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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate F - Food and Veterinary Office

DG(SANCO)/8312/2006 – MR Final

FINAL REPORT OF A FOLLOW-UP MISSION CARRIED OUT IN
THE PHILIPPINES
FROM 16 TO 27 OCTOBER 2006
ASSESSING THE PUBLIC HEALTH CONTROLS
AND CONDITIONS OF PRODUCTION OF
FISHERY PRODUCTS INTENDED FOR EXPORT TO THE EUROPEAN UNION

Please note that factual errors in the draft report have been corrected.

*Clarifications provided by the Competent Authorities of the Philippines are given as footnotes,
in bold, italic, type, to the relevant part of the report.*



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1. INTRODUCTION¹

The mission took place in the Philippines from 16 to 27 October 2006 and was undertaken as part of the Food and Veterinary Office's (FVO) planned mission programme.

The mission team comprised three inspectors from the Food and Veterinary Office and two national experts from Member States.

1.1. Background to the mission²

1.1.1. Historical background

The Philippines are presently listed in part I of the Annex to Commission Decision 97/296/EC. Commission Decision 95/190/EC lays down special conditions governing the import of fishery products (FP) and aquaculture products (AP) originating in the country and intended for export to the European Union (EU).

This mission was the follow up of a previous FVO mission to the Philippines carried out from 11 to 22 October 2004 (ref. DG(SANCO)/7355/2004). During this earlier mission, serious shortcomings were identified regarding the reliability of the official control system, the knowledge of the Community legislation, the lack of good hygiene practices and traceability, and the control of the main hazards in FP and AP³. This report has been published on the Internet at: http://europa.eu.int/comm/food/fvo/ir_search_en.cfm.

1.1.2. Production and trade information

Imports of FP from the Philippines are authorised from a total of twenty-five establishments (seven of which export canned tuna), as well as from twenty-two freezer vessels (FV)⁴. The Competent Authority (CA), the Bureau of Fisheries and Aquatic Resources (BFAR) requested to Commission services (on 25.9.2006) the delisting of two establishments. The mission team was informed on-the-spot that a third establishment requested itself removal from the list.

The total exports to EU Member States of FP and AP from the Philippines in 2004 and 2005 were, respectively, 36,624 and 44,567 tonnes (EUROSTAT data)⁵. According to information provided by BFAR, 36,338 tonnes of FP were exported to the EU, in 2004 (the data supplied by BFAR for 2005 did not include the exports of tuna and cannot therefore be compared with the data from EUROSTAT). Exports are mainly composed of canned tuna (*Katsuwonus pelamis*), canned sardines (*Sardinella* sp.), and smaller quantities of other species: fresh tuna loins (*Thunnus albacares*), milkfish (*Chanos chanos*), black tiger prawns (*Penaeus monodon*), octopus (*Octopus vulgaris*), tiny preserved shrimps (*Acetes* sp.).

¹ List of abbreviations and special terms is drawn up in Part 1 of the Annex to this report.

² References to Community Acts quoted in the report and legal basis for the mission are mentioned in Part 2 and Part 3 of the Annex to this report. All legal references refer, where applicable, to the latest amended version.

³ Prior to the 2004 FVO mission, another mission had been carried out in the Philippines, in 2001 (ref. DG(SANCO)/3320/2001), to assess the conditions of production of processed bivalve molluscs. The situation found in the country at that time was considered as not satisfactory and, as a consequence, imports were not authorised. In this regard, after the 2001 mission, the Commission services received no follow-up information or a request from BFAR to reassess the situation.

⁴ This list is in force from 10.08.2006 and is published on the Internet at: http://forum.europa.eu.int/irc/sanco/vets/info/data/listes/list_all.html#P.

⁵ Details of import data is given in Part 4 of the Annex to this report.

1.1.3. The Rapid Alert System for Food and Feed notifications

From 2004 to 2006, seven notifications⁶ were received from the Rapid Alert System for Food and Feed (RASFF) associated to products imported from the Philippines:

- 2006 (one notification): related to histamine in canned tuna in brine.
- 2005 (four notifications): all related to carbon monoxide (CO) treatment of tuna (*Tunnus albacares*).
- 2004 (two notifications): one related to chloramphenicol and aminoglycosides in frozen shrimps (*Solenicera* spp.); the other related to histamine in sardine.

Details were provided to the mission team regarding the follow-up measures put in place by BFAR to deal with these RASFF notices, which included the notification (and in some cases the delisting) of the establishment involved, on-the-spot investigations made by BFAR inspectors, (re)testing of the product, issuing of a *moratorium* on the use of CO, and recalling of shipments - these were destroyed or, when considered appropriate by BFAR, diverted to other (non-EU) markets.

1.2. Mission objectives and proceeding

The objectives of the mission were to:

- re-assess whether the CA is capable of guaranteeing that the special conditions governing imports of FP originating in the Philippines, as laid down in Decision 95/190/EC and in the hygiene legislation⁷.
- verify the extent to which the guarantees and the corrective actions submitted to the Commission services have been implemented, enforced and controlled by the CA following the recommendations of the previous FVO mission report.

In order to achieve these objectives, the mission team evaluated the organisation of the CA and its capacity for implementing provisions considered as at least equivalent to the relevant Community legislation).

In pursuit of these objectives, the mission team proceeded as follows:

- an opening meeting was held on 16 October with the CA. At this meeting the inspection team confirmed the objectives of and itinerary for the mission, and requested additional information required for the satisfactory completion of the mission.
- representatives from BFAR accompanied the inspection team during the whole mission.
- the following sites were visited:

COMPETENT AUTHORITY		
Central office	1	Manila
Regional offices	4	Regions 3, 4A, 7, 9 (the office of Region 12 not visited)

⁶ In 2003, a total of thirteen notifications were received through the RASSF.

⁷ Council Directives 91/493/EEC and 92/48/EEC were repealed by Directive 2004/41/EC of the European Parliament and of the Council, and are not applicable from 1 January 2006, which relate to (Regulations (EC) No 852/2004, Regulation (EC) No 853/2004, Regulation (EC) No 854/2004 and Regulation (EC) No 882/2004.

LABORATORIES INVOLVED IN THE OFFICIAL CONTROL		
– AP (Residues)		
Central	1	Manila (NRL/BFAR/FHL)
Regional	2	Region 4A, Region 7
Private	1	Manila (Laboratory A)
– FP and Water		
Central	1	Manila (BFAR/FPTL)
Regional	2	Regions 4A, 9,
Private	2	Manila (FDC/NFA), Region 12 (Laboratory B)
FOOD PROCESSING FACILITIES		
Fishing vessels	4	Region 4A, 12 (tuna)
Transport vessels	4	Regions 9 (two) , 12 (two) (tuna, sardines)
Establishments	23	Regions 3, 4A, 7, 9, 12 (tuna, sardines, prawns, milkfish, octopus)
OTHER FACILITIES		
Cold stores	3	Region 12
Landing site (private)	1	Region 9
Landing site, fish market	1	Region 12
Ice plants	2	Regions 9, 12

2. MAIN FINDINGS

REMARKS

- Recommendations from the DG(SANCO)/7355/2004 mission are in underlined letter type.
- Assurances given by the CA, in response to these Recommendations, are in *italic* letter type and between quotation marks.

2.1. Competent authority performance

2.1.1. Structure and organisation

The structure and means available to the CA responsible for the control of FP should be reinforced and adequate in order to assure efficient performance of their duties.

2.1.1.1. Assurances given by the CA

"(1) BFAR has restructured the Fish Inspection and Quality Control Section (FIQCS) into two units, i.e. HACCP-based Fish Inspection Unit (HFIU) and Administrative Support and Product Certification Unit (ASPCU), to focus more on the inspection and monitoring of establishments; (2) delineation of fish inspection functions to the HFIU and those of export product certification to the ASPCU; (3) provision of additional inspection kits, tools/office equipment, transport vehicle for fish inspections at national and at regional levels; (4) provision of separate offices for the above-mentioned units; (5) strengthening the evaluation of food control programmes (HACCP plans, GMP, SSOP) of the establishments; (6) increase in the number of trained fish inspectors, from 36 to 48, both at national and regional levels; further, cross-regional inspections are conducted to enhance the regional inspectors' capability and to mitigate the multitasking; (7) strengthening the implementation of the residue monitoring and disease surveillance programme at national and regional levels by the FHS."

2.1.1.2. Findings regarding the assurances given by the CA

(1) The mission team confirmed on-the-spot the implementation, in relation to the reorganization of the inspection services, of the following Fisheries Office Orders (FOO) issued (signed by the Director of BFAR):

- Special FOO N° 35 of 11 February 2005 transferred the Fish Inspection and Quality Control Section from the Post Harvest Technology Division to the Office of BFAR's Director (i.e. under its direct supervision);
- FOO N° 155 of 18 July 2005 created the Fish Inspection and Quality Assurance Service (FIQAS), composed of the:
 - ASPCU, which is responsible, in particular, for the management of documents, certification of FP and AP intended for export, issuance of FP quality and sanitary/health certificates, maintenance of FP export data records, organisation and documentation of training programmes for fish inspectors, fish health officers and industry personnel, coordination with regional offices on the management of FP safety, quality assurance and certification in their areas of jurisdiction;
 - HFIU, which is responsible, in particular, for desktop audit of Hazard Analyses Critical Control Points (HACCP) programmes, audit of fish inspectors and of establishments, hands-on training of fish inspectors, official verification and sampling of FP and AP for export, recommending approval/delisting of establishments based on results of inspections/monitoring, and coordinating with the regional offices on matters related to fish inspections in their areas of jurisdiction;
 - Laboratory Quality Assurance Committee (LQAC), which is responsible, in particular, for the formulation of systematic operational procedures in laboratories, upgrading and maintenance of laboratory equipment, monitoring and evaluating the operation of regional laboratories, establishing effective sampling procedures for the monitoring of residues, chemical and microbiological contaminants, and marine biotoxins (Paralytic Shellfish Poisoning and ciguatera) and the drafting of the respective manuals, formulation of protocols and implementation of the sharing of laboratory equipment.
- FOO N° 247 of 23 August 2006 details the powers and functions of regulatory officers (fish inspectors, fish health officers, fisheries quarantine officers and certifying officers) for the supply and quality assurance of FP and AP intended for human consumption, including the provision of transport vehicles for regulatory functions.

(2) The mission team observed reports of inspections carried out, since the creation of the HFIU in 2005, to vessels and establishments that are on the list of "accredited" (*i.e.* registered/approved) vessels and establishments authorised to export to the EU and, as well, of export certificates issued by the ASPCU (at central level) and by the regional offices in Region 12 (General Santos) and Region 9 (Zamboanga City).

(3) The mission noted new inspection kits (*e.g.* free residual chlorine), computers, transport vehicles assigned to inspection of farms and establishments (both at national and regional levels).

(4) The mission team visited the central offices of the ASPCU and HFIU, located in Manila, which include document centres, meeting rooms and offices/desks for officials of these units.

(5) The mission team saw (during the visits to BFAR central and regional offices and to establishments) evaluation of HACCP plans for all accredited establishments, performed by the HFIU.

(6) The mission team was provided with a list - included in the FOO N° 35 of 26 January 2006 - of 48 designated fish inspectors, 8 based at BFAR central office (in Manila) and 40 at regional level. They are authorised to conduct inspection of fish processing plants, fish ports/landing sites, FV, to perform pre-shipment inspection of FP and AP, to verify compliance with international rules and national laws and regulations on export.

(7) With the creation of the LQAC and with the assistance of the French Agricultural Research Centre for International Development (CIRAD) the residue monitoring and disease strengthening surveillance programme has been revised and improved (*cf.* 2.4. of this report).

2.1.2. Competence and knowledge of Community requirements, training

The knowledge of the above-mentioned Community requirements for FP and aquaculture products must be improved, both at central and local level, by means of training on legislation, specific procedures for EU exports and hygiene of production; specific training involving the private operators should be organised as well.

2.1.2.1. Assurances given by the CA

"(8) Improvement of knowledge of Community requirements was achieved through the participation of BFAR fish inspectors/regulatory officers to regional, national and international training, consultation meetings, dialogues, workshops, seminars to enhance their skills and update their knowledge; (9) review of the relevant and new EU legislations on food hygiene and feed control; and provision of copies of same to concerned parties; (10) a series of informal hands-on training, consultations and dialogues, mini-workshops with technical experts were conducted; (11) participation of BFAR in the implementation of various international/regional and ASEAN-wide projects related to trade and safety of fishery/aquaculture products."

2.1.2.2. Findings regarding the assurances given by the CA

(8 to 11) The mission team was provided with copies of *Curricula vitae* and training certificates for BFAR staff performing official controls. Staff performing inspections to establishments and laboratory staff have degrees in several areas related to fish and FP (*e.g.* aquaculture, technology, chemistry), and have also been trained in these and other areas, *e.g.* Community legislation, control techniques, food safety management systems, official certification, documentation and record keeping.

Several Fisheries Administrative Orders (FAOs), FOOs and instructions have been issued by BFAR which are applicable to FP and AP intended for export. However, some inconsistencies and contradictions were noted between these documents, *e.g.* histamine (FOO 194 of August 2005 and FOO 36 of February 2005), free residual chorine (FAO 211 and Philippine National Standards (PNS) for Drinking Water 1993).

The following table summarises the information received from BFAR on technical assistance provided by the EU to the Philippines, from 2004 to 2006:

Provider of Technical assistance (attendants)	Date, Location
1. EC-ASEAN, Regional Economic Cooperation Programme on Standards, Conformity and Assessment (one BFAR staff);	2004 (24.4.2004), France/La Rochelle
2. EC-DG/TRADE, Training on Residues (one BFAR staff);	2004 (22.11 to 3.12.2004), France/ Nantes
3. EC-DG/SANCO, Workshop on EU requirements for FP/AP (BFAR staff, other regulatory agencies and industry stakeholders association, academe);	2005 (9 to 11.2.2005), Philippines/Manila
4. EC-DG/SANCO, Seminar on Food Safety and Biotechnology (BFAR staff, other regulatory agencies and industry stakeholders association, academe);	2005 (25.1.2005), Philippines/Manila
5. EC-DG/TRADE, Sanitary and Phytosanitary Measures Agreement (SPS) technical assistance of two EU national experts on official control systems for FP/AP and residues (BFAR staff and industry sector);	2005 (21.6 to 15.7.2005), Philippines
6. EC-DG/SANCO, Workshop on EU FP/AP standards (3 BFAR staff and ASEAN member country representatives);	2006 (25 to 27.4.2006), Indonesia/Jakarta
7. EC/ITC/Asia Trust Fund, Upgrading BFAR Capability in fish inspection services, international consultants (BFAR and industry);	2005 (05.2005 to 05.2006), Philippines
8. EC-DG/TRADE, TREATI Workshops on SPS issues in the fisheries sector (BFAR staff, other agencies, laboratories and industry stakeholders);	2006 (13-14.06.2006), Philippines/Manila
9. EU/Trade Related Technical Assistance (TRTA) SPS Component, capability building, provision for BFAR/NRL accreditation, additional equipment, training, participation in Codex meetings, technical and advisory assistance (BFAR staff).	2006/2007 (Ongoing)

BFAR considered as "extremely useful and effective" the technical assistance obtained under points 5, as "very useful and effective" the activities under 1, 2, 7 and 8, as "useful and effective" the activities 3, 4 and 6 of the table, and expressed high expectations for the activities to be sponsored under point 9. According to BFAR, the latter has been delayed and is under revision to address any deficiency that may have been noted during the current FVO mission.

2.1.3. Filing of information

The CA should review the filing related to approved establishments/freezer vessels for export to the EU in order to verify that of all relevant information is available.

2.1.3.1. Assurances given by the CA

"(12) The files of individual establishments were reviewed, to ensure that information required is updated and accurate; (13) the documentation system and procedures for certification are documented in the certification manual; (14) an orientation seminar on records keeping and certification was conducted in Regions IV-A, IX and XII for the fish inspectors and stakeholders."

2.1.3.2. Findings regarding the assurances given by the CA

(12 and 13) During the visits to the offices of ASPCU and HFIU in Manila and to the regional offices of BFAR (as well as during the visits to establishments), the mission team confirmed that improvements covering file keeping, copies of routine inspections reports (with a frequency based on the rating granted to the establishment), valid certificates of accreditation/HACCP and in some cases corrective action plans had occurred. However, not all accredited establishments and vessels have provided an action plan to BFAR (in some cases one year after the inspection took place).

2.1.4. Official controls and general monitoring

The Philippine CA should apply the specific Community requirements laid down in the Annexes of Council Directives 91/493/EEC and 92/48/EEC and in Commission Decision 95/190/EC for the approval/registration and control/supervision of fishing vessels/wholesale market/establishments intended to export FP and aquaculture products to the EU.

2.1.4.1. Assurances given by the CA

"(15) The specific EU requirements for the approval, control, monitoring and supervision of fishery establishments, freezer vessels have been incorporated in the Manuals on Fish Inspection and Certification and the requirements are already being implemented; (16) the Manual on Verification Sampling is currently being developed for further improvement; however, verification procedures are already being implemented based on actual risk assessment and monitoring inspection of plants; (17) in addition to EU registered/accredited fishing/freezer vessels, other vessels and small commercial boats supplying raw materials to approved establishments are also being monitored by BFAR in close coordination with fish associations, LGU and PFDA, while approval of registration/accreditation is pending; further, other FV/boats are now in the process of applying for registration."

2.1.4.2. Findings regarding the assurances given by the CA

(15) The mission team observed during the visits to the central and regional offices and to all the establishments that, between November 2004 and September 2006, BFAR drafted/revised comprehensive checklists and forms. These can be considered as covering, in general, the relevant Community requirements, and have been distributed and are being used by inspectors. These include checklists for the inspection of plants, fishing/freezer vessels, fish ports/landing sites/auction and wholesale markets, ice plants and cold stores, HACCP evaluation (in accordance with Decision 94/356/EC and *Codex Alimentarius*), audit of documents, inspection of visual parasites, plant inspection reports, sample collection forms, and pre-shipment inspection reports. This last item is verified before export to the EU and includes: a) the certification of compliance with the requirements of the health attestations of Decision 95/190/EC; b) Annex V of Decision 2003/858/EC on animal health applicable to aquaculture products; and c) Section 6 of FAO N° 210 on local legislation applicable to fresh, chilled and frozen fishery/aquatic products.

The mission team found several corrective action plans sent by the Food Business Operators (FBOs) to BFAR. In most cases these plans, with deadlines for the correction of the deficiencies, were also available in the establishments visited.

The mission team was informed that BFAR inspectors perform organoleptic checks in the establishments. A document is issued by BFAR for clearance for domestic movement of fish and FP in accordance with Section 5 (e) of FAO 192, Series of 1997.

A revised inspection rating scheme (as of March 2006) has been put in place by BFAR. It includes a different number of deficiencies per category and, as a consequence, more frequent visits, *e.g.* plants categorised as AA are now monitored/inspected within a six monthly period (instead of the previous annual visit), following the validity of their accreditation.

During the visit to establishments, the observations of the mission team confirmed in general the ones made by BFAR and detailed in their inspection reports. However, in some cases deficiencies were noted by the mission team which had not been recorded by BFAR, *e.g.* no checks on water used by a cannery⁸ (coming from an open spring source), accredited cold stores⁹ with severe unhygienic conditions undermining accreditation, layout of one cannery, with possible cross contamination of cooked products and raw material.

The mission team observed that analyses for the detection of heavy metals (*e.g.* lead, cadmium, and mercury), and histamine are performed in samples collected by BFAR inspectors in the establishments. In the fresh tuna loins establishments, the sampling frequency has been reduced in particular in relation to histamine from monthly to quarterly (on the basis of temperature control, organoleptic evaluation per Regulation (EC) 2073/2005, and historical data).

(16) The mission team was provided with copies of version 3 of the "Manual on the Certification Procedures for Fishery and Aquaculture Products" (dated July 2006) and version 2 of the "Manual on HACCP-based Inspection and Accreditation Procedures for Fishery and Aquaculture Establishments and Products" (dated February 2006). The first includes details of certifying officers, and procedures for the issuing of sanitary/health certificates. The second includes national requirements and requirements of importing countries *i.e.* US, EU, Canada, Australia, Japan, Hong Kong, and China, and describes the different official control activities (*e.g.* accreditation of vessels and establishments, performance of inspections, export certification, of the production/export chain, laboratory analyses).

2.1.5. Official controls and general monitoring

The Philippine requirements should take into account the requirements of Council Directive 98/83/EC concerning potable water and the restrictions on the use of carbon monoxide and sodium disulphates as additives, similar to the provisions of Council Directive 95/2/EC on food additives other than colours and sweeteners during processing of FP intended for export to the EU.

2.1.5.1. Assurances given by the CA

"A) Potable Water: (18) BFAR issued FOO no. 210 providing supplemental requirements on safety and quality standards for the exportation of fishery

⁸ *In their comments to the draft mission report, the CA stressed that the water is analysed (in house and by BFAR) and can be considered as safe.*

⁹ *In their comments to the draft mission report, the CA confirmed that a cold store had been delisted, is in the process of implementing the necessary corrective actions and is reapplying for re-accreditation.*

products, including potable water and ice; whereas FOO N° 36 provides for proper collection of samples by designated personnel for official verification purposes;

B) Carbon monoxide: (19) in line with the recommendations of EC officials, BFAR imposed a ban on the exportation of frozen tuna treated with filtered smoke;

(C) Sodium disulphites (20) BFAR requires tests on sodium disulphites on aquaculture shrimps to ensure compliance to EU requirements."

2.1.5.2. Findings regarding the assurances given by the CA

(18) Drinking water: The mission team saw, in all the establishments visited, results of analyses of water samples taken following the issuing (on 17 March 2006), of a memorandum¹⁰ addressed from the director of BFAR to all regional directors. References are made to PNS for Drinking Water 1993 (DOH), and to Directive 98/83/EC.

The mission team observed, in all of the establishments visited, the use of water within the parameters prescribed by PNS for Drinking water, 1993 (i.e. between 0.2 and 0.5 parts per million of free residue chlorine.

Under Philippine rules, all microbiologic parameters of Directive 98/83/EC should be tested other than for *Clostridium perfringens*.

Furthermore, the mission team received no explanations for the following:

- Why only four of the 26 chemical parameters of Directive 98/83/EC (copper, fluoride, nitrate, and nitrite) are tested for¹¹;
- Why 15 indicators are required for water testing (pH, colour, odour, turbidity, chloride, iron, total hardness (CaO₃), manganese, copper, hydrogen sulphide, sodium, sulphate, electrical conductivity, aluminium, and total dissolved solids);
- Why there is an annual frequency for complete testing and a monthly partial testing for microbiology analyses for district water (public supply), ice and deep well water;
- Whether the defined frequencies take into consideration the volume of water used (e.g. in canneries);
- Why there are different standard limits for the above mentioned chemical parameters between the PNS and Directive 98/83/EC.

(19) BFAR informed the industry, on February 2005, that it has imposed a restriction on the export of fresh tuna CO treated to the EU in compliance with Directive 95/2/EC. Furthermore, BFAR informed the mission team that health certificates are not issued for the export to the EU and that no further problems (e.g. RASFF) have been reported regarding this issue.

(20) The mission team found satisfactory results of shrimp analyses for sodium disulphates carried out by the FBOs in-house, with the use of kits, or performed by third-party laboratories.

¹⁰ In this regard, a memorandum of October 2004 and the FOO N° 36 (February 2005) detailed already the microbiology analyses to be carried out and the frequency of sampling to be followed.

¹¹ *In their comments to the draft mission report, the CA stated that further to the information provided to the mission team, a technical consultation with the relevant authorities is being carried out for identifying appropriate water quality parameters and tests.*

2.1.6. Certification for export to the EU

The CA should put in place a uniform procedure related to the issuing of EU export health certificates and confirm that FP and aquaculture products exported to the EU comply with the requirements lay down in Annex A-IV (Health Certificate-Health attestation) of Commission Decision 95/190/EC of 17 May 1995.

2.1.6.1. Assurances given by the CA

(21) BFAR has adopted a uniform certification procedure at central and regional levels through the following measure: the health certificate formats are now printed only by the BFAR Head Office for purposes of uniformity and the forms are now printed with water marks for security reasons; additional certifying officers were given special orders/instructions and an orientation seminar on the requirements and procedures for the issuance of health certificates for export products; copies of relevant EU legislations (i.e. 96/93/EC) were likewise provided and explained to the certifying officers."

2.1.6.2. Findings regarding the assurances given by the CA

(21) The mission team was provided with a copy of version 3 of the "Manual on Certification Procedures for Fishery and Aquaculture Products" published in July 2006. The manual includes a list of certifying officers in BFAR central office, and Regions 6, 7, 9, 10, 11, and 12. The mission team saw copies of export health certificates which include all the relevant requirements of the Annex to Decision 95/190/EC and copies of pre-shipment inspection reports. The latter makes reference to points 1, 2 and 3 of Article 2 of Decision 95/190/EC, to Annex V of Decision 2003/858/EC on animal health, and to Section 6 of FAO 210 on fresh, chilled and frozen fishery/aquatic products.

The mission team noted that, as mentioned in the previous mission report, samples are tested prior to export (histamine for canned tuna on all shipments and quarterly for fresh tuna loins, according to the requirements of BFAR memoranda, in particular the one of 25 October 2004). The information available in some of the establishments visited by the mission team permitted to trace the results of analyses for batches exported to the EU.

2.2. Laboratory service

2.2.1. *The deficiencies should be addressed in the shortest delay, and as a matter of priority those related to the traceability of sampling, to ensure full reliability of the results of analyses.*

2.2.1.1. Assurances given by the CA

"A. Central Fish Health Laboratory

(22) Traceability: Formal instructions on proper collection of samples in the field have been issued to all fish health officers to include samples for Groups A1, A3, A6, B2a and B3a per memo dated 28 March 2006; (23) Accreditation: Development plan for the accreditation of the BFAR central laboratory has been considered under the SPS component of the EU-TRTA Programme;

2.2.1.2. Findings regarding the assurances given by the CA

(22) **Traceability:** During the visit, the mission team was informed that the laboratory remains the NRL for residues in AP¹². Also as previously reported, only screening analyses (in the context of the national residues control programme - NRCP) on chloramphenicol (CAP), nitrofurans, sulfamethazin, chlortetracycline (CTC) and oxytetracycline (OTC) are tested in the NRL. Residues confirmatory analyses are carried out by the Laboratory A in Manila (*cf.* 2.7 of this report for more details on the monitoring of residues in aquaculture).

The mission was able to identify improvements in the recording of samples (upon arrival to the laboratory), as the current system identifies samples taken by BFAR officials and by FBOs. An improvement since the last mission was noted regarding the quality checks on samples received in the laboratory, as now the temperature, the origin (industry or official monitoring) and the weight of the sample are documented.

As also observed in the last FVO mission, facilities and equipment were found satisfactory for the existing screening tests, as well as traceability of samples.

(23) **Accreditation/Quality:** The laboratory is not yet accredited against the standard ISO 17025¹³ but the quality manager (who is also the head of the laboratory) informed the mission team that the laboratory plans to submit, by the first quarter of 2007, the accreditation request to DTI. In this regard, a copy of the roadmap for the accreditation of the laboratory (which foresees the accreditation audit to take place at the end of 2007) was provided to the mission team.

Standard Operating Practices (SOPs) for testing for chloramphenicol and nitrofurans are used.

The EU-TRTA programme will finish on 31.12.2007 and the mission team was informed by BFAR that it will be possibly redrafted in light of the recommendations of this FVO mission report. The programme will provide assistance, among other activities, to the accreditation of this laboratory.

"B. Fishery Products Testing Laboratory (FPTL)

(24) Strengthening the implementation of GLP with emphasis on the proper sampling and analytical procedures to establish product traceability; (25) internal and external calibration and preventive maintenance of equipment have been adopted in collaboration with the dealers; (26) structural improvement of the FPTL considered upon transfer to a new location; (27) provision of additional laboratory equipment";

2.2.1.3. Findings regarding the assurances given by the CA

(24 to 27) Efforts to improve laboratory performances were observed by the mission team, however, some deficiencies still remain.¹⁴

¹² Meetings with the regional BFAR laboratories and two inter-comparative studies have already been organised by the NRL. However, suitability of the methods used by sub-contracted laboratories is not controlled.

¹³ The accreditation body in the Philippines is the Bureau of Product Standards (BPS), under the Department of Trade and Industry (DTI).

¹⁴ *In their comments to the draft mission report, the CA provided an extensive corrective actions plan for the FPTL.*

The laboratory is not accredited and the intention of the CA is to move (the construction of a new building is foreseen next year). The microbiological section is still situated at the ground floor and, despite implementation of corrective actions, presents limited facilities. Old equipment is still in use, registers of the equipment were found available and an effort to apply calibration was noted by the mission team; however, absence of temperature recording devices was still observed for the incubators and calibration is implemented using a non certified thermometer. New freezers and a laminar flow cabin were recently purchased. Participation in ring trials for *Staphylococcus aureus* are the only ones performed. Reference strains for the different microbes were not available.

A new section belonging to the laboratory and performing chemical analyses for heavy metals and histamine was created at the third floor of the same building. Registration of samples and file keeping for both sections (micro and chemicals) is done upstairs and this could compromise the work flow downstairs.

In case of positive samples a consistent procedure for traceability and follow up was put in place for both sections. Minor observations were noted in SOP (lack of details concerning instruments and references). It was also pointed out that latest training for personnel was provided in 2002.

C. Accreditation of private laboratories

(28) Tie up with ISO 17025 accredited laboratories (i.e. Laboratories A and B) for testing of fishery/aquaculture products for microbiological, chemical and veterinary drug residues.

2.2.1.4. Findings regarding the assurances given by the CA

(28) The inspection team was informed that the Fertiliser and Pesticide Authority (FPA), involved in the monitoring of organochlorinated and organophosphate compounds and heavy metals, is also responsible for the registration of fertilizers and pesticides. There is informal cooperation between FPA and BFAR but no details were provided to the mission team regarding the mentioned monitoring.

Details about the visits to other laboratories can be found in Part 5 of the Annex to this report.

2.3. Vessels

2.3.1. *The CA should review freezer vessels in order to only register those in compliance with the requirements of Council Directive 92/48/EEC. In addition, the list of these vessels should be provided to the Commission services.*

2.3.1.1. Assurances given by the CA

"Approved fishing/freezer vessels are continuously being monitored to verify compliance to EU requirements. Only those that meet and/or progressively showing substantial compliance with the EU requirements are retained on the Philippines list."

2.3.1.2. Findings regarding the assurances given by the CA

In total, twenty-two FV are registered by BFAR to export to the EU (*i.e.* as from 10.08.2006). The mission team was informed that the vessels inspection programme was progressively put in place by BFAR as from 2005. Seven of the listed vessels

have been rated as "non-compliant", two as "conditionally approved", eight as "compliant", and five as "pre-assessed". Some vessels are in dry dock for repairs or in different fishing grounds (near Philippines waters or far away) and are, according to BFAR, consequently not available for inspection. The last inspection for twelve of them has been carried out between January and November 2005 and five of the seven non-compliant vessels were last visited in 2005. Furthermore, for another five of them (as mentioned in the previous mission report), there was no corrective action plan supplied by the vessel's owner to BFAR. During the final meeting, BFAR supplied additional and updated information regarding the status of all the listed vessels and copies of the corrective action plans (including photographs of the vessels) provided to them by the vessels' owners.

The mission team was able to see (and visit one vessel), in the Navotas fish port (in Metro Manila) some of the "non-compliant" vessels which are under repair (their state of maintenance was very poor and under no conditions could they be fishing).

Commercial vessels – small, medium, and large vessels -, including transport vessels (and excluding traditional vessels) are also under the control of BFAR, which issues the commercial fishing vessel/gear licence. The mission team was provided in the regional office of BFAR (Region 9) with a copy of the list of commercial vessels.

The mission team also visited seven vessels, including two EU listed FV /transport vessels, three chilling/transport (commercial) vessels and two traditional fishing vessels, five of them in the port of General Santos and two in Zamboanga City. The first four vessels have satisfactory hygiene and structure conditions. It was noted that basic HACCP manuals were available (mentioning, sometimes, hold temperature as a critical control point).

Traditional vessels are under the category of "Special Commercial Boats". They are made of wood (including the surfaces that enter into contact with FP with flaking painting), and the water of melting ice enters also in contact with FP. These vessels have a fishing vessel safety certificate (issued by the Maritime Industry Authority, Department of Transportation and Communication), and need a Commercial Fishing Licence to enable them to engage in fishing operations (which is issued by BFAR).

2.4. Landing sites/wholesale markets

The mission team visited, in General Santos a port and fish market, which were found in an adequate state of maintenance, allowing hygienic procedures for the operations concerned. An annexed ice plant was also visited revealing some maintenance problems, wooden material and rusted ice breaker located outside the premises allowing physical ice contamination, and unhygienic procedures related to possible contamination with hyperchlorinated water (up to 200 p.p.m. of free residual chlorine).

A dock connected to a sardine canning plant - located in Region 9 - was also visited and was conveniently equipped for the unloading of sardines. However, a rusted ice breaker machine, which supplies vessels with ice, without adequate protection from (amongst the others), exhaust gas produced by its diesel engine, was observed.

2.5. Establishments

2.5.1. The CA should review establishments in order to only approve those in compliance with the requirements of Council Directive 91/493/EEC

including the provisions of Commission Decision 94/356/EC. In addition, the list of these establishments should be provided to the Commission services.

2.5.1.1. Assurances given by the CA

"The CA is continuously monitoring the approved establishments' compliance with EU requirements. Consequently, the list of approved establishment has been reduced to 26 only."

2.5.1.2. Findings regarding the assurances given by the CA

At the time of the previous mission, in October 2004, imports from the Philippines were authorised from ninety-six establishments, one cold store and sixty-five FV. BFAR, with the involvement of its central and regional services, reviewed the list of approved/registered establishments/vessels. This included the setting up of a routine HACCP-based inspection programme (depending on the inspection rating), and a procedure for (voluntary or mandatory) amendment of the list of approved establishments. As a result, the list was progressively reduced to the current twenty-five establishments and twenty-two vessels.

The mission team was informed that a number of establishments have recently requested their HACCP programmes to be assessed and are on the way to be accredited by BFAR.

From the twenty-three establishments visited by the mission team¹⁵, seventeen were found with deficiencies that can be easily rectified, five have major structural/layout deficiencies, and one was found with serious hygiene deficiencies deliberately hidden by the FBO from the mission team¹⁶.

The following deficiencies found by the mission team during the visits to establishments are given as examples: a) poor house keeping in cold stores; b) cold storage of FP (very poorly stacked) behind carton packages; c) deficient pest control; d) absence of hot water in wash-hand basins; e) cross contamination between cooked, thawed and raw materials; f) cooking facilities with poor hygiene conditions (rusted and dirty); g) chilling rooms with heavy condensation on the ceiling and rusted rails allowing contamination of exposed cooked tuna; h) broken floors; i) use (and re-use) of temporary packaging material with different EU approval numbers; j) use of wash basins with contaminated stagnant water in skinning areas; l) no written instructions for workers on rinsing hands after washing in hyper-chlorinated water; m) inconsistent HACCP plans under which heavy metals were sometimes included as control points and temperature controls of fresh/chilled FP were higher (up to 6°C) than those of the national legislation (0°C) and Community legislation (approaching that of melting ice).

2.6. Aquaculture farms

2.6.1. The registration by the CA of farms supplying raw materials to establishments exporting aquaculture products to the EU should be consistent with provisions of Article 9, Council Directive 96/23/EC.

¹⁵ There were, at the time of the mission, 25 establishments included in the list of approved establishments.

¹⁶ During the final meeting, BFAR handed over copy of a letter (dated 27.10.2006) addressed to the FBO informing him that the practices found during the FVO visit revealed a violation of both Philippines and Community regulations and that, as a consequence, the ice plant and cold store would be excluded from the EU list (with immediate effect). The FBO was further requested to rectify the mentioned deficiencies.

2.6.1.1. Assurances given by the CA

"BFAR has devised a system for the registration of aquaculture farms and is now being implemented."

2.6.1.2. Findings regarding the assurances given by the CA

Aquaculture farms are registered following instructions and procedures put in place by BFAR. The mission team was informed by BFAR (and could confirm in the establishments visited) that farms are registered following instructions issued, in November 2005, from the central to the regional services. This procedure makes reference to Article 9 of Directive 96/23/EC, Article 6 of Regulation (EC) No 852/2004 and Article 4 of Regulation (EC) No 853/2004. The mission team noted, in Region 3, that this is an ongoing process as more and more farms are being included in (and sometimes excluded from) the system.

The mission team also saw also farm reports (initial), of inspections carried out by BFAR in 2006, which cover the use of veterinary drugs, traceability, hygiene of works and record keeping by the farm.

2.7. Monitoring of residues in aquaculture

2.7.1. *The CA should address all the shortcomings mentioned in chapter 2.7 and provide the Commission with an accordingly amended residue monitoring plan.*

2.7.1.1. Assurances given by the CA

"The Residue Monitoring Report and Plan for 2005-2006 has been revised with the assistance of an expert from CIRAD (French Agricultural Research Centre for International Development), reflecting the findings and recommendations by an expert from the EC."

2.7.1.2. Findings regarding the assurances given by the CA

The Residue Monitoring Report and Plan for 2005-2006 had been submitted to and assessed by the Commission services (CS), to verify its conformity with the requirements of Directive 96/23/EC. In this regard, BFAR was asked by the CS to provide additional information (which was provided and was under evaluation at the time of the mission).

Although performing analyses for FBOs, Adamson and the Philippine Institute of Pure and Applied Chemistry laboratories are no longer testing for OTC, CAP, organochlorinated substances, organophosphates, lead and mercury, as Laboratory A is supposed to cover the official monitoring for these substances. Laboratories A and B are private laboratories that are subcontracted by BFAR to perform analyses taken in the context of the NRCP because, according to BFAR officials, official laboratories are not yet accredited and are not able to perform all the necessary analyses.

BFAR has a memorandum of agreement (MOA) with Laboratory A in Manila, which was put in place in January 2006. Apart from residues analyses (OTC, CTC, sulfamethazine (SMZ)), other analyses - CAP, nitrofurans, metabolites, and dyes - are subcontracted by Laboratory A/Manila to Laboratory A/Taiwan. However, no quality controls have been put in place, neither by the NRL nor by Laboratory A/Manila. The NRL has not yet audited this laboratory but plans to include it (and the necessary quality controls) in the next MOA.

The mission team visited three BFAR laboratories – the Central Fish Health Laboratory (which is the NRL for residues), and two regional laboratories (in regions 4A and 7) – and two private laboratories, one in Manila, Laboratory A (with which BFAR has a MOA), and the other in General Santos (Laboratory B).

BFAR addressed (on 28 March 2006), to its regional offices, comprehensive instructions for the implementation of the 2006 residues monitoring plan. These instructions cover the registration of aquaculture farms, official controls for the monitoring of residues, sampling of AP and feed, and traceability in establishments. The NRL plans to start, within the next two months, the screening analyses for substances of the groups A1, A3 and B2 (these substances were not analysed in 2005 at all).

The following cover all residues laboratories visited by the mission team:

Quality Assurance

The private laboratory in Manila is accredited against the standard ISO 17025. However, neither the current accreditation nor the scope for its renewal includes the analyses of residues (in food or in feed). All BFAR laboratories visited by the mission team are (formally or informally) in the process of accreditation;

All visited laboratories have a Quality Manual. However, in two of these laboratories (Laboratory A and region 7) they are only a collection of several SOPs¹⁷;

All laboratories have SOPs for the analytical methods for residues, although not always including all the requirements of the standard ISO 17025, *e.g.* criteria for acceptance/rejection of results, control quality samples (blank and spike samples);

All laboratories visited have general SOPs, *e.g.* for sampling, sample reception, and other guidelines;

Two inter-comparison tests - for the analyses of CAP and nitrofurans in feed - have already been organised in August 2005 by the NRL/BFAR, with the participation of four laboratories (the NRL itself, one regional laboratory and two private laboratories). One of the important conclusions included in the evaluation of the results, states that in the future "samples with a known concentration of the analyte should be done to confirm the accuracy of the results";

All laboratories visited have a comprehensive traceability system of samples, with a specific code used from the reception of the sample to the reporting of the analysis results;

All laboratories have *curricula vitae* for their staff, which include several training courses; although not always for veterinary drug residues (*e.g.* Laboratory A staff was not aware of the meaning of MRL- the Maximum Residue Level).

¹⁷ *In their comments to the draft mission report, the CA stated that the FHL has a Quality Manual for chemistry and microbiology, which was kept (at the time of the mission team visit) in the central file located in another building.*

Screening analytical methods¹⁸

Suitability

In general, the following screening methods have suitable detection limits (thus avoiding false compliant results):

BFAR central laboratory uses ELISA methods for the detection of OTC, CTC, SMZ, CAP, AOZ, AMOZ (the mission team was informed that this year also substances of the group A1, A3 and B2 will be included in the screening);

The two regional laboratories also use ELISA methods for the detection of CAP, AOZ, and AMOZ.

All BFAR laboratories include quality control samples in each batch of analysis.

Validation

Validation has been performed for all screening methods although not always all required parameters (ISO 17025 and Commission Decision 2002/657) have been studied, e.g. accuracy, suitability.

Confirmatory analytical methods¹⁹

Suitability

A private laboratory in Manila carries out confirmatory analyses using HPLC-UV (with fixed wavelength), for OTC, CTC, SMZ. Currently, neither the use of one wavelength nor the method (clean-up of the sample is not performed) is suitable to reach the required sensitivity of, at least, the MRL (*i.e.* the analytical methodology in use is not "fit for the purpose").

The SOPs presented to the mission team cover the analyses of sulphonamides in feed and food, and tetracyclines in feed. However, no SOP could be presented for OTC and CTC in food.

In general, the mentioned confirmatory methods have unsuitable confirmatory limits (thus, there could be false negative results).

The mission team was informed that Laboratory A/Taiwan²⁰, sub-contracted by Laboratory A/Manila, uses LC-MS-MS for the confirmation of CAP, AOZ and AMOZ and for the detection and confirmation of malachite green.

Validation

Validation has been performed for OTC, CTC, SMZ in feed and only for SMZ in food, but on unsuitable spiking levels (as the laboratory staff is not aware of the corresponding MRL).

¹⁸ Screening methods (as defined in Commission Decision 2002/657/EC) are used to detect the presence of a substance or class of substances at the level of interest. These methods have the capability for a high sample throughput and are used to sift large numbers of samples for potential non-compliant results. They are specifically designed to avoid false compliant results.

¹⁹ Confirmatory methods (as defined in Commission Decision 2002/657/EC) provide full or complementary information enabling the substance to be unequivocally identified and if necessary quantified at the level of interest.

²⁰ BFAR was not able to provide evidence of the work performed in this laboratory (in particular with regard to the suitability and validation of their methods).

3. GENERAL CONCLUSION

The mission team acknowledged the:

- satisfactory hygiene and structural condition of the majority of the establishments visited;
- satisfactory analyses results (below the maximum EU limits), in particular for histamine, found in all visited establishments;
- leadership and commitment of the majority of BFAR's staff met during the mission, and
- significant progress since the previous mission (particularly since the technical assistance of June/July 2005, *cf.* 2.1.2.2), mainly regarding the harmonisation of the official control system, in general, and in particular the:
 - registration of farms, and the use of screening analytical methods for certain residue substances (thus providing, for these substances, a good public health protection);
 - reporting of in-depth inspections to establishments and vessels;
 - training of staff and dissemination (and ongoing implementation) of manuals, procedures, guidelines, and checklists from the central to the regional services;
 - complete filing system of documentation relating to establishments and vessels.

However, in the context of the official controls, the following deficiencies were identified:

- FP (mainly tuna)
 - the inconsistent official control system, as: a) non-compliant FV/transport vessels are kept on the EU export approved list of registered vessels with or without a remedial action plan; b) other vessels that are non-listed and non-compliant also supply EU export approved establishments; c) cold stores with identified deficiencies supply these approved establishments as well;
 - controls of FP by FBOs and by BFAR are systematically performed but not in accordance with all the relevant Community requirements for: a) histamine (a fluorometric alternative analytical method is used without validation against the HPLC analytical reference method); b) heavy metals (sampling criteria and performance criteria of the analytical methods, *e.g.* the detection limit, are not satisfactory and not known by the laboratories visited);
- AP
 - the use of "not fit for the purpose" confirmatory methods for the analyses of residue substances and its improper validation and, related to this, the incomplete official supervision of contracted (and sub-contracted) private laboratories;
 - incomplete monitoring of the residue substances required by Directive 96/23/EC, *i.e.* A1, A3 substances and only three antibiotics from group B1.
- Drinking water

Performance of analyses covering many parameters but no reasoning as to why not all the requirements of Directive 98/83/EC are met.

General conclusion

Taking into consideration the above-mentioned findings and conclusions, and considering in particular the remarkable improvements since the last FVO mission, the mission team considers that BFAR should be in a position to ensure full control and certification of the

specific conditions governing imports of FP and AP originating in the Philippines, as laid down in Decision 95/190/EC, once all the issues related to vessels, establishments, cold stores and laboratories have been promptly and properly addressed.

4. CLOSING MEETING

During the final meeting held in Manila, on 27 October 2006, the mission team presented the findings and preliminary conclusions of the mission to the CA. At the meeting, BFAR acknowledged all the deficiencies identified by the mission team. They provided a number of oral and written guarantees - *e.g.* corrective action plans for most of the establishments and vessels visited by the mission team, delisting of one of these establishments, preliminary results for the validation of an alternative histamine testing method, comprehensive plans for the issues related to laboratories and residues. The CA undertook to send additional information to Commission services in order to address all the deficiencies.

5. RECOMMENDATIONS TO THE CA OF THE PHILIPPINES

BFAR should provide the Commission services with an action plan, including a timetable for its completion, within one month of receipt of the report, in order to address the following recommendations for products exported to the EU:

5.1. Legislation

- a) BFAR should consolidate the requirements applicable to the export of FP and AP to the EU, taking into account the relevant national and Community requirements;
- b) BFAR should make sure that these requirements, and the ones mentioned in 5.3, are known and followed by all BFAR staff, FBOs and by laboratories.

5.2. Establishments and vessels

- c) BFAR should check regularly all establishments and vessels supplying (directly or indirectly) FP and AP to the EU considering in particular the relevant requirements of Regulations (EC) No 852/2004 and No 853/2004 and maintain on the list of registered/approved vessels and establishments only those that comply with these requirements;
- d) BFAR should put in place official controls of FP and AP, which should cover the requirements of Chapter II of the Annex of Regulation (EC) No 854/2004.

5.3. Laboratories

- e) Laboratories that carry out the analyses of FP, AP and water samples taken during official controls (*i.e.* official laboratories) should be designated in accordance with the requirements of the standard PNS/ISO/IEC 17025;
- f) Before (and after) the accreditation is granted, official laboratories should provide BFAR with satisfactory guarantees of a quality control scheme;
- g) The designation of official laboratories should take into consideration the analytical methods laid down in the relevant Community legislation, and the validation of alternative analytical methods;
- h) The performance characteristics of the analytical methods need to be fit for the purpose and able to generate reliable results, considering all the parameters laid down in the relevant Community legislation, in particular Directive 96/23/EC, Decision 2002/657/EC, Commission Regulation (EC) No 466/2001/EC,

Commission Directive 2001/22/EC, Regulation (EC) No 2073/2004, Directive 98/83/EC;

- i) Official laboratories should be assessed by BFAR to verify whether they operate in accordance with the conditions mentioned in a), b), c), and d) of point 5.3 and any agreement BFAR has with them.

6. COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/comm/food/fvo/ap/ap_philippines_8312_2006.pdf

ANNEX

1. Abbreviations and special terms used in the report

AMAZ	3-amino-5-methylmorpholino-2-oxazolidinone (metabolite of Furaltadone)
AOZ	3-amino-2-oxazolidinone (metabolite of Furazolidone)
AP	Aquaculture Products
ASEAN	Association of South East Asian Nations
ASPCU	Administrative Support and Product Certification Unit
BFAR	Bureau of Fisheries and Aquatic Resources
CA	Competent Authority
CAP	Chloramphenicol
CIRAD	French Agricultural Research Centre for International Development
CO	Carbon Monoxide
CTC	Chlortetracycline
DG	Directorate General
DOH	Department of Health
EC	European Community
EU	European Union
EUROSTAT	Statistical Office of the European Communities
FAO	Fisheries Administrative Order
FIQCS	Fish Inspection and Quality Control Section
FOO	Fisheries Office Order
FP	Fishery Products
FBO/s	Food Business Operator/s
FPA	Fertiliser and Pesticide Authority
FPTL	Fish Product Testing Laboratory
FVO	Food and Veterinary Office
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
HACCP	Hazard Analyses Critical Control Point
HFIU	HACCP-Based Fish Inspection Unit
IEC	International Electrotechnical Commission
LGU	Local Government Unit
LQAC	Laboratory Quality Assurance Committee
MRL	Maximum Residue Level
NRL	National Reference Laboratory
OTC	Oxytetracycline
PFDA	Philippines Fisheries Development Agency
PNS	Philippine National Standards
p.p.m.	Parts Per Million
RASFF	Rapid Alert System for Food and Feed
SANCO	Health and Consumer Protection DG (European Commission)
SMZ	Sulfamethazine
SOP	Standard Operating Procedure
SPS	Sanitary and Phytosanitary Measures Agreement (WTO)
SSOP	Sanitation Standard Operating Procedure
TRADE	External Trade DG (European Commission)
TRTA	Trade Related Technical Assistance
WTO	World Trade Organisation

2. References to Community Acts quoted in the report

European legislation ²¹	Official Journal (OJ)	Title
Directive 95/2/EC	L 61, 18.3.1995, p. 1	European Parliament and Council Directive N° 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners.
Commission Decision 95/190/EC	L 123, 3.6.1995, p.20	Commission Decision 95/190/EC of 17 May 1995 laying down special conditions governing the import of fishery products and aquaculture products originating in the Philippines.
Commission Decision 97/296/EC	L 122, 14. 5.1997, p.21	Commission Decision 97/296/EC of 22 April 1997 drawing up the list of third countries from which the import of fishery products is authorised for human consumption.
Council Directive 98/83/EC	L 330, 5.12.1998, p.32	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.
Commission Directive 2001/22/EC	L 77, 16.3.2001, p. 14	Commission Directive 2001/22/EC of 8 March 2001 laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs.
Commission Regulation (EC) 466/2001	L 77, 16.3.2001, p.1	Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs.
Commission Decision 2002/657/EC	L 221, 17.8.2002, p. 8	Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results.
Regulation (EC) 852/2004	L 139, 30.4.2004, p. 1 Corrigendum OJ L 226 , 25.06.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
Regulation (EC) 853/2004	L 139, 30.4.2004, p. 55 Corrigendum OJ L 226 , 25.06.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.
Regulation (EC) 854/2004	L 139, 30.4.2004, p. 206 Corrigendum OJ L 226 , 25.06.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.
Regulation (EC) 882/2004	L 165, 30.4.2004, p. 1 Corrigendum OJ L 191, 28.5.2004, p. 2	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
Commission Regulation (EC) 2073/2005	L 338, 22.12.2005, p. 1	Commission Regulation (EC) N° 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

3. Legal basis for the mission

The mission was carried out under the general provisions of Community legislation and, in particular:

- Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, Article 46;
- Commission Decision 98/140/EC of 4 February 1998, laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in third countries.

²¹ Community legislation (Internet): http://europa.eu.int/eur-lex/en/search/search_lif.html

4. Imports of fishery products from the Philippines

CODE	301	302	303	304	305	306	307	1604	1605	TOTAL
FR	6	0	4	1	1	0	185	105	3	304
NL	7	0	0	50	25	33	1	2708	26	2850
DE	4	1	0	33	0	111	11	20204	0	20364
IT	1	0	1104	0	5	0	24	1220	4	2358
UK	39	1	54	63	8	126	3	9541	0	9835
IE	0	0	0	0	0	0	0	419	0	419
DK	2	0	0	15	0	0	0	379	0	396
GR	0	0	0	0	0	0	92	505	0	597
PT	0	0	0	0	0	3	387	50	0	439
ES	1	0	1362	0	0	0	20	92	0	1474
BE	0	0	0	26	0	0	81	576	1	684
LU	0	0	0	0	0	0	0	0	0	0
SE	0	0	1	0	0	0	0	1340	2	1343
FI	0	0	0	0	0	0	0	1910	0	1910
AT	0	0	10	0	0	0	0	415	0	424
2005	62	2	2535	188	40	273	804	40638	36	44576
2004	56	0	1923	296	110	296	1237	32641	64	36624
%	9%	100%	24%	-58%	-177%	-9%	-54%	20%	-80%	18%

FR	France	DE	Germany	DK	Denmark	SE	Sweden
BE	Belgium	IT	Italy	GR	Greece	FI	Finland
LU	Luxemburg	UK	Utd. King.	PT	Portugal	AT	Austria
NL	Netherlands	IE	Ireland	ES	Spain		

0301	Live fish
0302	Fish, fresh or chilled (excl, fish fillets and other fish meat of heading 0304)
0303	Frozen fish (excl, fish fillets and other fish meat of heading 0304)
0304	Fish fillets and other fish meat, whether or not minced, fresh, chilled or frozen
0305	Fish, fit for human consumption, dried, salted or in brine; smoked fish, fit for human consumption, whether or not cooked before or during the smoking process; flours, meals and pellets of fish, fit for human consumption
0306	Crustaceans, whether in shell or not, live, fresh, chilled, frozen, dried, salted or in brine, incl, crustaceans in shell, cooked by steaming or by boiling in water
0307	Molluscs, fit for human consumption, whether in shell or not, live, fresh, chilled, frozen, dried, salted or in brine, incl, aquatic invertebrates other than crustaceans and molluscs; flours, meals and pellets of aquatic invertebrates other than crust
1604	Prepared or preserved fish; caviar and caviar substitutes prepared from fish eggs
1605	Crustaceans, molluscs and other aquatic invertebrates, prepared or preserved

5. Visits to laboratories

The mission team also visited (*cf.* 2.7) the following laboratories performing analyses on FP and water:

- FOOD DEVELOPMENT CENTRE, NATIONAL FOOD AUTHORITY: Certified by BFAR, performs analyses for heavy metals and histamine. Samples have been brought to this laboratory by FBOs during the last 2 years. The current method for heavy metals do not comply with some of the verified performance criteria of Directive 2001/22/EC (the laboratory staff met during the visit was not aware of these requirements). However, the mission team was informed that new equipment has been purchased and it is in process of validation for heavy metals.
- LABORATORY B: This is an accredited laboratory for ISO 17025. Personnel are motivated and competent. Facilities are well maintained and equipped. Consistent file keeping was noted. Training road map is regularly organised for personnel despite recent budget constraints. However, the memorandum of agreement with the CA was not detailed for parameters and methods of analysis to be carried out for testing of potable water and FP . As example, the CA recommended the fluorometric as the method to be used for histamine; however, no validation of the above mentioned method was obtainable on the spot. It should be pointed out that HPLC is available in this laboratory. The fluorometric method is not yet accredited. Analyses for heavy metals are accredited. Incomplete forms for request of microbiological analysis (absence of sample specification) and incomplete supporting documents in the histamine SOP were seen as minor issues.
- REGIONAL LABORATORY (BFAR/Zamboanga City): This laboratory, situated in the compound of the regional BFAR offices, is not yet accredited. GLP manuals and SOPs for the majority of activities carried out in this laboratory have been already prepared as initial step toward the process of accreditation. The laboratory has three units (microbiology, chemical and fish health). The structure is simple but well maintained and properly organised. The personnel are motivated and a good filing system was also noted particularly with reference to traceability of samples. However, the following shortcomings were pointed out by the mission team in the microbiology unit: the absence of reference strains, absence of a book of instruments, low frequency of digital thermometer calibration (once in two years), media record book not updated.

In the chemical unit histamine for FP, TVB and TMA are performed. However, the concentration of the pure histamine solution was not indicated on the reference standard available, the laboratory quality manual presented frequent inconsistencies in page numbering and sampling procedure.