposable plastic sample container to prevent contamination and labelled accordingly with a unique number on the container. Each sample container was closed, sealed properly and chilled with ice during transportation to the laboratory. The samples could be kept in a refrigerator for several days. Plastic containers were placed in plastic bags to avoid contact with other samples. Every sample was separately packed in a plastic bag and frozen.

A report was produced after each sampling with at least the following information in it:

- Address of the authority that took the sample.
- Name and surname for identification.
- Sampling date, name and address of the exporter or the person in charge of the animals or the animal products.
- Remarks.

#### Sending of samples

Preliminary sample preparation was conducted in the regional laboratories. Duplicates of homogenised samples were prepared and frozen for immediate submission. One sample may be subjected for analysis of several analytes. Samples sent to FHMQAL were packed separately in clean sample containers to prevent contamination, coded for easy identification, and accompanied with sampling information for traceability purposes. Samples were chilled with ice bags and stored in

clean durable containers to prevent any damage and contamination during transportation.

#### Sample reception at the laboratory

At the receiving area, personnel assigned to receive samples checked the following information:

- Temperature of the sample and its visual aspects.
- Packaging and container.
- Labeling, code and accompanied sampling report.
- Quantity and weight of the sample as required by the analysis.

#### b. Method of Analysis

The Central FHMQAL is responsible for the analysis of residues in foodstuffs of aquatic animal origin. It is located at the BFAR Central Office in Quezon City. The FHMQAL is under the supervision of the chief of the FHMQAS and has five personnel, one in-charge of field operations (veterinarian), one in-charge of the laboratory (veterinarian), a permanent analyst (chemist), two temporary analysts (chemist), and one administrative support for receiving samples and releasing results. Chemists are involved in the analysis of residues.

FHMQAS issued formal instructions to the Fish Health Officers on how to carry out sampling and to ensure the traceability of the samples. It had also implemented quality checks (temperature and visual inspection) on samples received in order to confirm their suitability for analysis for this study. The FMHQAL either performed the analysis in its own facilities or in collaboration with a third-party laboratory i.e. SGS, Phils.

Chloramphenicol and nitrofurans (AOZ and AMOZ) residues in aquaculture and fishery products were analyzed by Enzyme-linked

Immunosorbent Assay (ELISA) using the RidaScreen Kit from Germany. The laboratory followed the required % recovery rate required in the kits.

#### c. Limit of Detection and Limit of Quantification

#### Chloramphenicol

Limit of detection (LOD): 0.05 ppb Limit of quantification (LOQ): 0.15 ppb

Nitrofurans (AOZ and AMOZ) Limit of detection (LOD): 0.10 ppb Limit of quantification (LOQ): 0.30 ppb

#### d. National Regulatory Limits

No national standard has been set yet on the maximum residue limits (MRL) for drugs and other substances in aquaculture. The standards used are the lowest ones set by the *Codex Alimentarius*, the United States Food Development Authority (US-FDA) and the European Union (EU). Foodbusiness operators placing products on export markets must comply with these values and they are monitored by the Competent Authority (CA).

Several drugs, including A6 nitrofurans, olaquindox, carbadox and A6 chlorampenicol, are banned through joint administrative orders from the DOH:

- a) Department of Health (DOH) and Department of Agriculture (DA) Joint Administrative Order No. 2, Series of 2000- Declaring ban/ phase out of the use of nitrofurans in foodproducing animals.
- b) DOH Administrative Order No. 91 and DA Administrative Order No. 60, Series of 1990-Declaring ban on the use of chlorampenicol in food-producing animals.

### 4. Results And Discussion

### a. Participation in Inter-laboratory Proficiency Testing and Results

Table 1. Results of inter-laboratory comparison on Chloramphenicol and Nitrofuran (AOZ).

Inclusive Dates	13 to 26 July 2004				
No. of Participating Laboratories	4				
Type of Analysis	No. of samples	No. of replicates per sample	Average Precision (RSD, %)		
Nitrofuran (AOZ)	4	12	61.5		
Chloramphenicol	4	12	43.5		

Inclusive Dates	31 May to 02 June 2005			
No. of Participating Laboratories	4			
Type of Analysis	No. of samples	No. of replicates per sample	Average Precision (RSD, %)	
Nitrofuran (AOZ)	trofuran (AOZ) 4		112.6	
Chloramphenicol	4	12	27.4	

Inclusive Dates	20 to 28 Nov 2007					
No. of Participating Laboratories	3					
	Blank	Samples	Spiked Samples			
Type of Analysis	No. of aliquots	No. of replicates per aliquot	No. of aliquots	No. of replicates per aliquot	Average Precision (RSD, %)	
Chloramphenicol	3	9	3	7	25.2	

#### b. Survey Results and Discussion

Table 2. Summary of results of survey on Chloramphenicol and Nitrofurans (AOZ and AMOZ) in aquaculture and marine fish products from 2005-2007.

Year	Sampling location	Sample	No. of samples	Analyte	Results (ppb)	Recovery Rate (%)	Remarks
2005	Processing Plants	Fresh frozen Shrimp Penaeus monodon	39	CAP AOZ	ND ND	80-120	As required by the kit
2006 Plants	Processing Plants	Shrimp Penaeus monodon	72 55	CAP AOZ	ND ND	80-120	As required by the kits
	Farms	Shrimp Penaeus monodon	68 64 63	CAP AOZ AMOZ	ND ND ND	80-120	As required by the kits
2007	Public markets	Crabs Scylla serrata	40	AOZ AMOZ	ND ND	112.82 102.5	-
	Public markets	Lobsters Panulirus sp.	32 3	AOZ AMOZ	ND ND	111.62 104	-
	Public markets	Groupers <i>Epinephelus</i> spp.	20	AOZ	ND	115.78	-

Laboratory: Central Fish Health Management and Quality Assurance Laboratory

Method of Analysis: Enzyme-linked Immunosorbent Assay (ELISA) RidaScreen Kit

Residues Analysed: Chloramphenicol (CAP), Nitrofuran (AOZ and AMOZ)

Dilution Factor: CAP: 1; AOZ: 2

LOD: CAP: 0.05 ppb; AOZ and AMOZ: 0.10 ppb LOQ: CAP: 0.15 ppb; AOZ and AMOZ: 0.30 ppb

In 2005, a total of 39 fresh frozen Shrimp (*Penaeus monodon*) samples were collected from the processing plants from August to December. The samples were analyzed for the residues of Chloramphenicol (CAP) and metabolites of Nitrofuran (AOZ) at the Central Fish Health Management and Quality Assurance Laboratory using Enzyme-linked Immunosorbent Assay (ELISA) Rida Screen Kit. The level of detection for chloramphenicol is 0.05 ppb and the level of quantification is 0.15 ppb. For the metabolites of nitrofurans (AOZ), the level of detection is 0.10 ppb and the level of quantification is 0.30 ppb. The samples were tested negative for both CAP and AOZ.

In 2006, a total of 140 fresh frozen Shrimp samples were taken, 72 from the processing plant and 68 from aquaculture farms. All 72 samples from processing

plants were analyzed for CAP and 55 of which were also subjected to AOZ analysis. No CAP and AOZ residues were detected in all samples. For the samples taken from the farms, 68 were analyzed for CAP, 64 and 63 of which were also analyzed for AOZ and AMOZ respectively. No CAP and AOZ residues were detected in all samples.

In 2007, marine fish were taken from public markets from March to November for the analysis of metabolites of nitrofuran (AOZ and AMOZ). A total of 40 fresh Mudcrab, 32 Lobster and 20 Grouper samples were collected. For Mudcrab samples, 40 were analyzed for AOZ and 3 of which were also analyzed for AMOZ, for Lobster samples 32 were analyzed for AOZ and 3 for AMOZ. For Grouper samples, 20 samples were analyzed for AOZ. Results showed that no AOZ and AMOZ were detected in all samples. The summary of analysis is presented in Table 2.

Antibiotics have a wide range of use to prevent bacterial growth and there is a use of banned drugs in fish and fish products. Wild caught crabs and lobsters are sometimes treated with the drugs to prevent diseases and prolong the shelf life of the products, however, the number of samples tested positive for chloramphenicol and nitrofuran are very few.

#### c. Corrective Actions

Presence of residues of banned antibiotics in harvested animals are subjected to the following corrective actions:

The farm owner is immediately informed of the presence of residues of banned antibiotics in shrimp/fish samples obtained from his farm, so that he can take appropriate measures to withdraw his products from export. For the next 12 months, the farm is subjected to more stringent checks for the residues in question. The results are also immediately provided to the concerned auction market owners and exporters who have to recall the products if the products are no longer under their control. No health certificates are issued in cases where banned antibiotics are tested positive.

The presence of residues of banned chemicals in shrimp/fish meat is also reported immediately to the Local Government Units concerned, with the recommendation of the proper action and application of National Laws and Local Ordinances pertaining to pollution and consumer protection. An investigation is carried out to determine the reasons for the presence of residues and the extent of the problem.

In cases of positive findings, the registration of the farm concerned will be suspended and the information will be given to the auction markets and processing plants the farm supplies to. The suspension will be lifted after three successive negative findings.

#### 5. Problems and Challenges Encountered

- Delayed release of funds, which caused problems in the implementation of the project as scheduled.
- There is a need to strengthen capability in analyzing residues with LC/MS/MS as methods used are for screening only.
- There is a need to have certified reference materials for method validation.

# 6. Recommendations and Suggestions for Future Follow up Action

- SEAFDEC-MFRD must continue its significant role in coordination work and networking among the participating countries.
- To continue activities on the harmonization of protocol procedures on the confirmatory analysis using sensitive equipment like the LC/MS/MS.
- Preparations of risk communications materials for information and education campaign.
- To cover more antibiotics and develop other methods of analysis like antimicrobial sensitivity assay.
- To provide financial assistance for the purchase of equipment and technical support in the implementation food safety program.